The Affordable Care Act and the Future of Addiction Medicine in Primary Care

Keith Heinzerling MD MPH
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The Affordable Care Act

• On March 23, 2010, President Obama signed comprehensive health reform, the Patient Protection and Affordable Care Act (ACA), into law.

• Aims of the ACA:
  – Expand coverage
  – Control health care costs
  – Improve health care delivery system
Impact of Affordable Care Act on Substance Abuse Treatment

• More people will have insurance
• More substance abuse services will be covered
• Increased emphasis on integrated and accountable care
ACA: More (but not all) Americans will have health insurance

- “Individual mandate”: All Americans must purchase insurance or pay a penalty
- Medicaid expansion: anyone under 65 with income up to 133% FPL is eligible for Medicaid (but states must decide to expand)
- The CBO estimates 13 million newly insured in 2014 and 20 million in 2015, but 31 million still uninsured in 2014
  - Still uninsured: 30% unauthorized immigrants, 20% Medicaid eligible but not enrolled, 5% in states not expanding Medicaid, 45% choosing not to purchase insurance
ACA: More substance abuse services covered (full parity, fewer *carve outs*)

• All insurance plans must cover 10 “Essential Health Benefits”:
  – Ambulatory patient services;
  – Emergency services;
  – Hospitalization;
  – Maternity and newborn care;
  – **Mental health and substance use disorder services, including behavioral health treatment**;
  – Prescription drugs;
  – Rehabilitative and habilitative services and devices;
  – Laboratory services;
  – Preventive and wellness services and chronic disease management;
  – Pediatric services, including oral and vision care.

• Private plans must provide these to be certified and offered via the Health Insurance Marketplace. States expanding their Medicaid programs must provide these in Medicaid. *MAINSTREAMING*
Substance abuse “essential” services under ACA in California

• Medi-Cal:
  – Voluntary Inpatient Detoxification
  – Intensive Outpatient Treatment Services
  – Residential Treatment Services
  – Outpatient Drug Free Services
  – Narcotic Treatment Services
Accountable Care Organizations (ACO) → shift to population-level approach

- Accountable Care Organizations (ACO)s:
  - Groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to a population of Medicare patients
  - Coordinated care: Aims to get patients the right care at the right time, especially those with chronic illness, with the goal of avoiding unnecessary duplication of services and preventing medical errors
  - Financial incentive for more efficient care → ACO shares in the savings it achieves for the Medicare program
ACO/population approach and substance abuse

• Fee-for-service system: reactive, patients seek (or don’t seek) care regardless of appropriateness
  – People with drug/alcohol problems often do not seek help

• Population-level approach: proactive, identify who needs care, how much care, when
  – **Case study:** ED visits by people with drug/alcohol problems
Emphasis and Incentives for Primary Prevention

• No patient co-pay and 10% federal funding for any approved prevention intervention
  – Approved prevention interventions must have Grade B (high certainty that the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial) or higher based on review of evidence by U.S. Preventive Services Task Force

• Don’t just treat end stage addiction, need to focus on early intervention in “pre-addicted”
Current substance abuse specialty treatment system can’t meet demand

Only 10% of patients needing addiction treatment currently get it. The 10% getting treatment have the most severe, end-stage addiction.

Current specialty system’s capacity

Can Primary Care-based services expand access to substance abuse treatment?

• Patients with harmful use (“pre-addiction”):
  – Screening and brief intervention

• Patients with substance use disorder (dependence):
  – Office-based addiction treatment:
    • Anti-addiction medication (buprenorphine, naltrexone)
    • Brief physician counseling (medication management)
    • Referral to specialty services and self-help if needed
FDA Approved Anti-Addiction Medications Available in Primary Care

• Alcohol Dependence
  – Naltrexone (Revia® and Vivitrol®)
  – Acamprosate (Campral®)
  – Disulfiram (Antabuse®)

• Opioid Dependence (heroin, Rx opioids)
  – Buprenorphine (Suboxone® and Subutex®): requires DATA 2000 Waiver to prescribe
  – Naltrexone (Vivitrol®)

• No approved medications for cocaine, methamphetamine, marijuana, ecstasy, etc. (refer patients to clinical trials!)
What about methadone?

Limited to observed dosing at specialized Opioid Treatment Programs
Three tools to treat drug or alcohol dependence in Primary Care

• **Medication**: reduce withdrawal or cravings, prevent relapse from stress, cues, priming

• **Counseling**: CBT, motivational enhancement, medication management; usually outpatient

• **Support**: Self-help groups (AA, SMART Recovery), family/friends, supportive environment (sober living)
Medical Management Counseling

• Brief physician-delivered counseling for patients receiving anti-addiction medications (buprenorphine, naltrexone, etc.)
• Emphasize/support adherence to medication and counseling/support services
• Use motivational approach and avoid confrontation which will elicit denial and resistance from the patient
• Focus on the process of behavior change instead of whether patient is abstinent or not:
  – Praise patient for reductions in use, attending counseling sessions, increased insight/motivation
Medical Management Counseling (2)

• Assess alcohol/opioid use since last visit
  – “Tell me about your alcohol/opioid use since our last visit.”
  – Congratulate patients that did not drink/use opioids.
  – For patients who did drink/use opioids ask
    • “Were you able to cut down some?”
    • “Even though you did drink/use opioids, it is good that you are here and I will continue to help you to change your drinking/opioid use.”
    • Trouble shoot a plan to address patient’s triggers for drinking/opioid use.

• Assess medication adherence and any medication side effects
  – “Patients often tell me they sometimes miss their medication or forget to take it. Does this happen to you?”
  – NOTE: continue medication through lapses of drug/alcohol use
Medical Management Counseling (3)

• Assess participation in counseling or self-help programs.
  – Specialized counseling and/or self-help should NOT be mandated if patient doing well with medication and Medical Management Counseling alone.
  – Encourage increased participation in specialized drug/alcohol counseling or self-help if patient struggling
  – **NOTE**: some counselors or Alcoholic Anonymous members may discourage patients from taking medications. There is **no prohibition** against medications in any Anonymous fellowship or counseling program. If necessary patients should change to a different meeting or program.
 Injectable, Extended-Release Naltrexone for Alcohol Dependence

• Monthly intra-gluteal injection of extended release naltrexone 380 mg (Vivitrol®)
• Approved for alcohol or opioid dependence

• Ethanol releases endogenous opioids (e.g. β-endorphin)
• Opioid release mediates ethanol-induced euphoria and reward
• Naltrexone = mu-opioid receptor antagonist that reduced ethanol-induced stimulation, positive mood, craving, and enjoyment in human lab studies (Ray and Hutchison, 2007)
Side effects of injectable naltrexone

• Mild nausea (usually resolves within days)
• Injection site reactions
  – Tenderness, mild pain, nodules at site common and NOT major problem (treat with NSAIDs, ice, warm compress, etc.)
  – Rarely cellulitis and/or abscess (may need antibiotics or drainage)
• Rare side effects:
  – Precipitation of opioid withdrawal in opioid dependent patients, hepatotoxicity, difficulty achieving analgesia with opioids due to opioid blockade, depression, possible opioid sensitivity/overdose following discontinuation of naltrexone, and eosinophilic pneumonia.
Outcomes with injectable naltrexone for alcohol dependence in Primary Care

- Patients who received all three planned monthly injections (N=40) had significant reductions in drinking days and heavy drinking days.
- Heavy drinking days were still less even when including patients who received less than three injections.

Managing patients on injectable naltrexone

• Optimal length of treatment for naltrexone in alcohol dependence not known
  – Start with 3 to 6 monthly injections. OK to continue if patient desires

• OK to give missed/late injection as long as no intervening opioid use

• Naltrexone antagonizes opioid analgesics. Patients requiring opioids while on injectable naltrexone should be treated in a hospital by specialists
Buprenorphine/naloxone for opioid dependence

• μ-opioid receptor partial agonist
• DATA 2000 waiver to prescribe. Must complete 8 hour training and register with DEA.
• Suboxone®: buprenorphine/naloxone
  – Naloxone to prevent abuse via IV route
  – Film: 2/0.5 mg, 4/1 mg, 8/2 mg, 12/3 mg
  – Tablets: 2/0.5 mg, 8/2 mg
• Subutex®: buprenorphine
  – Tablets: 2 mg, 8 mg
• Long half-life: 24-42 hours
Buprenorphine: Partial Agonist Ceiling
Effect may Increase Safety

Low OD risk with buprenorphine UNLESS combined with alcohol or sedatives (benzos) so AVOID these while on buprenorphine

TABLE. Drug-related deaths involving opioids, by type of opioid — Drug Abuse Warning Network Medical Examiner System, 13 states, 2009

<table>
<thead>
<tr>
<th>Opioid</th>
<th>No.</th>
<th>MME</th>
<th>RR</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All deaths</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>20</td>
<td>0.8</td>
<td>0.02</td>
<td>(0.01-0.04)</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>364</td>
<td>7.7</td>
<td>0.28</td>
<td>(0.25-0.32)</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>550</td>
<td>14.3</td>
<td>0.42</td>
<td>(0.38-0.47)</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>74</td>
<td>9.1</td>
<td>0.27</td>
<td>(0.21-0.34)</td>
</tr>
<tr>
<td>Morphine</td>
<td>824</td>
<td>20.2</td>
<td>0.64</td>
<td>(0.58-0.70)</td>
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<tr>
<td>Oxycodone</td>
<td>1,097</td>
<td>8.7</td>
<td>0.26</td>
<td>(0.24-0.28)</td>
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<tr>
<td>Methadone</td>
<td>1,034</td>
<td>33.6</td>
<td>1.00</td>
<td>referent</td>
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<tr>
<td>Total*</td>
<td>3,294</td>
<td>10.4</td>
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<table>
<thead>
<tr>
<th>Single-drug deaths</th>
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<tbody>
<tr>
<td>Buprenorphine</td>
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<tr>
<td>Fentanyl</td>
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<tr>
<td>Hydrocodone</td>
</tr>
<tr>
<td>Hydromorphone</td>
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<tr>
<td>Morphine</td>
</tr>
<tr>
<td>Oxycodone</td>
</tr>
<tr>
<td>Methadone</td>
</tr>
<tr>
<td>Total*</td>
</tr>
</tbody>
</table>

Abbreviations: MME = morphine milligram equivalent; RR = rate ratio; CI = confidence interval.
* Counts for each opioid might not sum to the total shown for all deaths because some deaths involved more than one opioid.

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Buprenorphine: Sublingual Administration

Suboxone (buprenorphine HCl/naloxone HCl dihydrate)

Subutex (buprenorphine HCl/sublingual tablets)

DEMONSTRATION FILM

The sublingual film in this package does not contain any active pharmaceutical ingredients. It is intended solely for the purpose of demonstrating the method of administration of the dosage form in a physician's office. Contains artificial sweetener.
Buprenorphine: side effects and drug interactions

- Side effects: constipation, headache, sedation, withdrawal, hepatitis (RARE)
- Drug-Drug Interactions
  - CNS Sedatives (Alcohol, Benzodiazepines): RESPIRATORY DEPRESSION, OVERDOSE, DEATH
  - Buprenorphine metabolized by CYP3A4
  - CYP3A4 inhibitors: azole antifungals (ketoconazole), macrolide antibiotics (erythromycin), and HIV protease inhibitors
  - CYP3A4 inducers: efavirenz, phenobarbital, carbamazepine, phenytoin, rifampicin
Patients NOT appropriate for buprenorphine in primary care

• Pregnant patients
• Patients with co-morbid benzodiazepine and/or alcohol dependence (risk of overdose)
• Patients with severe, unstable psychiatric conditions
• Patients who have failed multiple previous treatments for opioid dependence
• Patients with acute or severe liver disease
• Refer to specialty (methadone) program
Three stages of Buprenorphine treatment

• Induction (days 1-3)
  – Buprenorphine (partial agonist/antagonist) will precipitate opioid withdrawal if mixed with full opioid agonists
  – Must be in at least moderate opioid withdrawal before starting buprenorphine

• Stabilization (days 4-7)
  – Average dose: 16 mg buprenorphine a day
  – Maximum dose 32 mg buprenorphine a day

• Maintenance
  – Research strongly supports longer treatment periods
  – Monitor for abuse/diversion of buprenorphine and/or abuse of alcohol/sedatives with buprenorphine (OD risk)
Adding specialized drug counseling does not improve outcomes of Buprenorphine plus MM counseling

<table>
<thead>
<tr>
<th></th>
<th>CBT (n=53)</th>
<th>CM (n=49)</th>
<th>CBT+CM (n=49)</th>
<th>NT (n=51)</th>
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<tbody>
<tr>
<td><strong>Induction Phase (Weeks 1-2)</strong></td>
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<tr>
<td>TES</td>
<td>0.54 (0.35)</td>
<td>0.46 (0.39)</td>
<td>0.42 (0.36)</td>
<td>0.52 (0.33)</td>
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<tr>
<td>COWS</td>
<td>5.68 (1.93)</td>
<td>5.76 (2.87)</td>
<td>6.03 (2.10)</td>
<td>5.72 (2.43)</td>
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<tr>
<td>VAS</td>
<td>57.26 (22.90)</td>
<td>51.94 (23.77)</td>
<td>56.67 (18.09)</td>
<td>49.14 (20.41)</td>
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<td><strong>Behavioral Treatment Phase (Weeks 3-18)</strong></td>
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<tr>
<td>TES</td>
<td>0.52 (0.38)</td>
<td>0.56 (0.39)</td>
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<td>0.53 (0.36)</td>
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<tr>
<td>COWS</td>
<td>1.25 (1.06)</td>
<td>1.01 (1.16)</td>
<td>1.16 (1.15)</td>
<td>1.19 (1.17)</td>
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<tr>
<td>VAS</td>
<td>26.59 (25.23)</td>
<td>19.72 (21.88)</td>
<td>19.86 (21.31)</td>
<td>19.25 (18.24)</td>
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<td><strong>Medication-Only Treatment Phase (Weeks 19-34)</strong></td>
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<tr>
<td>TES</td>
<td>0.64 (0.49)</td>
<td>0.66 (0.47)</td>
<td>0.73 (0.44)</td>
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<td><strong>Week 40 Follow-Up</strong></td>
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<tr>
<td>TES</td>
<td>0.62 (0.49)</td>
<td>0.65 (0.48)</td>
<td>0.73 (0.44)</td>
<td>0.62 (0.48)</td>
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<td><strong>Week 52 Follow-Up</strong></td>
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<tr>
<td>TES</td>
<td>0.61 (0.49)</td>
<td>0.64 (0.48)</td>
<td>0.72 (0.44)</td>
<td>0.61 (0.48)</td>
</tr>
</tbody>
</table>

Managing patients on Buprenorphine

• Pain management on buprenorphine
  – Avoid opioids if possible. Buprenorphine does have some analgesic effect
  – Cautious, short term use of opioids with buprenorphine OK (e.g. tooth extraction)
  – May need to stop buprenorphine for patients with severe pain or requiring surgery (get expert advice)

• Do not stop buprenorphine if patient becomes pregnant
  – Opioid withdrawal or relapse may trigger miscarriage
  – Consider switching to buprenorphine only formulation (safety of naltrexone in pregnancy not established)
Buprenorphine Maintenance

• Optimal duration of treatment not known
  – Relapse COMMON after stopping buprenorphine
  – Some patients may be on indefinitely

• Discontinuing buprenorphine
  – SLOWLY taper down to 1-2mg a day
  – “Comfort” meds as needed after buprenorphine stopped (NSAIDs, acetaminophen, muscle relaxant, cautious use of benzodiazepine if needed)
Integrating Addiction Medicine into Primary Care at FQHCs: early experience from the SUMMIT trial

High Utilizers and the ACA: New Models for Working with Drug Users Conference
April 21, 2014

Karen Lamp, MD; Allison J. Ober, MSW, PhD; Keith Heinzerling MD, MPH
(PI: Kate Watkins, MD)
RAND is collaborating with Venice Family Clinic (VFC) to study how to increase the delivery of SUD treatments in primary care.

- VFC is a Federally Qualified Health Center (FQHC)
- 25 permanent medical providers and hundreds of volunteers and residents
- Fully integrated behavioral health care provided by LCSWs
We are Comparing Two “Implementation Strategies” for Delivering OAUD EBPs

INTEGRATED COLLABORATIVE CARE (ICC)*
- Delivery System Redesign
- Patient Self-Management Support
- Clinical Information Systems
- Decision Support

versus

EDUCATION AND RESOURCES (E&R)
- Printed Educational Materials
- Access to Resources
- Provider Education & Training

Medication Assisted Treatment (MAT):
- Suboxone®
- Vivitrol®

and/or

Motivational Interviewing-Based Behavioral Therapy (BT):
- An MI-based Manual-Driven Therapy

Early experience with integration at Venice Family Clinic

• Challenges encountered:
  – Getting provider buy in
  – Getting management buy in
  – Screening not detecting at risk patients
  – Patients have multiple medical, psychiatric, and social co-morbidities
Early anecdotal impressions on keys to successful integration

• Identify Provider Champions
• Identify an accessible expert consultant until you develop in-house expertise
• Provide your staff with simple, clear written protocols
• Get support from your Senior Management team
• Integrate behavioral health and case management into the care team
Conclusions/Future Directions

• ACA offers a historically unique opportunity to re-design how substance use and abuse are treated and conceptualized in the US

• But many questions on how best to take advantage of this opportunity are still unanswered:
  – How to best implement SBIRT and office-based treatment into primary care?
  – Technology to increase “treatment” capacity?
  – More medical treatments for addictions?
  – Is there a “pre-addiction”, can addiction be prevented, what are effective preventive interventions?