U.S. Department of Justice

Federal Bureau of Prisons

Washington, D.C. 20534

July 8, 2015

MEMORANDUM FOR RADM NEWTON E. KENDIG, ASSISTANT DIRECTOR
HEALTH SERVICES DIVISION

MS. LINDA T. MCGREW, ASSISTANT DIRECTOR
REENTRY SERVICES DIVISION

(b)(6),(b)(7)(C)

FROM: RADM (b)(6),(b)(7)(C) BOP Chief Pharmacist
Health Services Division

CAPT (b)(6),(b)(7)(C) Chief Drug Treatment Programs
Reentry Services Division

for

Ms. (b)(6),(b)(7)(C) Community Treatment Coordinator
Reentry Services Division

CAPT (b)(6),(b)(7)(C) Chief Pharmacy Logistics
Health Services Division

SUBJECT: MAT Symposium Background, Overview, and Recommendations

Background

The Office of National Drug Control Policy (ONDCP) has articulated the national impact of illicit drug use across the country through its release and annual update of the National Drug Control Strategy. The Strategy calls for a response to the opioid abuse epidemic, which includes heroin and prescription drugs like oxycodone, hydrocodone, and methadone. This epidemic results in the death of approximately 45 Americans a day. Specific to corrections, the Strategy addresses the efforts to improve prevention and reentry programs to protect public safety and improve outcomes for people returning to communities from prisons and jails. The concerning intersection between public safety and public health is obvious.

The Federal Bureau of Prisons (BOP) has historically provided substance abuse treatment through the Residential and Non-Residential Drug Abuse Treatment Programs (RDAP and NRDAP). Over 35,000 inmates with substance use disorders participate in these programs each year. These programs have been very successful for the majority of inmates while incarcerated within the BOP. However, outside the more controlled environment seen within corrections, treatment programs that combine medication assisted and behavioral therapy increase the likelihood of success. As such, the introduction of MAT into the reentry process provides a comprehensive response to enhance the likelihood of effective treatment and functional reentry back into society, with a hope of preventing relapse, overdose, and re-arrest/re-incarceration; all of which are associated with high societal costs.

A MAT Field Trial was initiated in October of 2013 in response to the National Drug Strategy. It was established to identify and work through the logistical challenges that needed to be addressed in providing MAT to inmates transitioning to community custody. On June 17-18, 2015, the BOP convened a MAT Symposium that included key stakeholders of the agency to explore options for the short, intermediate, and long term expansion of MAT. Obstacles and lessons learned from the MAT Field Trial were presented and discussed. The following represents an overview of the Symposium as well as recommendations for expansion.

Symposium Overview

Day One of the Symposium was designed to familiarize all participants with the history and the components of the field trail. Challenges and lessons learned were presented by key stakeholders including Health Services Division; Reentry Services Division; Administration Division; Correctional Programs Division; Information, Policy and Public Affairs Division; and Office of General Counsel. BOP relations were fostered through the invitation of a representative of the Office of National Drug Control Policy (ONDCP), who presented an overview of the National Drug Strategy and participated in Day One discussions.

Day Two of the Symposium featured a presentation by Dr. Josh Lee of the NYU School of Medicine, Department of Population Health. Dr. Lee addressed Pharmacotherapies for Opioid Disorders in Criminal Justice Populations. The remainder of Day Two was designed to involve the stakeholders in breakout discussion groups on specific topic areas to include Identification of MAT

Participants, Provision of MAT within a BOP Institution, and Provision of MAT within Community Custody. Topics centered on discussions related to needed resources (e.g., fiscal, human capital, IT, contracting) and research components. Additionally, discussions included how to operationalize and overcome obstacles associated with a MAT expansion. A summary of the breakout group discussions was provided. The day concluded with the stakeholders identifying short, intermediate, and long term targets of a MAT expansion as detailed below.

Recommendations

Field Trial - This will continue into Fiscal Year 2016 with the existing participant list and collateral duty of BOP staff, unless current participants become unqualified or withdraw from the Field Trial.

Short Term - Fiscal Year 2016 and 2017

- (b)(5)
-
-
-
-

- (b)(5)
-
-
-
-

Intermediate - Fiscal Years 2017 and 2018

- (b)(5)
-
-
-

- (b)(5)
-

Long Term - Fiscal Years 2018 and Beyond

- (b)(5)
-
-

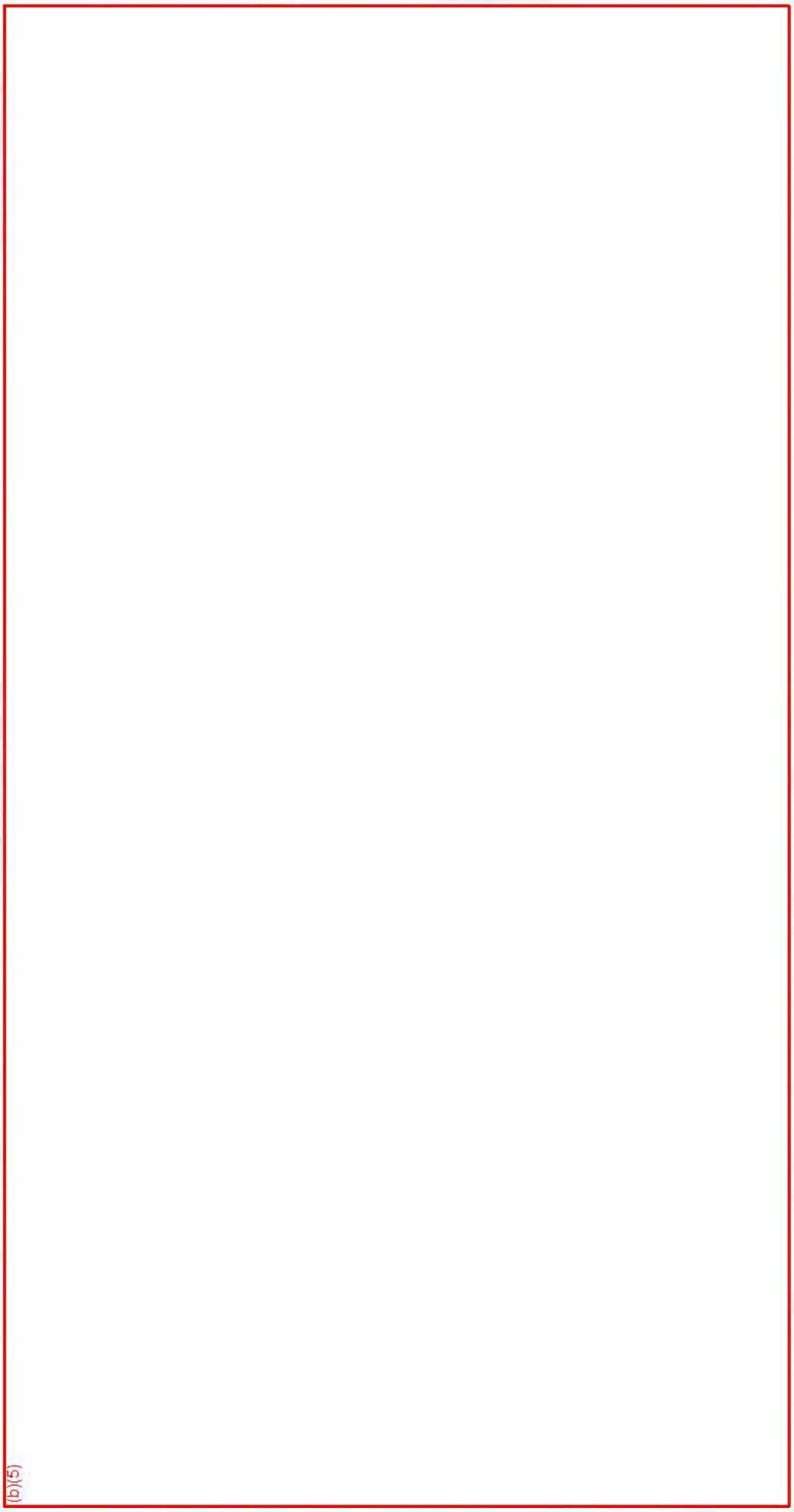
Decisions to be Discussed

- (b)(6),(b)(7)(C)
-
-
-
-

cc: (b)(6),(b)(7)(C), Sr Deputy Assistant Director
Health Services Division

(b)(6),(b)(7)(C) Sr Deputy Assistant Director
Reentry Services Division

Attachments:
Transitional Care Team Organizational Chart
Current MAT Process Flow Chart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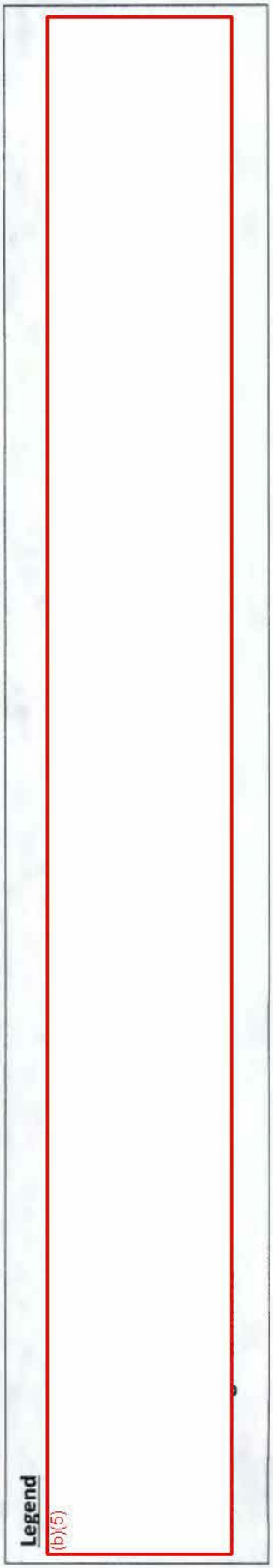
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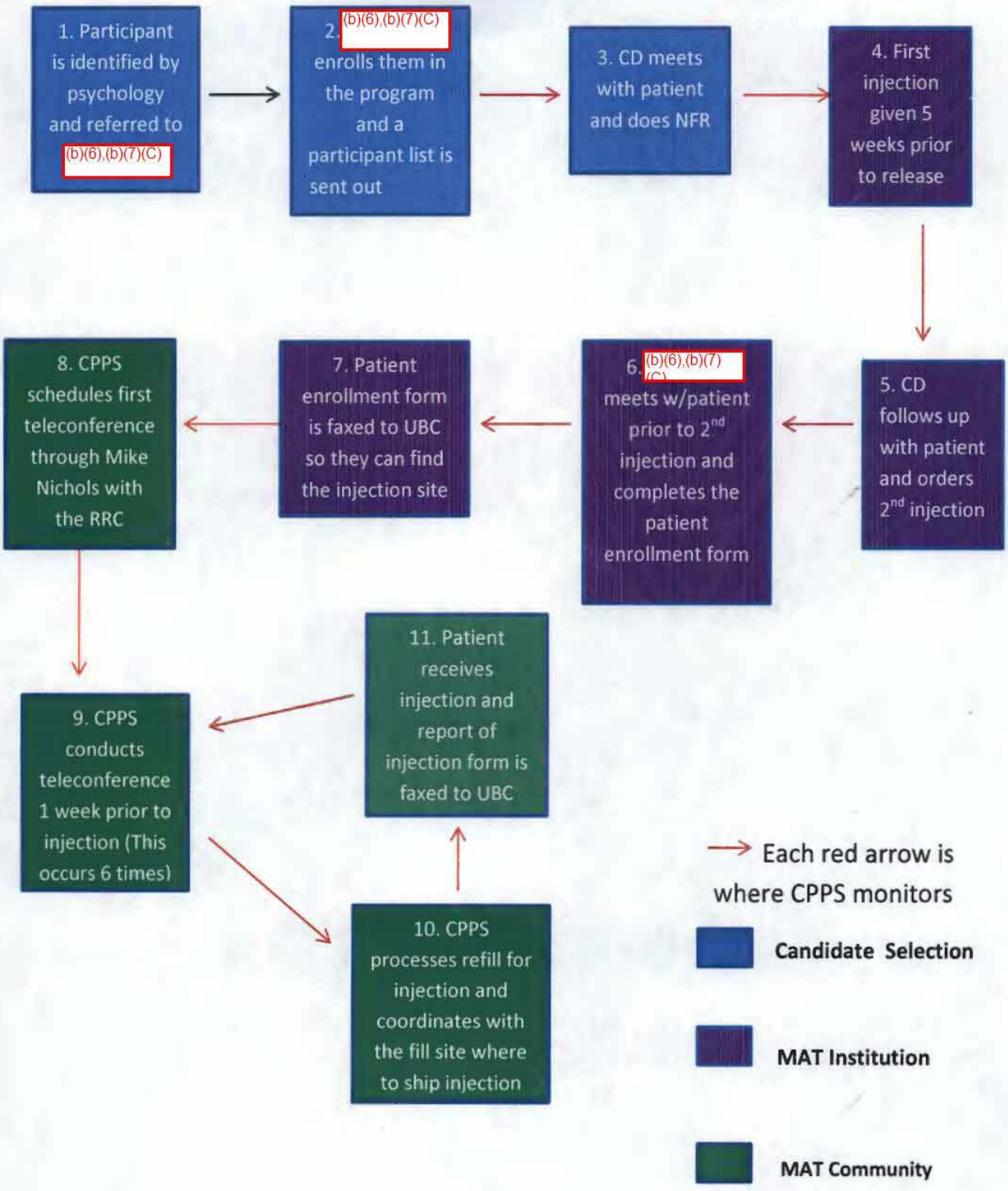
MAT Program

Current Process



MAT Symposium June 17-18, 2015

MAT Medications & Intro to Field Trial

(b)(6),(b)(7)(C) **Pharm.D.**
Rear Admiral, US Public Health Service
Director, Pharmacy Programs
Federal Bureau of Prisons

- Correctional Health = Public Health
- Medication Assisted Therapy

Importance of Correctional Health

- Correctional Health is Public Health!!
- 2 1/2 Millions wake up in prison/jail every day
- ~ 5,000 correctional facilities (>3,000 local jails; 1,800 state/federal correctional institutions)
- Iron Law of Corrections
- Approx. 14% of persons with HIV in the U.S. pass through the correctional system each year
- 35% of all TB cases, and 29% of all Hepatitis C cases pass through the nation's correctional facilities at some point in time

Importance of BOP to Corrections

- The BOP Brand!
- Leading all of corrections
  - State DOCs
  - County City/Jails
  - DOD
  - ICE
  - Countries (Canada, England, Russia, Kazakhstan)
- BOP's work transcends all of corrections b/c of you
  - CPGs, Policies, Procedures, Professionalism, etc.
- Recruitment
  - Employer of choice
  - Help someone aspire to correctional medicine

Medication Assisted Therapy (MAT)

- Background
- Corrections & MAT
- Options
- BOP Strategy
- Field Trial
- Next Steps

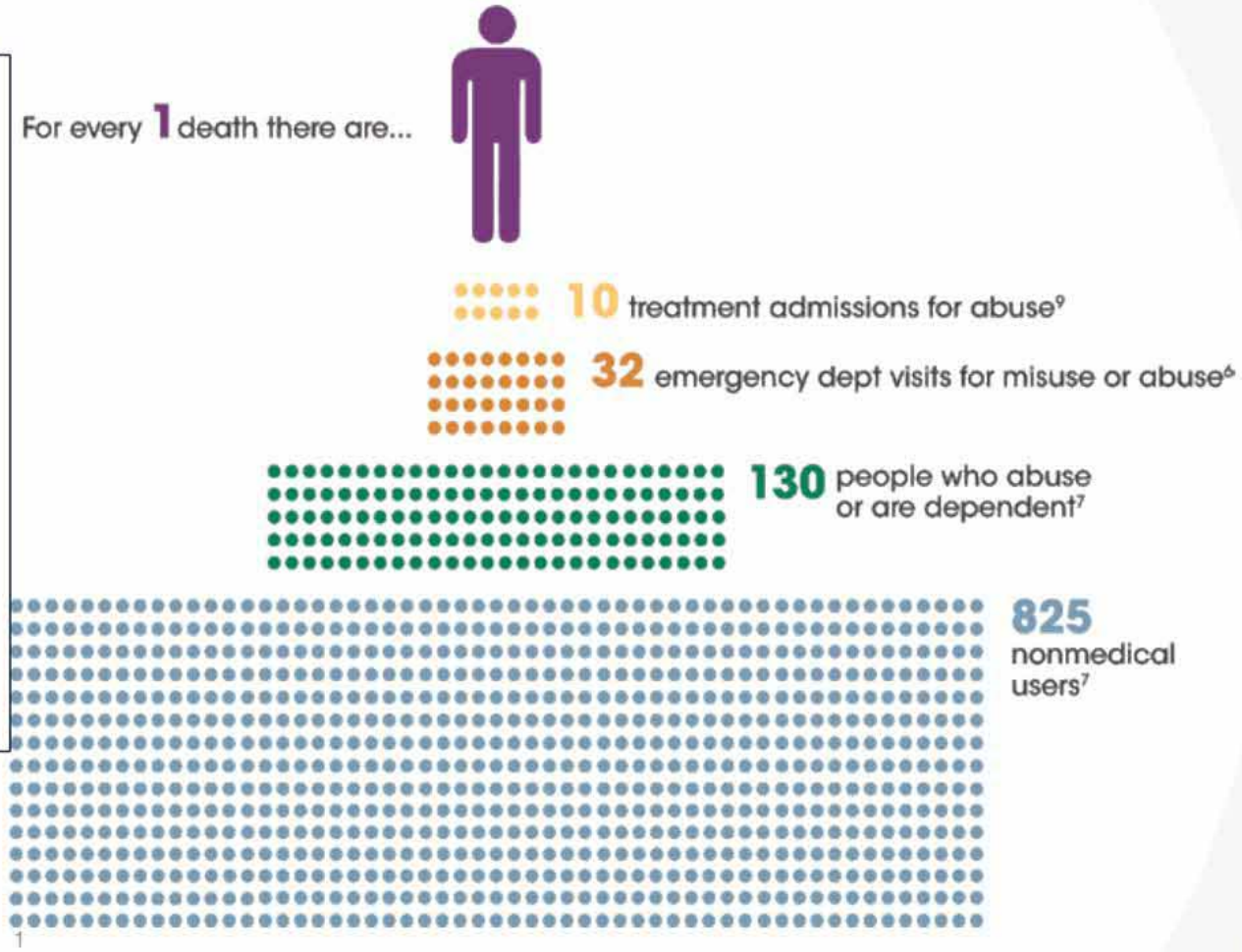
Statistics

www.ONDCP.gov – more available

US: 2010

- 38,300 Rx drug overdose deaths (100 / day)

- 16,600 Rx drug overdose deaths due to prescription opioids (4 fold increase from 2000)



Vital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999--2008
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm
Policy Impact: Prescription Painkiller Overdoses,
http://www.cdc.gov/homeandrecreationalsafety/rxbrief/

MAT – The Backdrop

- White House Office of National Drug Control Strategy (ONDCP)
  - Formulates policies and goals to "reduce drug use and its consequences."
  - National Drug Control Strategy
    - 2014 BOP Deliverables
      - Federal prescriber training
      - MAT Field Trial
  - 2011 Published the Prescription Drug Abuse Prevention Plan
    - Establishes goals in the areas of law enforcement, provider education, opiate tracking/monitoring, and opiate disposal

MAT – The Backdrop cont…

- White House Office of Management & Budget (OMB)
- Inquiries
  - Attorney General, Senator Briefings, Congressional, Special Interest Groups
- Freedom of Information Act (FOIA) Requests
  - Media, family
- Other Jurisdictions
  - State Prisons, County & Local Jails

MAT - Relevance to Corrections

- Correctional Health is Public Health
- National Drug Control Strategy
  - President's Plan to Reform Drug Policy
    - Prevent drug use before it begins
    - Expand access to treatment
    - Reform criminal justice system
    - Support Americans in recovery

MAT – Overview of Medication Options

- Methadone vs Buprenorphine vs Naltrexone
- Agonist vs Antagonist Therapy
  - Agonist
    - Methadone
    - Buprenorphine
    - LAMM (levacetylmethadol)
  - Antagonist
    - Naltrexone

Naltrexone (Vivitrol™) Advantages within corrections

- non-addictive
- no innate abuse potential, street value, or opioid overdose potential
- not a controlled substance
- shown to have fewer opioid abuse related hospitalizations (**prevents OD's from other opioids**)
- additional benefit of reducing alcohol craving and abuse
- no special licenses, certifications, registrations to prescribe or dispense, greatly reducing administrative burdens
- data suggests short term treatment (e.g., 6 months) may be efficacious vs potential life-long agonist therapy
- long acting injectable formulation overcomes limitation of poor compliance seen with daily oral therapy

MAT – BOP Strategy

- Inmate Populations to consider
  - Intake – important to have good detox protocol
  - Incarcerated – Outcomes to consider
    - Negative patient outcomes – opioid deaths?
    - Security issue outcomes (i.e., corruption, manipulation, diversion)
    - Community MAT trials
      - Extrapolate/translate to highly structured correctional environment?
  - Release
    - Risk of OD & relapse exponentially greater
    - Group w/ largest potential for positive outcomes
    - Limited resources to highest benefit and return on investment

Magazine

Breaking good: Vivitrol, a new drug given as a monthly shot, is helping addicts stay clean

By Cara Tabachnick March 13

Troy Garver, who was addicted to prescription pain medication, went to prison for selling morphine pills in 2014. Now he's trying to rebuild his life. As a part of his recovery he

MAT – Vivitrol at Release Studies

- Initiatives/Studies:
  - Washington County (Maryland)
    - Partnership between Health Department & Detention Center
  - Barnstable County (MA) Correctional Facility
  - 2008 feasibility study
    - 42% of patients received all six months of therapy
    - Lower re-incarceration rates reported
      - Jerry J, Collins G. Medication-assisted treatment of opiate dependence is gaining favor. Cleveland Clinic J of Med. 2013 Jun; Vol 80, No 6: 345-49.
  - 2014 Open Label Pilot Study
    - 37% of patients received all six injections
    - No differences in re-arrest reported
      - Lee J, McDonald R, Santana-Correa N, Grossman E, Rotrosen J, Gourevitch MN. Extended-release Naltrexone for Opioid Relapse Prevention at Jail Re-entry. Presented at the American Society of Addiction Medicine (ASAM) Annual Medical-Scientific Conference, Chicago IL; April 28 2013.
  - 2014 Randomized study
    - 57% of group received all six injections
    - 0 ODs in Vivitrol group – 7 ODs in standard care group
      - O'Brien CP, Friedmann PD, Nunes E , Lee JD, Kinlock TW, Lynch K, Cornish J. Depot Naltrexone as relapse prevention for parolees with Opioid Use Disorder. Presented at: College on Problems of Drug Dependence Annual Meeting. June 14-19, 2014.

MAT – BOP Vivitrol Field Trial

- Three institutions – release to one of two RRCs
  - Dallas-Fort Worth Metroplex
  - 10 patients identified
- Phase 1 of MAT (Local institution)
  - Patient selection and screening
  - Injections initiated two months prior to release
  - 2 Vivitrol injections provided
- Phase 2 of MAT (RRC)
  - Integrated into telehealth model
    - Overseeing psychiatrist visits via telehealth prior to release
    - Clinical Pharmacists provide ongoing interviews and prescription orders via a Collaborative Practice Agreement
    - BOP Pharmacy Dispenses and ships to site of administration
    - Contract with company to administer injections
  - Six injections at RRC (8 total injections)

MAT – Remaining Questions

- Effect on recidivism, ODs, & opioid relapse within RRC environment?
  - Needs to be studied
  - BOP Information, Policy, & Public Affair's Office of Research and Evaluation involvement
- Convergence of competing public health priories w/ limited resources
  - HepC, HIV, biologics, cancer medications, vaccinations, etc

MAT – Next Steps

- MAT Symposium
  - Field Trial Lessons Learned
    - Beyond the Brick and Mortar Prison
    - Highly visible and Resource Intense
    - Drug Info Research
    - Adjustment of Current Model
  - Expansion => Regional => National
    - Total inmates eligible over year
      - ~200 RRC contracts
    - Fiscal resources ($8-12 million)?
    - Human Capital Resources – more positions needed
    - Lots of communication issues / details to iron out
- **Develop Framework and Identify needed resources**
- **All Stakeholder Discussions (unit team, contracting, reentry, corrections, designations, health services, ORE)**

MAT Challenges and Lessons Learned

(b)(6),(b)(7)(C), PharmD, BCPP
Central Processing Pharmacist
Psychiatric Clinical Pharmacist Consultant

Central Processing Pharmacy Services (CPPS) Challenges and Lessons Learned

CPPS Challenges and Lessons Learned

- CPPS is currently responsible for many various aspects dealing with coordination of the patient receiving the Vivitrol® injection

- There are three CPPS pharmacist responsible for the coordination of the MAT program
  - (b)(6),(b)(7)(C)
  -
  -

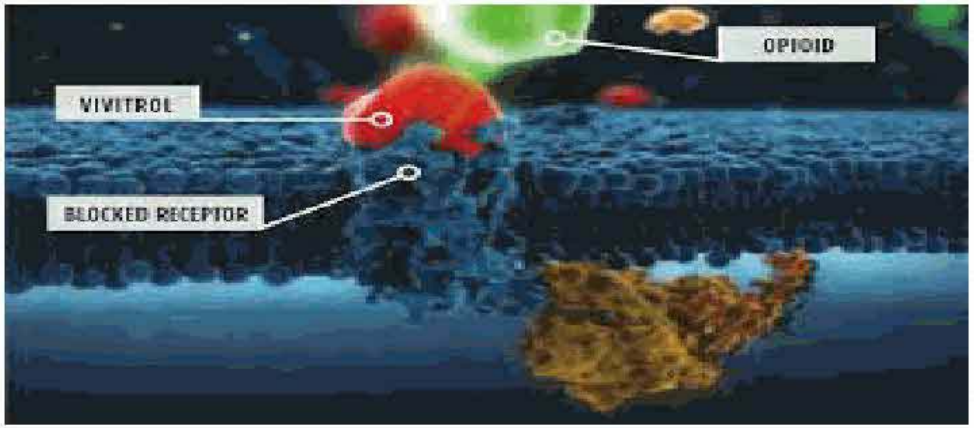
CPPS Challenges and Lessons Learned

- Out of 10 possible participants 3 participants have received injections
  - 1st participant received 8 total injections
    - Completed the full field trial
  - 2nd participant received 3 total injections (2 in-house and 1 at RRC then withdrew from the program)
  - 3rd participant received 1 injection so far (still at the institution)
  - 4th participant pending -1st injection is tentatively due 4/27/16

CPPS Challenges and Lessons Learned

- Other 6 participants were removed from the program
  - Two were removed due to medical reasons
  - One withdrew out of lack of interest
  - One left institution early prior to beginning the trial
  - One received a detainer and no longer has an RRC date
  - One failed/withdrew from the drug treatment program and will not go to the RRC

CPPS Challenges and Lessons Learned



- Current Process
- Central Processing Pharmacy Services (CPPS) role
- Challenges and Lessons Learned

CPPS Challenges and Lessons Learned

1. **Patients are identified and enrolled in field trial**

- CPPS Pharmacist Role
  - None

- Challenges and Lessons Learned
  - No process in place to identify who is enrolled in the program
    - Need a referral process in place for enrollment into the program
  - Some of the participants enrolled in the field trial did not meet criteria
    - Ex. Not addicted to opioids
    - Early release, detainer
  - Lack of participants
  - Need case management involvement

CPPS Challenges and Lessons Learned

2. **Participant list sent out to notify of enrollment**

- CPPS Pharmacist Role
  - CPPS pharmacist adds participants to tracking spreadsheet
- Challenges and Lessons Learned
  - Communication gap between institution CD – no process to notify CD at the institution
  - Need a "MAT Case Manager"

CPPS Challenges and Lessons Learned

3. **Institution CD meets with patient for medical clearance for the program and enters the NFR and orders appropriate labs**

- CPPS Pharmacist Role
  - Notify CD and RMD of upcoming injection due so patient will be scheduled to be seen, NFR entered, and prescription entered
  - Review NFR and approve if criteria is met, review labs in BEMR
- Challenges and Lessons Learned
  - No established medical or Non-formulary use criteria
    - CPPS created both criteria –will be reviewed at the BOP National P&T
  - No process in place for notification of CD to see patient
    - CPPS started notifying CD and RMD that the patient needed to be seen **
  - No baseline labs on file –need earlier scheduling of patient for evaluation
  - Need MAT program buy-in at the local institution

CPPS Challenges and Lessons Learned

4. **First injection given to the patient 5 weeks prior to release to the RRC**

- CPPS Pharmacist Role
  - Monitors eMAR to verify injection given
  - Adds date of injection to monitoring spreadsheet
- Challenges and Lessons Learned
  - First injection may now be given as early as 9 weeks prior to release in order to receive 3:3 injections (3 in-house, 3 at RRC)
  - May not always have enough notice to do 3 in-house**

CPPS Challenges and Lessons Learned

5. **CD follows up with patient and orders last in-house injection (one week prior to release)**

- CPPS Pharmacist Role
  - Verified the injection was given
  - Enters date on tracking spreadsheet
- Challenges and Lessons Learned
  - Appropriate documentation needs to take place in BEMR (ex. eMAR)

CPPS Challenges and Lessons Learned

6. (b)(6),(b)(7)(C) **meets with patient via teleconference to establish a doctor-patient relationship prior to release to the RRC. Patient enrollment form is completed at this time.**

- CPPS Pharmacist Role
  - Fills out the patient enrollment form and sends to (b)(6),(b)(7)(C) to complete and sign after the teleconference has taken place
  - Have to coordinate with multiple people to get RRC information to put on the form
- Challenges and Lessons Learned
  - Second participant was unable to meet with (b)(6),(b)(7)(C) (CD had to order the 6 month prescription)**
  - When program expands, (b)(6),(b)(7)(C) may not be able to meet with every patient
    - Need dedicated MAT providers or institutional CD responsible for filling out the patient enrollment form

CPPS Challenges and Lessons Learned

7. **Enrollment form is sent to UBC so an injection site can be located in close proximity to the RRC**

- CPPS Pharmacist Role
  - Faxes completed form (Prescription) to UBC
- Challenges and Lessons Learned
  - UBC must receive this form prior to patient leaving to allow time to find an injection site

UBC
United BioSource Corporation

CPPS Challenges and Lessons Learned

8. **CPPS schedules and conducts conference calls with the patients at the RRC to conduct the Vivitrol® Questionnaire (occurs one week prior to each injection)**

- CPPS Pharmacist Role
  - Coordinate with (b)(6),(b)(7)(C) Supervisory Community Treatment Coordinator, to schedule the first call (he provides RRC contact and phone #)
  - Created Vivitrol® Questionnaire to have a way to determine if patient meets criteria to continue with the program
  - Conducts the questionnaire with the patient and scans copy into BEMR (8 teleconferences completed)
- Challenges and Lessons Learned
  - Questionnaire duplicates the Report of Injection form being completed by the injection site
  - Extremely difficult to coordinate teleconference with the patient due to works schedules, class schedules, etc…
    - Patients did not like having to miss work for the teleconference

CPPS Challenges and Lessons Learned

9. **Vivitrol® refills are processed in BEMR and shipped to the injection site**

- CPPS Pharmacist Role
  - Enters admin note in BEMR and processes refill
  - Notifies POX that the refill has been processed
  - Notifies POX shipping information and contact name at the injection site
- Challenges and Lessons Learned
  - Very challenging with the few patients in the current MAT trial, tracking will be very challenging when the program expands
    - Shipping addresses
    - Timing of shipping
    - Prescription orders and refills

CPPS Challenges and Lessons Learned

10. **Patient reports to injection site to receive injection and the Report of Injection Form is completed and faxed to UBC then UBC faxes form to POX**

- CPPS Pharmacist Role
  - Monitor to see if patient received injection
  - Add injection date to tracking spreadsheet
  - Review Report of Injection form to verify next injection was scheduled
- Challenges and Lessons Learned
  - Report of injection form is not always faxed to POX in a timely fashion
    - Patient #1 missed injection and had to reschedule and no one was ever notified
    - Need to have a better mechanism for receiving faxes*
  - Report of injection form is hard to read after faxed and scanned
  - No guidance established on what to do if patient misses an injection
  - Transportation to injection site will be an issue for patients and may interfere with work schedules

CPPS Challenges and Lessons Learned

- Other Challenges Noted
  - Coordination
    - Multiple steps in the process involve coordination with multiple people
      - Institution physicians and pharmacist, RMD, Patients, Halfway house staff, UBC, Injection site
    - Recommend having one person oversee the entire coordination of each step
  - Staffing
    - More staff will be needed for expansion of this program

Remote Fill Site Challenges and Lessons Learned

Remote Fill Site Challenges and Lessons Learned

- FCC POX currently is responsible for shipping Vivitrol® injections to the injection sites
- Current Process:
  - Orders are processed by a CPPS pharmacist**
  - POX prints the Rx label and fills the prescription
  - Rx is then shipped to the injection site (Shipping address is provided by a CPPS pharmacist)
  - Scan into BEMR report of injection form
- To date 7 injections have been shipped by POX

Remote Fill Site Challenges and Lessons Learned

- Purchasing – Initial barrier
  - Not only affected Vivitrol®, but all specialty medications
  - Process has since been streamlined with no recurring issues at this time

Remote Fill Site Challenges and Lessons Learned

- Filling of Vivitrol® prescriptions
  - No issues with this process
- Shipping of Vivitrol® prescriptions
  - Most time consuming issue
  - Currently POX incurs shipping costs
  - Requires purchase card, YREGDOC#, and approving official signature
  - Added burden when processing the purchase card statement at the end of the month

Remote Fill Site Challenges and Lessons Learned

- Scanning the Report of Injection Form
  - Injection site faxes form to POX
  - POX scans copy into BEMR
- Issues with this process
  - Image is not always legible after being scanned/faxed multiple times
  - Communication issues when the form is not received in a timely manner (have to communicate through the third party contractor)

Proposed Changes

Proposed Changes

- Shipping solution for the fill site
  - Central Office/Re-entry Affairs create a FedEx account linked to a purchased card held in that department that POX would have access to
  - Would dramatically reduce time needed at the remote fill site while also providing a simple means for acquisition of shipping supplies w/o the need for reimbursement

Proposed Changes

- Staffing
  - With the expansion of the program, staffing levels may need to be adjusted depending on the size of the program
- If a FedEx account is established POX could provide the following services based on staffing
  - 100 participants per year
    - Current staffing
  - 100-500 participants per year
    - One additional ancillary staff
  - 500+ participants per year
    - Additional pharmacist needed

Proposed Changes

- Reduce number of injections
  - Currently 2 injections are given in-house and 6 once released (8 total)
  - Propose to give 3 in-house and 3 once released (6 total)
    - Current participant #3 will only receive 6 total injections
    - Giving more in-house injections will be more cost effective
    - Highest time for risk of relapse is during the first month after release

Proposed Changes

- No need to conduct the Vivitrol® Questionnaire
  - Duplicates many questions already asked by the injection site pharmacist
  - Very time consuming and inconvenient for the patient
  - Update the Report of Injection Form to add a check box if they would like a pharmacist to contact them
  - Contact the patient twice once released to RRC to follow up

Proposed Changes

- Contract out the injections so they are supplied by the contractor/injection site
- This would remove having a BOP fill site for Vivitrol®
  - No additional staff would be needed at the fill site for expansion of the program
  - No additional cold storage required for the fill site
  - Remove the coordination of multiple steps, streamlining the process**
  - No longer an issue of returning the injection if the patient does not show for his appointment

Cost Information

- Walgreens:
  - Misc. injections: AWP-10% + $75 per diem= $1386.00-$138.60+$75.00 = $1322.40 per injection
- Coram:
  - Misc. injections: AWP-15% + $70 per diem= $1386.00-$207.90+$70 = $1248.10 per injection
- Current Cost:
  - $693.97+$160 UBC charge + $35 packing/shipping =$888.97 per injection
- Cost savings of $360 per injection, x 3 injections = $1080 per inmate
  - Factors to consider: not each patient will receive 3 injections, no additional staff salaries and benefits for fill site, cold storage chain being broken and product can't be reused

Questions?