The Changing Landscape of Prescription Opioid Abuse in the United States

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Disclosure

• Most manufacturers of prescription opioids or stimulants subscribe to RADARS System.

• RADARS System is the property of Denver Health and Hospital Authority, a political subdivision of the State of Colorado.

• Subscribers to RADARS System receive information, but do not participate in developing the System, data collection, or analysis. They do not have access to the raw data.

• Employees are prohibited from personal financial relationships with any company.

• Off-label use will be discussed in this presentation.
Self-Assessment Question 1

Which statement regarding abuse deterrent opioids analgesics is true?

A. There is only one product on the US market recognized by FDA as having abuse deterrent features.

B. The introduction of an abuse deterrent formulation of oxycodone extended release was promptly followed by decreased oral, nasal and intravenous abuse of that drug.

C. Abuse deterrent formulations can’t work because they are intended only for established intranasal or intravenous abuser.

D. Abuse deterrent formulations are feasible only for extended release formulations of opioid analgesics.
What is the relationship between abuse of prescription opioid analgesics and use of heroin in the United States?

A. Abuse of both heroin and prescription opioid analgesics are increasing
B. Abuse of heroin is increasing while abuse of prescription opioid analgesics is decreasing.
C. Abuse of prescription opioid analgesics is increasing while abuse of heroin is decreasing.
D. Abuse of both heroin and prescription opioid analgesics are decreasing.
Learning Objectives

1. The learner will understand the prescription opioid analgesic formulations that are most likely to be abused.
2. The learner will understand trends in the abuse of prescription opioids and heroin in the United States.
Outline

• Background
• Pain and the Downward Spiral
• The Role of Formulations: immediate release, extended release, abuse deterrent (ADFs)
• Potential Implications for the Pain Specialist
Case

• 32 y.o. high performing health care professional receives “Vicodin” for a minor procedure.

• 6 months later, he is arrested for buying hydrocodone-acetaminophen on the street, forging prescriptions, etc.

• What happened?
US Epidemic of Prescription Opioid Deaths

http://www.cdc.gov/drugoverdose/data/index.html
Progression of Opioid Misuse in Pain Patients

- **Person in Pain**
- **Pain Relief from Opioid**
- **Susceptible Person**
  - **Chew**
  - **Crush**
  - **Snort**
  - **Inject**

**Filling the Balloon**

RADARS SYSTEM
How Did We Fill the Balloon?

Person in Chronic Pain

Pain Relief from Opioid

Susceptible Person

Chew

Crush

Swallow

Pain Patients

Substance Abuser

Snort

Inject

Pain Relief from Opioid Person in Chronic Pain Susceptible Person Pain Patients Substance Abuser

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Is Something Working?

http://www.cdc.gov/drugoverdose/data/index.html

> 16,000 Deaths Annually
How Can We Empty the Balloon?

- Pain Relief from Opioid
- Person in Chronic Pain
- Susceptible Person

Rx Opioid Abuse in the US

- Chew
- Crush Swallow
- Snort
- Inject

- Treatment
- Heroin
- Death

Pain Relief from Opioid

- Person in Chronic Pain
RADARS System - Mosaic Surveillance of Prescription Drug Abuse - 2015

**Acute Health Events**
- 49 Poison centers
- 46 states
- 512,609 cases
- 552,732 opioid mentions

**Drug Transactions**
- Criminal Justice
- 260 agencies; 49 states
- 188,635 cases with 194,999 opioid mentions

**Illicit Market Price**
- StreetRx.com
- Users/Buyers, 50 states
- 25,250 price entries for an opioid

**Entering Treatment**
- Opioid Tx Program
- 72 programs; 42 states
- 43,861 cases with 201,099 opioid mentions

**Entering Treatment**
- SKIP
- 135 practices, 47 states
- 12,328 cases with 80,617 opioid mentions

**New Initiates**
- College Survey
- 2000 students, 50 states
- 6,201 cases with 15,636 opioid mentions

**Web Monitoring**
- > 150 million sites monitored
Something is Working
Trends in Abuse of Prescription Opioids in the US

Figure 1. Drug Diversion, Poison Center Program, RADARS System, 2002–2013.

The red boxes in Panels B through E indicate the vertex of the quadratic curve.

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Figure 2: Heroin Use and OxyContin Abuse Before and After OxyContin Reformulation

A. National Poison Data System
B. Opioid Treatment Program
C. Survey of Key Informant Patients
D. College Survey

Reform.
Figure 2. Panel E - Rate of Reported Heroin Use in the National Survey on Drug Use and Health (SAMHSA)
Other Evidence for a Change

• Prescription opioid abuse is decreasing or has flattened in several systems.
  – RADARS System®, Navippro®
  – National Survey of Drug Use and Health (NSDUH)
  – National Vital Statistics (mortality)
  – Several regional analyses (e.g. Kentucky, Florida)

• Large reservoir of abusers
  – Switching to alternatives – heroin abuse increasing
  – Entering treatment
The Role of Formulations

• Preponderance of deaths caused by extended release preparations.
• When the rooster crows, the sun rises...
Apple is the Cause of Deaths from Prescription Drug Abuse?
Extended Release vs. Immediate Release Formulations of Opioid Analgesics

IMS, 2015
Poison Center Program - Abuse Exposures Oxycodone ER, 2009-2013
Drug Diversion Program
Oxycodone ER, 2009-2013

Per 100,000 people:
- IR
- ER

Per 10,000 Rx:
- ER
- IR
Role of Abuse Deterrent Formulations?

• Plausible ADF Formulations
  – OxyContin®, Opana ER® (Intac®), Nucynta ER (Intac®)
  – Exalgo®, Oxecta®, Embeda®
  – Suboxone®, buprenorphine/naloxone combos

• Do they affect rates of abuse in a meaningful manner over large portion of United States?

• Do they affect outcomes?
  – Injection? Mortality?

• Supportive studies
  – Street Price?
  – Behaviors?
  – Adverse Events?
Model for Oxycodone Extended Release
RADARS System Poison Centers

![Graph showing intentional exposures per 100,000 population from 2005 to 2011. The graph indicates a decrease in intentional exposures starting in 2010, labeled as 'New Formulation', 'Effective', and 'Ineffective'.]

October 21-22, 2010: Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting Announcement
Poison Center and Drug Diversion Programs
Oxycodone ER, 2009 - 2015
Poison Center Program
Oxycodone ER, Route of Use, 2009 - 2015
What is the Role of Pain Practitioner?

Good Clinical Practice

Person in Chronic Pain

Pain Relief from Opioid

Susceptible Person

ADFs Reduce Progression of Substance Misuse

Chew
Crush
Snort
Inject

Substance Abuser
Battle of the ADFs

Bob and Paul are hiking when they encounter a bear. Bob starts putting on his tennis shoes. Paul says, "What? You can't outrun a bear!" Bob says, "I don't have to outrun the bear—I just have to outrun you!"
Responding to an Epidemic

Rx Nonmedical Use in Florida

James N. Hall
Center for Applied Research on Substance Use and Health Disparities
Nova Southeastern University
Florida Legislative Actions

• 2009: FL Senate Bills 462 and 440 – PDMP
• July 2010 – Senate Bill 2272 to **shut down illicit pain management clinics**...
• August 2010 – New **tamper-resistant** reformulated OxyContin OP shipped.
• February 2011 – Operation Pill Mill: **South Florida**
• March 2011 – Florida Law Enforcement **Drug Strike Force created**
2011

July 1, 2011 - House Bill 7095 goes into effect. It

– Bans direct dispensing by medical practitioners,
– New permitting & inspection regulations for pharmacies,
– Shortening from 15 days to 7 days the PDMP dispensing reporting requirement,
– Codified new patient standard of care measures for physicians with enhanced penalties,
– $3 million for law enforcement Strike Force to close pill mills
Number of Selected Lethal Rx Opioid Occurrences Among Deceased Persons in Florida Jan 2008 to Jun 2012

Source: FDLE – Drugs Identified In Deceased Persons by Florida Medical Examiners Jan 2008 - Dec 2012 Reports
Number of Heroin-related Deaths in Florida: 2000 – 2012

SOURCE: Florida Medical Examiners Commission Reports 2000-2012
Implications

• Prescription opioid drug abuse “improving.”
• Focus on the true pain patient’s transition to abuse and addiction
• Clinical care seems most important in prevention.
• ADF’s have meaningful role, but not panacea. Not just for the high-risk patient?
• More focus on IR opioid formulations is needed.
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Question and Answer

Thank you!

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