Screening for Addiction and Monitoring for Aberrant Behavior in Patients with Chronic Pain

National Combined Councils Meeting
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Presented by:

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Objectives

- Define and distinguish the concepts of addiction, substance abuse, dependence and pseudoaddiction.
- Identify epidemiological and clinical risk factors for aberrant behavior in populations with chronic pain.
- Demonstrate the ability to use clinical tools to assess risk of addiction.
- Develop practical strategies to manage aberrant behavior.

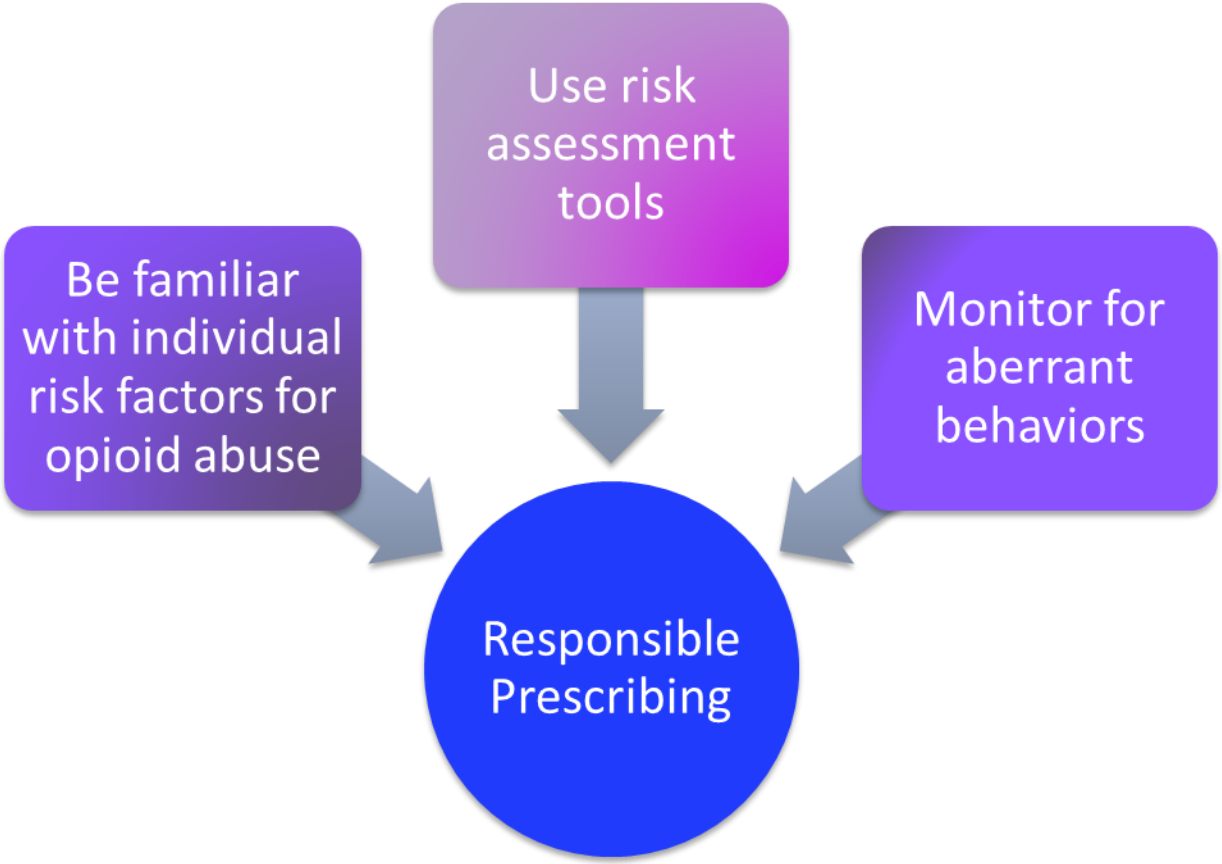
Daniel P. Alford, MD, MPH, FACP, FASAM, opioid expert and associate professor of medicine at BU:

"WARNING…

A controversial statement follows:

I strongly believe that physicians can be trained to prescribe opioids for chronic pain **safely** and **effectively."**

Framework for opioid risk management



ASAM Definition of Addiction

- A primary, chronic disease of brain reward, motivation, memory and related circuitry.
- Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations.
- This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

http://www.asam.org/DefinitionofAddiction-LongVersion.html

Aberrant Behavior

Aberrant Behavior is behavior that suggests prescription misuse, abuse, or addiction. (SAMSHA TIP 54)

"Prescribing opioids will lead to abuse/addiction in a small percentage of chronic pain patients, but a larger percentage will demonstrate ADRBs and illicit drug use. These percentages appear to be much less if CPPs are preselected for the absence of a current or past history of alcohol/illicit drug use or abuse/addiction." (Fishbain et al.)

Prevalence of Addiction in Chronic Pain Patients

- Structured review of available studies of development of aberrant behavior/addiction in patients on opioids for chronic pain.
- 24 studies with 2,057 patients with rate of 3.27% for abuse/addiction.
- Rate of abuse/addiction in patients with no past or current SUD was 0.19%
  - Fishbain DA. *Pain Med*. 2008;9:444-58.

Aberrant Behavior Prevalence

- 17 studies of 2,466 chronic pain patients found rate of 11.5% for aberrant behavior.
- For patients without SUD, rate was 0.59%.
- 5 studies (15,542 patients) by urine toxicology: 20.4% had no Rx opioid or an opioid not prescribed.
- 5 studies (1,965 patients): 14.5% had illicit drugs.

Risk Factors for Aberrant Behavior

- Lifetime history of substance use disorder (alcohol, tobacco, illicit substances)
- Psychiatric co-morbidity
- History of pre-adolescent sexual abuse
- Family history of substance abuse
- History of legal problems
- Younger age (16 – 45)
- Increased functional impairment

Risk Factors Predictive of Dependence

- Analysis of electronic health records of outpatients receiving 4 or more prescriptions for opioids in last 12 month for chronic pain.
- Diagnostic interviews with 705 patients.
  - Boscarino JA. *Addiction.* 2010;105:1776-1782.
- Age > 65, pain impairment, MDD and use of psychotropic medications had a combined OR of 8.
- Adding history of opioid abuse or severe dependence raised OR to 56.

mild

- Requests for higher doses
- Requests for specific formulation
- Occasional loss of prescription
- Occasional increase of dose without permission

moderate

- Use of Rx to treat symptom other than pain
- Stockpiling Rx in time of reduced symptom
- Significant energy spent assuring supply
- Multiple unsanctioned dose escalations
- Recurrent prescription losses
- Decline in function from baseline
- Concurrent use of illicit substances

severe

- Continual escalation of dose
- Seeking Rx from other providers or ER
- Stealing drugs
- Consistently buying Rx off street
- Diverting/Selling Rx
- Forging prescriptions
- Injection of oral Rx

Risk Assessment Tools

- **SOAPP®-R**
  - 24 item patient reported mood sx, family history, legal history, designed to predict which pts require more monitoring, has associated monitoring/treatment recommendations.
  - Sensitivity 81%, specificity 68%, PPV 57%, NPV 87%
  - Cutoff score of 18
- **DAST©**
  - 28 item patient report on prescription use, substance use behaviors.
- **DIRE©**
  - Clinician rated assessment of 4 domains: dx, intractability, risk, efficacy.
- **ORT©**
  - Patient reported personal and family hx substance abuse, age, psychiatric dx, age, hx sexual abuse. Stratifies into low, moderate, high risk.

Ongoing Risk Assessment Tool

- **COMM™**
  - 17 item patient self-reported medication use behaviors over previous 30 days
  - Score of 9 or above has positive LR 3.48 and negative LR 0.08 for medication misuse

All cited risk tools are available online:

http://www.painedu.org

http://www.emergingsolutionsinpain.com

How to Use Risk Assessment Tools

- Should not be used to deprive patients of pain management or opioid therapy but to identify those who are at risk for addiction.
- Use only with informed consent with advisement that refusal may for safety reasons alter treatment plan.
- They should be used to help guide us to determine the frequency and intensity of monitoring during the course of treatment.
- They should be use to develop the most efficacious and safest treatment strategy.

Suggestions for High Risk SOAPP-R Category [score >21]

- Review past medical records; contact prior providers
- Stated expectation of UDS at every visit
- Provide smaller amounts of meds [eg. 2 weeks]
- Family involvement
- Consider consultation with addictions specialists and/or psychiatrists
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications)
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy

Suggestions for Moderate Risk SOAPP-R Category [score 10-21]

- Periodic urine screens are recommended.
- Psychiatric consultation if appropriate
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

Suggestions for Moderate Risk SOAPP-R Category [score <9]

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

Balancing Benefits/Risks

- There are no absolute rules: ongoing analysis of risk/benefit balance in each individual case.
- Involve patient in process of shared decision- making and mutual rights and responsibilities.
- Document your reasoning for continued use based on function and lack of side effects.
- Obtain early and frequent consultation for challenging cases and problem behaviors.

Judge the Treatment NOT the Patient

Appropriate

Do the benefits of this treatment outweigh any side effects and risks of harm to the patient or society?

Not Appropriate

Is the patient good or bad?

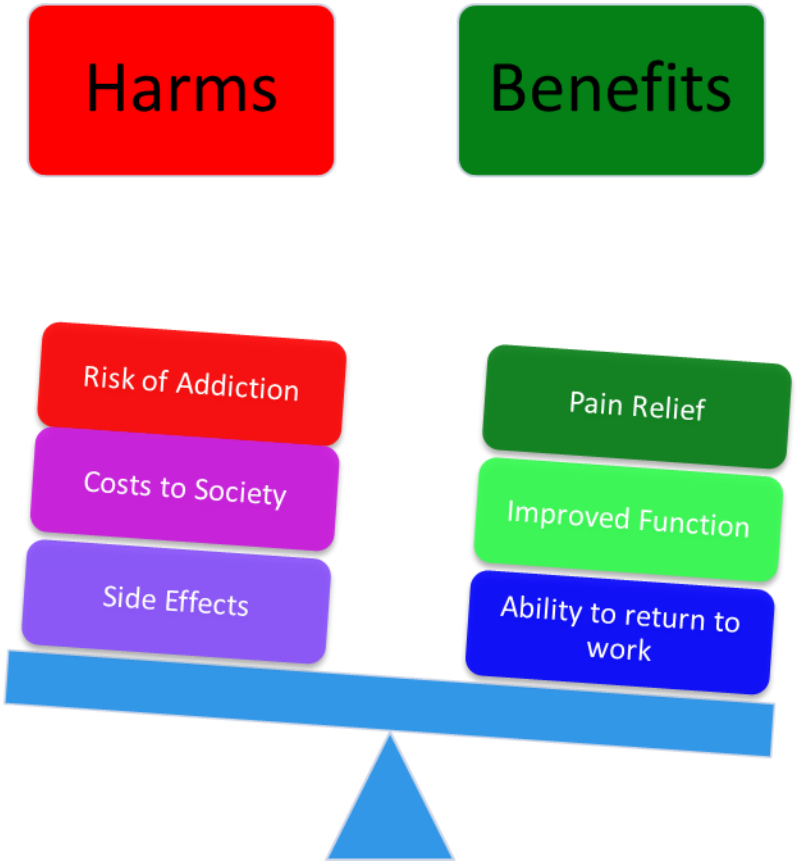
Does the patient deserve pain meds?

Should I trust the patient?

Should he/she be punished or rewarded?

Adapted from Alford

Balancing Benefits/Harms



Balancing Benefits/Risks

- Clinical interview and judgment are still the gold standard of risk assessment/management.
- Patients with addiction less likely to use illicit drugs if painful conditions controlled.
- Less risk of developing other addiction-related diseases (HIV, Hep C, syphilis) due to IV drug use.
- Less risk of developing addiction to other substances of abuse if pain controlled.

Management of Risk

- **UNIVERSAL PRECAUTIONS:**

  every patient is potentially at risk

  – Opioid agreements
  – Risk screening and ongoing assessment
  – Monitoring of urine toxicology
  – Prescription monitoring programs
  – Pill counts for those at high risk
  – Frequent visits with limited number of pills dispensed for those at high risk

Management of Risk: Opioid Agreements

- Mainly a tool to communicate expectations of both provider and patient.
- A means of obtaining informed consent.
- Educate patient on rationale, risks/benefits.
- Set specific goals (functional).
- Set expectations for monitoring.
- Identify specific responses for aberrant behaviors.

Management of Risk: Urine Toxicology

- Always obtain informed consent.
- Use results therapeutically.
- Know the limitations of toxicology screens.
- A tool for assessing adherence with medical treatment plan just like checking blood sugar in diabetes.
  - Main utility of standard toxicology is to identify use of illicit substances
- Adjust frequency of monitoring to match level of risk.

Managing Aberrant Behavior within the Practitioner-Patient Relationship

- Medicalize, don’t stigmatize the non-adherence, as with any other disease such as diabetes.
- Ask and try to empathically understand the reasons for the behavior.
- Be open and non-judgmental regarding the explanation even if you don’t believe it.

Questions For Patient and Practitioner

Patient

- Were you confused about how to take the prescription?
- Did you think more pills, more relief?
- Were you overly active and then have more pain & take more?
- Have you been depressed or anxious and the drugs made you feel better?

Practitioner

- Has the pain condition progressed?
- Is there a new pain generator?
- Is there an undiagnosed psychiatric disorder needing treatment?
- Have you set and followed limits and rules?
- (SAMSHA TIP 54)

Therapeutic Responses to Mild/Moderate Aberrant Behaviors

- Increase frequency of visits, even if brief check ins with nursing staff.
- With permission, obtain collateral information/family support for plan.
- Increase frequency or sophistication of toxicology screening, e.g., test for alcohol.
- Provide smaller quantities of opioids and other controlled substances.

When to Taper Opioids

- Moderate-severe aberrant behavior that continues despite repeated warnings and implementation of more close monitoring.
- Humane, long taper if can be safely done.
- Begin alternative pharmacological and non-pharmacological treatments for pain.
- DO NOT abandon the patient even if you refer.

When to Stop Opioids

- Patients exhibit aberrant behaviors in the severe category and represent a danger to the patient and the public.
- Danger such that may not allow humane tapering.
  - Injection of oral medication
  - Selling prescription
  - Forging/stealing prescription

When to Refer to an Addiction Expert

- Aggressive demands for medications.
- Forging or stealing prescriptions.
- Selling or diverting medications
- Obtaining drugs from multiple prescribers
- Injecting oral/topical medications

Adapted from NY State Office of Alcoholism and Substance Abuse Services: Clinical Practice Guidance Number 2012.2: Referral to a Pain or Addiction Specialist. Available at http://www.oasas.ny.gov/AdMed/recommend/guide2ref.cfm

When to Refer to Pain Expert

- Uncertain or questions about whether to use opioids to treat chronic pain.
- Patient with multiple psychiatric and medical comorbidities who needs opioids chronically.
- Complexity and risk profile of patient requires a level of documentation and monitoring not available in the practice setting.
- Intensity of pain & disability requires other pain interventions.

Summary

- The management of chronic pain with opioids is challenging and rewarding.
- Practitioner's responsibility is to provide:
  - Evidence-based risk assessment
  - Individualized treatment plan
  - Ongoing monitoring of functioning, adherence, impairment, and psychiatric symptoms.
  - Responsible prescribing.

References and More

- Gavin DR; Ross HE; Skinner HA. (1989) 'Diagnostic validity of the Drug Abuse Screening Test in the assessment of DSM-III drug disorders', *British Journal of Addiction* 84(3): 301-307.
- Webster LR, Webster RM. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the opioid risk tool. *Pain Med.* 2005;6(6):432-442.
- Yudko E, Lozhkina O, Fouts A. A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. J Subst Abuse Treat. 2007;32:189-198
- Belgrade MJ, Schamber CD, Lindgren BR. The DIRE Score: Predicting Outcomes of Opioid Prescribing for Chronic Pain. J Pain. 2006;7:671-681.

Prescription Drug Monitoring Programs (PDMPs):

Use as a Clinical Monitoring Tool to Enhance Patient Safety

IHS National Combined Councils Meeting

Plenary Session

June 26, 2014

Presented by:
CDR Cynthia Gunderson, PharmD
Chief Pharmacist, PHS Indian Hospital, Red Lake, MN

Learning Objectives

Participants will be able to:

- Understand PDMP background and purpose
- Describe the way PDMP data can enhance clinical practice
- Describe prescriber responsibilities
- Discuss IHS PDMP Participation including legal considerations
- Discuss IHS future initiatives

NSDUH Data

- SAMHSA data
- National Survey Drug Use
  - Source— friends and family;
  - 2011-2012
    - AI/AN aged 12 and older were more likely to have used a pain reliever for nonmedical use at least once in the past year (7.8 percent vs. 4.8 percent)
    - AI/AN aged 12 and older nonmedical use of prescription-type psychotherapeutics for 12 or older is also disparate (10.9% vs 6.4%)

NSDUH Data

- During 2002-2005
  - AI/AN aged 12 and older were more likely to have used a pain reliever for nonmedical use at least once in the past year (18.4 percent vs. 14.6 percent)
  - AI/AN aged 12 and older to have reported a illegal drug use disorder (5.0 percent vs 2.9 percent)

PDMP Background

According to the **National Alliance for Model State Drug Laws (NAMSDL)**, a PDMP is a ***statewide*** electronic database which collects designated data on substances dispensed in the state.

The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency.

The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession. [1]

PDMP Basics

- **State-run programs**
  - States legislate
    - Who reports
    - Who has access
    - Frequency that the reports are done
    - How the dispensers (aka pharmacies) report
      - American Society of Automation in Pharmacy (ASAP) versions
      - Required reporting elements

- **VARIABILITY AND LACK OF STANDARDIZATION**

Case #1

- MJ is a 68 YOM with vascular dementia with an anxiety component. He receives lorazepam 0.5mg TID from his PCP for anxiety. He was not responding to this treatment, so the PCP referred the patient to a behavioral health provider.
- BH provider started patient on clonazepam 1mg BID. The patient took the prescription to an outside pharmacy and filled it.
- Patient continued taking both lorazepam and clonazepam.

Case #1 (continued)

- Two weeks later, the patient presented to the ED after falling and hitting his head. He complains of hip pain. Xray reveals that patient fractured his hip.
- In the process of determining the cause of his fall, a PDMP query was requested. The pharmacist noted both the lorazepam that was filled at the IHS pharmacy and the clonazepam from the referral provider. When questioned, the patient revealed that he was taking both medications.

PDMP Purpose

1. Support access to legitimate medical use of controlled substances
2. Identify, deter, or prevent drug abuse and diversion
3. Facilitate the identification of persons addicted to prescription drugs
4. Educate individuals about PDMPs and the use, abuse and diversion of and addiction to prescription drugs [1]
5. ONDCP has defined PDMPs as an integral clinical tool to detect and deter prescription drug abuse [2]

Query

- **IHS practitioners have actively queried PDMP databases for over 7 years**
  - Practitioner access considerations—states define practitioner access
    - Classification: MD, RP, RN, etc.
    - Enrollment form
  - Practitioner responsibilities
    - Privacy
    - Utilization—best practices
  - Use of delegates
    - Some states authorize delegate accounts. Primary account must be enrolled and authorized first.

Types of Reports

- **Solicited** (Reactive reporting)
  - Prescriber/healthcare professional request for patient profile information from the PDMP

- **Unsolicited Reporting** (Proactive reporting)
  - A report generated and provided by the PDMP to the prescriber or dispenser of a particular patient that has exceeded dispensing thresholds established by the PDMP

Report Interpretations

- Early refills
- Dr. shoppers
- Cocktails
- Poly-pharmacy (multiple medications)
- Multiple prescribers
- Dose escalation (MEDs)
- Medications changes
- Acute vs chronic meds

Responsibilities

- Access to PDMP data helps prescribers
  - Check for addiction or undertreated pain
  - Check for misuse, multiple prescribers
  - Check for drug interactions or other harm
  - Use reports for compliance with pain agreements
- Prescriber should enroll for a query account in the state in which he/she prescribes
- Recommendation: Prescriber to conduct patient queries <u>prior</u> to patient appointments to facilitate meaningful interactions
- Retrospective report access at the pharmacy level is effective; however, it is not optimal

Responsibilities (continued)

- Document findings in the medical record
- Delegated Authority
  - PDMP access can be delegated as provisioned in state legislation. Most PDMP programs allow delegate access to registered users:
    - Pharmacy Technicians
    - Registered Nurses

Case #2 – Misuse/Diversion

- KK is a 47 year old female with mild DJD confirmed with imaging. She has reported allergies to all NSAIDs (GI reaction). She is maintained on Hydrocodone 5/325 mg 1 tablet every 6 hours and Gabapentin 900 mg 3/day. She established care with a RL provider in October 2013, under a Controlled Substance Treatment Agreement.
- PDMP queries were NOT conducted upon initiation of her prescriptions at RL.

Case #2 (continued)

- She refilled her prescriptions monthly when due.
- Pharmacy received a called in report that patient is selling her pain medications. At this time, the pharmacy staff completed a PDMP query.
- Patient had been filling Hydrocodone concurrently at the Walmart Pharmacy from a different provider. When questioned about her use, she stated she didn’t know that she “couldn’t” take both prescriptions from each provider filled at different pharmacies. She hung up on the nurse.

Prescription Drugs:

Have they become part of our culture?

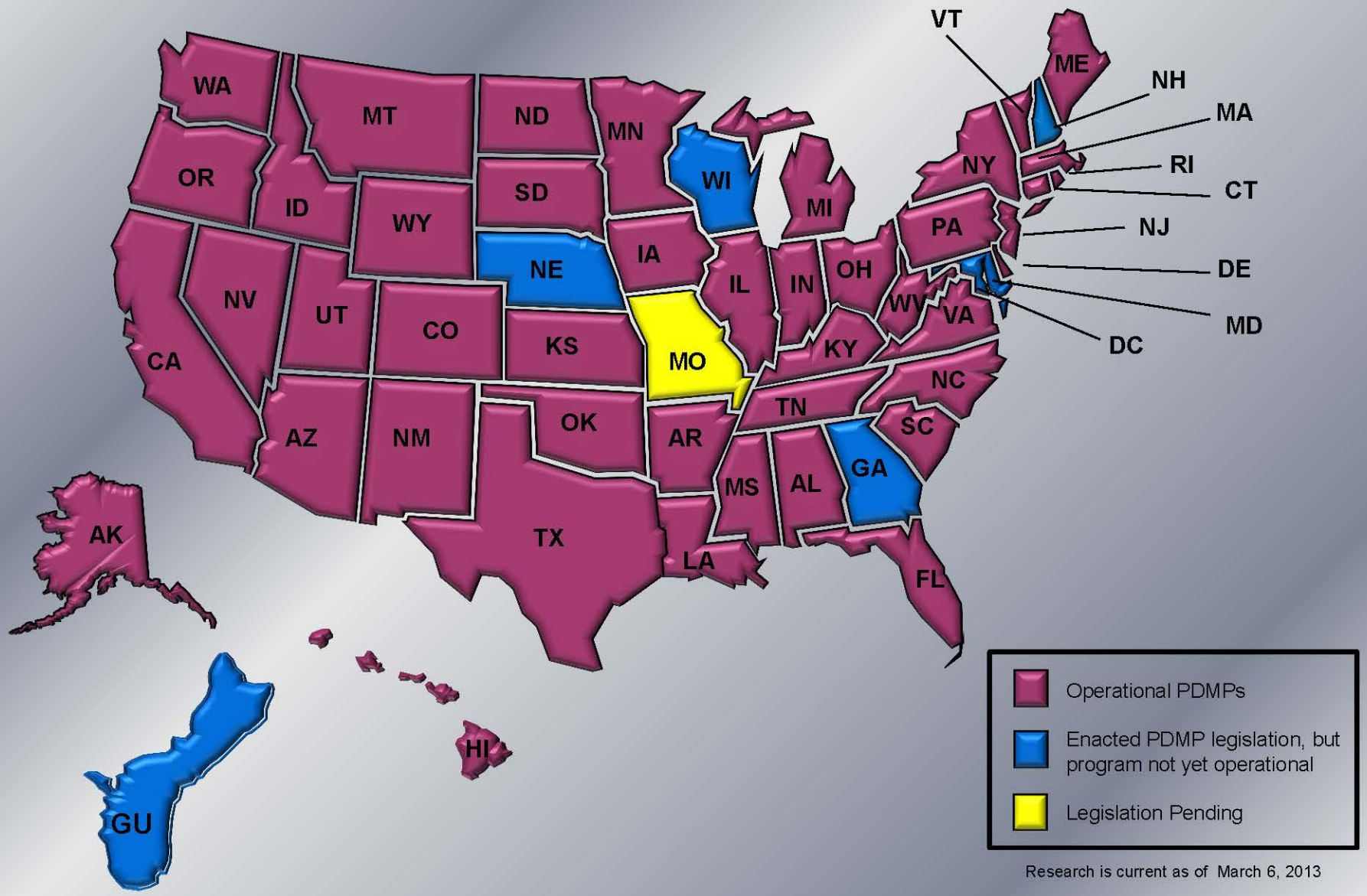
Why Report?
Is an integrated record necessary?

- **Pros**
  - Complete, accurate, comprehensive dispensing record for ALL controlled substances
  - Ability to mitigate harm from prescription drug abuse
    - Isolate potential abuse trends
    - Early referral to substance abuse treatment
- **Cons**
  - Cost: Programming and deployment costs to address variability between state programs
  - Logistics
    - Training and maintenance needs to address lack of standardization
    - Reporting responsibilities in small pharmacies—'one more thing'

PDMP Training & Technical Assistance Center

Status of Prescription Drug Monitoring Programs (PDMPs)

** To view PDMP Contact information, hover the mouse pointer over the state abbreviation*



Research is current as of March 6, 2013

Reporting Status

- Barriers and IHS response
  - Lack of standard state formats:
    - Each state legislates the American Society of Automation in Pharmacy (ASAP) standard. There are a total of 6 standards currently in use
      - » IHS RPMS software will report in format designated by site.
  - Lack of standard state data elements:
    - Each state legislates the data elements and the frequency with which it will require reporting
      - » IHS RPMS software will allow site to select required elements.
  - Lack of standard state vendor:
      - » IHS OIT has developed working relationships with all vendors
  - IHS is currently <u>not</u> required by statute to report; however prescription drug abuse prevention is a priority AND PDMPs are a proven tool to promote safe medication use and mitigate abuse potential

Reporting Recommendations

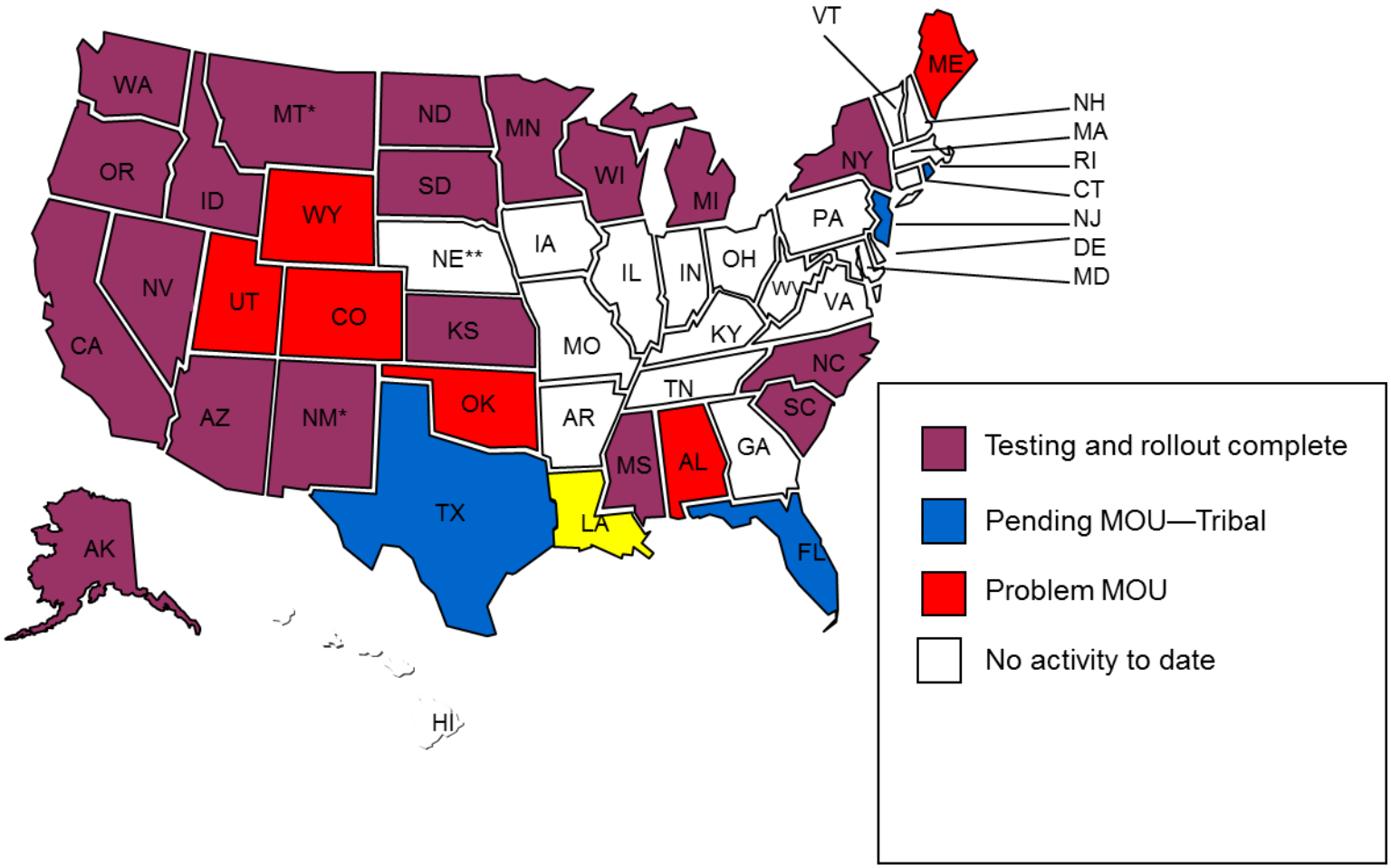
- Obtain MOU

- Encourage daily reporting to increase integrity of database

- Integrate reporting into your daily workflow to ensure it is done

IHS PDMP Reporting Deployment Status

March 2014



**NE—utilizes HIE to report

IHS Defined Priorities

- Training/Educational Materials
  - Define recommended prescriber training materials regarding prescription drug abuse (VA/NIDA/ONDCP)
    - http://www.drugabuse.gov/nidamed/etools
  - Enhance community education regarding PDMPs and detection of prescription drug abuse

Beyond Reporting: PDMP Clinical Impact

- Outcomes
  - IHS is working with state and federal stake holders to develop metrics to measure impact and use of PDMP data
    - Morbidity and mortality analysis: # of fatal and non-fatal overdoses—IHS ED data; CHS extracts
    - Clinical decision making
    - Threshold determination
    - Link between MEDs and OD risk—compounded risk for poly-pharmacy patients

Legal Considerations

- HIPAA--Access to data
  - State PDMP registered users
    - Use of data is governed by state legislation
    - Federal legal considerations
    - Unauthorized disclosure to patients (if copy of report is placed in the chart and unintentionally disclosed to the patient)
- Posting in EHR
    - Consideration—some states do not authorize patient access to PDMP data. If full results are posted in EHR, there may be a conflict between practice and state law.
      - Check with your APC regarding best practice considerations

Future IHS Initiatives

- Interconnects: Allow registrants to query state system and return multiple state's data (legislated, MOUs)
  - Purpose: Reduce time spent with log-in
  - Currently operational between 15 PMP states
- EHR enhancement request submitted to document query was conducted and reviewed, in the event that PDMP review becomes a future Meaningful Use measure
- Integration with Health Information Exchange (HIE) to integrate PDMP data into the EMR—considered a best practice
- Automated reporting using SFTP

Future IHS Initiatives (continued)

- Evaluate all possible RPMS query solutions including integrating PDMP into EHR
- Assist Federal partners and tribal entities in further defining best practices
- Recommend PDMP review as part of comprehensive peer review as required for clinical privileges
- IHS Circular pending

PDMPs and Substance Abuse Treatment Programs

- Reporting considerations
  - Methadone & OTPs: Dispensing data will not appear on a PDMP Query. 42CFR Sec. 2.13
  - Suboxone—appears on PDMP query
- Access to data
  - Methadone & OTPs: Practitioners access encouraged. In some states mandated (KY)

http://www.samhsa.gov/

http://www.aatod.org/

How Do I Get Involved?

- **Obtain more information**
  - Contact the state program where you practice
    - http://www.pdmpassist.org/content/state-pdmp-websites
- **Get registered (see above websites)**
- **Get training**
  - Your state may offer PDMP training and registration on-site
- **Conduct Queries**
  - If you are a prescriber or provider as recommended
  - If you are a CEO advocate/require registration
- **Educate your patients—PDMP participation signs, information regarding the use of PDMP data, etc.**
- **Get help if needed: grants, information, etc.**

Questions

- Email Cynthia Gunderson: cynthia.gunderson@ihs.gov

References

1. Green, Sherry (CEO). "PRESCRIPTION DRUG MONITORING PROGRAMS: A BRIEF OVERVIEW NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS (NAMSDL)". www.namsdl.org (accessed October 2012).
2. "Epidemic: Responding to America's Prescription Drug Abuse Crisis". http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescriptiondrugs/rx_abuse_plan_0.pdf (accessed July 2012)
3. Clark, T; Eadie, J; Kreiner, P; Strickler, G. "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices". http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf (accessed September 2012)
4. http://www.pdmpassist.org/pdf/pmpprogramstatus2013_a.pdf (accessed April 2014)
5. NSDUH-- SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2012. These estimates can be found in the 2012 NSDUH Detailed Tables 1.49B-1.52B and the corresponding standard errors can be found in Tables 1.49D-1.52D.