Coalition for Care
IHA's Hospital Engagement Network

Indiana Hospital Association
INDIANA PATIENT SAFETY CENTER

Considerations for Safe Opioid Prescribing and Use

October 23, 2014

Indiana Hospital Association

Indiana Hospital Association

Webinar Agenda

- Welcome & Introductions

  Carolyn Konfirst, Patient Safety/Quality Advisor, Indiana Hospital Association

- Considerations for Safe Opioid Prescribing and Use

  John Hertig, Pharm.D., Associate Director, Purdue University College of Pharmacy, Center for Medication Safety Advancement (CMSA)

  Trang Truong, Pharm.D., Resident, Purdue University College of Pharmacy, Center for Medication Safety Advancement (CMSA)

- Wrap-up/Questions

PURDUE PHARMACY

CENTER FOR MEDICATION SAFETY ADVANCEMENT

Considerations for Safe Opioid Prescribing and Use

Trang Truong, Pharm.D.
Center for Medication Safety Advancement
Purdue University, College of Pharmacy

Objectives

- Identify safety risks associated with the use of opioid medications and implement evidence-based best practices.
- Recognize high risk behaviors associated with opioid use and discuss strategies to mitigate these risks.
- Assess the potential impact of the new Indiana opioid prescribing law.

ADVERSE DRUG EVENT (ADE) CHANGE PACKAGE

Preventing Adverse Drug Events

2014 UPDATE

Opioids

Indicator Name: **ADE's due to Opioids** (ADE-11) **= EOM ADE - 111**

Numerator: Number of patients treated with opioids who received naloxone during the review period.

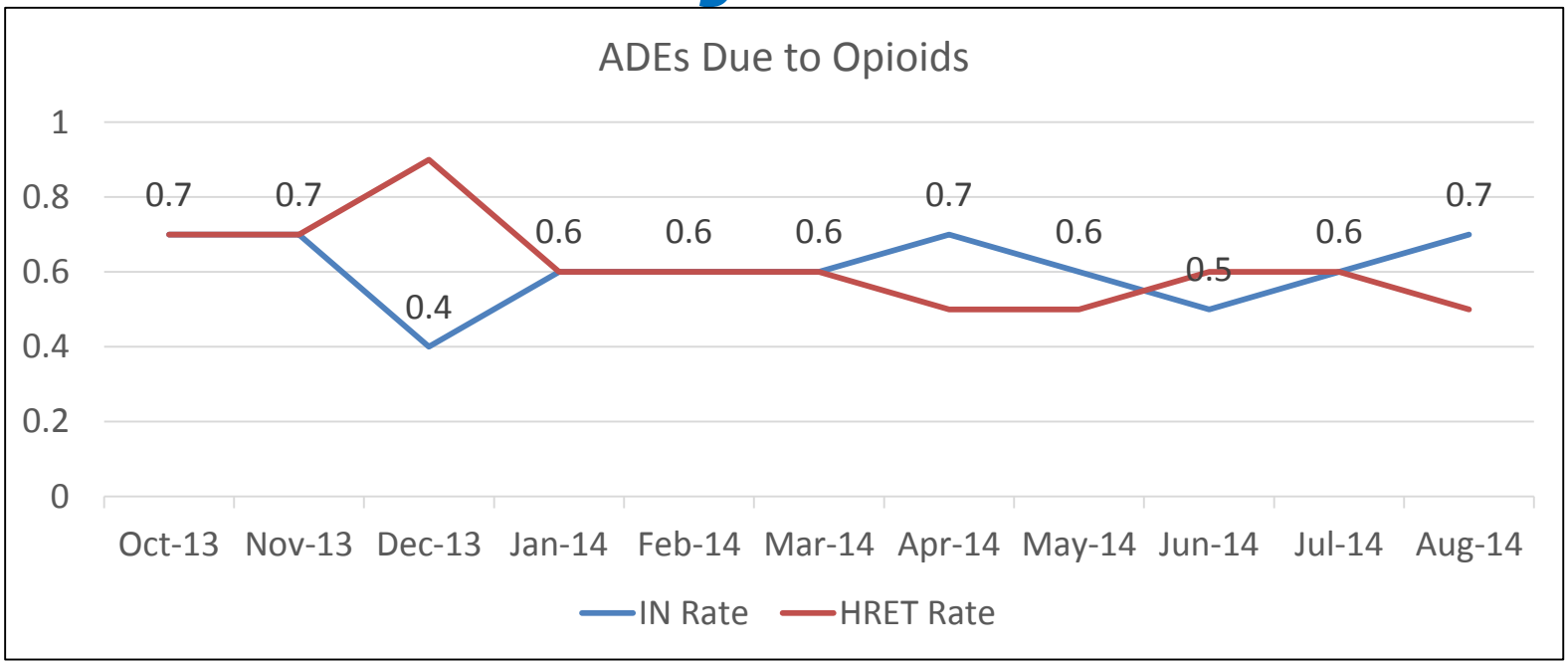
Denominator: Number of inpatients and patients in hospital outpatient departments who received an opioid agent during the review period. Exclusion: ED patients; naloxone use for nausea or pruritus.

PURDUE PHARMACY | CENTER FOR MEDICATION SAFETY ADVANCEMENT

fHRET-HEN. Adverse Drug Event (ADE) Change Package - Preventing Adverse Drug Events 2014 Update. 2014.

Opioids: How are we doing?

Overview of Indiana Data



Number of Hospitals	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14
IN	37	39	41	71	72	74	70	69	68	57	42
HRET	310	327	358	634	640	676	567	563	539	468	355

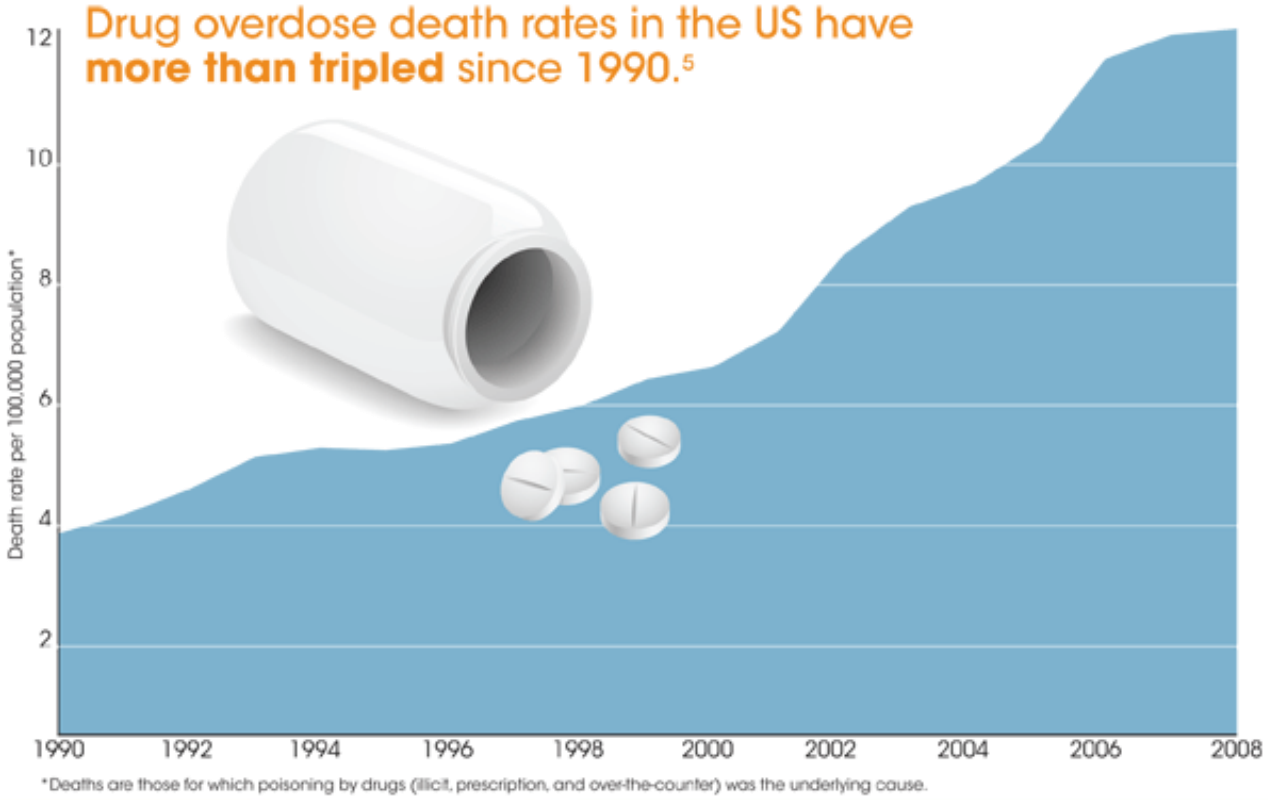
The analyses upon which this publication is based were performed under Contract Number No. HHSM-500-2012-00017C, entitled, "Hospital Engagement Contractor for Partnership for Patients Initiative." This publication's contents are solely the responsibility of the authors and do not necessarily represent the official views of The Centers for Medicare & Medicaid Services.

Tips for Accurate Measurement

- Small numbers and volumes can be hand collected
- Daily concurrent review of patients on opioids by pharmacy
- Weekly or monthly retrospective review of labs for patients on opioids
- Attach reporting sheet or sticker to naloxone for easy reporting of utilization
- Multiple doses of naloxone to the same patient during a hospital stay count as one event

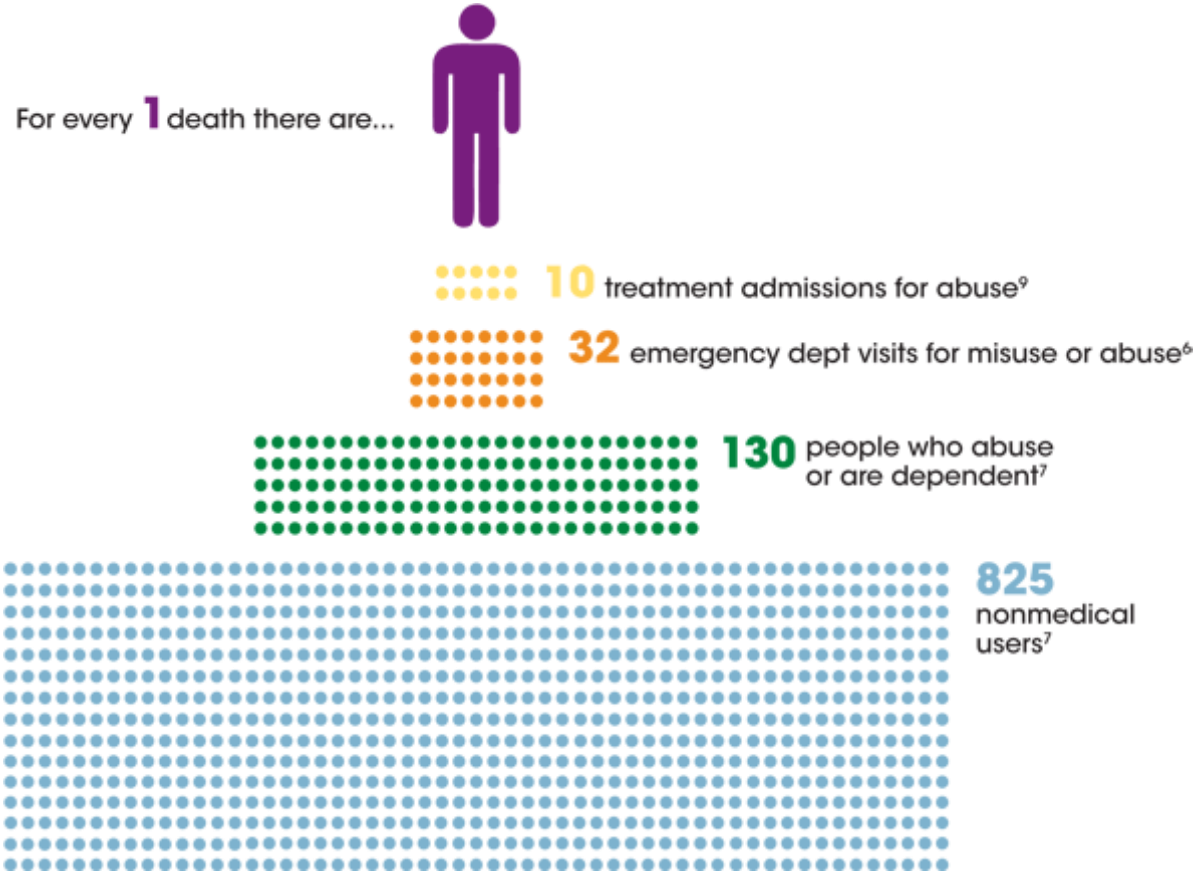
Background

- CDC declared prescription drug abuse to be a “national” epidemic



Significant problem in the US

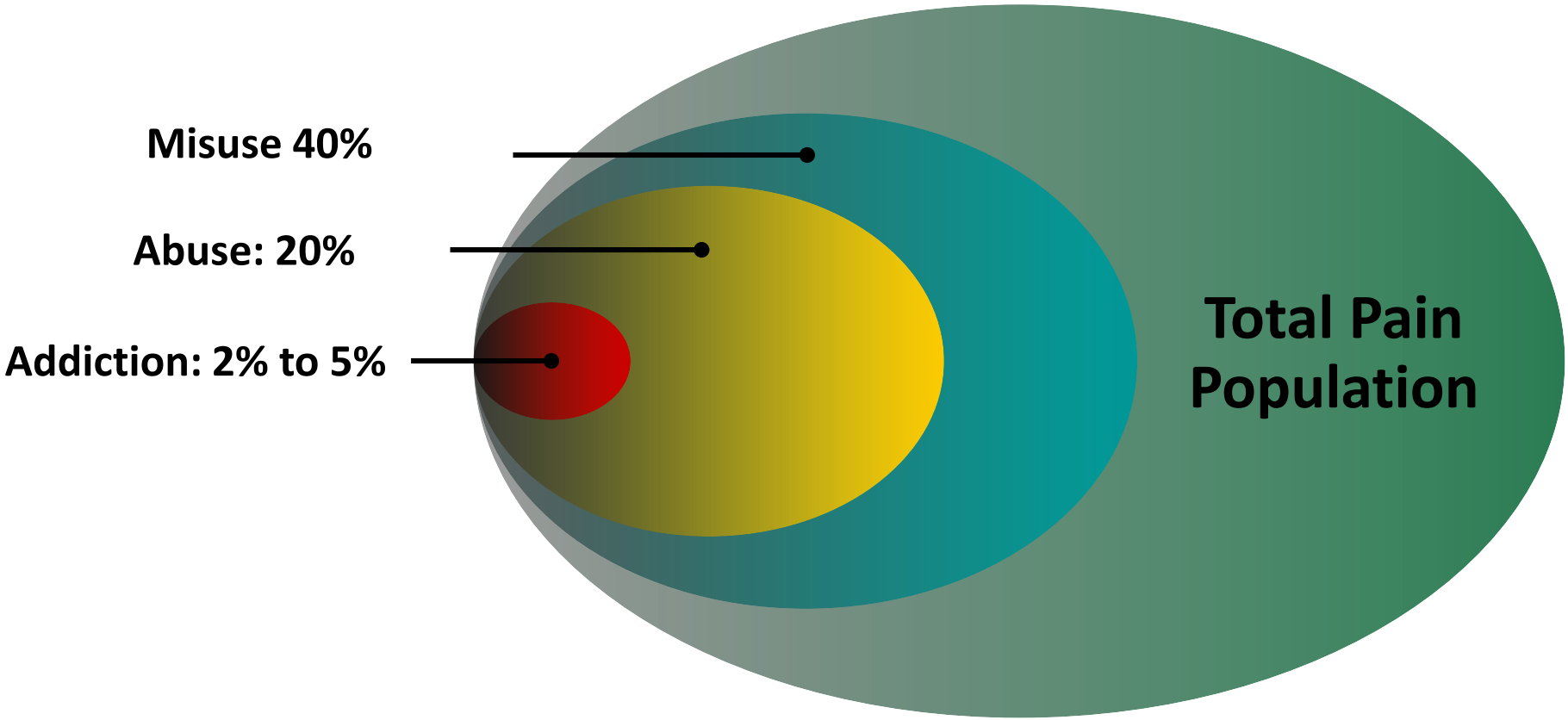
14,800 prescription painkiller deaths in 2008



Examples of Specific Medications

- Most common abused classes of prescription drugs:
  - Opioids: hydrocodone (Vicodin), oxycodone (Oxycontin): relief of pain
  - Anxiolytics: benzodiazepines (Xanax, Valium), barbiturates (butalbital, Fiorecet): reduce anxiety, insomnia
  - Stimulants: amphetamine (Adderall), methylphenidate (Ritalin): attention deficit disorder, narcolepsy

Prevalence of Misuse, Abuse, and Addiction



Webster LR, Webster RM. *Pain Med.* 2005;6(6):432-442.

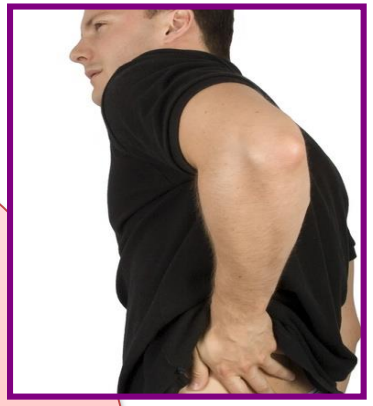
Who misuses/abuses opioids and why?

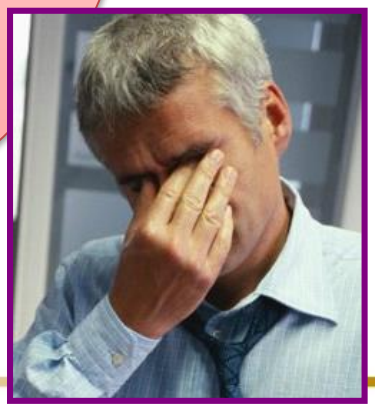
Nonmedical Use

- Recreational abusers
- Patients with disease of addiction

Medical Use

- Pain patients seeking more pain relief
- Pain patients escaping emotional pain





Risk Factors for Aberrant Behaviors/Harm

Biological	Psychiatric	Social
• Age ≤ 45 years • Female gender • Family history of prescription drug or alcohol abuse • Cigarette smoking	• Substance use disorder • Preadolescent sexual abuse (in women) • Major psychiatric disorder (e.g., personality disorder, anxiety or depressive disorder, bipolar disorder)	• Prior legal problems • History of motor vehicle accidents • Poor family support • Involvement in a problematic subculture

Back SE, et all. *Am J Drug Alcohol Abuse*. 2011; 37(5): 313–323.
Katz NP, et al. *Clin J Pain*. 2007;23:103-118; Manchikanti L, et al. *J Opioid Manag*. 2007;3:89-100. Webster LR, Webster RM. *Pain Med*. 2005;6:432-442.

Who is most at risk for opioid prescription overdose?

- **Doctor shoppers** – people who obtain multiple controlled substance prescriptions from multiple providers.

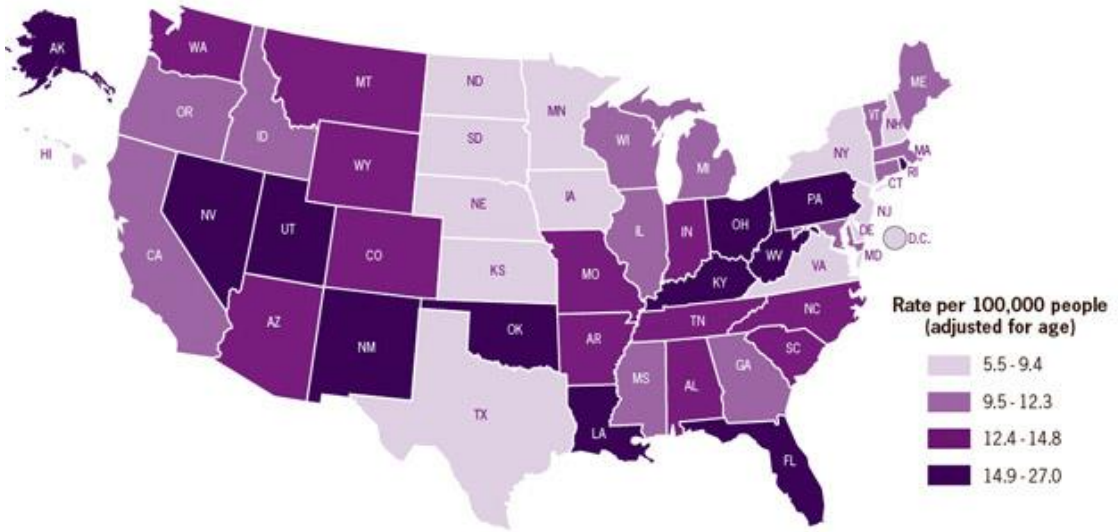
- People who take high daily dosages of prescription painkillers.

- Those who misuse multiple abuse-prone prescription drugs.

CDC. Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses. Available at http://www.cdc.gov/injury/about/focus-rx.html Last viewed on October 1, 2014.

Where overdose deaths are the highest

- Drug overdose epidemic is most severe in the Southwest and Appalachian region.



- Rates vary substantially between states.

National Vital Statistics System, 2008

What can be done to mitigate prescription drug diversion and misuse through screening and prevention?

Four focus areas:

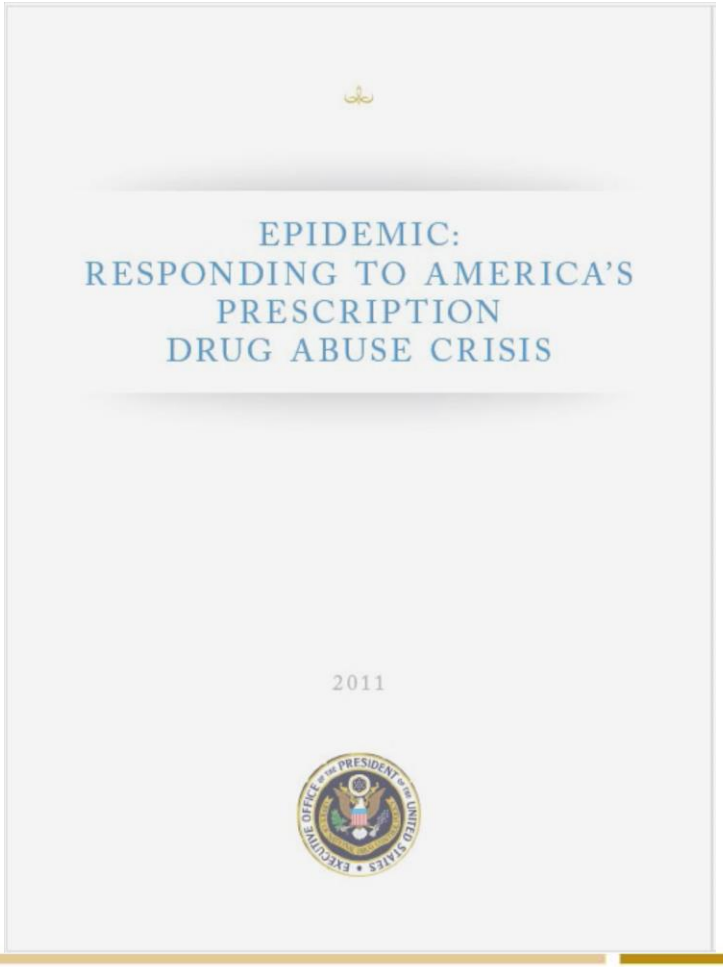
1. Improve systems to track prescriptions and identify misuse
2. Identify prevention policies and programs that work
3. Increase health care provider accountability
4. Educate health care providers, policy makers, and the public

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC. Saving Lives and Protecting People: Preventing Prescription Painkiller Overdoses. Available at http://www.cdc.gov/injury/about/focus-rx.html Last viewed on October 1, 2014.

Four focus areas:

1. Education
2. Prescription Drug Monitoring Programs
3. Proper medication disposal
4. Enforcement



R. Gil Kerlikowske. Prescription Drug Abuse: the National Perspective, September 2013. Available at: http://www.astho.org/Annual-Meeting-2013/Presentations/R-Gil-Kerlikowske-Prescription-Drug-Presidents-Challenge-Session Last viewed on October 1, 2014.

Best Practices for Screening

Screening Tools

SAMHSA
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

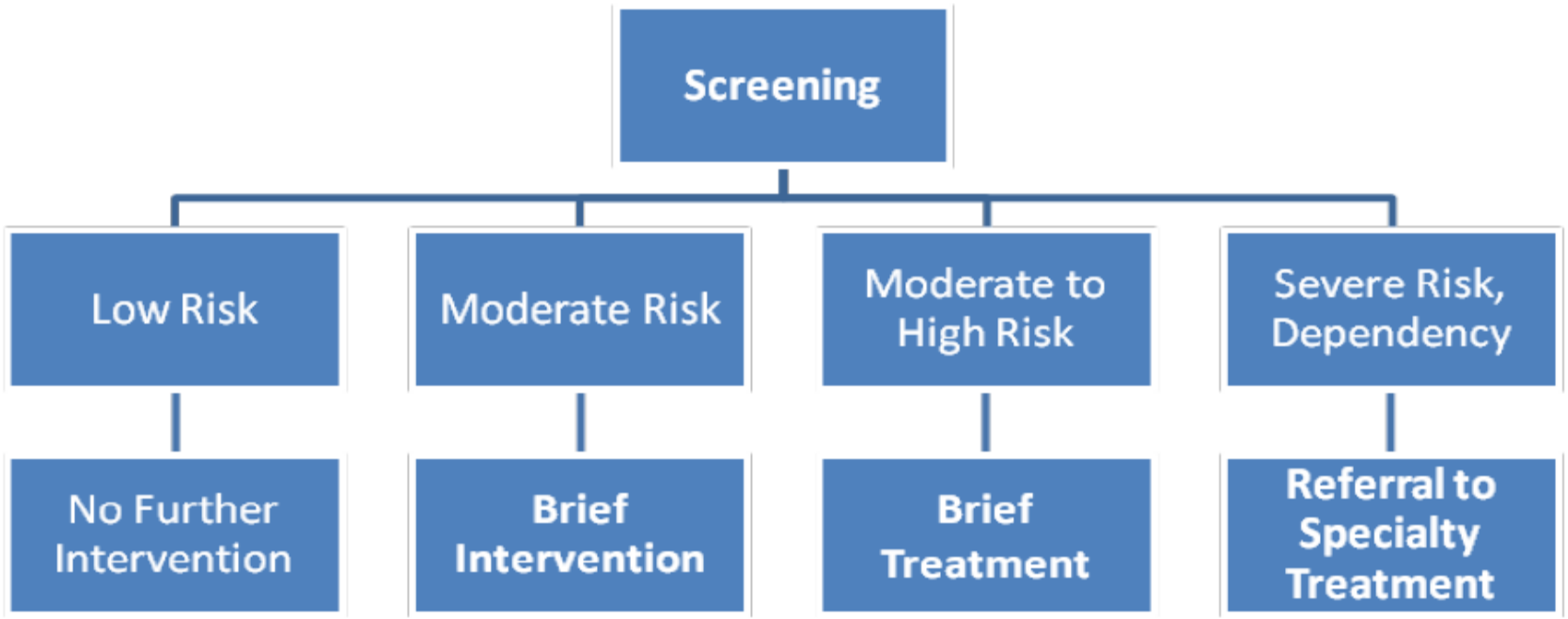
Screening, Brief Intervention and Referral to Treatment (SBIRT) Requirements

1. Brief, initial screening is accomplished within 5-10 minutes;
2. Screening is universal, part of the intake process;
3. Addresses a specific behavioral characteristic deemed to be problematic, or pre-conditional to substance dependence or other diagnoses;
4. The services occur in a public health, or other non-substance abuse treatment setting;
5. The program includes a seamless transition between brief universal screening, intervention or treatment and referral to specialty substance abuse care; and
6. Strong research or substantial experiential evidence supports the model.

Abuse and Mental Health Services Administration (SAMHSA). White Paper on Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Healthcare. Available at: http://www.samhsa.gov/prevention/SBIRT/SBIRTwhitepaper.pdf

SBIRT Process

Chart 1. FLOW CHART FOR SBIRT PROCESS



Abuse and Mental Health Services Administration (SAMHSA). White Paper on Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Healthcare. Available at: http://www.samhsa.gov/prevention/SBIRT/SBIRTwhitepaper.pdf

SBIRT Effectiveness

Table 1. EFFECTIVENESS OF SBIRT AND ITS COMPONENTS FOR BEHAVIORAL HEALTH CONDITIONS

	Screening	Brief Intervention[1]	Brief Treatment[2]	Referral to Treatment	Evidence for Effectiveness of SBIRT
Alcohol Misuse/Abuse	✓	✓	✓	✓	Comprehensive SBIRT effective (Category B classification, USPSTF)
Illicit Drug Misuse/Abuse	✓	*	*	✓	Growing but inconsistent evidence
Tobacco Use	✓	✓	✓	✓	Effective brief approach consistent with SBIRT (USPSTF; 2008 U.S. Public Health Service (PHS) Clinical Practice Guideline
Depression	✓	—	✓	✓	No evidence to date for depression
Trauma/Anxiety Disorders	✓	*	—	✓	No evidence to date for trauma/anxiety disorders

Key:

✓ Evidence for effectiveness/utility of component

* Component Demonstrated to show Promising Results

— Not Demonstrated and/or Not Utilized

Abuse and Mental Health Services Administration (SAMHSA). White Paper on Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Healthcare. Available at: http://www.samhsa.gov/prevention/SBIRT/SBIRTwhitepaper.pdf

Screening Tools

ORT-9 (Opioid Risk Tool)

- Family history of substance abuse
- Personal history of substance abuse
- Age (mark box if 16-45 years)
- History of preadolescent sexual abuse
- Psychological disease

CAGE-AID Questionnaire

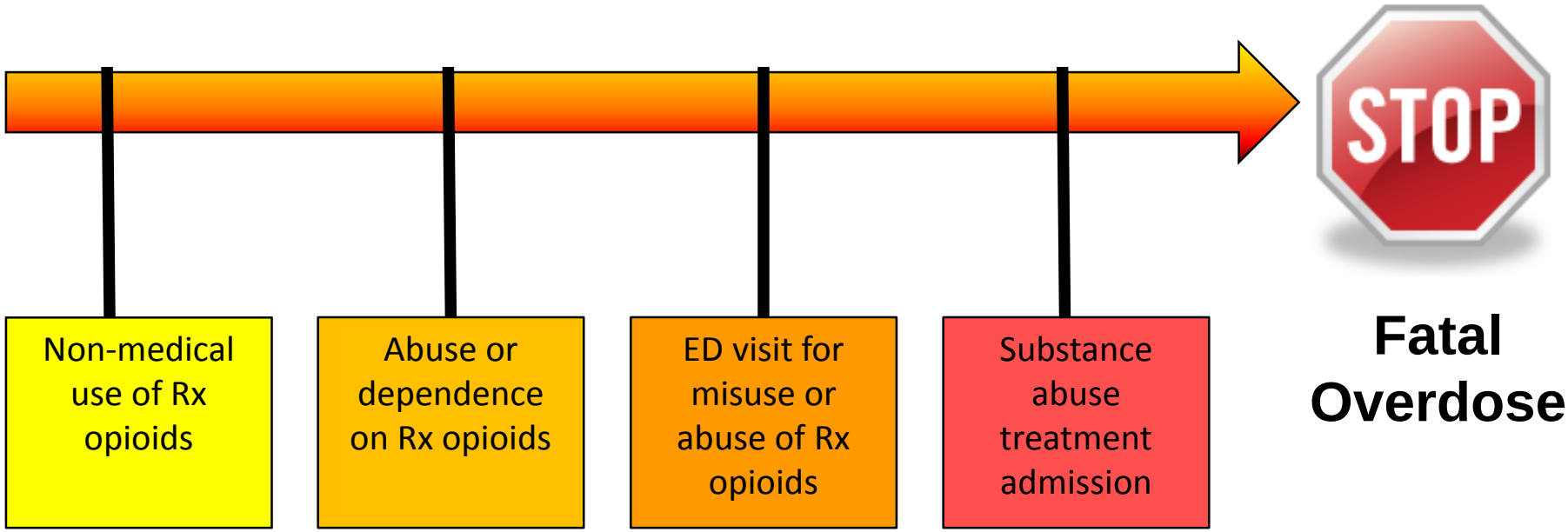
- Have you ever felt that you ought to cut down on your drinking or drug use?
- Have people annoyed you by criticizing your drinking or drug use?
- Have you ever felt bad or guilty about your drinking or drug use?
- Have you ever had a drink or used drugs first thing in the morning to steady your nerves or get rid of a hangover?

Risky use: 1 or less

Substance use disorder: 2 or more

Richard L. Brown, et.al. *Journal of the American Board of Family Medicine*. 2000;95-106.

Best Practices for Prevention



Pain Management – 10 Principles of Universal Precautions

1. Diagnosis with appropriate differential
2. Psychological assessment including risk of addictive disorders
3. Informed consent (verbal or written/signed)
4. Treatment agreement (verbal or written/signed)
5. Pre-/post-intervention assessment of pain level and function
6. Appropriate trial of opioid therapy adjunctive medication
7. Reassessment of pain score and level of function
8. Regularly assess the "Four A's" of pain medicine: *Analgesia, Activity, Adverse Reactions, and Aberrant Behavior*
9. Periodically review pain and comorbidity diagnoses, including addictive disorders
10. Documentation

Gourlay DL, Heit HA. *Pain Med*. 2009;10 Suppl 2:S115-123.
Gourlay DL, et al. *Pain Med*. 2005;6(2):107-112.

Considerations

- What is conventional practice for this type of pain or pain patient?
- Is there an alternative therapy that is likely to have an equivalent or better therapeutic index for pain control, functional restoration, and improvement in quality of life?
- Does the patient have medical problems that may increase the risk of opioid-related adverse effects?
- Is the patient likely to manage the opioid therapy responsibly?
- Who can I treat without help?
- Who would I be able to treat with the assistance of a specialist?
- Who should I not treat, but rather refer, if opioid therapy is a consideration?

Clinic Visits

- Initial comprehensive evaluation
- Risk assessment
- Prescription monitoring assessment
- Urine drug test
- Opioid treatment agreement
- Opioid consent form
- Patient education

Differential Diagnosis of Aberrant Drug-Taking Attitudes and Behavior

- Addiction (out-of-control, compulsive drug use)
- Pseudoaddiction (inadequate analgesia)
- Other psychiatric diagnosis
  - Organic mental syndrome (confused, stereotyped drug-taking)
  - Personality disorder (impulsive, entitled, chemical-coping behavior)
  - Chemical coping (drug overly central)
  - Depression/anxiety/situational stressors (self-medication)
- Criminal intent (diversion)

Passik SD, Kirsh KL. *Curr Pain Headache Rep*. 2004;8:289-294.

Treatment Agreement

- A treatment plan and informed consent serve as documentation of risk/benefit

- Treatment Agreement (use for those at high risk for abuse/addiction)
  - One physician/one pharmacy
  - Urine drug screen when requested
  - Agreement to return for pill count when asked to do so
  - Medication Levels
  - Number/frequency of all refills
  - Reason for discontinuation (violation of agreement, misuse of medication, abuse of other substances)

Informed Consent

- Address specific risks of the treatment
  - Side effects (short and long term)
  - Physical dependence, tolerance
  - Risk of drug interactions or combinations (respiratory depression)
  - Risk of unintentional or intentional misuse (abuse, addiction, death)
  - Legal responsibilities (disposing, sharing, selling)

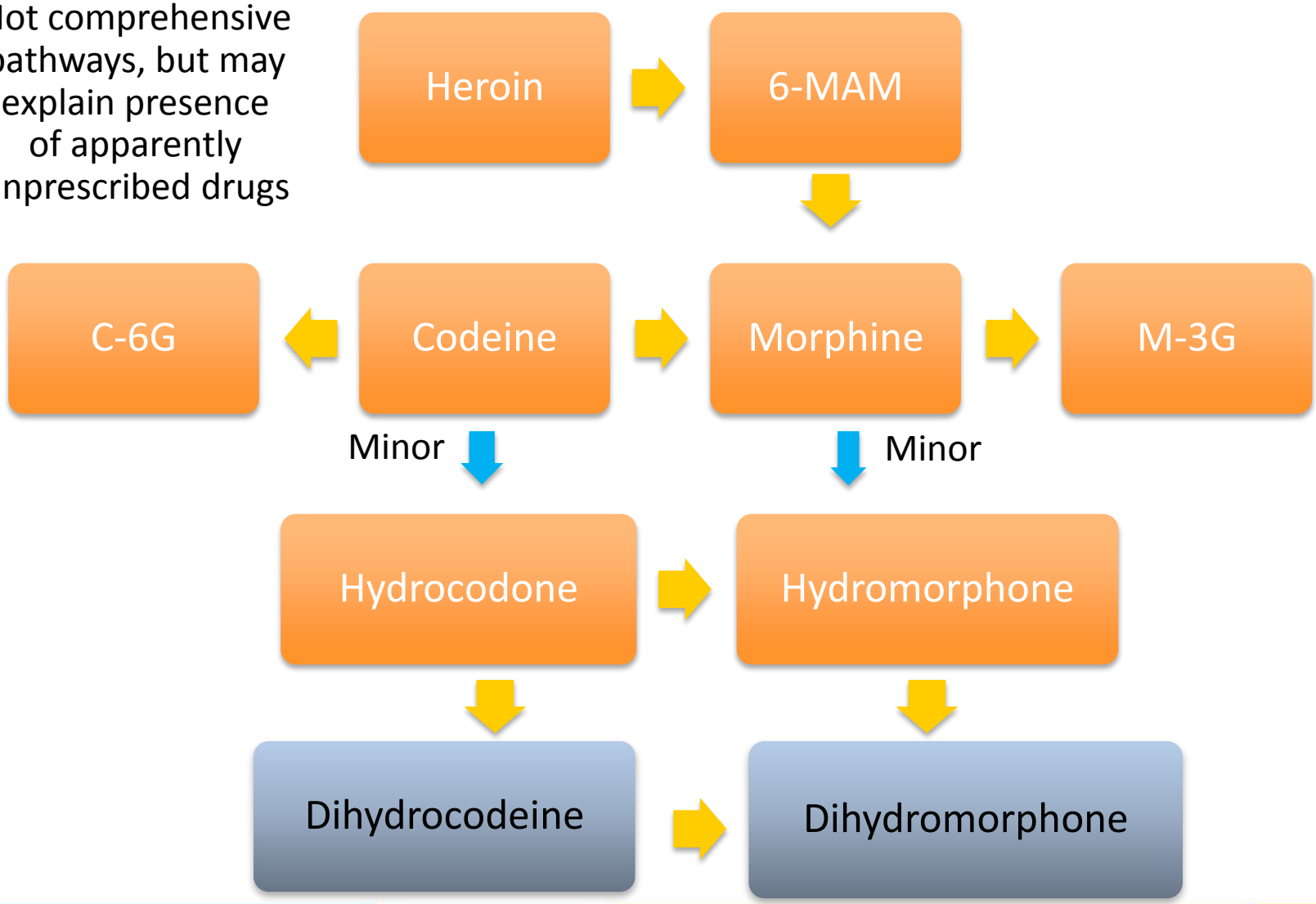
Paterick et al. Mayo Clinic Proc, 2008.

Urine Drug Testing

- When to test?
  - Randomly, annually, PRN
- What type of testing?
  - POC, GS/MS
- How to interpret
  - Metabolism of opioids
  - False positive and negative results
- What to do about the results
  - Consult, refer, change therapy, discharge

Opioid Metabolism

Not comprehensive pathways, but may explain presence of apparently unprescribed drugs



Gourlay D, et al. http://www.familydocs.org/assets/171_UDT%202006.pdf. Accessed March 2010; Cone EJ, et al. *J Anal Toxicol*. 2006;30:1-5; Heit HA, Gourlay D. Personal Communication. 2008.

Detection Times of Common Drugs of Misuse

Drug	Approximate Retention Time
Amphetamines	48 hours
Barbiturates	Short-acting (eg, secobarbital), 24 hours Long-acting (eg, phenobarbital), 2–3 weeks
Benzodiazepines	3 days if therapeutic dose is ingested Up to 4–6 weeks after extended dosage (≥ 1 year)
Cocaine	2–4 days, metabolized
Ethanol	2–4 hours
Methadone	Approximately 30 days
Opiates	**2 days**
Phencyclidine	Approximately 8 days Up to 30 days in chronic users (mean value = 14 days)
Propoxyphene	6–48 hours

Gourlay DL, Heit HA. *Pain Med*. 2009;10 Suppl 2:S115-123.

Identifying Who Is at Risk for Opioid Abuse and Diversion

- Predictive tools
- Aberrant behaviors
- Urine drug testing
- Prescription monitoring programs
- Severity and duration of pain
- Pharmacist communication
- Family and friends
- Patients

Signs of Potential Abuse and Diversion

- Doctor shopping
- Request appointment toward end-of-office hours
- Arrive without appointment
- Reluctant to have thorough physical exam, diagnostic tests, or referrals
- Resistance to changes in therapy
- Fail to keep appointments
- Unwilling to provide past medical records or names of HCPs
- Lost/stolen prescriptions, prescription forgery, or early refills

However, emergencies happen:
not every person in a hurry is an abuser/diverter

Drug Enforcement Administration. *Don't be Scammed by a Drug Abuser.* 1999.
Cole BE. *Fam Pract Manage.* 2001;8:37-41.

How to Measure Risk for Overdose

- Daily dose for opioids
  - (High, e.g., > 100 MME/day)

Conversion Table for Opiate-like Drugs Into Morphine Equivalents[13]

Opiate	Dose in Morphine Equivalents, mg
Morphine, subcutaneous or intramuscular	10
Hydromorphone, subcutaneous or intramuscular	1.5
Hydromorphone, oral	7.5
Codeine, subcutaneous or intramuscular	120
Codeine, oral	200
Oxycodone, oral	20

Presentation by Len Palauzzi, MD, MPH. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. Prescription Behavior Surveillance Using PDMP Data. April, 2013.
Vendittoli P, Mekinen P, Drolet P, et al. *J Bone Joint Surg Am*. 2006; 88(2):282–289.

How to Measure Risk for Overdose

- Prescription drug combinations
  - Additive sedating effects
  - Opioids overlapping with benzodiazepines or muscle relaxants or both
- Large distances
  - Patient residence to prescriber office compared with nearest prescriber
  - Patient residence to pharmacy compared with nearest pharmacy
- Multiples
  - Prescriptions from the same class
  - Classes of scheduled drugs
  - Prescribers or pharmacies or both

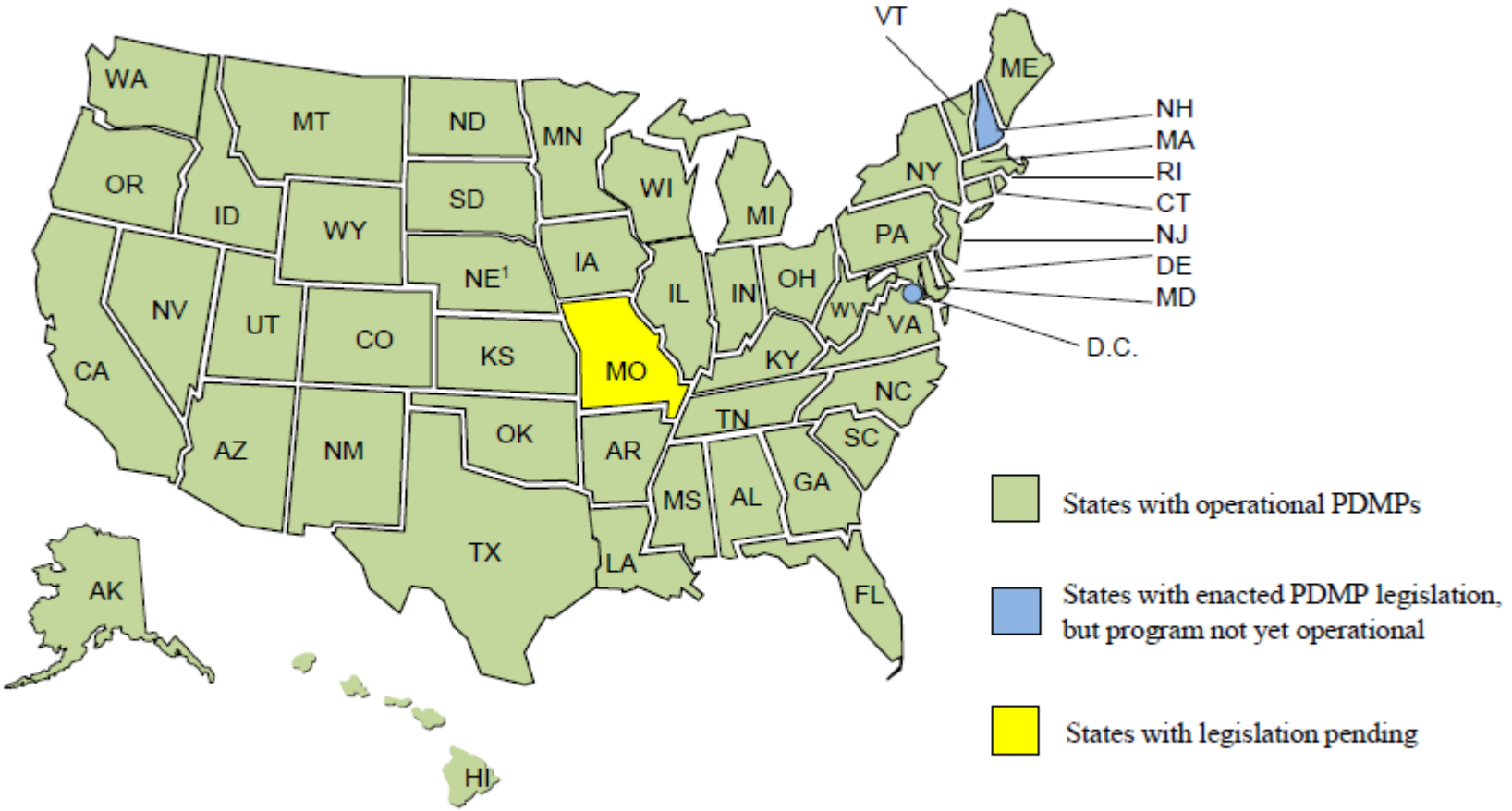
Presentation by Len Palauzzi, MD, MPH. National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. Prescription Behavior Surveillance Using PDMP Data. April, 2013.

CDC Recommendations for Overdose Prevention

- **Prescription Drug Monitoring Programs (PDMP)**
  - Focus resources on patients at highest risk and prescribers who clearly deviate from accepted medical practice.
- Patient review and restriction programs.
- Health care provider accountability.
- Laws to prevent prescription drug abuse and diversion.
- Better access to substance abuse treatment.

Presentation by the National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention of the Centers for Disease Control and Prevention. Policy Impact: Prescription Painkiller Overdoses. April 2013.

Status of State Prescription Drug Monitoring Programs (PDMPs)



In Indiana . . .

- Spread of “pill mill”
  - A physician or clinic, and occasionally a pharmacy, that is prescribing or dispensing controlled substance narcotics inappropriately for non-medical reasons.

In Indiana . . .

- Indiana ranks as one of the highest states in the nation for prescription painkiller abuse
- Between 1999 and 2009, prescription overdose in Indiana increased 502%
- In 2012, 5.7% of Hoosiers reported using prescription painkiller for nonmedical reasons

Indiana Pain Management Prescribing Rules

Senate Act 246 was enacted to prevent “pill mill” spread and increasing number of Hoosiers abusing prescription drugs

- Medical Licensing Board (MLB) adopted rules, effective Dec. 15, 2013
- Prescribing rules apply to:
  - Long term prescribing of opioid containing substances for chronic pain
  - If a patient has been prescribed for more than 3 consecutive months
    - >60 opioid containing pills per month or a morphine equivalent dose of >15 mg/day
- Exclusions:
  - Patients who are terminally ill
  - Residents of an Indiana licensed health facility
  - Patients enrolled in an Indiana licensed hospice program
  - Patients enrolled in a palliative care program that is part of an Indiana licensed hospital or hospice

Medical Licensing Board

- Physicians must personally perform initial patient evaluations
- Use non-opioid medications when appropriate
- Patient must be informed of risks
- Patient visits should be scheduled
- INSPECT report must be run initially and then annually
- Drug monitoring test initially and annually (postponed until Jan 1, 2015)
- Treatment agreement

Indiana's Prescription Monitoring Program (INSPECT)

- An INSPECT report summarizes the controlled substances a patient has been prescribed, the practitioner who prescribed them and the dispensing pharmacy where the patient obtained them.
- Requires pharmacies to:
  - Submit controlled substance data within 7 days of dispensing that controlled substance
  - Submit controlled substance data every 7 days if dispensing at least 1 controlled substance prescription per week
- INSPECT will be moving closer to real-time reporting over the next year and a half as the program goes to 3 day reporting on 7/1/15, then 24-hour reporting effective 1/1/16.

What are the results in Indiana?

No official reports to date

- Report from the Health Finance Commission is not available
- Report from the Division of Mental Health and Addiction is not available

Lawsuit against Medical Licensing Board

- *Wierciak, et al. v. Individual Members of the Medical Licensing Board of Indiana*

- Filed January 8, 2014 by the American Civil Liberties Union (ACLU)
  - Patients prescribed opioids for chronic pain management should not be forced to consent or be subject to annual drug testing as a condition of treatment
  - Claimed that the required annual drug testing constitutes an unreasonable search and therefore violates the Fourth Amendment

- The lawsuit seeks a court order prohibiting the MLB from requiring patients to consent to and undergo drug testing when not medically indicated

Overall Clinical Pearls

- Chronic pain affects millions of patients each year with a significant impact on quality of life and overall health.
- Pain management using opioids can be challenging for both clinicians and patients.
- Health care providers often face challenges in assessing pain management needs while balancing potential risks of misuse and abuse of opioids.
- Safe and effective pain management strategies are critical to both improving patient outcomes and minimizing risks associated with opioid prescription.


THANK YOU

Evaluation & Follow-up

- Webinar funded by CMS through the *Partnership for Patients*
- CMS reviews results and wants 80% of participants to evaluate educational sessions
- Please complete the simple three question evaluation by Oct. 30, 2014:
  - https://www.surveymonkey.com/s/2014_10_23_ADEOpioidWebinar

IHA Contacts

Karin Kennedy
Patient Safety/Quality Advisor
kkennedy@ihaconnect.org
317-423-7737

Carolyn Konfirst
Patient Safety/Quality Advisor
ckonfirst@ihaconnect.org
317-423-7799

Kathy Wallace
Interim Director,
Indiana Patient Safety Center &
Director of Performance Improvement
kwallace@ihaconnect.org
317-423-7740

Annette Handy
Patient Safety/Quality Advisor
ahandy@ihaconnect.org
317-429-3657

Colleen O'Brien
Patient Safety/ Quality Advisor
cobrien@ihaconnect.org
317-429-3610

Bridget Hannon
Patient Safety Analyst/Coordinator
bhannon@ihaconnect.org
317-423-7798

Kaitlyn Boller
Patient Safety Analyst/Coordinator
kernst@ihaconnect.org
317-423-7742

Danyah Wafa
Patient Safety
Analyst/Coordinator
dwafa@ihaconnect.org
317-423-7756