Interim Buprenorphine: Leveraging Medication and Technology to Bridge the Gap in Treatment Access



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Current U.S. Opioid Epidemic

- One of the most devastating public health crises of our time
 - Nearly 12 million Americans reported opioid misuse in 2016



- Consequences of opioid use disorder (OUD) include:
 - Emergency department visits, premature death, HIV, hepatitis, criminal activity, lost workdays, and vast economic costs



SAMHSA, 2017

Barriers to treatment

- Opioid agonist medications (i.e., methadone, buprenorphine) are highly effective in reducing illicit opioid use, overdose, premature death.
- However rural communities struggle with a persistent shortage of opioid agonist treatment (OAT) availability:
 - Only 1.3% of physicians authorized to prescribe buprenorphine practice in rural areas
 - 82.5% of rural counties have no buprenorphine-authorized physicians (Rosenblatt et al., 2015)
 - <u>Specific to Vermont</u>:
 - 30% of waivered physicians, were not prescribing at all
 - Of the remaining providers, most were only treating a small handful of patients, translating to a current utilization rate of 10% (Sigmon, 2015)
 - The waitlist for treatment in VT's primary opioid treatment program reached a nearly 2-year delay to lifesaving treatment (Sigmon, 2014).
 - Innovative approaches are urgently needed to expand access to evidence-based treatments for OUD.



Rolling Stone, 2014



Interim Buprenorphine Treatment

- Novel approach to reducing risk of overdose and illicit opioid use among Vermonters stuck on waitlists.
- Treatment components:
 - 1. Automated medication dispensing Buprenorphine dispensed in a secure computerized device to support medication administration while minimizing nonadherence
 - 2. Daily monitoring Nightly calls from an automated Interactive Voice Response (IVR) phone system to assess any opioid use, withdrawal and craving
 - **3. Random call-backs -** participants contacted by IVR on random schedule to return to the clinic for UA, pill count, dose ingestion dose under nurse observation
 - 4. Automated HIV and HCV Education Interactive educational application delivered via iPad









Randomized pilot trial

- 12-week outpatient randomized pilot study to evaluate initial efficacy
- Participants (n=50):
 - >18 years old

Weeks 4, 8, and 12.

- Meet DSM-V criteria for OUD
- Provide opioid-positive urine at intake
- Currently waitlisted for opioid treatment



Waitlist Control: Remained on waitlist but completed Week 4, 8, and 12 follow-



Interim Buprenorphine vs. Waiting List for Opioid Dependence

N ENGL J MED 375;25 NEJM.ORG DECEMBER 22, 2016

- 12-week outpatient randomized pilot trial to evaluate initial efficacy
- 50 participants randomized to IBT or Continued Waitlist Control



- Participants randomized to IBT achieved significantly greater abstinence from illicit opioids.
- At 4-, 8- and 12-week assessments, 88%, 84% and 68% of IBT participants abstinent vs. 0%, 0% and 0% of WLC participants.



Study Week

 IBT participants demonstrated greater reductions in IV opioid use.



Secondary Outcomes



- Participants in both groups presented with elevated depression severity.
- No change in WLC participants.
- Depression symptoms decreased significantly among IBT participants (Streck et al., 2018, Experimental and Clinical Psychopharmacology)



- IBT participants demonstrated significant improvements in HIV and HCV knowledge.
- These improvements persisted throughout the 12-week study, without additional educational sessions (Ochalek et al., in press, *Drug and Alcohol Dependence*)

Research Questions

- Low-barrier buprenorphine dosing with waitlisted opioid-dependent individuals is promising.
 - What about with opioid users not interested in "treatment"? Despite increased access to treatment efforts is this approach helpful for reaching highest-risk Vermonters?
- Technology-assisted components (e.g., computerized med dispenser, IVR monitoring) may help to support clinical stability and minimize nonadherence.
 - Research questions: Disseminate to the most rural, underserved counties? Provide longer durations of medication?



Ongoing randomized trial

- 24-week outpatient randomized trial
- Participants: <a>18 years old, meet DSM-V criteria for OUD, provide opioid-positive urine at intake, not currently receiving opioid agonist treatment
- <u>IBT</u>: Visited clinic every 2 weeks to ingest dose, provide UA, and receive remaining doses via Med-O-Wheel. Daily IVR monitoring of recent drug use, craving and withdrawal. Random-call backs (~2x/mo). Monthly follow-up assessments.
- <u>Waitlist Control</u>: Remain on waitlist but complete same monthly follow-ups.

Demographic and Drug Use Characteris	stics <i>(n</i> = 55)	
Age	38.42 (11.90)	
Male, %	52.7	
White, %	90.9	
Employed full-time, %	50.9	
Education, years	12.50 (1.62)	
Duration of regular opioid use, years	9.78 (6.40)	
Past-month opioid use, days	26.95 (5.01)	
Ever used IV, %	56.4	
Heroin as current primary opioid, %	12.7	
Ever used heroin, %	67.3	
Beck Anxiety Inventory (BAI)	8.59 (10.36)	
Beck Depression Inventory (BDI)	14.31 (12.00)	



Treatment Adherence

- IBT participants are demonstrating favorable adherence to the treatment protocol:
- The buprenorphine dosing regimen: 98.8% of doses taken in accordance with the treatment protocol





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- Daily IVR calls: 94.4% of daily IVR calls completed





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- Daily IVR calls: 94.4% of daily IVR calls completed
- Random call-back appointments: IVR participants attended 84% of random-call back appointments





Illicit Opioid Abstinence



Illicit Opioid Abstinence

IBT Illicit Opioid Abstinence





Psychiatric Symptoms

 Beck Anxiety Inventory: Participants in the IBT group reported reductions in symptoms of anxiety that are not statistically significant



Psychiatric Symptoms

 Beck Depression Inventory: Participants in the IBT group participants are reporting reductions in depressive symptoms at the 4-, 12-, and 24-week assessments relative to baseline



Conclusions

- Innovative strategies needed to increase access to treatment for OUD, particularly in Vermont and other rural geographic areas
- Providing low-barrier buprenorphine dosing, without formal psychosocial counseling, to opioiddependent individuals who are not currently enrolled in treatment may significantly reduce drug use and related risks
- Individuals randomized to IBT demonstrated favorable adherence to the treatment protocol
- Preliminary evidence suggests that individuals who receive IBT may achieve significant reductions in illicit opioid use that endure over the course of a 24-week trial
- Although buprenorphine treatment is easier to access in the state of Vermont than it was several years ago, individuals who receive IBT appear to achieve better outcomes than their peers randomized to WLC in terms of illicit opiate use
- Although participants who were randomized to IBT did not receive formal psychosocial counseling, they
 reported significant reductions in depressive symptoms at the 4-, 12-, and 24-week assessments relative
 to baseline



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Questions?









Opioid Prescribing for Pain: Primary Care, Oral Health and Post Operatively

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2019 Northeast Regional IDeA conference, August 2019

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- Brief review of Opioid Prescribing Guidelines and Rules
- Opioid prescribing in primary care
- Opioid prescribing after surgery
- Opioid prescribing in oral health



 Recommendations for Prescribing Opioids for <u>Chronic Pain</u> Outside of Active Cancer, Palliative, and End-of-Life Care

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49.

CDC guidelines 2016 (condensed)

- Use alternatives to opioids whenever possible
- Explain the risks and benefits
 - Informed consent
- Focus on function
- Start low and go slow
- Track progress carefully
 - Surveillance for misuse
- Avoid benzodiazepines



July 1, 2017 Vermont Rules





VT Prescribing Rules, <u>chronic</u> opioid therapy

- Patient written consent and agreement, updated annually
- Use of PDMP at least annually
- Office assessment
 - Function
 - Risk for aberrant behavior
 - Revisit interval 90 days
- Co-prescribing of naloxone for high dose or concomitant benzodiazepine

VT Prescribing Rules, <u>acute</u> opioid therapy

- Patient written consent and agreement
- Quantity and dose limits
- PDMP if 10+ pills

Managing Opioids Safely and within Vermont Rules

Only prescribe opioids if expected benefits for both pain and function are anticipated to outweigh

risks to the patient. If opioids are used, combine

with non-opioid alternatives.

SUMMARY FOR MEDICAL AND DENTAL PRESCRIBERS

Recommend Non-Opioid and Non-Pharmacological Treatment

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- and/or acetaminophen
- Acupuncture
- Chiropractic
- Physical therapy
- Yoga

Query the Vermont Prescription Monitoring System (VPMS)*

First-time Prescriptions:

- · Prior to writing a first opioid prescription for greater than 10 pills (e.g. opioids, tramadol)
- Prior to writing a first prescription for a benzodiazepine, buprenorphine, or methadone
- Prior to starting a patient on a chronic opioid (90+ days) for non-palliative therapy
- Re-evaluation: At least annually (at least twice annually for buprenorphine)
- Centers for Disease Control (CDC) recommendation: every prescription, or at least every 90 days
- Replacement: Prior to writing a replacement (e.g. lost, stolen) of any scheduled II-IV controlled substance

Provide Patient Education and Obtain Informed Consent

Discuss Risks *in-person* with the patient or legal representative regarding potential side effects, risks of dependence and overdose, alternative treatments, appropriate tapering, and safe storage and disposal of opioids

CDC: Establish realistic treatment goals for pain and function and establish patient and clinician responsibilities
 for managing therapy, including when to discontinue therapy

Provide Written Patient Education: Use the Vermont Department of Health (VDH) Opioid Patient Information Sheet or a handout that contains all of the same information at a 5th grade reading level or lower. www.healthvermont.gov/sites/default/files/documents/pdf/adap_opioid_patient_information.pdf

Obtain a Signed Informed Consent document from the patient or legal representative that contains all of the required elements stated in the Opioid Prescribing Rule, section 4.3.3.1.

Use Available Resources: The Opioid Patient Information Sheet and an example informed consent document are available in multiple languages and may be found online at: www.healthvermont.gov/news-information-resources/ translated-information/language.

Additional resources may be found at: www.healthvermont.gov/alcohol-drugs/professionals/help-me-stay-informed and www.cdc.gov/drugoverdose

Prescribe Nasal Naloxone when Indicated

High Dose: 90+ Morphine Milligram Equivalent (MME) per day

Concomitant benzodiazepine: Patients prescribed both an opioid and a benzodiazepine (CDC recommends avoiding these combinations)

CDC: History of overdose, history of substance use disorder, 50+ MME per day prescriptions

Arrange for Evidence-based Treatment for Patients with Opioid Use Disorder

CDC: Offer evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder



* Prescriber registration with the VPMS is mandatory. For the complete rules, visit the Vermont Prescription Monitoring System Rule (7/1/17) and Rule Governing the Prescribing of Opioids for Pain (3/1/19) found at www.healthvermont.gov. CDC Guidelines: Dowell D, et al. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. JAMA. 2016 Apr 19;315(15):1624-45. PMID: 26977696

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Complete Continuing Education Requirements

Complete at least two hours of continuing education for each licensing period on the topic of Controlled Substances. Visit vtad.org, your licensing board, or check with your professional society for information and available courses.

Prescribe the Lowest Effective Dose of Immediate-release Opioids

- For acute pain, prescribe 0-5 days of therapy. See table below.
- Prescription limits only apply to first prescriptions for opioid naïve patients
- Include the maximum daily dose or a "not to exceed" equivalent on the prescription

Evaluate Patients Regularly Using Best Practices

- Reevaluate patients (and document) at least every 90 days (both VT Rules and CDC)
- Calculate MME. Consider 50-89 daily MME a "yellow light" and 90+ MME a "flashing red light."
- Use evidence-based tools to evaluate pain and function (e.g. PEG), and potential for abuse and diversion (e.g. COMM)
- CDC: A 30% improvement in PEG score is clinically meaningful. If benefits do not outweigh risks, taper opioids.
- CDC: Use urine drug screening prior to initiating opioids. Rescreen at least annually.

Document, Document, Document

- · Medical evaluation, including physical and functional exams and assessment of comorbidities
- Diagnoses which support the use of opioids for chronic pain and whether to continue opioids
- Individual benefits and risks, using evidence-based tools (e.g. RAPID3, SOAPP, COMM)
- Non-opioid and non-pharmacological treatments tried and trial use of the opioid
- VPMS query
- Patient discussion about the risk of overdose, including any precautions the patient should take
- VDH Opioid Patient Information Sheet provided
- That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine or prescribed and taken any other controlled substance
- Signed Controlled Substance Treatment Agreement: update at least annually
- · Acknowledgement that a violation of the agreement will result in a re-evaluation of the therapy plan

Opioid Prescription Limits for Acute Pain (Prescribe Immediate-Release Formulations)

PEDIATRICS

Consider discussing the benefits and risks of prescribing an opioid to a pediatric patient with a colleague or specialist. Use extreme caution. Calculate dose for patient's age and body weight. Consider the indication, pain severity, and alternative therapies. Limit prescriptions to 3 days or less with an average MME of 24 or less. Do not write additional prescriptions without evaluating the patient.

ADULTS	Average Daily	Total RX	
MINOR PAIN (Examples: sprains, headaches, tooth extraction)	No opioids	No opioids	
MODERATE PAIN (Examples: non-compounded bone fractures, soft tissue surgery, most outpatient laparoscopic surgery)			
Hydrocodone 5mg	MME: 24 / 0-4 tablets	0-5 days / 0-20 tablets	
Oxycodone 5mg	MME: 24 / 0-3 tablets	0-5 days / 0-15 tablets	
SEVERE PAIN (Examples: non-laparoscopic surgery, joint replacement, compound fractures)			
Hydrocodone 5mg	MME: 32 / 0-6 tablets	0-5 days / 0-30 tablets	
Oxycodone 5mg	MME: 32 / 0-4 tablets	0-5 days / 0-20 tablets	

Extreme pain (beyond severe) in adults is limited to a 7 day max with a 350 MME max. This should be rare. Prescribing outside of this table (i.e. exceptions) must be clearly documented. For the complete rules, with the Rule Governing the Prescribing of Opioids for Pain (3/1/19) found at www.healthvermont.gov. CDC Guidelines: Dowell D, et al. CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016. JAMA. 2016 April 2)315(15):1224-5. PMID: 25977696

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Questions

- Who is prescribing?
- What are the changes over time?
- How can we do a better job?

Who is prescribing?



What is the trend over time?



Population summary of opioid prescribing

9.1% of ~62,000 subjects received an opioid in 2018

- Of those on an opioid:
 - Chronic 25.1%
 - High dose 5.1%
 - GABA agonist co-prescription
 - Any GABA use 32%
 - Weekly use 20%
 - Daily use 9%




Primary care summary

- Wide variability in prescribing within practices
 - Patient factors (age, co-morbidities, tolerance)
 - Prescriber factors (duration in practice, setting, schedule, style)
 - "Typical" Annual prescribing
 - 90 patients total
 - 5-20 "chronic" patients
 - MME 250,000 (25K-1.6M)
- Benchmarking and peer comparison across prescribers will likely be useful for exploration of variability

Primary Care QI Projects

Or...implementing the guidelines



Opioid QI Projects - 2012-2019

Rationale

- Public health problem
- Standards of care are changing
- A small number of cases can cause a lot of office drama/disruption/splitting/ night calls/etc
- Prescribers need more implementation, less education
- QI facilitator using LEAN management approach to improve prescribing in community practices
 - Funded by VDH

Primary care strategies

- Referral to a comprehensive pain clinic
- Peer consultation



- Team-based care
 - "Pain Team"
 - "MAT-style" team

Office of Primary Care and Area Health Education Centers (AHEC) Program

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Opioid Prescription Management Toolkit for Chronic Pain Sustainable Solutions for Vermont: Practice Fast Track and Facilitators Toolkits

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What are these toolkits and why were they created?

These toolkits collect the best practice strategies for managing opioid prescriptions in primary care (and other) ambulatory settings. The strategies resulted from a two-year project (The Opioid Prescribing Quality Improvement Project, 2012-2014) to identify the most helpful methods used to create predictable and wellmanaged opioid prescribing patterns for physicians, nurse practitioners, and physician assistants and their patients.

What are some of the best practice strategies for managing opioid prescriptions?

New regulations about the prescribing of chronic opioids require the use of consent forms/treatment agreements and use of the prescription monitoring system. The standard of care supported by boards of medical practices across the country recommend, under certain circumstances, a variety of practice strategies to safely prescribe and monitor chronic opioid treatment. These strategies include assessing risk for misuse, use of pill counts and urine drug testing, best-practice documentation, and standardizing prescribing intervals to minimize communication issues among patient, office staff and prescriber, and others.

What are some of the results from the opioid prescribing two-year project?

All ten practices enrolled in the project reported positive results from the best practice strategies they chose to implement from the toolkit. The strategies helped prescribers standardize their approach and increase confidence in managing opioid prescriptions, helped practices change their support systems, and increased provider and staff satisfaction regarding the way opioid prescriptions are managed.

Who should read these toolkits and how are they different?

East Track Toolkit: This toolkit is intended for ambulatory care practices whose leaders, providers, and staff want to improve the process of managing opioid prescriptions for their chronic pain, non-palliative care patients. It is for practices with a team ready to make a quick start on a few of the 17 strategies and provides practical advice on getting started, how to adjust practice workflow, and how to implement changes. The toolkit includes an extensive appendix with policies, sample tools, and references.

<u>Facilitator Toolkit</u>: This toolkit is intended for practices that have not yet made a decision to work on opioid prescription management and need to develop a rationale, leadership support, and team to work on this topic. It provides three stages of development: preparation, design (of workflow), and implementation. It provides detailed guidance on measurement, team facilitation, work flow analysis, and follow up. It is best used by facilitators, staff, or leaders interested in supporting a transformative change in opioid prescription management. It includes the same appendix as the Fast Track Toolkit, with additional materials to support facilitation.

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Im	proving	Opioid	Prescrib	ing:	
Su	stainabl	e Solutio	ons for V	ermont	

CT US

Improving Opioid Prescribing Toolkit - Practice Fast Track (PDF)



mproving Opioid Prescribing: Sustainable Solutions for Vermont

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Improving Opioid Prescribing Toolkit - Facilitator Manual (PDF)

Post-operative prescribing

What is the contribution of post-operative prescriptions to the opioid supply?

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Background and study design

Background

- Variability in post-operative discharge prescribing
- Goals
 - Assess current opioid prescribing at discharge over 1 year
 - Develop standard approaches
- Methods
 - ~ 11,000 operations
 - 66% outpatient
 - Ortho, Gen surg, Ob/gyn, Urology

MME for common surgeries



Patient perspective

- Phone call one week post-op
- "How many pills do you have left?"

Patient use

- General & orthopedic surgery
 - 93% of patients were given an opioid
 - 12% did not fill
 - 29% did not use at all
 - Most used less than prescribed
 - Overall about 30% of prescribed opioid was used

• Fujii et al, 2018. J Am Coll Surg, 226(6):1004-1012

Post operative trend after July 2017 rules



MacLean et al, 2018. Pain Medicine; 20:1212

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	Base	eline period (Ju	ıl-Dec 2016)	Post	t-rule period (J	ul-Dec 2017)	
Specialty, procedure	Number of procedures	Proportion with any opioid	MME ^a prescribed median (Q1-Q3) ^b	Number of procedures	Proportion with any opioid	MME ^a prescribed median (Q1-Q3) ^b	Difference in median MME [95% Cl] ^c
Overall	5,981	71%	113 (0-240)	5,872	64%	68 (0-150)	-45 [-50, -40]
General Surgery ^d	1,420	73%	80 (0-160)	1,413	71%	64 (0-80)	-16 [-24, -8]
Appendectomy (laparoscopic)	108	94%	106 (80-155)	67	78%	64 (30-72)	-36 [-55, -17]
Cholecystectomy (laparoscopic)	155	94%	120 (80-160)	134	85%	64 (45-80)	-56 [-73, -39]
Colectomy, partial (lap or open)	69	77%	160 (75-240)	82	68%	80 (80-150)	-80 [-123, -37]
Hernia (inguinal, ventral, incisional)	177	90%	96 (64-160)	235	95%	64 (48-80)	-82 [-44, -20]
Mastectomy, partial	102	73%	48 (0-80)	86	65%	40 (0-72)	-8 [-21, 6]
Gynecology	827	62	75 (0-200)	785	60	60 (0-80)	-15 [-29, -1]
Hysterectomy (laparoscopy)	114	92%	225 (160-263)	132	91%	75 (75-80)	-150 [-164, -136]
Hysterectomy (open)	28	96%	260 (225-320)	37	89%	80 (75-150)	-200 [-241, -159]
Laparoscopy	25	88%	113 (75-120)	28	96%	75 (38-75)	-38 [-61, -14]
Urethral sling procedure	47	70%	60 (0-113)	35	86%	37.5 (32-75)	-23 [-49, 4]
Orthopedic Surgery	2,464	78%	225 (75-450)	2,441	75%	113 (50-300)	-112 [-133, -92]
Carpal tunnel release	152	39%	0 (0-100)	170	43%	0 (0-50)	0 [-20, 20]
Hip arthroplasty	144	88%	594 (450-775)	154	84%	375 (238-520)	225 [-290, -160]
Knee arthroplasty	146	77%	523 (300-700)	119	91%	500 (280-650)	-20 [-93, 53]
Knee arthroscopy	98	97%	155 (96-225)	136	91%	67.5 (64-80)	-83 [-109, -56]
Lumbar arthrodesis	40	77%	513 (388-880)	40	90%	450 (250-735)	-75 [-300, 150]
Rotator cuff repair (arthroscopic)	42	100%	533 (450-600)	33	100%	268 (225-400)	-272 [-357, -188]
Trigger finger release	33	27%	0 (0-100)	38	29%	0 (0-25)	0 [-12, 12]

Prescriptions at discharge after selected surgical procedures before and after organizational and policy changes

Prescriptions at discharge after General Surgery procedures

	Baseline period (Jul-Dec 2016)	Post-rule period (Jul-Dec 2017)	
Procedure	MME prescribed median (Q1-Q3)	MME prescribed median (Q1-Q3)	Difference in median MME [95% CI]
Appendectomy (laparoscopic)	106 (85-155)	64 (30-72)	-36 [-55, -17]
Cholecystectomy (laparoscopic)	120 (80-160)	64 (45-80)	-56 [-73 <i>,</i> -39]
Colectomy, partial (lap or open)	160 (75-240)	80 (80-150)	-80 [-123, -37]
Hernia (inguinal, ventral, incisional)	96 (64-160)	64 (48-80)	-32 [-44, -20]

Oral Health

What is the contribution of dentists and oral surgeons to the opioid supply?



Annual opioid prescribing by discipline

Prescribing metric	General Dental	Oral surgery
Number of Rx, median	21	490

Source: VPMS (2014) and UVM Medical Center (2011-2018)

Post operative study in oral surgery

Patients

- 3rd molar extractions (N=46 + 20)
- ~56% used some opioid
- Typical prescription
 - Average 60 MME/Rx (i.e. hydrocodone 5 mg #12)
- How much did patients use?
 - Median of 4 of the original 12 hydrocodone pills (20 MME)

Resources

- CDC guidelines
 - http://www.cdc.gov/drugoverdose/prescribing/guideline.html
 - See also the phone app with includes an opioid calculator
- www.PainEDU.org
 - SOAPP, COMM (screening tools for misuse)
- Safe and Effective Opioid Prescribing for Chronic Pain (BU)
 - www.opioidprescribing.com
- Prescriber's Clinical Support System for Opioid Therapies
 - www.pcss-o.org/
- Vermont Prescription Monitoring System
 - <u>http://healthvermont.gov/adap/VPMS_reports.aspx</u>
- Brandeis PDMP Center of Excellence
 - <u>http://pdmpexcellence.org</u>
- Larner College of Medicine Office of Primary Care
 - <u>http://www.med.uvm.edu/ahec/home</u>

Questions





Improving Access to Treatment of Opioid Use Disorder in Pregnancy

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III Dartmouth-Hitchcock





Disclosures

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A Case

- Melinda is a 32 year old woman who presents to an emergency room at a rural community hospital in New Hampshire with abdominal pain, nausea and vomiting.
- Melinda discloses she has been using heroin. She recently had a positive pregnancy test so she has been trying to stop using.
- Unsure of last menstrual period = unknown gestational age

III Dartmouth-Hitchcock



The Facts

- 10% of all pregnancy associated deaths nationally are attributed to opioids, this proportion is far higher in New Hampshire^{1,2}
- Women with opioid use disorder are 4 times more likely to die during hospitalization³
- At increased risk of preterm labor, stillbirth, cesarean section and a number of other obstetric complications
- Other associated comorbidities: endocarditis, abscess, Hepatitis C and other infectious diseases, neonatal abstinence syndrome
 - 1. Gemmill et al. Am J Obstet Gynecol 2019
 - 2. NH Annual Report on Maternal Mortality, 2019
 - 3. Maeda et al. Anesthesiology 2014

//// Dartmouth-Hitchcock



New Hampshire Maternal Mortality Data 2016 and 2017

- 12 maternal mortalities
- 2/12 pregnancy related, other 10 deemed "pregnancy associated"
- 11/12 deaths occurred postpartum
- 8/12 had Medicaid insurance
- 11/12 had documented mental health diagnoses

Leading cause of death: accidental drug overdose

- 6/12, cause of death = overdose
- Another 3 died of causes related to substance abuse

//// Dartmouth-Hitchcock

Evidence-Based Treatment

- Recent national guidelines
- Recommended treatment for OUD in pregnancy is opioid agonist therapy (OAT)
 - Methadone or buprenorphine with naloxone
 - Safety data lacking for naltrexone or injectable buprenorphine
- Rural areas: buprenorphine often much more practical





Obstetric Care for Women with Opioid Use Disorder









Back to our patient...

- Melinda's fundal height was 30 cm. An ultrasound was obtained showing an estimated gestational age of 32 weeks. The fetus had a normal heart rate. Her cervix was examined and she was found to not be in labor. Prenatal labs and screening for infectious diseases was performed
- She had an evaluation for causes of abdominal pain and nausea/vomiting, other causes were ruled out and the leading diagnosis was opioid withdrawal.
- The patient desired treatment for her opioid use disorder

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Initiating Buprenorphine During Pregnancy

- Can be performed in the emergency room, in an obstetric or treatment provider's office, or an obstetric unit
- Gestational age, patient status, and local resources should guide induction setting
- Transfer to a hospital with more resources is warranted if OAT cannot be initiated otherwise or if patient has concurrent benzodiazepine or alcohol dependence
- Inpatient units should develop specific protocols for initiating OAT
 - Provide intravenous fluids liberally
 - Treat nicotine dependence
 - Use clonidine cautiously
- Ensure patient has follow up appointments in place at time of discharge

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Models for Outpatient Treatment of Perinatal OUD

- Traditional referral-based approach
 - Maternity care
 - Opioid Agonist Treatment (OAT)
 - Behavioral Health
- Co-located services
- Fully integrated programs
 - Team based approach
 - Real-time communication
 - Shared philosophy of care



behavioral health and primary care practices were co-located in the same building



behavioral and mental health providers spent **time together at** weekly meetings

practice integration



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https://www.rand.org/pubs/research_briefs/RB9789.html



How Did Our Patient Do?

- Transferred from small rural hospital to a tertiary care center
- 2 day hospitalization -> discharged on 16 mg Buprenorphine daily
- Returned to her home community and prenatal care provider
- Had difficulty getting an appointment with a local buprenorphine provider, which caused a 2 week interruption in treatment
 - During this time she traded for buprenorphine/naloxone on the street
- Delivered at 38 weeks following spontaneous labor
- Child Protection actively involved due to late entry to treatment





What would make treatment more available to rural women with OUD in pregnancy?

- Empowering prescribers in low volume obstetric services to initiate buprenorphine
- More treatment providers willing to treat pregnant women
- Better coordination of care between addiction treatment and obstetric providers
- More social support services for families in early recovery
 - Transportation and housing assistance
 - Ability to bring children to treatment or subsidized childcare
 - Increased support in postpartum period to prevent relapse and overdose





What Are We Up To in NH?

Integrated Opioid Treatment in Obstetrics (iMAT-OB) project

Three year project to improve access to OAT for pregnant women in prenatal care settings

Immediate access to buprenorphine for opioid use disorder in maternity care context through 3 months postpartum

- Fully integrated model
- Team based approach



iMAT-OB Implementation

- Implementation pilot at 6 diverse maternity care practices across New Hampshire
- Prenatal providers (MD, APRN, CNM) at each site obtained buprenorphine waivers
- Core elements of model
 - Maternity care
 - OAT
 - Behavioral health
 - Peer recovery support
 - Case management
- "Hub" site provides support for complex cases

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Expanding Resident Training

Dedicated perinatal substance use clinic within general Ob/Gyn clinic

- Care providers are 4 PGY2 Ob residents with MD and CNM attendings
- Residents complete buprenorphine waiver training
- Focus on access to treatment and coordinating care with treatment provider
- Team based approach:
 - Behavioral health
 - Recovery Coach
 - Community Health Worker

Patient feedback: "I feel so important when I come here."

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In the words of the residents

Since completing this training, residents report being more comfortable:

- Screening for substance use
- Speaking frankly with patients about SUD and pregnancy
- Counseling for tobacco cessation
- Prescribing nicotine replacement therapy in pregnancy
- Discussing MAT in pregnancy
- Counseling patients about NAS

3/4 senior residents report they would prescribe buprenorphine in pregnancy if their community had a need after graduation





Summary

- OUD during pregnancy requires specialized treatment
- Buprenorphine is often more practical treatment in rural areas
- Increased knowledge about substance use treatment in pregnancy among prenatal care providers, addiction treatment providers and emergency room providers will benefit patients and communities





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The heart and science of medicine. UVMHealth.org/MedCenter

Initiating Medication Assisted Treatment in the Emergency Department

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UVMHealth.org/MedCenter

I have no conflicts of interest or financial disclosures

Opioid Epidemic

Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018



Opioid Epidemic

Figure 1: Number of All Drug-Related Deaths Among Vermont Residents



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Drug Related Fatalities Brief 2017, Vermont Department of Health



Medication-Assisted Treatment (MAT) with methadone or buprenorphine is most effective current treatment for opioid use disorder (Schukit, 2016)



2mg Buprenorphine / 0.5mg Naloxone Sublingual Film



Emergency Department–Initiated Buprenorphine Treatment

Engagement in Treatment



D'Onofrio et al 2015, 2017

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Hub and Spoke Model



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UVMMC Addiction Treatment Program

-Supervise treatment until patient transferred to primary care provider, referred to a higher level of care or drops out of treatment

-Typically 8 weeks at ATP before referral





Previous Standard of Care at ED

- Treat acute symptoms of overdose
- Provide brochure with information about to local treatment programs.



Start Treatment and Recovery (STAR)



1. Recruitment Identification, Prescreening, Consenting, Screening

2. Buprenorphine/ Naloxone Induction

3. Referral to ATP

4. Outcome Assessment at 1 week, 3 & 6 months



Inclusion/Exclusion Criteria

Indicators of OUD

- Acute overdose symptoms consistent with opioid withdrawal (i.e. piloerection, diarrhea, tachycardia, cravings, and pupillary dilation)
- EMS use of naloxone
- Abscesses in antecubital fossa or other areas consistent with injection drug use
- History of endocarditis

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Exclusion Criteria

- Over 18 or under 65 years old
- Current participation in an alternate treatment program
- Previously enrolled
- Inability to communicate
- Psychosis
- Suicidality
- Hepatic impairment
- Critical Illness
- Incarceration
- History of suboxone injection

Recruitment

1. Recruitment

Identification, Prescreening, Consenting, Screening 2. Buprenorphine/ Naloxone Induction 3. Referral to ATP

4. Outcome Assessment at 1 week, 3 & 6 months



Induction

1. Recruitment Identification, Prescreening, Consenting, Screening 2. Buprenorphine/Naloxone Induction 3. Referral to ATP

4. Outcome Assessment at 1 week, 3 & 6 months



Addiction Treatment Program

1. Recruitment Identification, Prescreening, Consenting, Screening 2. Buprenorphine/ Naloxone Induction

3. Referral to ATP

4. Outcome Assessment at 1 week, 3 & 6 months



Outcome Assessment







- Pharmacy regulations (80% ED physicians x-waivered)
- Manage expectations in transition low-barrier ED to higher barrier ATP
- Extra training for nursing staff



Clinical Precautions

- Do not give Bup/Nal to patients who have taken methadone in the last 48 hours, unpredictable precipitated withdrawal can occur.
- Do not give Bup/Nal to patients who are currently intoxicated with alcohol, benzodiazepines, stimulants, etc. Encourage these patients to return later or follow up at the ATP.
- Do not give Bup/Nal to patients who are prescribed opioids for chronic pain. These patients can still be referred to the ATP if there is concern for misuse.
- Treat excessive sedation with naloxone bolus and infusion.
- Precipitated withdrawal is generally self-limited but when severe can be treated symptomatically with lorazepam, clonidine, ondansetron, loperamide, and ibuprofen as needed while proceeding with induction.



Screening Statistics

18,731 ED Visitors Screened

4.4% Visitors had indicators OUD



Percent ED Visitors Indicators

Number Enrolled per Month



61 Enrolled in 5 months

Enrolled 0.3% of all ED visitors screened

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- 30.6% over 65 or under 18 years old
- 65.5% no potential indicators of OUD
- 2.8% currently in other treatment
- 0.6% altered mental state, suicidal, medical provider discretion
- 0.18% previously enrolled, history suboxone injection
- 0.07% time constraints
- 0.07% incarcerated
- 0.06% in medical extremis, hepatic impairment
- 0.02% non English speaking, did not pass screen

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Participant Characteristics

- Age range 20-63 years old, average age 36
- White 88%, Black 5%, Multiracial 5%, Native American 2%
- Arrived by car 60%, by foot 21%, public transport 16%, ambulance 2%



Participant Characteristics

Chief Complaint in ED	n (%)
Overdose	1 (2)
Withdrawal	13 (21)
Referral from Recovery Program	30 (47)
Opioid Related Medical Condition	13 (21)
Other	4 (6)
Total:	61



Participant Characteristics

Most Problematic Substance		
for Individual	n (%)	
Heroin	39 (65)	
Dilaudid	4 (6)	
Morphine	3 (5)	
OxyContin	3 (5)	
Heroin & Fentanyl	2 (3)	
Percocet	4 (6)	
Non-Prescribed Suboxone	4 (6)	
Percocet, Vicodin, & Dilaudid	1 (2)	
General Opiates	1 (2)	
Total:	61	





- Short-term enrollment levels similar to D'Onofrio 2015
- Positive feedback from Emergency Department physicians and community
- Next step to compare UVMMC ED and bridge clinic with similar rural ED without bridge clinic



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Enrollment Peak Times





The Opioid Epidemic in Rural Northern New England:

Preliminary Findings from the

Drug Injection Surveillance and Care Enhancement for Rural Northern New England (DISCERNNE) Study

Kerry Nolte, University of New Hampshire Tom Stopka, Tufts University School of Medicine Aurora Drew, The Dartmouth Institute Randall Hoskinson, UMass Medical/ Baystate PI: Peter D. Friedmann, UMass Medical/ Baystate

Supported by NIDA/ NIH 1UG3DA044830 and 4UH3DA044830

NIDA RFA: "HIV, HCV and Related Comorbidities in Rural Communities Affected by Opioid Injection Drug Epidemics in the United States: Building Systems for Prevention, Treatment & Control "



Background: HIV Risk Among Rural Drug Users Scott County, Indiana 2014-2015



Peters et al. NEJM 2016



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Study Aims (UG3 phase ended July 2019)

- Characterize risk, policy and service environment in 11 rural counties in MA/VT/NH
 - Fatal and non-fatal opioid overdose burden, HIV/HCV/STIs
 - Service needs and resources
- 2. Build capacity to deliver specimens to the GHOST laboratory

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Epidemiologic, Policy, and Legal Scan

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Preventive Medicine xxx (xxxx) xxxx



The opioid epidemic in rural northern New England: An approach to epidemiologic, policy, and legal surveillance

Thomas J. Stopka^{a,*}, Erin Jacque^b, Patsy Kelso^c, Haley Guhn-Knight^d, Kerry Nolte^e, Randall Hoskinson Jr^d, Amanda Jones^c, Joseph Harding^f, Aurora Drew^g, Anne VanDonsel^c, Peter D. Friedmann^d

- Review of state and local policy, public health data, clinical care infrastructure, and national datasets
- Health policy analysis and summaries:
 - Prescription Drug Monitoring Programs
 - HIV and HCV surveillance and treatment

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- Syringe access
- GIS and spatial analyses: Opioid-related burden; access to services

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Naloxone access

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Good Samaritan laws

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Epidemiologic, Policy, and Legal Scan: **GIS and Spatial Analyses Examples**

Hepatitis C Virus









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Drive Time Access: Syringe Service Programs





1 - 50



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Epidemiologic, Policy, and Legal Scan: Summary of Key Findings

Vermont:

- Lower opioid overdose rates compared to NH and MA
- 2x higher fatalities in VT Counties with no SSPs
- Caledonia County, VT, which has an SSP, saw a reduction in HCV rates
 - 164.5/ 100,000 in 2014 to 148.3 in 2016

New Hampshire:

 STIs and fatal overdose are serious issues in western and northwestern NH, but prevention and tx services concentrated in Southeastern NH

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Methods

Quantitative, Social Network, & Lab

- Sample and Recruitment
 - Opioid use or IDU, age 18+, English-speaking
 - Respondent Driven Sampling
- Measures
 - 90-minute quantitative and social network survey
 - Rapid HIV, HCV, syphilis testing
 - Confirmatory laboratory testing
 - Positive samples sent to GHOST Lab

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Saliva toxicology

Qualitative

- Stakeholder Interviews = 31
 - Healthcare and addiction providers, public health, law enforcement
- Persons who inject drugs interviews = 22

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 Focus on drug use, treatment experiences, and community changes



Methods: Sites and RDS Participants May 2018-July 2019

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Nursing

- n = 565 participants- 42 seeds
- 11 locations included in preliminary results presented here:
 - MA 83
 - Greenfield 83
 - VT 282
 - Bellow's Falls 36
 - Brattleboro 129
 - Newport 28
 - Springfield 49
 - St. Johnsbury 34
 - White River Junction 6*

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– NH - 200

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- Canaan 2
- Claremont 35
- Keene 146
- Berlin 17



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Results: Keene, NH RDS Map of HCV Status

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Black = HCV negative Yellow = HCV positive Green = Missing

= RDS Seed

Keene, NH Respondent Driven Sampling Network Map by HCV Status

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Results: Drug Use

Ever used "to get high"

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Current drug of choice

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Results: HCV and Syringe Access

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% of participants who are HCV+



"Nowadays they just say 'well what, do you got hep C? I got hep C...' And they'll joke around like 'well hep C's got so many different strands that well you'll just get another strand'... It's like a joke." - PWID

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Results: HIV

- 80% ever tested for HIV
 - 84% of those tested received results
 - 2% receiving results were HIV+ (N=7)
 - 3 participants receiving HIV medical care and medication, 4 were not

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• No new HIV cases detected



Results: Overdose

% participants who have ever...



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Results: Addiction Treatment



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Results: Treatment and Recovery Barriers

 "I've been to a lot of places that needed come up dirty to get into but if you're trying to stay clean and you're realizing that you can't do it without some sort of help they're forcing you to go use and right there once you relapse it's ah shit, this is going to, f--k going over there. I can go to my buddy and get what I need." – PWID

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Reasons for Not Getting Needed Care

- 49% Afraid of Disrespect
- 42% No Transportation
- 31% Treated Poorly in Past
- 28% Don't Trust Doctors
- 28% Don't Care About Health
- 23% Could Not Pay

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Results: Distance to Needle Exchange and Hep C Status

Odds ratio for HCV+ status				
	OR	95% CI		
Distance to needle exchange				
(ref = walking distance)				
< 30 minute drive	1.44	0.84	2.45	
30 to 60 minute drive	2.60	1.13	5.95	
> 60 minutes	8.04	1.02	63.10	













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Discussion: Significant Population at Risk

- CDC analysis underestimates risk
- High rates of overdose
 - Naloxone needs to be easily accessible to high risk populations
- High rates of syringe sharing and HCV
 - Easy access to syringes is protective, need for more harm reduction services

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- Low barrier HCV treatment needed, telemedicine may help
- Challenges accessing medication for OUD
- Barriers to care persist
 - Stigma, distrust and transportation

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Discussion: Is Northern NE at Risk for an HIV Outbreak?

	DISCERNNE	Scott County
	N=563	N=196
Male, %	58%	58%
Median age (IQR)	34 (28-42) years	33 (27-41) years
Non-Hispanic white, %	88%	99%
Any incarceration, %	29% past 6 mos.	54% past year
Shared inj equip %	53% past 30 days	70% ever
Sex for money or drugs	10% past 30 days	9% ever

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*Pete The University NEJM 2016

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UH3: Intervention to Enhance Care 2019-2022

1. Examine the effectiveness of a model of mobile telemedicine treatment for HCV integrated with syringe services programming, versus the current clinical practice of referral to a local or regional provider, enhanced with care navigation.





2. Validate the accuracy of dried blood spot (DBS) testing for HCV viral load as a potential surveillance strategy to address limited access to phlebotomy services in rural areas.



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UH3: Intervention to Enhance Care 2019-2022

Study Hypotheses

Mobile tele-HCV care will be associated with:

- Hepatitis C treatment initiation
- Sustained virologic response 12-weeks post treatment
- Syringe sharing behavior

Secondary outcomes

- HAV and HBV vaccination completion rates
- Medication for opioid use disorder (MOUD) initiation
- Health-related quality of life (HRQOL)
- Substance use









Study Team

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Questions?

Thank you to...

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- Local harm reduction, opioid use disorder treatment and medical care partners
- Dartmouth Institute
- Massachusetts Department of Public Health

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- UMMS-Baystate
- University of New Hampshire
- UVM School of Medicine



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...and our Funders (NIDA/CDC/SAMHSA/ARC)!

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Vermont Hub-and-Spoke Model of Care for Opioid Use Disorders:

An Evaluation

Richard A. Rawson, Ph.D. Research Professor Vermont Center on Behavior and Health Department of Psychiatry University of Vermont Burlington, Vermont 05401

Enrollment in MTOUD 2014-2018 (July)

Number of people receiving MAT in hubs and spokes and number waiting for services over time



Source: Hub Ceesus and Waitlist, VMPS for Spokes

Warmont Department of Paulti-



The H&S Evaluation: Quantitative Component In-Treatment Group

- Quantitative data on drug use and functioning were collected from 80 individuals receiving treatment in the H & S system.
- Patients were self-selected and from all regions in the state.
- Participants had to have been receiving continuous treatment for at least 6 months at the time of the interview.
- The groups were stratified to include 40 patients on methadone in the hubs and 40 on buprenorphine in spokes.
- Each group was 50% male and 50% female and 18 years old or older.



The H&S Evaluation: Quantitative Component Out-of-Treatment Comparison Group

- A comparison group of 20 individuals currently not in treatment.
- 10 received treatment for OUDs in the past, but not in the past 12 months
- 10 never had never been in treatment for OUDs



The H&S Evaluation: Data Collection Time Points

- Evaluation time points- self-reported opioid and other drug use and functioning is collected regarding to two points in time
 - <u>In-treatment group:</u>
 - 90 days before the date of admission to treatment (T1) (retrospective recall)
 - 90 days before the in-person interview (T2)
 - <u>Out-of-treatment group</u>
 - 90 days before the date 12 months before the interview (T1) (retrospective recall)
 - 90 days before the date of interview (T2)
- T1 T2 interval In-treatment group: Mean duration: 30 months
- T1 T2 interval Out-of-treatment group: Duration: 12 months



The H&S Evaluation: Assessment Domains

- Drug and alcohol use
- Opioid use
- Injection use
- Education/employment
- Criminal justice involvement
- Family and relationship functioning
- Health and healthcare utilization
- Multiple areas of mental health functioning
- Opioid overdose
- Satisfaction with life areas
- In addition, patients were asked about stigma and their views of the treatment received and its overall effectiveness.



Hub and Spoke Evaluation Project Results



The H&S Evaluation: Participant Characteristics

- Mean age at time of interview: 37 years old
- Marital status: Single-47%; Divorced-21%; Married/ living together-32%
- Education: 12.5 years
- Currently employed: full time-22%; part time-20%
- Currently in school: 8%
- On parole or probation: 27%



The H&S Evaluation: Out-of-treatment Participants

Out-of-treatment participants showed no statistically significant change between T₁ and T₂ in any measure of functioning, including drug use, over a 12-month period.



The H&S Evaluation: Change in Opioid Use





The H&S Evaluation: Non-opioid Use





Drug/alcohol use in last 90 days

- % of participants reporting no opioid use in the past 90 days at T2
 85.0%
- % of participants reporting no opioid or other drug use, excluding tobacco, alcohol or cannabis, at T2
 62.5%
- % of participants reporting no substance use, excluding tobacco, at T2 30.0%



The H&S Evaluation: Medical Utilization and Overdose





The H&S Evaluation: Criminal Justice Measures





The H&S Evaluation: Family Conflict and Mood States

Conflict and Mood among In-Treatment Participants





The H&S Evaluation: Satisfaction with Life





The H&S Evaluation: Treatment Effectiveness Scores

Treatment effectiveness assessment scores of hub vs. spoke participants



Improvement Domains



The H&S Evaluation: Gender Differences

- Most background/demographic characteristics were similar for men and women.
- A higher proportion of females reported they had histories of mental illness, were more likely to have children, and used opioids for a shorter period.
- The response to treatment was comparable for males and females.
- Females reported higher levels of perceived stigma.



The H&S Evaluation: Methodological Limitations

- Sample sizes are under-powered
- Participants self selected
- All data is self-report
- This was not a controlled research trial and the out of treatment group are not a true control group
- Sample results should be used in combination of other studies and data



The H&S Evaluation: Hub Participant Themes

- Participation in MTOUD produced many profound benefits in several domains of patients' lives.
- Hub procedures and routines were generally viewed as creating an impersonal, arbitrary, and somewhat unpleasant experience.
- Standing in long lines for dosing was viewed as a dehumanizing and degrading experience.
- Counseling provided at the hubs was generally viewed as helpful in promoting successful recovery. The high rate of counselor turnover was cited as problematic.
- Participants treated at the hubs reported substantial perceptions of stigma around addiction.



The H&S Evaluation: Spoke Participant Themes

- Participation in MTOUD had profound benefits in many domains of patients' lives.
- The spoke environment was a powerful positive influence on participants' self-esteem and attitude toward treatment.
- Participants reported their relationships with their doctor was a very powerful and positive aspect of treatment.
- Receiving MTOUD at spokes was very similar to receiving routine medical care.
- Participants felt minimal stigma at spokes and reported feeling very positive about their treatment experience.



The H&S Evaluation: Conclusions



The H&S Evaluation: Conclusions

Participation in MTOUD was associated with:

- a very large reduction in opioid use
- a substantial reduction in other drug/alcohol use, except cannabis.
- a substantial reduction in drug injection
- a large reduction in ED visits and overdoses.
- a slight increase in education/training activities, but not in days of employment.
- a 90% reduction in both days of illegal activity and contacts with police.
- a substantial decrease in family conflict and improvement in measures of mood.


The H&S Evaluation: Conclusions

- Participants treated in the hubs with methadone and those treated in the spokes with buprenorphine showed similar and positive responses to MTOUD in virtually all measurement domains.
- Participants in both settings viewed MTOUD positively and as very helpful to them.
- Spoke patients view their relationship with their MD as very valuable.
- Spoke patients rated their care as helping them to a greater degree in three of the four assessed domains.



The H&S Evaluations: Closing Thoughts

- The Vermont Hub-and-Spoke System of Care for Opioid Use Disorders is an innovative and constructive public health response to the opioid epidemic of the 21st century in the United States.
- The H & S system has markedly expanded access to MTOUD and improved participants' lives.
- The services provided within this model have saved many lives and have allowed many Vermonters to discontinue opioid use and improve their lives.



Thank you rrawson@uvm.edu

