

Alcohol and Prescription opiate abuse: Responsibilities of Stakeholders to reduce the problem

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Presentation objectives (1)

- To consider the responsibilities that government, industry and academia have for reducing Alcohol and Prescription opioid abuse
- What are Researchers contributing to epidemiology, prevention and innovative treatments?

Presentation objectives (2)

- What are Educators contributing in community, primary school and higher education centers to improve prevention, transfer the technology of innovative treatments and inform future leaders of American policy about these addiction problems?
- To show government responses in collecting epidemiological data, supporting NIH research, program modeling at VA, and making national policies at FDA, DEA, CSAT, CSAP & ONDCP

Presentation objectives (3)

- How are industry and academia collaborating for medication developments?
- Long acting depot formulations of treatments
- Long acting immunotherapies
- Dual treatments – naltrexone (Alc+Opiate)
- Marketing tamper-resistant or low abuse liability opiate formulations

Epidemiology: Government

- Prevalence of alcohol & opioid abuse: Yearly surveys, Monitoring the Future
- Poisonings in the USA: DAWN & NSDUH
- RADARS: Abuse by treatment seekers and within treatment programs
- Sub-populations: Adolescents, ethnicity

Medical Examiner: Academic

- Increased rate of combined alcohol-opiate deaths
- Prescription Opiates, not heroin
- Has need arisen for public education of adolescents about how to get and use naloxone in order to reverse overdose?

Education:

Academics & Government

- Community: Local and state legislation for prevention and treatment, not incarceration
- Primary school: improve prevention education programs beyond simple drug education to include decision & social skills
- Higher education: training counselors about innovative treatments & science of addiction
- Higher education: inform future leaders of American policy about these addiction problems & science of addiction

Alcohol & Drug Screening: Academic + Government

- Need high rate to screen in medical setting:
 - Alcohol (yes), opiates (no)
- Self report screening sufficient?
 - Alcohol (yes), opiates (no)
- Urine toxicology vs blood test confirmation:
 - Medical patients prefer giving blood sample
 - Stigma of urine toxicology
- Screening in non-medical settings:
 - Schools, jobs, elsewhere?

Pharmacokinetics: Academic

- Interacting pharmacogenetics
 - Mu opiate receptor and beta endorphin levels
- Metabolic interactions in liver
 - Cytochrome P450: 2D6, 2A4
 - Prolonged duration of action, tolerance
- Combined toxicity in liver
 - Hepatitis: alcohol + viral
 - Cirrhosis

Pharmacodynamics: Academic

- Interacting catecholamine and GABA brain pathways
- Opiate pathways and reinforcement
- Genetic variation and risk of addiction
 - Mu opiate receptor polymorphism leading to 3 fold increased sensitivity
- Family history and low beta endorphin (BE)
 - Large BE release by alcohol, direct stimulation of super-sensitive mu receptors by opiates

Pharmacogenetics: Academia + Industry

- A few associations already identified
- Optimally match patient to medication and enhance medication efficacy
- 80% efficacy in genetically selected pats, even if only 25% of all pats, is better than 20% efficacy for all pats.
- Mu opiate receptor polymorphism to use naltrexone for alcoholism

Clinical Management: Academic

- Inpatient resources are scarce, outpatient management is critical
- Withdrawal management can be complex and require more than one medication
- Detoxification is only start of treatment
- Depot naltrexone for both addictions after detox

- Maintenance RX for opiates quite effective: Methadone and Buprenorphine
- Maintenance RX for alcohol can combine disulfiram + methadone or buprenorphine

New Medications:

FDA and Industry Partnership?

- Shared public health concerns
- Monitoring post marketing: gold standard?
- In-vitro characteristics of abuse-resistant formulations of opiates
 - Physical barriers: add pepper, pill coatings
 - Delivery systems: transdermal, depot
 - Chemical barriers: pro-drug, add naloxone

Data & Dollars for good Policies: Government

- Government has collected useful & timely epidemiological data
- Supporting NIH research: more collaboration between NIDA & NIAAA
- VA model programs: alcohol screening and RX good, opiate screening evolving
- Making national policies at FDA, DEA, CSAT, CSAP & ONDCP

VA Model Programs: Government

- Substance Use Disorders QUERI
 - Quality Enhancement Research Initiative
- National VA program to implement best practices in following RX guidelines
- Setting Performance Monitors: Tied to salary bonus of Hospital Director & Providers
- Developing and testing new methods to implement changes in poor RX practices

VA Model Program QUERI: Government + Academics

- New educational approaches to implement change at organizational & provider levels
- Beyond lectures and one-time trainings
- Local champions & adapting technologies
- Follow-up coaching / facilitation for months
- Rapid and regular feedback to programs & providers about success in implementing change & meeting Performance Monitors

VA Model Program Outcomes: Government QUERI

- Alcohol screening: over 95% in Primcare
- RX: Alcohol brief interventions & naltrexone
- Opiate screening: pharmacy enables easy tracking of prescriptions for detecting abuse
- RX: Limited Methadone: 32 pgm / 160 sites
- RX: Suboxone on formularies nationally
- RX: Depot naltrexone available for dual addiction, not opiate alone (off label)

National Policies: Government

- FDA: Clarify approval standards for opiate formulations with reduced abuse liability
- DEA: Clarify standards for schedule 3 placement of opiate formulations with reduced abuse liability
- CSAT: Monitoring community abuse, suboxone, new dual opiate-alcohol RX
- CSAP: Consider outcomes of school prevention
- ONDCP: Settings to screen for opiates & alcohol, success of national SBIRT program in ED & school based clinics

Conclusions:

Government-Academia-Industry

- FDA & DEA are critical path agencies for policies to make abuse-resistant opiates available for public health concerns
- VA has good model systems in screening and RX with QUERI implementation program
- Academia can link with Industry to innovative pharmacotherapies of dual addiction
- Industry is producing abuse-resistant opiates
- Govt leads monitoring for public health risks of new abuse-resistant opiate medications