Virginia Opioid Addiction ECHO* Clinic

March 1, 2019

*ECHO: Extension of Community Healthcare Outcomes
Helpful Reminders

- Rename your Zoom screen, with your name and organization.
Helpful Reminders

• You are all on mute please unmute to talk
• If joining by telephone audio only, *6 to mute and unmute
Helpful Reminders

- Please type your full name and organization into the chat box.
- Use the chat function to speak with IT or ask questions.
VCU Opioid Addiction ECHO Clinics

• Bi-Weekly 1.5 hour tele-ECHO Clinics
• Every tele-ECHO clinic includes a 30 minute didactic presentation followed by case discussions
  • Didactic presentations are developed and delivered by inter-professional experts in substance use disorder
• Website Link: www.vcuhealth.org/echo
# Hub Introductions

<table>
<thead>
<tr>
<th>Role</th>
<th>Team Members</th>
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</thead>
<tbody>
<tr>
<td>Clinical Director</td>
<td>Mishka Terplan, MD, MPH, FACOG, FASAM</td>
</tr>
<tr>
<td>Administrative Medical Director ECHO Hub and Principal Investigator</td>
<td>Vimal Mishra, MD, MMCi</td>
</tr>
<tr>
<td>Clinical Expert</td>
<td>Lori Keyser-Marcus, PhD</td>
</tr>
<tr>
<td>Didactic Presentation</td>
<td>Courtney Holmes, PhD</td>
</tr>
<tr>
<td>Program Manager</td>
<td>Gerard Moeller, MD</td>
</tr>
<tr>
<td>Practice Administrator</td>
<td>Bhakti Dave, MPH</td>
</tr>
<tr>
<td>IT Support</td>
<td>David Collins, MHA</td>
</tr>
<tr>
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<td>Vladimir Lavrentyev, MBA</td>
</tr>
</tbody>
</table>
Introductions:

• Name
• Organization

Reminder: Mute and Unmute to talk
*6 for phone audio
Use chat function for Introduction
What to Expect

I. Didactic Presentation
   I. Pharmacotherapy for Stimulant Use Disorder
   II. Gerard Moeller, MD

II. Case presentations
   I. Case 1
      I. Case summary
      II. Clarifying questions
      III. Recommendations

   II. Case 2
      I. Case summary
      II. Clarifying questions
      III. Recommendations

III. Closing and questions

Let's get started!
Didactic Presentation
Pharmacotherapy for Stimulant Use Disorder

F. Gerard Moeller, M.D.
Professor and Chair, Division of Addiction Psychiatry
VCU School of Medicine
Disclosure

• Grant funding from Nektar and Indivior
• All medications to be discussed are off-label indications (*there is no FDA approved treatment for stimulant use disorder*).
The Current Pathway for Medication Development

• Discovery of novel compounds based on current theories
• Testing in animal models for safety/efficacy
• Human safety testing
• Clinical trials in patient populations
Challenges in Clinical Trials for Addictions

- Medication Compliance
- Treatment Retention
- Subject Heterogeneity
- Subject Recruitment

- Administer Medications in clinic
- Contingency Management
- Inclusion Criteria
- Subject Compensation
New Targets for Medication Development for Stimulant Use Disorder

• Focus initially was on reward systems
• Treatments focused solely on blocking reward have been disappointing (dopamine antagonists)
• More recently the model of medication development has examined other pathways to reduce cocaine use
Effects of Chronic Stimulant Use on the Brain that Could Increase Impulsivity/Cue reactivity

- Reduced dopamine D2 receptors
- Reduced presynaptic dopamine release
- Reduced serotonin function
- Can these effects be altered by medication?
Medications For Cocaine Dependence

• Disulfiram (Antabuse)
  • Originally used to treat comorbid alcohol and cocaine dependence
  • Several studies show efficacy in single diagnosis cocaine users
  • Possibly mediated by disulfiram’s effects as a dopamine beta hydroxylase inhibitor
  • Increases dopamine by blockade of dopamine breakdown
Disulfiram Clinical Trial

- Carroll et al., 2004
  - 121 Cocaine Dependent Subjects Randomized
  - Double blind placebo controlled trial
  - Four treatment groups
    - Disulfiram 250mg/Day plus Cognitive Behavioral Therapy
    - Disulfiram 250mg/Day plus Interpersonal Therapy
    - Placebo plus Cognitive Behavioral Therapy
    - Placebo plus Interpersonal Therapy
Results
Disulfiram Clinical Trial

- Carroll et al., 2004
  - Significant effect of drug and CBT on cocaine use
  - Effect present even in non-alcohol abusing cocaine users
  - In subjects without elevated LFTs side effects minimal, no serious adverse reactions
  - Risks of disulfiram include liver and interaction with alcohol in clinical use
  - Disulfiram can also increase cocaine levels
Clinical Trial Results of Other Medications that Increase Dopamine

Randomized controlled trial of levodopa-carbidopa and behavior therapy for cocaine-dependent outpatients

(Schmitz et al., Drug and Alcohol Dependence, 2008)
## Study Design

<table>
<thead>
<tr>
<th>Therapy Condition</th>
<th>Medication Condition</th>
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<tbody>
<tr>
<td>Clinical Management (CM)</td>
<td>Placebo</td>
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<tr>
<td>CM + Cognitive Behavior Therapy (CBT)</td>
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<tr>
<td>CM + CBT + Contingency Management Procedures (CMP)</td>
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Schmitz et al., 2008
Pharmacotherapy

- Levodopa 800 mg and Carbidopa 200 mg (Sinemet® CR) or Placebo
- Packed in capsules with riboflavin (100 mg) to monitor compliance, dispensed in Medication Event Monitoring (MEM) bottles
- 1-week dose run-up
- 12-week fixed dose (M-W-F clinic visits)

Schmitz et al., 2008
Therapy Conditions

Clinical Management (CM)
- Delivered by clinic nurse
- 10-15 minute sessions, once a week
- Ongoing assessment of patients’ clinical status

Cognitive Behavioral Therapy (CBT)
- Delivered by master-level therapists
- 50-60 minute sessions, once a week
- Focus on coping skills training

Contingency Management Procedures (CMP)
- Vouchers delivered contingent on cocaine-negative urines
- Incremental increases in voucher value with consecutive occurrences of the target behavior

Schmitz et al., 2008
Cocaine Use:
Significant Therapy x Medication Effect

F(2, 126) = 3.44, p=.04.

Schmitz et al., 2008
L-Dopa/Carbidopa for Cocaine Dependence

• Well tolerated
• Reduction in cocaine positive urines when combined with contingency management
• Unfortunately, second study not positive
Dopamine Enhancement Therapy for Cocaine Dependence

• Some evidence of reduction in cocaine use with several different medications
• Effect appears greatest when combined with contingency management
• Evidence for DA enhancement model in other stimulants?
Bupropion for Methamphetamine Dependence

• Bupropion antidepressant and weak dopamine reuptake inhibitor
• Depression significant problem in meth users
• Two studies have shown reduction in methamphetamine use in low to moderate users (Shoptaw et al., 2008, Elkashef et al., 2008).
Bupropion for Methamphetamine

● Bupropion (150mg BID) showed reduction in meth use for low users (0-2 MA positive urines during 2-week screening, or < 19 days of use in last 30)

● Well tolerated without significant side effects

● There is a risk of seizures in patients treated with bupropion

● Results from secondary analysis, need to be confirmed in other studies
Controlled trials of Modafinil for Cocaine Dependence

A Double-Blind, Placebo-Controlled Trial of Modafinil for Cocaine Dependence

Charles A Dackis*, 1, Kyle M Kampman 1, Kevin G Lynch 1, Helen M Pettinati 1 and Charles P O’Brien 1, 2

1 University of Pennsylvania School of Medicine, Philadelphia, USA; 2 Department of Veterans Affairs Medical Center, Philadelphia, USA

Despite years of active research, there are still no approved medications for the treatment of cocaine dependence. Modafinil is a glutamate-enhancing agent that blunts cocaine euphoria under controlled conditions, and the current study assessed whether modafinil would improve clinical outcome in cocaine-dependent patients receiving standardized psychosocial treatment. This was a randomized, double-blind, placebo-controlled trial conducted at a university outpatient center (from 2002 to 2003) on a consecutive sample of 62 (predominantly African American) cocaine-dependent patients (aged 25–63) free of significant medical and psychiatric conditions. After screening, eligible patients were randomized to a single morning dose of modafinil (400 mg), or matching placebo tablets, for 8 weeks while receiving manual-guided, twice-weekly cognitive behavioral therapy. The primary efficacy measure was cocaine abstinence based on urine benzoylcegonine levels. Secondary measures were craving, cocaine withdrawal, retention, and adverse events. Modafinil-treated patients provided significantly more BE-negative urine samples (p = 0.03) over the 8-week trial when compared to placebos, and were more likely to achieve a protracted period (≥3 weeks) of cocaine abstinence (p = 0.05). There were no serious adverse events, and none of the patients failed to complete the study as a result of adverse events. This study provides preliminary evidence, which should be confirmed by a larger study, that modafinil improves clinical outcome when combined with psychosocial treatment for cocaine dependence.

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Neuropsychopharmacology (2005) 30, 205–211, advance online publication, 3 November 2004; doi:10.1038/sj.npp.1300600

Keywords: modafinil; cocaine; glutamate; pharmacotherapy; abstinence; addiction
Modafinil for Cocaine

Figure 1  Weekly cocaine abstinence in modafinil and placebo groups, defined as the percentage of urine samples that were (1) submitted (requiring attendance), and (2) found to be BE-negative. Missing urines are therefore imputed as positive.

Dackis et al., 2005
Follow-up study with Modafinil

Modafinil for the treatment of cocaine dependence


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Cocaine-related disorders
Alcoholism
Pharmacotherapy
Risk factors

ABSTRACT

Aim: Modafinil was tested for efficacy in facilitating abstinence in cocaine–dependent patients, compared to placebo.

Methods: This was a double-blind placebo-controlled study, with 12 weeks of treatment and a 4-week follow-up. Six outpatient substance abuse treatment clinics participated in the study. There were 210 treatment-seekers randomized, having a diagnosis of cocaine dependence: 72 participants were randomized to placebo, 69 to modafinil 200 mg, and 69 to modafinil 400 mg, taken once daily on awakening. Participants came to the clinic three times per week for assessments and urine drug screens, and had one hour of individual psychotherapy weekly. The primary outcome measure was the weekly percentage of cocaine–non-use days.

Results: The GEE regression analysis showed that for the total sample, there was no significant difference between either modafinil group and placebo in the change in average weekly percent of cocaine–non-use days over the 12-week treatment period (p > 0.75). However, two secondary outcomes showed significant effects by modafinil 200 mg: the maximum number of consecutive non-use days for cocaine (p = 0.02), and a reduction in craving (p = 0.04). Also, a post hoc analysis showed a significant effect of modafinil that increased the weekly percentage of non-use days in the subgroup of those cocaine patients who did not have a history of alcohol dependence (p = 0.02).

Conclusions: These data suggest that modafinil, in combination with individual behavioral therapy, was effective for increasing cocaine–non-use days in participants without co-morbid alcohol dependence, and in reducing cocaine craving.

Published by Elsevier Ireland Ltd.

Anderson et al., 2009
Modafinil for Cocaine Dependence

• Initial study showed reduction in cocaine positive urines
• Follow-up larger study negative overall
• Secondary analysis showed reduced cocaine use in single diagnosis cocaine users, not in dual diagnosis cocaine-alcohol users (needs to be confirmed)
Serotonin Reuptake Inhibitors and other Antidepressants for Cocaine Dependence

- Initial positive open label studies in 1990s
- Later double blind studies less successful
- SSRIs not generally effective
- Citalopram combined with behavioral therapy has been shown to reduce cocaine use
Citalopram plus Contingency Management for Cocaine Dependence

- 76 cocaine dependent subjects randomized to Citalopram 20 mg/day or placebo
- 12 Week double-blind trial
- All subjects receive contingency management in addition to pharmacotherapy
- Percentage of positive urine drug screens for benzoylecgonine and craving outcome measures (Moeller et al., 2007)
Citalopram plus CM Significantly Reduced Cocaine Positive Urines

Percent Positive UDS By Week (Moeller et al., 2007)
Cocaine Users with Impaired Decision Making Did not Responded to Citalopram

Cocaine Users with Intact Decision Making Responded to Citalopram

Longest Estimated Consecutive Cocaine—Free Urines as Function of Baseline Iowa Scores

<table>
<thead>
<tr>
<th>Label</th>
<th>Risk Ratios</th>
<th>Standard Error</th>
<th>Alpha</th>
<th>Confidence Limits</th>
<th>Chi-Square</th>
<th>Pr &gt; ChiSq</th>
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</thead>
<tbody>
<tr>
<td>Iowa Score Under Placebo</td>
<td>1.0012</td>
<td>0.0097</td>
<td>0.05</td>
<td>0.9825</td>
<td>1.0205</td>
<td>0.02</td>
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<td>Iowa Score Under Citalopram</td>
<td>1.0317</td>
<td>0.0053</td>
<td>0.05</td>
<td>1.0213</td>
<td>1.0422</td>
<td>36.42</td>
</tr>
</tbody>
</table>

(Green et al., 2009)
Citalopram for Cocaine Dependence

• Single site study positive for 20mg daily
• No significant adverse events
• Intact decision making as measured by Iowa Gambling Task predicts good response to citalopram
• Larger study negative
Topiramate

• Johnson et al., 2013 JAMA Psychiatry
• 12 week trial of topiramate 300mg vs. placebo plus CBT in 142 cocaine dependent subjects
• Titration of topiramate over 5 weeks
Topiramate

From Johnson et al., 2013

Figure 2. Weekly Mean Proportion of Cocaine Nonuse Days From Baseline Through Study Week 12

Without imputing missing data

With imputing missing data
Other studies not entirely positive with topiramate

Kampman et al., 2013:

• Topiramate was not significantly better than placebo in preventing relapse (planned primary cocaine outcome),

• Significantly more topiramate than placebo-treated subjects achieved three weeks of continuous abstinence from cocaine at the end of the trial (20% vs. 7%)

• Subgroup analyses showed topiramate appeared to be more effective in patients with more severe cocaine withdrawal symptoms
Other Behavioral Targets Related to Drug Use

- Impulsivity and Drug Cue reactivity
### 5-HT$_2C$R Agonists and Antagonists Effects on Impulsivity and Cocaine Self-Administration Preclinical Studies

From Cunningham and Anastasio, 2014

<table>
<thead>
<tr>
<th>5-HT Manipulation</th>
<th>Action</th>
<th>Impulsive Action</th>
<th>Cocaine Self-Administration</th>
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</thead>
<tbody>
<tr>
<td>Ro60-0175</td>
<td>5-HT$_2C$R agonist</td>
<td>↓</td>
<td>↓/↓</td>
</tr>
<tr>
<td>WAY163909</td>
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<td>MK 212</td>
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<tr>
<td>SB242084</td>
<td>5-HT$_2C$R antagonist</td>
<td>↑</td>
<td>↑/NE</td>
</tr>
<tr>
<td>---</td>
<td>5-HT$_2C$R knockdown in mPFC</td>
<td>↑</td>
<td>↑/↑</td>
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</table>
Preliminary Data Effect of Lorcaserin on Craving in Cocaine Users in Phase I study
Summary

• As of now, there are no FDA approved medications for stimulant use disorder
• Some medications have produced reductions in stimulant positive urines in subsets of patients with stimulant use disorder
• Larger trials have failed with most of these medications
Summary

• While medications may be of some benefit in some patients,
• Risks and benefits of medications for stimulant use disorder should be discussed with patients before starting medications
• Medication alone (without behavioral therapy) unlikely to be effective
• Since not FDA approved, some insurance companies may not cover costs of medications
Questions?
Case Presentation #1
Sunny Kim, NP

• 12:35pm-12:55pm [20 min]
  • 5 min: Presentation
  • 2 min: Clarifying questions- Spokes (participants)
  • 2 min: Clarifying questions – Hub
  • 2 min: Recommendations – Spokes (participants)
  • 2 min: Recommendations – Hub
  • 5 min: Summary - Hub

Reminder: Mute and Unmute to talk
*6 for phone audio
Use chat function for questions
Case Presentation #1
Sunny Kim, NP

QUESTION: Should pt transition back to sublingual buprenorphine?

Background:
32 yo African American female pt with OUD severe currently in 6 months remission. Past medical history including OUD, c-section x 2, and GB removal. Current meds of albuterol 90 mcg 2 puff four times daily PRN SOB, buprenorphine extended release 300 mg every 30 days, ibuprofen 800 mg TID PRN pain.

First opioid use when she was 18 yo. Started with PO prescription opioids became intranasal (IN) use within 2-3 yrs. Started using heroin when she was 27 yo. Only IN, used 5-6 times daily. Denies IV heroin use. Peak amount up to 3 g daily and she was spending $250 daily. 2008 pt was arrested for prescription fraud and 2016 pt was arrested for prostitution. All legal issues triggered by OUD.
Case Presentation #1
Sunny Kim, NP

Treatment Plan:

Pt initiated her MAT with buprenorphine 7/11/2017. Pt stabilized on 16 mg/4 mg of SL buprenorphine/naloxone daily. Maintained her recovery since Aug 2018 and currently in remission >6 months. Pt requested transition to SQ extended release buprenorphine (Sublocade) because she liked the idea of not having to take SL buprenorphine daily and not dealing with the pharmacy attractive. 12/26/2018 initial buprenorphine 300 mg SQ given at the clinic and next injection scheduled for 1/23/2019.
Case Presentation #1
Sunny Kim, NP

Treatment Plan:

1/11 (16 days after first injection) pt developed withdrawal like symptoms which improved with SL buprenorphine. Agreed to prescribe supplemental SL buprenorphine and instructed pt to not exceed daily use of 8 mg. Despite adverse event pt wanted to continue with Sublocade.

1/21 (26 days after first injection) pt returned and requested to “take a break” because she had social obligations and did not want to take a chance of getting into withdrawal. Agreed to prescribe SL buprenorphine. Instructed pt to use as needed to control her withdrawal symptoms and minimize the dose as much as she can. Pt agreed to resume Sublocade within 2 wks.

2/4 (40 days after first injection) pt returned 28 SL buprenorphine films used out of 56 films that was prescribed. Second Sublocade 300 mg SQ injection given

2/25 (21 days after second injection) pt returned states that opioid withdrawal symptoms returned 14 days after second injection. Pt used 12 mg of SL buprenorphine daily. Agrees to return 3/1 for third Sublocade 300 mg SQ injection
Case Presentation #1
Sunny Kim, NP

**Original** Case Presentation & Related Recommendations:

If pt choose to stay with Sublocade she may need SL buprenorphine until she develop multiple depots of Sublocade. Using both SL and SQ buprenorphine may cause complications with the payers and pt may need to purchase her SL buprenorphine with cash

Continue providing injection every 26 days may also cause complications with the payers.
Continue providing 300 mg Sublocade after second injection may cause complications with the payers.
Case Presentation #2
Thokozeni Lipato, MD

• 12:55pm-1:25pm [20 min]
  • 5 min: Presentation
  • 2 min: Clarifying questions- Spokes
  • 2 min: Clarifying questions – Hub
  • 2 min: Recommendations – Spokes
  • 2 min: Recommendations – Hub
  • 5 min: Summary - Hub

Reminder: Mute and Unmute to talk
*6 for phone audio
Use chat function for questions
QUESTION: Is there a safe way to manage this patient with sickle cell disease and chronic pain secondary to avascular necrosis on opioids?

Background:
44 YO M, high school degree, employed, lives with his wife who tries to manage opioids, but holding them for him. No behavioral interventions tried.

Patient has a diagnosis (sickle cell disease and avascular necrosis) for which opioids are an integral part of the treatment. He has been on HIGH dose chronic opioid therapy for many years (more than 7; total daily MME of 660). Over the years his UDS has been negative for opioids, making use concerned for diversion; however, we now suspect overuse of his chronic opioids after talking with him and his wife. Both admit to him running out early; over-sedation; and even what appear to be apneic episodes at night.
Case Presentation #1
Thokozeni Lipato, MD

Propose Diagnoses:
1. Opioid dependency
2. Chronic pain from AVN
3. Opioid use disorder vs pseudo-addiction
4. Cocaine abuse

Patient treatment goals: 1) Decrease pain so he can be more functional, but functional goals not set yet, 2) Has enough opioids so he won’t have withdrawal

Treatment Plan:
1. Have him formally evaluated for an opioid use disorder
2. Engage in some form of behavioral therapy, such as CBT for chronic pain, but also address his cocaine use
3. More frequent visit (every 2 weeks), more frequent UDS
4. Develop specific functional goals
Case Studies

• Case studies
  • Submit:  www.vcuhealth.org/echo
  • Receive feedback from participants and content experts
Thank You

The success of our telehealth program depends on our participants and those who submit case studies to be discussed during clinics. We recognize the following providers for their contributions:

- Diane Boyer, DNP from Region Ten CSB
- Michael Fox, DO from VCU Health
- Shannon Garrett, FNP from West Grace Health Center
- Sharon Hardy, BSW, CSAC from Hampton-Newport News CSB
- Sunny Kim, NP from VCU Health
- Thokozeni Lipato, MD from VCU Health
- Faisal Mohsin, MD from Hampton-Newport News CSB
- Jennifer Phelps, BS, LPN from Horizons Behavioral Health
- Jenny Sear-Cockram, NP from Chesterfield County Mental Health Support Services
- Bill Trost, MD from Danville-Pittsylvania Community Service
- Art Van Zee, MD from Stone Mountain Health Services
- Sarah Woodhouse, MD from Chesterfield Mental Health
Submit Feedback

Opportunity to formally submit feedback

- Survey: [www.vcuhealth.org/echo](http://www.vcuhealth.org/echo)
- Overall feedback related to session content and flow?
- Ideas for guest speakers?
Claim Your CME and Provide Feedback

- **www.vcuhealth.org/echo**

- To claim CME credit for today's session
- Feedback
  - Overall feedback related to session content and flow?
  - Ideas for guest speakers?
Access Your Evaluation and Claim Your CME

Virginia Opioid Addiction ECHO

Welcome to the Virginia Opioid Addiction Extension for Community Health Outcomes or ECHO, a virtual network of health care experts and providers tackling the opioid crisis across Virginia. Register now for a TeleECHO Clinic!

Network, Participate and Present

- Engage in a collaborative community with your peers.
- Listen, learn, and discuss didactic and case presentations in real-time.
- Take the opportunity to submit your de-identified study for feedback from a team of addiction specialists.
- Provide valuable feedback & claim CME credit if you participate in live clinic sessions.

Benefits

- Improved patient outcomes.
- Continuing Medical Education Credits: This activity has been approved for AMA PRA Category 1 Credit™.
- Virtual networking opportunities using two-way video conferencing.
- No cost to participate.
- If unable to attend a live clinic session, learn how to access the CME website to view the recording and claim credit.

Telehealth
Access Your Evaluation and Claim Your CME
Access Your Evaluation and Claim Your CME

- [www.vcuhealth.org/echo](http://www.vcuhealth.org/echo)
- To view previously recorded clinics and claim credit
Access Your Evaluation and Claim Your CME
**Previous Clinics (2019)**

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<th>Topic</th>
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<tbody>
<tr>
<td>Trauma Informed Care and Treating Those Experiencing Opioid Addiction</td>
<td>01/04/19</td>
<td>Video of Clinic Slide Presentation</td>
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<tr>
<td>Syringe Exchange</td>
<td>05/19/19</td>
<td>Video of Clinic Slide Presentation Narwhal Laws Needle Exchange Program Flyer Bill to Remove Cooperation Law</td>
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**Learning Objectives:**

- Identify individuals who have experienced trauma.
- Understand the impact of trauma on human development particularly related to substance use and misuse.
- Learn components of trauma informed care.

**Syringe Exchange**

- Led by Anna Skaril, MSW, MPH
- **Learning Objectives:**
  1. Understand current legislative landscape in regards to syringe exchange in VA.
  2. List benefits to clients and community of syringe exchange.
  3. Define harm reduction.
VCU Virginia Opioid Addiction TeleECHO Clinics

Bi-Weekly Fridays - 12-1:30 pm

Mark Your Calendar --- Upcoming Sessions

03/15  Policy with Maternal Substance Use Disorder  Valerie L’Herrou, JD
03/29  Motivational Interviewing  Lori Keyser-Marcus, PhD

Courtney Holmes, PhD

Please refer and register at vcuhealth.org/echo
THANK YOU!

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