Management of Benzodiazepines in Medication-Assisted Treatment

ATTC Webinar April 17, 2014
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Dawn Lindsay, Ph.D.
Learning Objectives

• At the conclusion of this presentation, the participant will be able to:
  – Define the major issues surrounding the use of benzodiazepines in the context of medication assisted treatment (MAT), including impairment, clinical outcomes and risk management concerns.
  – Describe the application of the RAND/UCLA Appropriateness Method (RAM) to the development of clinical practice guidelines
  – Explain potential challenges in the implementation of clinical guidelines addressing benzodiazepine use to the practice of medication-assisted treatment.
City of Philadelphia

Department of Behavioral Health and Intellectual disAbility Services

- Office of Mental Health
- Office of Addiction Services
- Community Behavioral Health
- Intellectual disAbility Services
About Community Behavioral Health

• Manages the HealthChoices Program for behavioral health on behalf of the city and county of Philadelphia since 1997
• 450,000-475,000 Medicaid recipients
• Approximately $800M per year
• Contracts with 250+ providers
• Guided by values of Recovery, Resilience, and Self-Determination
About Community Care

• Behavioral Health Managed Care Company
• Founded in 1996
• Federally tax exempt non-profit 501(c)(3)
• Sole member corporation (UPMC) – provider owned
• Licensed as a Risk-Assuming PPO
• Major focus: publicly-funded behavioral healthcare system
About Community Care

- Medicaid/HealthChoices membership: over 700,000
- Commercial/Medicare membership: 450,000.
- Statewide HealthChoices presence; 39 of 67 Pennsylvania counties.
- 10 offices across the Commonwealth.
About IRETA

• Institute for Research, Education and Training in Addictions
• 501 (c) (3) nonprofit founded in 1999 to improve recognition, prevention, treatment, research and policy related to addiction and recovery.
• IRETA aligns addiction research and practice to improve outcomes for individuals, families and communities.
• National SBIRT ATTC
• Located in Pittsburgh, PA
Community Care Methadone Provider Initiative

• A Quality Improvement Initiative between Counties, Methadone Providers, and Community Care, 2011-2013
Objectives

• To identify members enrolled in Methadone treatment programs who are concurrently filling benzodiazepine and / or opiate prescriptions.

• Collaborate with Methadone providers to reduce the incidence of concurrent utilization and ultimately improve care.
# Frequency of Benzodiazepine use among members in methadone programs in Allegheny County

<table>
<thead>
<tr>
<th>Time Period</th>
<th># Members in Methadone for at least 10 days (den)</th>
<th># Members with at least 10 days of Methadone + 1 Rx of Benzo (num)</th>
<th>Percent (num/den)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1-2011</td>
<td>1639</td>
<td>588</td>
<td>35.8%</td>
</tr>
<tr>
<td>Q2-2011</td>
<td>1664</td>
<td>568</td>
<td>34.1%</td>
</tr>
<tr>
<td>Q3-2011</td>
<td>1708</td>
<td>578</td>
<td>33.8%</td>
</tr>
<tr>
<td>Q4-2011</td>
<td>1707</td>
<td>576</td>
<td>33.7%</td>
</tr>
<tr>
<td>Q1-2012</td>
<td>1718</td>
<td>575</td>
<td>33.5%</td>
</tr>
<tr>
<td>Q2-2012</td>
<td>1727</td>
<td>574</td>
<td>33.2%</td>
</tr>
<tr>
<td>Q3-2012</td>
<td>1614</td>
<td>536</td>
<td>33.2%</td>
</tr>
<tr>
<td>Q4-2013</td>
<td>1731</td>
<td>532</td>
<td>30.7%</td>
</tr>
<tr>
<td>Q1-2013</td>
<td>1718</td>
<td>448</td>
<td>26.1%</td>
</tr>
<tr>
<td>Q2-2013</td>
<td>1731</td>
<td>425</td>
<td>24.6%</td>
</tr>
</tbody>
</table>
Intervention

• Community Care generates member reports on a monthly basis and sends to the Methadone Providers in Allegheny County.

• Member report includes medications filled and prescriber information.

• Methadone providers use the information to help address clinical issues with the member.
## Comparison

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-Period (May-June 2011)</th>
<th>Post-Period (May-June 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members on Benzodiazepines Only</td>
<td>60.2%</td>
<td>40.6%</td>
</tr>
<tr>
<td>Members on Opiates Only</td>
<td>22.0%</td>
<td>7.4%</td>
</tr>
<tr>
<td>Members on Both Medications</td>
<td>17.8%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Members on No Medications</td>
<td>-</td>
<td>40.6%</td>
</tr>
<tr>
<td>Total Benzodiazepine Scripts</td>
<td>1048</td>
<td>437</td>
</tr>
<tr>
<td>Total Opiate Scripts</td>
<td>475</td>
<td>148</td>
</tr>
</tbody>
</table>
Conclusions

• Quarterly trend currently shows a downward trend in the percentage of members on methadone and concurrent benzodiazepine medications.

• The impact analysis showed that 40% of the members still in Methadone treatment in the post period were no longer filling opiates or benzodiazepines.

• Members filling concurrent opiate prescriptions also went down, from 22% vs. 7.4% in the post period.
Community Behavioral Health
QI Project 2012-2014

• **Analysis:**
  – Identify Community Behavioral Health (CBH) Members in Philadelphia who are in methadone treatment and concurrently prescribed benzodiazepines and/or other opiates.

• **Interventions:**
  – CBH generates monthly member reports including medications filled and prescriber information and sends to the methadone providers in Philadelphia County. Methadone providers use reports to help address clinical issues with the member.
  – In 2012, release of the *Clinical Guidelines for the Management of Benzodiazepines in Medication-Assisted Treatment*:
    
Analysis: Data Sources

• Analysis periods: July 1, 2010 – September 30, 2010 and July 1, 2013 – September 30, 2013
• Paid methadone clinic claims from all contracts for the analysis period.
• Paid Medicaid pharmacy claims for the analysis period.
Analysis: Methodology

- Identify members in methadone treatment for at least ten days in Q3 2010 and those in methadone treatment for at least ten days in Q3 2013.
- Identify members in the above population who also filled prescriptions for benzodiazepines or opiates during the same period.
- Identify the benzodiazepines and opiates used.
### Table 1: Demographics for members with concurrent methadone and benzodiazepine/opiate usage

<table>
<thead>
<tr>
<th>Demographic</th>
<th># of Members in 2010</th>
<th># of Members in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged 18-34</td>
<td>604</td>
<td>525</td>
</tr>
<tr>
<td>Aged 35-50</td>
<td>803</td>
<td>701</td>
</tr>
<tr>
<td>Aged 51-64</td>
<td>486</td>
<td>398</td>
</tr>
<tr>
<td>Aged &gt;=65</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Male</td>
<td>773</td>
<td>903</td>
</tr>
<tr>
<td>Female</td>
<td>1106</td>
<td>703</td>
</tr>
<tr>
<td>ASIAN</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>BLACK OR AFRICAN AMERICAN</td>
<td>423</td>
<td>328</td>
</tr>
<tr>
<td>N.AMER.INDIAN/ALASKAN NATIVE</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>OTHER</td>
<td>1140</td>
<td>255</td>
</tr>
<tr>
<td>WHITE</td>
<td>2</td>
<td>1015</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1879</strong></td>
<td><strong>1606</strong></td>
</tr>
</tbody>
</table>
Table 2: Methadone Recipients (2010 n=4,380; 2013 n=4,678) with Benzodiazepine and Opiate Rxs

<table>
<thead>
<tr>
<th>Prescription in conjunction with at least 10 days of paid methadone claims</th>
<th># of Members (%) in 2010</th>
<th># of Members (%) in 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzo Rx only</td>
<td>788 (18%)</td>
<td>809 (17%)</td>
</tr>
<tr>
<td>Opiate Rx only</td>
<td>522 (12%)</td>
<td>365 (8%)</td>
</tr>
<tr>
<td>Benzo AND Opiate Rxs</td>
<td>569 (13%)</td>
<td>432 (9%)</td>
</tr>
<tr>
<td>Benzo OR Opiate Rx</td>
<td>1,879 (43%)</td>
<td>1606 (34%)</td>
</tr>
</tbody>
</table>
### Table 3: Benzodiazepines prescribed with methadone

<table>
<thead>
<tr>
<th>Benzodiazepine</th>
<th># of Prescriptions 2010</th>
<th># of Prescriptions 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam</td>
<td>842</td>
<td>571</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>958</td>
<td>654</td>
</tr>
<tr>
<td>Clorazepate</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Diazepam</td>
<td>181</td>
<td>34</td>
</tr>
<tr>
<td>Estazolam</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Flurazepan</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>184</td>
<td>43</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>40</td>
<td>3</td>
</tr>
<tr>
<td>Temazepam</td>
<td>246</td>
<td>79</td>
</tr>
<tr>
<td>Triazolam</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>2497</strong></td>
<td><strong>1392</strong></td>
</tr>
</tbody>
</table>
Table 4: Opiates prescribed with methadone

<table>
<thead>
<tr>
<th>Opiate</th>
<th># of Prescriptions 2010</th>
<th># of Prescriptions 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>176</td>
<td>92</td>
</tr>
<tr>
<td>Codeine</td>
<td>443</td>
<td>92</td>
</tr>
<tr>
<td>Diphenoxylate</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>38</td>
<td>7</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>658</td>
<td>117</td>
</tr>
<tr>
<td>Meperidine</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Methadone</td>
<td>169</td>
<td>21</td>
</tr>
<tr>
<td>Morphine</td>
<td>68</td>
<td>9</td>
</tr>
<tr>
<td>Naltrexone</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>927</td>
<td>416</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>125</td>
<td>0</td>
</tr>
<tr>
<td>Tramadol</td>
<td>424</td>
<td>226</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>3067</strong></td>
<td><strong>981</strong></td>
</tr>
</tbody>
</table>
Summary of QI Project

• High rates of methadone and benzo/opiate co-Rx in baseline analysis
• Significant declines in methadone/opiate co-Rx and methadone/opiate&benzo co-Rx
• Slight decline in % of members with methadone/benzo co-Rx
• Significant reduction in total benzo and opiate Rxs among methadone recipients
Need for Clinical Guidelines

• Use of benzodiazepines in MAT is a complicated and multi-faceted issue without clear clinical guidance

• Published literature, treatment protocols and guidelines demonstrate variation and inconsistency in clinical practice

• There is a need to establish a set of principles for the appropriate use of benzodiazepines in MAT
Management of Benzodiazepines in MAT Project

• Idea grew as a result of discussions between DBHIDS and providers in Philadelphia regarding the need to develop guidelines for the use of benzodiazepines in MAT
• IRETA developed and submitted proposal to DBHIDS
• CCBH shared experience developing Buprenorphine Best Practice Guidelines and provided resources for literature review and conference
Kick-Off Conference

Management of Benzodiazepines in Medication-Assisted Treatment

COLLEGE OF PHYSICIANS
Philadelphia, Pennsylvania
FEBRUARY 9, 2012
Kick-Off Conference

• Kick-Off Conference was planned for ~150 stakeholders in Philadelphia, Pennsylvania and the larger region.

• Expert panel members from Philadelphia and beyond were selected to speak at the conference and participate in the guideline development process.

• Logistical support for the conference provided by SAMHSA
RAND/UCLA Appropriateness Method

• RAND/UCLA Appropriateness Method was developed in the 1980s to assist in identifying overuse/underuse of medical procedures.
• While RCTs are the gold standard of clinical evidence, not always available or detailed enough
• RAND/UCLA Method combines scientific evidence and clinical knowledge
RAND/UCLA Appropriateness Method

RAM used for:

– Procedures that are used frequently
– Procedures that are associated with a substantial amount of morbidity and/or mortality
– Procedures that consume significant resources
– Procedures with wide variations among geographic areas in rates of use
– Procedures whose use is controversial
RAND/UCLA Appropriateness Method

Research shows:

• Method is reliable and reproducible
• Method is more rigorous than consensus-based decision-making (i.e., avoids groupthink)
• Requires a multidisciplinary expert panel to reduce bias
RAND/UCLA Appropriateness Method

Steps in the Process:

- Literature Review
- Rating Process
- Clinical Guidelines
RAND/UCLA Appropriateness Method

Steps in the Process:

1. Literature Review
2. Rating Process
3. Clinical Guidelines
Literature Review

- PubMed Search
- MeSH terms
  - “benzodiazepines” AND “methadone”
  - “benzodiazepines” AND “buprenorphine”
  - “benzodiazepines” AND “naltrexone”
- Filtered for references within the past 10 years
- Titles for 370 references scanned, 100 abstracts reviewed, 20 articles selected as most relevant.
Literature Review

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction
A Treatment Improvement Protocol TIP 40

Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs
A Treatment Improvement Protocol TIP 43

Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence

PCSS-B Training
An Educational Resource for Those Treating Patients with Opioid Dependence

PCSS Guidance

Topic: Management of psychiatric medications in patients receiving buprenorphine/ naloxone

Author: John A. Renner, Jr., M.D.

Last Updated: 4/17/06

Guideline Coverage:
This topic is also addressed in Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (TIP 40), pages 19-22 and 72-76. http://buprenorphine.samhsa.gov/Bup%20Guidelines.pdf and in Methadone-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs (TIP 43), page 35-42.

Clinical Question:
Draft Guidelines

• Based on literature review, existing clinical guidelines, and extensive consultation with medical advisor (Dr. Trusandra Taylor) and consultant (Dr. Carl Sullivan), draft guidelines were constructed

• Companion background paper was developed
RAND/UCLA Appropriateness Method

Steps in the Process:

- Literature Review
- Rating Process
- Clinical Guidelines
Expert Panel

• Louis E. Baxter, Sr., MD, FASAM
• Peter R. Cohen, MD
• Peter A. DeMaria, Jr., MD, FASAM, DFAPA
• Antoine Douaihy, MD
• Karol Kaltenbach, PhD
• Abigail Kay, MD, ABPN, ABAM
• Jan Kusserow, RN, BSN, CCM
• Laura F. McNicholas, MD, PhD
• Jane C. Maxwell, PhD
• Laura A. Murray, DO
Rating Process

• Expert panel rated proposed clinical guidelines on **appropriateness** using background paper and clinical experience to guide ratings
  – Round 1 Ratings
  – Expert Panel Meeting
  – Round 2 Ratings

• Two dimensions of ratings: appropriateness and agreement
Expert Panel Meeting

- Via webinar 9/27/2012
- Chaired by Matthew O. Hurford, M.D.
- Prior to the meeting, expert panel members were provided with summary results of Round 1 Rating and how their ratings compared with the group
Expert Panel Meeting

- During the meeting, experts discussed clinical guideline statements that were rated Uncertain as to appropriateness and/or for which a criterion level agreement was not reached during Round 1 Rating.
- Goal of meeting was *not* consensus but simply focused on discussion
Clinical Guidelines

- The Rating Process, Expert Panel Meeting, and feedback from experts throughout the process, resulted in a set of clinical guidelines that were then edited to remove redundancy and improve clarity and readability.

- Patient education tips were included with each category of guidelines.
RAND/UCLA Appropriateness Method

Steps in the Process:

Literature Review → Rating Process → Clinical Guidelines
Clinical Guidelines

• General Guidelines
  – *CNS depressant use is not an absolute contraindication for either methadone or buprenorphine, but is a reason for caution because of potential respiratory depression.*
  – *People who use benzodiazepines should be considered at risk for adverse drug reactions including overdose and death*
Clinical Guidelines

• General Guidelines
  – Many people presenting to services have extensive multiple substance dependence and all substance abuse, including benzodiazepines, should be actively addressed in treatment
  – Risk management strategies are critical
  – Clinicians should ensure that every step of the decision-making process is documented
Clinical Guidelines

• Assessment for MAT
  – Given the prevalence of benzodiazepine use among the MAT population, MAT assessment should include careful examination of benzodiazepine use and education about benzodiazepine use.
Clinical Guidelines

• Addressing Benzodiazepine Use
  – *If assessment for MAT shows benzodiazepine use, determine its context and create a plan to address it.*
Clinical Guidelines

• MAT Induction
  – For anyone in MAT, the induction period carries with it the most risk of harm. Extra care is required when inducting a person who uses benzodiazepines.
Clinical Guidelines

• MAT for people with concurrent benzodiazepine use
  – A person’s use of benzodiazepines may change over time, or even from visit to visit. Effective, individualized treatment includes ongoing communication, appropriate dosing, and careful monitoring.
Clinical Guidelines

• Noncompliance with treatment agreement
  – Individuals in MAT may deviate from the treatment agreement. Clinical judgment is required to address noncompliance.
Clinical Guidelines

• Risk Management/Impairment Assessment
  – Clinicians should use caution with people in MAT who use benzodiazepines because they have increased risk for adverse drug reactions including overdose and death.
Clinical Guidelines

• Special Circumstances:
• People in MAT seeking benzodiazepines
  – Giving benzodiazepine prescriptions to people in MAT is controversial. Guidelines specific to the practice of benzodiazepine prescribing in the context of MAT are listed below. Clinicians are advised to use recovery-oriented approaches to education and risk management approaches as detailed in the rest of the guidelines.
Clinical Guidelines

• **Special Circumstances:**
• **Benzodiazepine Maintenance**
  – *Benzodiazepine maintenance treatment is controversial… Providing a maintenance benzodiazepine dose in the context of MAT should be considered a last-resort option after other alternatives have been exhausted.*
Thank you!

Contact information:
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Dawn Lindsay, Ph.D.: dawn@ireta.org