Legal, health service, and cultural barriers to medication-assisted treatment for opioid use disorder

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Learning objectives

◦ 1) To summarize the **history of federal laws regulating methadone and buprenorphine** treatment for OUD, as well as the relationship of the development of these laws to stigma towards OUD.

◦ 2) To identify **barriers faced by people in the criminal justice system**, especially in adult drug courts, and potential solutions to address these barriers

◦ 3) To examine the **challenging relationship between 12-step support groups and MAT**, including within specialty SUD treatment centers, and to identify responses individual support groups and treatment centers can take to addressing such stigma
Good news, bad news

- **Life-saving** treatment options are available for opioid use disorder
  - Methadone
  - Buprenorphine
- **MORE** effective than other OUD treatments

- **Underutilized**
  - One of least utilized OUD treatments
  - Last resort

- **Largely inaccessible**
  - Only offered in 30% of residential centers
  - Banned in up to 50% of drug courts
  - 30% of rural counties lack a single buprenorphine provider
  - Some states only have a handful of OTPs (i.e. methadone clinics)

Alderks, 2017; Andrilla, 2018; Huhn et al., 2020; LaRochelle et al., 2018; Matusow et al., 2013; National Academies, 2019; Randall-Kosich et al., 2019; Sharma et al., 2016; Sharma et al., 2017; Wen et al., 2020
Research question

Question: Why is an effective medical treatment not part of mainstream medicine?

Let’s take a historical journey through health services and health policy for OUD treatment.

- OUD treatment law/policy research review
- OUD health services research review
- OUD medicine research review
- Original qualitative & quantitative data collection & analysis
PATH DEPENDENCY
Harrison Act
• 1914
• USSC 1919

Methadone & Nixon
• Pilot studies
• Opioid treatment programs

Buprenorphine
FDA approved
• DATA 2000
• CARA 2016
**Harrison Narcotics Tax Act of 1914**

- Purpose: “An Act to provide for the registration of, with collectors of internal revenue, and to impose a special tax on all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium or coca leaves, their salts, derivatives, or preparations, and for other purposes.” (HNTA 1914)

- Section 2: “Nothing contained in this section shall apply ... to the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act in the course of his professional practice only” (HNTA 1914)

- “If a practicing and registered physician issues an order for morphine to an habitual user thereof, the order not being issued by him in the course of professional treatment in the attempted cure of the habit, but for the purpose of providing the user with morphine sufficient to keep him comfortable by maintaining his customary use, such order is not a physician's prescription under exception (b) of § 2 of the act.” (Webb v. United States, 249 U.S. 96, 99-100 (1919))

- **Bottom line**: Physician cannot prescribe morphine to a “habitual user” for purpose of keeping him/her “comfortable”
“The Treasury Department swiftly closed the clinics and made it personally and professionally risky for physicians to "maintain" a narcotic addict for any reason…This story, as summarized above, became part of the "lore" that affected medical practice and research for almost 50 years and had a profound influence on government officials when the issue of narcotic maintenance again emerged in relation to methadone.”
Between HNTA & Nixon

- Alcoholics Anonymous is formed (eventually leads to NA)
  - Addiction is a disease that requires total abstinence from the substance of misuse
  - Reliance on Higher Power in lieu of drug
  - Don’t just stop drinking. Change the way you live your life.
  - Basic process: follow 12-steps, attend meetings, sponsor/be sponsored

- Minnesota model established:
  - Blending professional inpatient treatment w/ 12-steps and recovery experienced staff
  - Hazelden Foundation
  - Nationally most treatment centers rely on 12-steps

White, 1998; Anderson et al., 1999
Nixon Administration & Methadone

- Narcotic Addiction Rehabilitation Act (1966): federal assistance to develop a local and state system of treatment
- 1950s-60s: Pilot work by Jerome Jaffe, Vincent Dole, Marie Nyswander, Robert DuPont
- INDs for “research” (i.e. treatment)
- Nixon excited by promise of methadone treatment to lower crime rates
- Nixon task force (led by Jaffe) recommends methadone treatment
- Nixon establishes Special Action Office for Drug Abuse Prevention & “drug czar” Jaffe
- FDA proposes closed methadone distribution system for addiction treatment (1972)
- Federal funding 1970-1973:
  - TREATMENT: $33.5 million → $350.3 million
  - ENFORCEMENT: $8.5 million → $45.7 million
- Jaffe resigns; replaced by Dole

IOM 1995; Raz, 2017; White, 1998
OTP requirements

- Registration with feds and state
- Admission
- Urine drug screening
- Counseling
- Daily observed dosing → take-homes
- Dosage maximums

“While conceived of as a treatment modality, the main goal of methadone maintenance programs was crime reduction, and the methods these programs developed were distinctly nonmedical. Individuals treated in methadone clinics were subject to regular and observed urine testing, were disciplined if there was evidence of ongoing substance abuse, and complied with strict regulations designed to prevent methadone diversion, including the requirement of consuming the drug on the premises.” (Raz, 2017, p.79)
Methadone barriers

- Racial overtones → concerns about treatment being used to “control” minority populations
- Lack of OTPs in rural areas
- Zoning and other political barriers
- Transportation
  - Daily visits interfere with employment, holding down a job
- Misconceptions abound: “hand cuffs”, “just another drug”, “gas station”
  - Family members
  - AA and NA
  - Residential treatment centers
  - Media
  - Criminal justice system
- Cost (esp. if not covered by Medicaid)
- OTPs ONLY treat SUD, and SUD is stigmatized

Andraka-Christou & Capone, 2017; Andraka-Christou, 2019; Andrilla et al., 2018; Huhn et al., 2020; Krawczyk et al., 2017; Matusow et al. 2013; Sharma, 2016; Sharma, 2017; Monico et al., 2015; White, 2011; White et al., 2013
What images come to mind when you think of the following terms?

- Opioid treatment program (i.e. methadone clinic)
- Primary care physician’s office
Buprenorphine

- Successfully used in France during 1990s
- FDA reviewing approval for mono product and buprenorphine-naloxone product
- Congress passes DATA 2000
  - Office-based exception to principles of Harrison Act
  - Special education required for most practitioners
  - Apply to SAMHSA, get DEA X waiver
  - 30 patients only for the whole practice!
  - Physicians only
- DEA reschedules buprenorphine from CSA Schedule V $\rightarrow$ III
- Buprenorphine FDA approved
- Congress amends DATA for the first time: 30 patients max per physician
- Congress amends DATA for the second time: 30 patients for 1st year, then can have up to 100 patients
- Congress amends DATA for the third time (CARA 2016):
  - NPs, PAs (but state scope of practice laws)
  - Up to 275 patients if in qualified practice setting (small %)
- Implantable version: prescriber needs to meet DATA requirements; implanter needs to have REMS certification
Buprenorphine barriers

- Approx. 30% of rural counties lack waivered practitioner
- Approx. 70% of residential treatment facilities don’t offer buprenorphine
- Only 1 in 20 CJ participants referred
- Practitioners don’t want “those” kinds of patients
- Cost, insurance restrictions
- Stigma
  - Family members
  - Twelve-step groups
  - Residential treatment centers
  - Criminal justice system

Andraka-Christou & Capone, 2017; Andraka-Christou, 2019; Andrilla et al., 2018; Huhn et al., 2020; Krawczyk et al., 2017; Matusow et al. 2013; Sharma, 2016; Sharma, 2017; Monico et al., 2015; White, 2011; White et al., 2013
A note on COVID-19

- Mostly really bad news. Overdoses expected to increase.
- One silver lining. Some federal legal restrictions temporarily decreased
  - Take homes permitted for stable patients up to 28 days
  - Take homes permitted for unstable patients up to 14 days
  - CMS reimbursing telemedicine
  - Buprenorphine induction via telemedicine permitted
  - UDS requirements decreased

SAMHSA, 2020
Potential solutions to MAT barriers

- Legal
  - Eliminate patient limits
  - Decrease or eliminate DEA-X waiver requirements
  - Permit stabilized methadone patients to move into office-based settings
  - Prohibit prior authorization requirements and quantity limits for MAT
  - SSAs only contract with providers that accept people with MAT, provide or refer for MAT
  - States expand Medicaid, fund CJ MAT

- Peer support groups: vocalize a policy accepting of people utilizing MAT

- Residential treatment centers: permit people utilizing MAT, provide MAT, and/or refer for MAT

- Medical schools/health care organizations:
  - Educate health care practitioners about OUD symptoms
  - Project ECHO, other mentoring programs
  - EDs begin MAT for patients who overdosed
  - Low threshold treatment

- Criminal justice institutions
  - All prisons/jails offer all forms of MAT
  - All drug courts permit all forms of MAT
  - All institutions refer for MAT
  - Decisions made by treatment professionals; treatment compliance monitoring by justice professionals
Additional References


Additional References


THE OPIOID FIX

AMERICA'S ADDICTION CRISIS AND THE SOLUTION THEY DON'T WANT YOU TO HAVE

BARBARA ANDRAKA-CHRISTOU