

Buprenorphine and pregnancy: Vermont program development and outcomes

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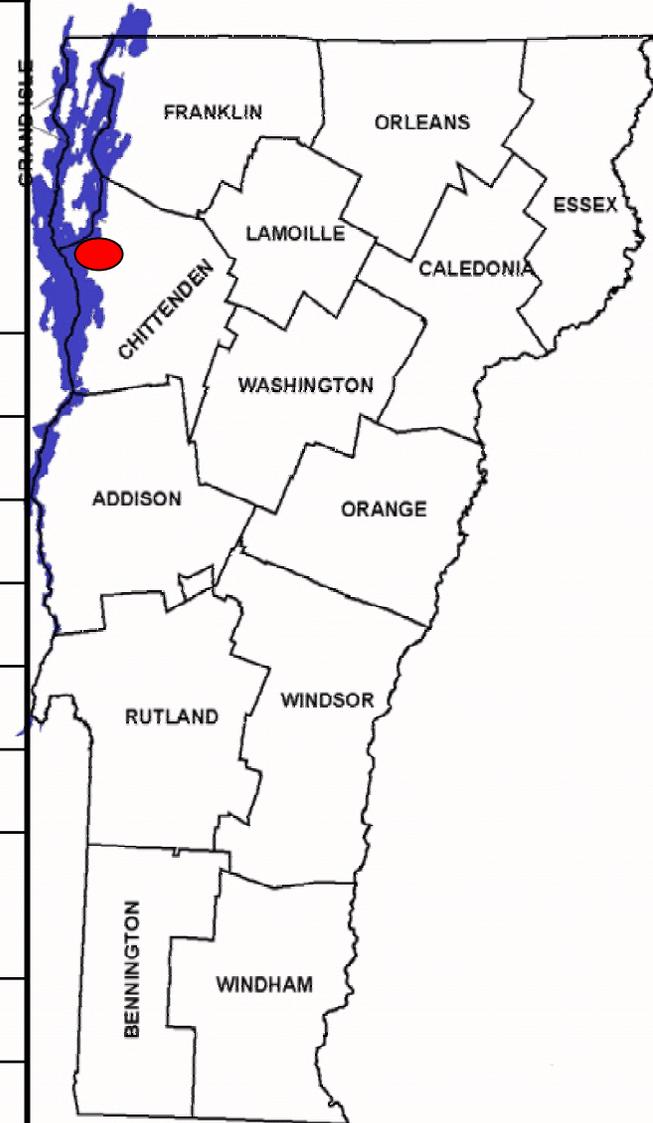


Outline: Buprenorphine in pregnancy

- Program development
- Where are the buprenorphine providers
- Pregnancy outcomes
- What works
- What needs improvement
- A word about pain (there is a reason it is called “labor”)

Vermont population statistics (versus Baltimore, MD) (2000-2006 census)

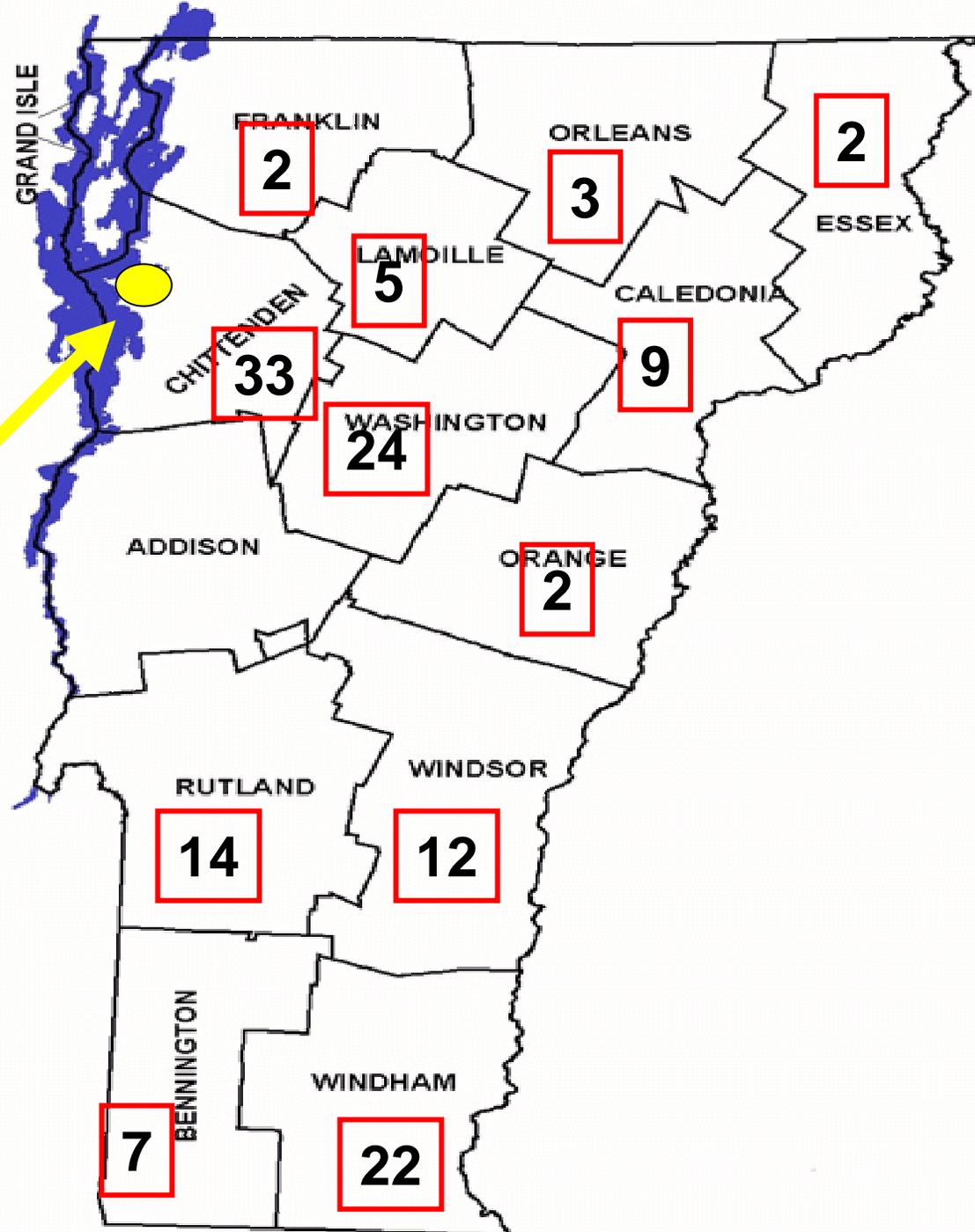
| Demographics | Vermont | Chittenden County (Burlington and nearby towns) | Baltimore, MD |
|-----------------------------|------------------|--|-----------------|
| Population | 623,908 | 150,000 | 628,670 |
| White | 97% | 95% | 32% |
| Black | 1% | 1.3% | 64% |
| American Indian | 0.4% | 0.3% | 0.3% |
| Asian | 1% | 2.4% | 1.5% |
| Hispanic | 1% | 1.5% | 1.7% |
| High school graduate | 86.4% | 91% | 68% |
| Median income | \$44, 550 | \$52,800 | \$30,000 |
| Person/sq mile | 66 | 272 | 8058 |



Vermont Buprenorphine providers by county (2006)

(We are here)

Weekly
commutes over 1
hour each way for
treatment are
common



Development of a program in the non-urban setting

| | 2000-2002 | 2003 | 2004 | 2005 | 2006 | 2007 |
|---|---------------|-----------------|------------------|------------------|------------------|------------------|
| Number of patients delivered | 15 | 18 | 24 | 41 | 51 | 66 |
| Methadone (%) | 15 | 18 | 19 | 34 | 32 | 33 |
| Buprenorphine (%) | 0 | 0 | 5 | 7 | 19 | 32 |
| Center based (methadone clinic or mobile methadone)(%) | 3/15 (20%) | 4/18 (22.2%) | 11/24 (45.8%) | 29/41 (70.7%) | 28/51 (54.9%) | 33/66 (50.0%) |



Women assessed and treated case by case; most received methadone through the pharmacy; counseling recommended; limited other services; visiting nurse referral

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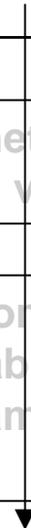


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Expansion of Chittenden Center (methadone) with strong commitment to enrolling pregnant patients as soon as possible; reliable substance abuse counseling and comprehensive services (mental health); structured program; monthly multidisciplinary meetings

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Expansion of buprenorphine with more community based care, both in obstetric office and primary care offices; women treated with methadone remain in center based care

CHARM: Children and Recovering Mothers

- Multidisciplinary group (obstetrics, neonatology, addiction specialist, social work, DCF, visiting nurses, Chittenden Center)
- Meet monthly
- Maintain a case list
- Follow-up for a year post-partum
- All patients sign a consent for discussion
- There is a Memorandum of Understanding among all groups regarding the use of information

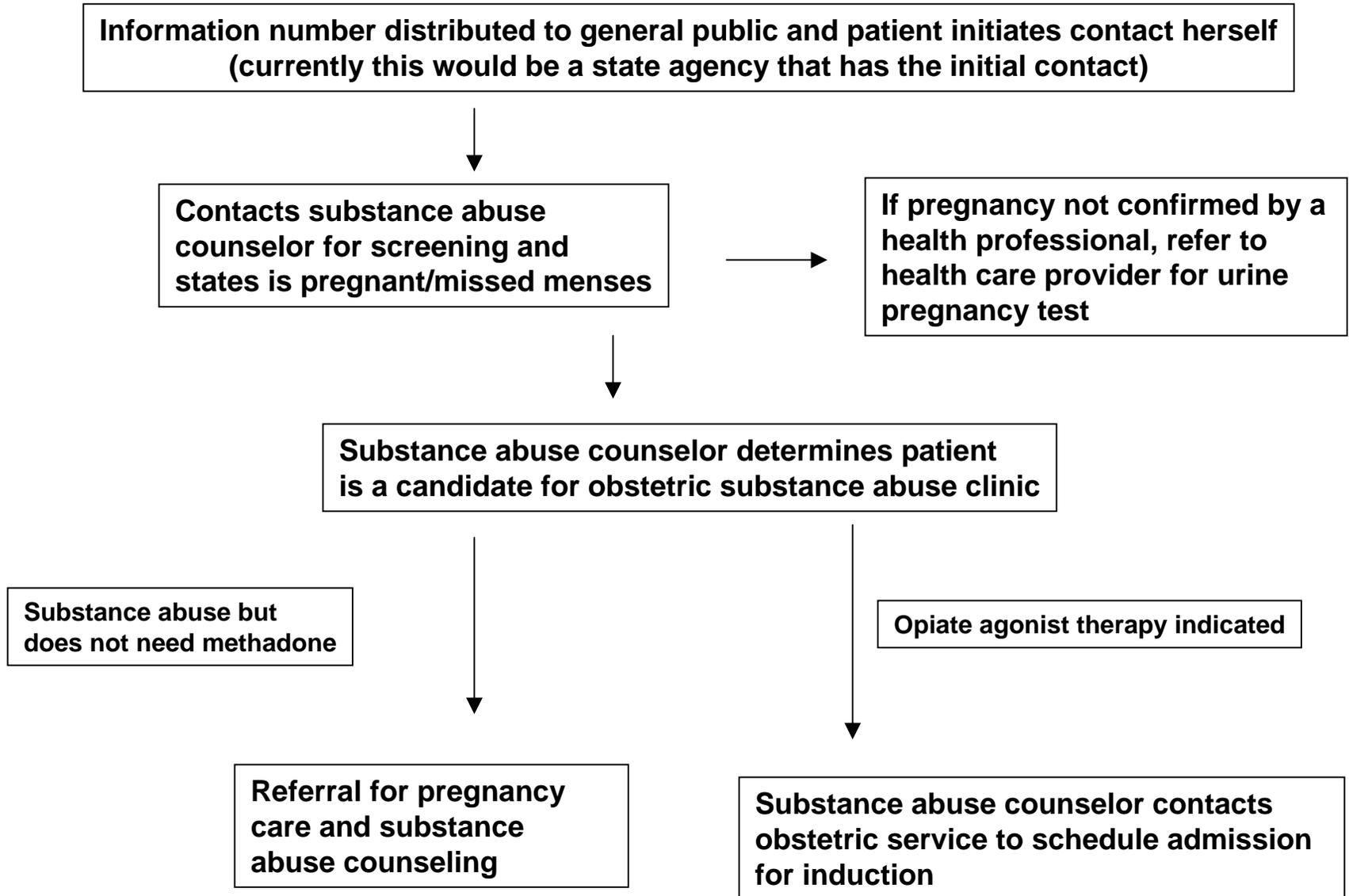
Goal: To ensure wrap around services are available to all patients; DCF is then aware of who is engaged in treatment and who is not

Rules of engagement

- Pregnancy is not an indication for emergent treatment in the absence of other medical/obstetric complications
- Admissions are scheduled and if appointments are missed, they are rescheduled
- Non-compliance may result in loss of opiate agonist therapy (although criteria are much less stringent than the non-pregnant population)

How is the patient entered into the program for opiate agonist therapy?

New pregnancy: patient initiates contact, no current treatment



New pregnancy : provider initiates contact (most common)

General information number for providers only with a patient needing substance abuse treatment:

Patient referral for treatment directly to obstetric clinic



- Referral MD**
- Patient name**
- Confirms opiate dependence (patient currently using opiates per referring provider)**
- Pregnancy confirmed by health professional**
- Schedule office visit or admit: next weekday AM- Mon-Thurs (referring provider contacts patient with this information, day and time); frequently done with patient in the referring providers office**

New pregnancy diagnosis: known history of substance abuse, stable on buprenorphine in community



Determine compliance with BOTH substance use (clean urine drug screens) and substance abuse counseling

Compliance documented



One time visit to obstetric clinic for assessment of other risk factors, compliance

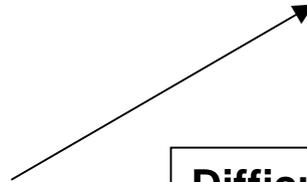
Provider uses flow sheet to track dose and urine drug screens



Non-compliant or unable to document compliance

Referral to obstetric service for closer, integrated care

Difficulty with community care



Pediatric referral to ensure delivery in a hospital in which NAS scoring and treatment are available

Visit Flow Sheet

Methadone/Buprenorphine Prenatal Visit

Date:

Name
MR#

Dose:

Withdrawal symptoms (check all that apply):

_____ craving

_____ sweating

_____ lacrimation

_____ runny nose

_____ gooseflesh

_____ yawning

_____ abdominal pain

_____ diarrhea

Have you used other drugs in the last 2 weeks?

_____ yes _____ no

Have you seen a substance abuse counselor in the past 2 weeks (provide name)?

_____ yes _____ no

If no, do you have a substance abuse counselor (provide name)?

_____ yes _____ no

Have you seen the social worker in the last 4 weeks?

_____ yes _____ no

If no, have the patient schedule a visit with her next prenatal visit

Pregnancy outcome 2000-2006 during program development (methadone and buprenorphine): improved maternal and neonatal outcomes

| Maternal | 2000-2002 n=15 | 2003 n=17 | 2004 n=24 | 2005 n=39 | 2006 n=51 | P difference | P trend |
|---|--------------------|-------------------|-------------------|---------------|---------------|--------------|---------|
| Gest age initial prenatal visit | 15 (9, 24) | 13 (10, 15.5) | 11 (7.3, 17.3) | 10 (8, 16) | 10 (8, 16) | 0.12 | 0.07 |
| GA start of opiate agonist therapy | 21.9 (15.2, 33) | 18 (9.9, 32.5) | 16 (0, 23) | 13 (0, 25) | 4 (0, 17) | 0.001 | <0.001 |
| Start opiate agonist therapy prior to pregnancy | 1/12 | 2/18 | 7/24 | 15/37 | 22/46 | 0.001 | <0.001 |

| Neonatal | 2000-2002 n=15 | 2003 n=18 | 2004 n=24 | 2005 n=41 | 2006 n=51 | P difference | P trend |
|------------------------------------|-------------------|------------------|------------------|------------------|------------------|--------------|---------|
| Birthweight (singletons only) | 2808±379 | 2696±608 | 2919±664 | 3164±574 | 2959±543 | 0.02 | 0.16 |
| Birthweight z score | -1.10±0.88 | -0.93±0.66 | -0.45±0.97 | -0.33±1.06 | -0.56±0.95 | 0.06 | 0.10 |
| Required rx for NAS scores (%) | 13/15 (86.7%) | 10/18 (55.6%) | 15/24 (62.5%) | 25/43 (58.1%) | 25/51 (49.0%) | 0.08 | 0.03 |
| Length of stay _≥ 37 wks | 8.1±5.7 | 6.3±3.2 | 6.1±2.8 | 6.2±3.8 | 6.6±3.7 | 0.56 | 0.91 |
| Discharged to mother custody | 9/15 (60.0%) | 15/18 (83.3%) | 20/24 (83.3%) | 36/43 (83.7%) | 45/51 (88.2%) | 0.19 | 0.03 |

Pregnancy outcomes: Methadone versus buprenorphine 2004-2007: some benefits of buprenorphine but may reflect more compliant, healthier population

| | n | Methadone | n | Buprenorphine | p |
|---|------------|----------------------------|-----------|------------------------------|---------------|
| Maternal age (years) | 120 | 24.9± 4.3 | 66 | 25.2± 4.2 | 0.59 |
| Smoker (%) | 120 | 103 (85.8) | 66 | 59 (89.4) | 0.51 |
| Gestational age at initial visit | 116 | 10 (8, 15) | 63 | 10 (8, 15) | 0.91 |
| Gestational age at start of opiate agonist therapy | 103 | 10 (0, 21) | 58 | 0 (0, 14.5) | 0.01 |
| Gestational age at delivery | 120 | 38.6 (36.8, 39) | 66 | 39.7 (38.2, 40.1) | 0.001 |
| Preterm (%) | 120 | 22 (18.3) | 66 | 8 (12.1) | 0.30 |
| Birthweight (gm) | 122 | 2896±588 | 67 | 3207±593 | 0.0006 |
| Birthweight z-score | 122 | -0.63±0.94 | 67 | -0.31±1.03 | 0.03 |
| Neonatal abstinence syndrome | 122 | 63 (51.6) | 67 | 19 (28.3) | 0.002 |
| Neonatal hospital stay | 108 | 6.5±3.5 | 55 | 4.9±1.7 | 0.002 |

What has worked well as more patients have transitioned to buprenorphine

- Increased access to the general population has increased pre-conception care: this may explain some of the improved outcomes
- Easier (and less expensive) access to treatment (driving distance and frequency)
- More women can be treated and maintain jobs and childcare (anecdotal)

Unique challenges of increased buprenorphine access and continued use in pregnancy

- Any drug that is used more in the community will be used more in pregnancy
- Not FDA approved for pregnancy use
- No long term neonatal outcome studies
- Our data may reflect very careful patient selection and may not be reproducible without understanding this process
- Poor patient disclosure to community physicians; difficulty in identification of newborns that require NAS scoring and treatment
- Potential for fewer necessary ancillary services
- Case reports of SIDS in exposed infants (we had 2 unexplained neonatal deaths; another report had a similar incidence)
- Breastfeeding confusion (we recently switched to suboxone immediately post-partum)
- Diversion of buprenorphine (Subutex)

Where should we go?

- **Understand how buprenorphine is prescribed to pregnant women and obtain outcomes (especially neonatal, SIDS)**
- **Both cohort and randomized trials are needed as they address different questions (medication effects versus real world outcomes)**
- **Examine how urban and less urban populations differ in treatment response, needs, outcomes, etc**
- **Examine how ancillary services are provided in patients treated in a primary care office (counseling, mental health issues, partner issues)**

What should we do now?

- **Understand how buprenorphine is prescribed in your community and what services are available to patients (we use IOPs)**
- **Develop relationships with obstetrics and pediatrics and develop a care plan for all treated pregnant patients**
- **Ensure wrap around services- visiting nurse, parenting, WIC, etc are available**
- **Understand the role of partner use in pregnancy and outcome**

Program development

- Multidisciplinary
 - CHARM team, consent to share info with all providers
 - Neonatology- prenatal consultation
 - Communication with bup providers
 - Insistence on intensive outpt or residential counseling
 - False starts with bup (admit, treat, script, disappear)
 - Admit for initiation
 - Discussion re: methadone drug of choice, discussion of barriers to treat with methadone, documentaion bup not fda approved and no long term outcomes, risk/benefit of treat with bup vs no rx (ie: oxy 20 mg qd)
 - Weekly dosing unless very well established; no more than 2 weeks; high street value of bup without naloxone
 - Weekly nursing visit: assess dose, change as indicated
 - Switch back of suboxone when del even when breast feeding; discussion with peds if baby is being treated
 - Identify a bup provider during preg for postpartum
 - Communication with bup proivder if not compliant with prenatal care; ask them to switch to get scripts from me- then they have to ocme weekly; back to provider when PP
 - Identification of poor bup candidates (often during preg) and switch to methadone or offier iop, res program
 - Work closely with addiction specialists (I amnot one) if I have questions; mentoring of bup
 - Mandatory weekly drug screens; if any +benzo to methadone or residential program; if cocaine iop, residential or methadone
-
- Mistakes;
 - Not requiring intensive initial treatment
 - Giving people a number of relapses before stopping prescribing
 - Patient identification
-
- Future:
 - Work with outpt induicton program to avoid admission
 - Expand to allow prescribing for a year postpartum
 - Randomize to subutex vs suboxone for breastfeeding
 - Ideally identify an iop in each referral area and work primarily with those few to develop a tight net
 - Develop better confidential communication system to aid in compliance of both counseling and prenatal care