COUNSELING VIVITROL PATIENTS FOR RECOVERY

David R Gastfriend MD
Director, FADAA Peer Mentoring Project
Scientific Advisor, Treatment Research Institute
Chief Architect, CONTINUUM – The ASAM Criteria Decision Engine™

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Shareholder and former employee of Alkermes, Inc.
Royalty recipient
from the American Society of Addiction Medicine for the licensing of CONTINUUM™
Chief Medical Officer, DynamiCare Health™
COUNSELING VIVITROL PATIENTS FOR RECOVERY

• Why?
• What?
• Who?
• How?
WHY?

- Why is Drug Dependence So Tough?
- Why Has Counseling Dominated Care?
- Why Do Researchers Push Meds?
- Why Don’t We Emphasize Adherence?
Public Health Model of an Epidemic Addiction:

▲ Promoters
▼ Responses

Agent
▲: receptor affinity, purity, faster routes of administration
▼: blockade, catabolisim

Host
▲: genetic, congenital & acquired vulnerability, comorbidity
▼: resilience, coping

Environment
▲: access, lower cost, prescribing
▼: culture change, neighborhood policing, sanctions
Brain Reward: With us throughout evolution
Brain Regions & Circuits in Addiction

- Memory/Learning
- Executive Function
- Inhibitory Control
- Motivation/Drive
- Reward
- Memory/Learning

Regions:
- PFC
- OFC
- ACG
- D. Striatum
- NAcc
- Hipp
- VP
- Amyg
Interventions

- Psychosocial Therapies
- 12 Step Programs
- Monitoring

Pathophysiology

Cortex
Role:
- Decision making
- Thinking
- Reasoning
- Learning

Limbic Region
Role:
- Basic Drives
- Experience of Reward, Euphoria

Interventions
- Agonist Medications
- Antagonist Medications

Behavior: Mediators & Moderators

- Maturation, sanctions
- Support, counseling
- Opportunity, Outward Bound
- Contingency Management
Oral Medication Discontinuation Rates
VA Study (Hermos et al., ACER 2004)

- Treatment durations – virtually identical for both drugs
- 35% filled for 1 mo or less; 50% for ≤ 2 mos; 75% refill ≤ 5 mos.
- Discontinuation risk: 1.4–2.3 X greater than for statins or SSRIs
Oral Naltrexone Adherence in Alcohol Dependence

- Nonadherent: 86%
- Adherent: 14%

- Over 5 million employees from 50 large national employers
- 1138 oral NTX patients
- 52% did not refill even once (Median = 1 Rx)
- Only 14% filled prescriptions for 6 months

Stephenson et al., American Academy of Addiction Psychiatry, 2006
Oral Naltrexone Adherence in Alcohol Dependence

Non-adherent patients were significantly more likely to have ...

- Inpatient detoxification admissions
- Non-alcohol specific hospital admissions
- Non-alcohol specific ER visits
- No counseling participation

Stephenson et al., American Academy of Addiction Psychiatry, 2006
Agonists: Treatment Retention

Mean retention on BUP:
Yser, Addiction 2014: 66 days
Baser, AJMC, 2011: 69 days
Fishman, CPDD 2011: 67 days (adol/young adults)
92% relapse within 8 wks of taper (Weiss et al., 2011)

20% Lo Meth
58% Bup
53% LAAM
73% Hi Meth

Study Week

Percent Retained

Development of XR-NTX

- Problem of nonadherence was well understood by 1975\textsuperscript{1}
- The promise of naltrexone was undermined by nonadherence
- NIAAA and NIDA awarded grants that led to development of Medisorb\textsuperscript{*} technology
- XR-NTX uses the Medisorb extended-release properties, first introduced in Risperdal\textsuperscript{®} Consta\textsuperscript{†}

\textsuperscript{*} Medisorb is a registered trademark of Alkermes, Inc.
\textsuperscript{†} Risperdal Consta are registered trademarks of Janssen Pharmaceutical.

Reference:
1. NIDA Monograph, Narcotic Antagonists: The Search for Long-acting Preparations
Persistence of Monthly Refills
Private national pharmacy claims data in all Alcohol Use Disorder patients who filled an initial Rx

Medication Adherence Rate Comparison

- **XR-NTX**  N=133
- **Acamprosate**  N=3012
- **Disulfram**  N=1006
- **Naltrexone**  N=1135

% of Members With A Refill

# of Months After Initial Rx Was Filled

Un H, Addiction Health Services Research Conference, Boston 2008
WHAT?

- What is Adherence Pharmacotherapy?
- What is the Clinical Benefit?
- Why Go Through Detox?
- What are the Side Effects?
- What are the Long-Term Effects?
- What Happens to Quality of Life?
- What Happens to Treatment & AA?
- What Happens to Enjoyment & Pleasure?
INJECTABLE XR-NTX FOR OPIOID DEPENDENCE: A Double-Blind, Placebo-Controlled, Multicentre Randomised Trial (The Lancet, 2011;377:1506-1513)

E Krupitsky¹, EV Nunes², W Ling³, A Illeperuma⁴, DR Gastfriend⁴, BL Silverman⁴

¹ Bekhterev Research Psychoneurological Institute, St Petersburg State Pavlov Medical University, St Petersburg, Russia
² New York State Psychiatric Institute and Department of Psychiatry, Columbia University, New York, NY, USA
³ Department of Psychiatry and Biobehavioral Sciences, University of California Los Angeles, Los Angeles, CA, USA
⁴ Alkermes, Inc., Waltham, MA

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**Objective:** To assess the efficacy, safety and patient-reported outcomes of an injectable, once monthly extended-release formulation of the opioid antagonist naltrexone for the treatment of patients with opioid dependence after detoxification.
Secondary Endpoint: Treatment Retention

Placebo - Median days of treatment = 96
VIVITROL (n=126) - Median days of treatment = 168

Log-rank P = 0.0042 (adjusted)

6-Month Retention on XR-NTX: 3 Studies

Study Retention in 24-Week Treatment Period

- Health Prof’ls Study (N=48)
- 1-Year Safety Study (N=101)
- Phase III (N=126)
WHAT?

- What is Adherence Pharmacotherapy?
  - Prescribing to sustain a long-term clinical benefit

- What is the Clinical Benefit?
  - Prevention of relapse
  - Creating a biochemical foundation for recovery

- Why Go Through Detox?
  - The “Pay Now, Fly Later” Plan

- What are the Long-Term Effects?
  - Retention in counseling
  - Decreased craving, drug use, relapse to dependence
  - Stability for building coping skills & relationships
  - NOT, in & of itself, recovery or health
“Ask your doctor if taking a pill to solve all your problems is right for you.”
There is no single proven method, however, success has been found with Inpatient AND Outpatient approaches

Success = >50% of patients retained through 1st XR-NTX injection without precipitated withdrawal

KEY: Close contact & attention to the patient’s changing needs

Setting expectations, providing support AND structure
Withdrawal is commonly compared to the flu
- Aches, pains, insomnia, nausea, anergia
- Anxiety, irritability, dysphoria, anhedonia

**Aggressive** symptomatic treatment helps
- Insomnia: zolpidem, trazodone, quetiapine
- GI distress: H2 blockers
- Anxiety/hyperarousal: clonazepam, clonidine

Most symptoms remit in 2-4 weeks
- Prolonged symptoms are rare & likely represent additional psychopathology
Mean SF-36 physical component scores at Baseline were similar in the XR-NTX and placebo groups (50.4 vs. 50.7) and remained at or above U.S. norms (=50) at endpoint.

Mean SF-36 mental component scores were similar at Baseline (35.0 vs. 35.4), but at endpoint, the XR-NTX group had normalized to 50.4 vs. 45.3 for placebo (~half an SD below normal).
XR-NTX & Self-Help Attendance (Alcohol)
% Attending Self-Help Over 6 Months: All Patients (N=624)

Mean % subjects

Prior 30 days: 11.2
Placebo: 10.2
XR-NTX 190 mg: 11.3
XR-NTX 380 mg: 13.1
**XR-NTX & Pleasure (Alcohol)**

% Reporting Daily Activities as Pleasurable (N=72)

- **Gambling (N=26)**
- **Shopping (N=70)**
- **Eating sweets (N=72)**
- **Exercising or participating in sports (N=57)**
- **Eating spicy foods (N=56)**
- **Playing cards or games (N=41)**
- **Reading (N=71)**
- **Watching sports (N=51)**
- **Sexual relations (N=55)**
- **Being with friends (N=70)**
- **Eating good food (N=74)**
- **Listening to music (N=71)**
- **Drinking alcohol (N=53)**

O’Brien et al., Am J Addiction 2010
WHO?

- Who Should Be Considered for Meds?
- Who Benefits the Most from Vivitrol?
- Who Should NOT Receive Vivitrol?
- Is Vivitrol for Criminal Justice Patients?
- Who Should Be Involved in Care?
LASSIE! GET HELP!!
XR-NTX: For Whom?

- Motivated to be abstinent, opioid-free & undergo withdrawal
- Preparing to leave rehab or jail/prison opioid-free
- Monitored by judges, professional boards, employers, schools or sports teams that may not allow agonist treatment
- Structure & social supports in place (however, chronicity & severity can be either mild or severe)
- Rejects agonist treatment or has failed agonist treatment
- Succeeded with agonist treatment and wants to conclude it
- Wants shorter-term medication that can be easily concluded
- Late adolescent/emerging adult with shorter duration addiction
- Has both opioid and alcohol dependence
Conclusions: Who Responds?

- Traditional consensus on NTX-PO in opioid dependence: Mainly for narrow range of good prognosis patients, e.g., professionals, high motivation & good social supports.
- Monthly formulation: designed for adherence\(^{Willette\ 1976}\)
- No significant baseline predictors
- XR-NTX (vs. PBO) Good efficacy in higher severity patients, i.e., those with worse global severity with the CGI-S, higher craving, lower function (EQ-5D) & quality of life, & HIV+
- Results suggest that XR-NTX was effective in promoting abstinence from opioids & preventing relapse after detox across a range of demographic and severity characteristics.
Selection Criteria: Offer XR-NTX If Patient...

- Just withdrawn from opioids; or abstinent but intense craving
- Leaving inpatient rehab or incarceration
- Has begun intermittent use, but not yet dependent relapse
- Despite maintenance agents, frequently uses opioids anyway
- Discontinuing maintenance – as a “landing pad” transition
- Young adult or late adolescent
- Subject to drug testing or job sanctions for maintenance
- Dependent on both opioids and alcohol

- **Treatment Matching** is key: There is no superior approach – *except the one that works for the particular patient!*
- Segregated care = **BAD care**; patients need integrated care
HOW?

- How Do You Describe Vivitrol At Intake?
- How Do You Address Ambivalences?
- How Should Family Be Included?
- Doctors & Other Strangers
- How Will I-We-They Know If It Works?
- How to Contract For Success
- Logistics for Successful Adherence
- Exploring The Patient’s Perceptions
- How Does Craving Change?
XR-NTX in Rehab: Data Sources

- Administrative records from 3 inpatient CRC rehabs in PA
- CRC is the largest U.S. provider of specialized behavioral healthcare, treating >30,000 individuals daily
- Electronic records characterized 7,687 opioid dependent detox/rehab inpatients in terms of demography, diagnosis, payer & hospital course.

Conclusions

1. XR-NTX patients were significantly less likely to leave AMA, more likely to complete rehab, have longer LOS & greater entry to continuing care.

2. Women: as likely as men to receive XR-NTX; Race did not appear to be a factor in treatment selection.

3. XR-NTX can be successfully administered to opioid dependent patients after detox & before discharge from inpatient rehab.
XR-NTX in Rehab: Results

- Injected
- Not injected
- Not Prescribed

p < .001 vs XR-NTX

Bar charts showing:
- AMA
- Treatment Complete
- Attended Post-discharge visit
- Length of Stay (Days)

Significance markers indicate statistical differences with asterisks.
“We find that all of us, as a society, are to blame, but only the defendant is guilty.”
Extended-Release Naltrexone for Alcohol and Opioid Problems in Missouri Parolees and Probationers

Paul Crits-Christoph, Ph.D. a,*, Christie Lundy, Ph.D. b, Mark Stringer, M.A. b, Robert Gallop, Ph.D. c, David R. Gastfriend, M.D. d

a Department of Psychiatry, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA
b Division of Behavioral Health, Missouri Department of Mental Health, Jefferson City, MO
c Department of Mathematics, West Chester University, West Chester, PA
d Treatment Research Institute, Philadelphia, PA

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ABSTRACT

The purpose of this study was to compare the naturalistic outcomes of parolees and probationers with alcohol and/or opioid problems who were treated with extended-release naltrexone (XR-NTX) to those treated with other medication-assisted therapies or psychosocial treatment only. Methods consisted of using intake and discharge data collected as part of SAMHSA’s Treatment Episode Data Set (TEDS) assessments, controlling for group differences using propensity scores that were based on a range of intake variables. Results showed that patients receiving XR-NTX had longer durations of care (compared to oral naltrexone and psychosocial treatment only) and were more likely to become abstinent (compared to oral naltrexone, buprenorphine/naloxone, and psychosocial treatment only). Findings were similar for the total sample and those with opioid problems. These XR-NTX results were found in the absence of significant differences in rates of self-help participation. No differences were found in employment or arrests in this relatively short time frame. This study documents the real-world effectiveness study of current FDA-approved addiction medications in parolees/probationers and encourages the use of XR-NTX in such a criminal justice population.

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Naturalistic outpatient treatment, retrospectively analyzed; XR-NTX (N=156), Oral Naltrexone (N=45), Bup/Nal (N=168), No Meds (N=2513)
HOW?

- Losing the:
  Craving (good!); High/Euphoria (OK); Escape (Uggh...)
- How Does Vivitrol Promote The 1st Step?: Awareness
- How Will I Cope?! Emotion Without Escape
- How to Talk About Vivitrol In A.A.
- Is There Spirituality After Technology?
- Foster Self-Efficacy: Via exploration, NOT discontinuation
- Remembering Vulnerability: Notes, Journals, Rating Scales
- Setbacks & Contingencies: Plan ahead, Restart
- How Long Should Vivitrol Be Continued?
  6 mos? 12 mos? 13 mos? Or, based on criteria...
Attitudes: Harmful & Helpful

- Attitudes that do a disservice to patients:
  - “If you’re using drugs, you’re not really sober; I did it the hard way”
  - “If you just work the program, you won’t need any drugs”
  - “You can’t treat a drug problem with a drug”
  - “If you are on drugs, you can’t speak at a meeting”

- Attitudes that are justified by the science:
  - We don’t withhold medication from heart disease patients, saying: “You have to stop smoking & lose weight on your own, like I did”!
  - Chronic diseases, like hypertension & asthma have meds. If we want addiction to be treated as equal to other medical illnesses, we need to accept the role of medicine in addiction treatment, too.
  - Opioid patient on XR-NTX: “I never understood it before… but now I know how it is that non-addicts can just ignore drugs. And suddenly I see what it means that I really do have an addiction.”
CRC Vivitrol Procedure

- Upon Admission
  - Patients sign Alkermes Release form to verify if patient’s insurance will cover medication
- History and Physical (within 24 hours of admission)
  - Medical staff discusses Vivitrol as an option along with continuing care
- Mid-stay
  - Lecture by medical staff regarding Vivitrol in conjunction with continuing care
  - Information posted within center to promote Vivitrol
  - Meet with designated staff members to verify benefit and continue the authorization process
- Before Discharge
  - Medication shipped directly to center to facilitate injection prior to discharge
  - Continuing Care with provider in home area is set for follow up injections
XR-NTX: Testing the Blockade

- As many as half of patients will “test” blockade
- Usually during the 1\textsuperscript{st} month after detox; many on D/C day
- Thus, 1\textsuperscript{st} injection is better 2d before D/C; if given on last day & risk of testing, supplement with NTX-PO
- Most, after unsuccessfully testing 1-3 times, stop testing
- Rarely, (but reported) patient could use high amounts such that physical dependence could recur
XR-NTX: Managing Discontinuation

- Patients discontinue prematurely for innumerable reasons: it’s the disease
- Better to regularly anticipate ambivalence & explore it in counseling
- If patient discontinues, remember that blockade can continue for as long as 6 weeks after injection
- It is not uncommon for a patient to want to restart XR-NTX later; This is a good sign that predicts a longer retention
- If patient restarts XR-NTX after cessation, must review need for detox
“Nobody ever asks ‘How’s Waldo?’”
I have a 19 year old son who did the usual progression from marijuana to percs and oxys. He went through several rehabs and relapses and was one week shy of completing an extended care program and hitting his one week clean mark.

He relapsed and spent 5 weeks in a downward spiral that finally reached IV heroin. He reached out for help to his sponsor and others he knew from his program and AA. He went to his psychiatrist who suggested he try Vivitrol.
The doctor first put him on a two week trial of oral naltrexone to see how he would tolerate the drug before committing to the shot. He waited 7 days after his last use before starting, but all the opiates were not out of his system. He went through a bad period of withdrawal, including a psychotic episode.
He made it through the two weeks though and got his first shot mid-June. He's since had 3 shots, and is a little over 3 months clean.

The stated side effects include depression, and I have noticed that he is a little more "edgy" right about when he gets the shot. When he was considering it, the guys from AA discouraged him, saying it was a crutch. He went ahead anyway, feeling that it was his last shot.

The risk is that some addicts try to beat it with large quantities of dope-this produces overdose. The risk of overdose at "regular" dosages is also increased after it is stopped. So an addict needs to be really committed to recovery, because if you relapse, you are at greater risk of death. I was terrified when he told me he was trying it - but - it wasn't my choice, it was his.

It seems to be working for him. He is working a program of recovery, holding a job, and attending college. He swears by the shots, and says he would recommend them to anyone.
Today is the 25th day after my vivitrol shot. (it lasts 30+ days) I also just got 1/2 g uncut #4 straight from the village of Azad Afghanistan. The plan was to wait until like the 35th day so i would get maximum benefit. But my dumb ass decided to try to break through the naltrexone blockade with about 80% pure heroin. I ended up using 3/10 g. i could feel something similar to a rush and could feel the heroin. But as I'm sitting here typing 5 minutes later there is not much euphoria at all.

Okay now im starting a slight nod. If anyone has any experience/suggestions on this please comment
Patient Management

Addressing Culture Obstacles

• Involve both the treatment staff and the patient population
• Two long-established expectations that HINDER recovery:
  1) that only a 12-Step approach is acceptable OR
  2) that every patient “deserves” opioid substitution meds
• Requires team education on the research that counseling alone is worse than counseling + an FDA-approved med
• Also, team needs to hear health economics findings: Counseling-only care is wasteful, vs. counseling + MAT.
• Teams need to talk with Vivitrol-treated patients who also used counseling and mutual-help

[ ] Supervisors:
  Need to review weekly LIST of supervisees’ patients & last/missed visit

[ ] Teams:
  Need to review weekly LIST of team’s patients & last/missed visit info
Patient Management

Overcoming Logistic Hurdles

• The preferred situation: Fully establish logistics before patient care
• This is not always the case
• Important to mentor RE key front desk personnel responsibilities, insurance coverage determination/managed care interaction, specialty pharmacy ordering, shipping readiness confirmation, cold storage/shelf-life & product tracking, supply management.
• Mobilize the treatment system to overcome specific logistical hurdles
  ❑ Set up PRE-VISIT ORDERING/SHIPPING procedures from 1st prescription
  ❑ Set up patient phone call reminders 2 days before injection & follow-up
  ❑ Set up Spouse/Significant Other authorizations for contact if no-shows
Converting Screenings into Medication Administrations

- In medicine, patients accept most treatment recommendations made by their physician.
- In addiction, well under 50% of patients screened eligible for Vivitrol actually get injected.
- The largest cause of drop-off is lack of readiness for definitive care, due to the motivational disruption of addictive disease.
- This problem is followed by culture obstacles in the treatment environment.
- Patient failure to engage is commonly due to:
  - detoxification procedures that create delays
  - incomplete/ineffective withdrawal
Patient Management

Up Front: Achieving Patient Readiness – Key patient messages

• The nature of the disease:
  out-of-control, chronic, relapsing, life-threatening

• XR-NTX: highly effective for preventing relapse to opioid dependence

• XR-NTX: ↪ craving & drug use early in recovery enhances self-efficacy

• XR-NTX: ↪ trigger responses without emotional or cognitive side effects

• Side effects can occur & can usually be addressed – so let us know

• Program will help with: Scheduling, reminder calls,
  supportive other F/U calls, justice system communications/tracking

  ❑ Vivitrol Ambassadors – have been very successful; a recovery support
  ❑ Vivitrol Groups – to increase efficiency, foster retention & persistence
Patient Management

• **Patient Retention** – Patients must see the need for longitudinal care & mutual-help; anticipate relapse risks & loss of motivation. Coordinate messaging & visit reminders with patients, supportive others, program & justice system staff

• **Educate Supportive Others/Family**
  – Obtain consent to involve ≥1 supportive others for initial & follow-up to reinforce safety & retention with both MAT & counseling

• **Address Drug-Seeking, Persistence Issues & Diversion**
  – Heighten vigilance for the blockade testing, overriding or seeking opioids to divert for income – despite Vivitrol

• Address blockade avoidance (late re-injection, premature discontinuation)
  - Monitor patients’ attendance & urine drug tests
  - Timely communication across addiction, medical & justice teams, significant others/family
  - Re-assess/modify treatment plan when escalation is needed, **not just the meds**
Patient Management

- Co-occurring Disorders Management
- Medication Discontinuation Planning & Follow-Up
  XR-NTX is long-term treatment
- XR-NTX lacks WD; only needed to stabilize craving, establish disease acceptance & recovery
- The Team + patient must determine Vivitrol’s duration: use ASAM
  Based on treatment engagement, recovery effort & function

- Post Medication Outcome Tracking – Addiction is chronic; must track patients after MAT & determine need to restart
  – before new physiological dependence (avoids detox), before other morbidity & while opportunity to re-engage is open

- Get follow-up reports on post-MAT outcomes & advise RE patient’s need for re-assessment & med re-start
Patient Management

Drug-Drug Interactions
• There are few drug interactions with XR-NTX (except for opioids)

Precipitated opioid withdrawal – not a side effect, but is an adverse event
• Encourage calls to report; monitor induction closely for success

Adverse Events
• Early learning curve – for BOTH counselors & patients
• Common mild-moderate side effects:
  • Nausea (1st 3 days of 1st shot)
  • Site tenderness
  • These are expected: Anticipate routinely with every patient & address readily

Serious Adverse Events
• May require emergency room or surgical evaluation or treatment (rare).
• ~92% of subjects reporting receipt of a pain med for a pain-related AE received at least one more XR-NTX dose

• ~95% of all pain-related AEs reported were not associated with study discontinuation*

*As defined by no additional XR-NTX doses after the dosing of pain medication for a pain-related AE (Note: AEs or SAEs occurring >7 weeks after previous XR-NTX dosing were omitted from our analysis).
Figure 14.3.1.1 Figure for the Percent of Discontinued Subjects by Number of Injections and Weeks from Previous Injection and Treatment Group Full Analysis Set

Note: If a subject discontinues more than 4 weeks from the previous injection, the discontinuation is censored at 4 weeks from the previous injection.
XR-NTX: 4\textsuperscript{th} Week Effect

- Anecdotally, patients report XR-NTX wearing off by 4\textsuperscript{th} week
- Russian Phase IV RCT analyzed week-by-week findings
- Week 4 did show: \(\uparrow\) craving, drug use, dropout
- BUT, at the same rate in BOTH XR-NTX and Placebo groups
- Conclusion: 4\textsuperscript{th} Week Effect is real, BUT non-pharmacological
- Therefore, \textit{counseling} must address \textit{expectancy/ambivalence}
- Anticipate the 4\textsuperscript{th} week effect from the start of treatment
- With the patient, caregivers & supportive others
- Prepare for re-injection with counseling & contingency management
HOW LONG? ASAM Criteria Treatment Plan

- Use CRITERIA for XR-NTX Discontinuation: Patient has...
  - Dimension 1: Consistent period of no alcohol or drug use
  - Dimension 2: Stable health management; no SUD complications
  - Dimension 3: Stable MH management; no SUD complications
  - Dimension 4: Readiness – Good disease awareness/acceptance
  - Dimension 5:
    - Self-knowledge of risks, triggers & vulnerabilities
    - Success enduring both negative AND positive stressors
  - Dimension 6:
    - Active recovery efforts & lifestyle
    - Stable participation, vocationally & socially
Counseling VIVITROL Patients for Recovery

Clinical Phenomena Commonly Seen with XR-NTX (Implications: Both good & bad)

- “My friend had this Suboxone that really helped me…”
- “That guy who got the shot: I wanna be on whatever he’s on”
- The Pink Cloud
- “D#@m-it, this SH*! works…”
- “HELP, I’m STUCK without an escape for 30 F*#@ing days!!!”
- “OK, I’m good to go now”
- [silence…Elvis has left the building]
Counseling VIVITROL Patients for Recovery

• Why? Because addiction is TOUGH & recovery is painful
• What? Integrated XR-NTX + counseling yields BEST results
• Who? Patients who are prepped for long-term treatment
• How? With realistic expectations, supports, monitoring & program internal accountability structures, discontinuing by planned criteria