Risk Management in Chronic Pain Patients

Outline for today

- What does safe opioid prescribing consist of?
- What are the elements of practice that payers should be encouraging prescribers to do? (e.g. urine drug monitoring, reviewing prescription monitoring program data, SBIRT, mental health assessment, addiction consultations, etc.)
- The impact of insurance reimbursement on the clinical practice of safe opioid prescribing
- How often is the payer a barrier to safe opioid prescribing practice?
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Physican Perspective

- Can I do it right?
  - Even if I do can I do it without getting in trouble?
- Can I get appropriate reimbursement for what is needed to be done in order to be considered doing it right?

FSMB Model Policy

Basic Tenets

- Pain management is important and integral to the practice of medicine
- Use of opioids may be necessary for pain relief
- Use of opioids for other than a legitimate medical purpose poses a threat to the individual and society
- **Physicians have a responsibility to minimize the potential for abuse and diversion**
- Physicians may deviate from the recommended treatment steps based on good cause
- Not meant to constrain or dictate medical decision-making

FSMB, Federation of State Medical Boards

Physician attitudes toward opioid prescribing for patients with persistent noncancer

- internists were more likely to be concerned about ***illegal diversion*** (adjusted odds ratio=10.0, P=0.004), were more concerned ***about causing addiction*** (38% vs. 0%, P<0.001), and were more likely to be concerned about ***their inability to prescribe the correct opioid dose*** (adjusted odds ratio=11.1, P=0.020).
- DISCUSSION: Factors shown to have an adverse affect on opioid prescribing disproportionately impact on the attitudes of internists compared with geriatricians.
- is also a differential impact on how internists care for their elderly patients with chronic pain.

JJ, Alfandre D, Moore C.
Clin J Pain. 2007 Nov-Dec;23(9):799-803.

Influences of attitudes on family physicians' willingness to prescribe long-acting opioid analgesics for patients with chronic nonmalignant Pain

- two thirds of physicians indicated that they were "somewhat willing" to "extremely willing" to prescribe long-acting opioids to their patients with CNMP
- Approximately 80% of physicians believed that long-acting opioids would be effective in controlling pain and would improve overall quality of life in patients with CNMP.
- However, **78% indicated that they were "somewhat likely" to "extremely likely" to encounter regulatory scrutiny if they prescribed long-acting opioids for CNMP, and about half (51%) of the respondents believed prescribing them would lead to patient addiction**.
- Unwilling physicians held stronger beliefs that prescribing opioids would lead to patient abuse, addiction, and regulatory scrutiny compared with willing physicians.
- CONCLUSIONS: About two thirds of physician respondents were willing to prescribe long-acting opioids for patients with CNMP, and physician attitudes were marginally favorable

Joanna L. Starrels William C. Becker, MD; Daniel P. Alford, MD, MPH; Et L

APS and AAPM Guidelines: Managing Chronic Nonmalignant Pain

Conduct a comprehensive evaluation, including risk stratification	Periodically reassess patients
Counsel patients and obtain informed consent	Anticipate, identify, and treat opioid-associated adverse events
Individualize treatment	Integrate nonopioid therapies as adjunctive treatment
Evaluate potential causes for repeated dose escalations; wean or taper off if necessary	Consider as-needed therapy for breakthrough pain

APS=American Pain Society; AAPM=American Academy of Pain Medicine.
Chou R, et al. *Pain*. 2009;10(2):113-130.

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Why Screen the Patient?

"It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has."

— *Sir William Osler*

What Are Universal Precautions?

1	Diagnosis With Appropriate Differential
2	Psychological Assessment, Including Risk of Addictive Disorders
3	Informed Consent
4	Treatment Agreement
5	Pre- and Post-Intervention Assessment of Pain Level and Function
6	Appropriate Trial of Opioid Therapy With/Without Adjunctive Medication
7	Reassessment of Pain Score and Level of Function
8	Regularly Assess the “4 A’s” of Pain Medicine
9	Periodically Review Pain Diagnosis and Comorbid Conditions, Including Addictive Disorders
10	Documentation

Gourlay DL, et al. *Pain Med*. 2005;6(2):107-112.

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Risk Assessment Tools Highlights

- ORT, SOAPP & DIRE
  - Best assess abuse potential among those being considered for long-term opioid therapy
- COMM & PMQ
  - Characterize degree of medication misuse or aberrant behavior once opioids are started
- DAST-10 & PMQ
  - More suitable for assessing current alcohol and/or drug abuse than potential for such abuse

Passik SD, et al. *Pain Med.* 2008;10 Suppl 2:S145-166.

Truth be told…

- The major weakness of all such screeners is a dependence on honesty….

доверие, но проверяет

Risk Factors for Aberrant Behaviors/Harm

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

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.

Risk Stratification and Patient Management

Characteristic	Low Risk	Moderate Risk	High Risk
Substance abuse	Never	Past	Current
Smoking (nicotine)	Never	Past	Current
Family history of addiction	None	Significant	Significant
Psychosocial factors	No major diagnoses; minor diagnoses treated or stable	Past major diagnoses; current issues with minor diagnoses	Current major diagnoses untreated or unstable
Age	Older	N/A	Younger
History of sexual abuse	No	N/A	Yes
Controlled prescriptions lost or stolen	No	N/A	Yes
Unauthorized substances in urine drug screens	Consistently negative	Initially positive	Consistently positive
Recommendations based on risk stratification			
Healthcare setting	Primary care	Primary care with specialist support	Specialty pain management

Gourlay DL, et al. *Pain Med*. 2005;6(2):107-112.

Evidence Screening May Help

- For the abuse/addiction grouping: 24 studies with 2,507 CPPs exposed calculated abuse/addiction rate of **3.27%**.
- Within this grouping for those studies that had preselected CPPs for COAT exposure for ***no previous or current history of abuse/addiction,*** the percentage of abuse/addiction was calculated at **0.19%.**
- For the ADRB grouping, there were 17 studies with 2,466 CPPs exposed and **a calculated ADRB rate of 11.5%**.

Fishbain D, Cole B, Lewis, J. Pain Medicine 2008

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Opioid Treatment Agreement

Patient Name:_____ Date:_____

Opioid (narcotic) treatment for chronic pain is used to reduce pain and improve what you are able to do each day. Along with opioid treatment, other medical care may be prescribed to help improve your ability to do daily activities. This may include exercise, use of non-narcotic analgesics, physical therapy, psychological counseling or other therapies or treatment. Vocational counseling may be provided to assist in your return to work effort.

To the doctor: Keep signed originals in your file; give a photocopy to the patient. Renew at least every 6 months.

I, _____, understand that compliance with the following guidelines is important in continuing pain treatment with Dr. _____.

1. I understand that I have the following responsibilities:
   a. I will take medications only at the dose and frequency prescribed.
   b. I will not increase or change medications without the approval of this doctor.
   c. I will actively participate in RTW efforts and in any program designed to improve function (including social, physical, psychological and daily or work activities).
   d. I will not request opioids or any other pain medicine from physicians other than from this doctor. This doctor will approve or prescribe all other mind and mood altering drugs.
   e. I will inform this doctor of all other medications that I am taking.
   f. I will obtain all medications from one pharmacy, when possible known to this doctor with full consent to talk with the pharmacist given by signing this agreement.
   g. I will protect my prescriptions and medications. Only one lost prescription or medication will be replaced in a single calendar year. I will keep all medications from children.
   h. I agree to participate in psychiatric or psychological assessments, if necessary.
   i. If I have an addiction problem, I will not use illegal or street drugs or alcohol. This doctor may ask me to follow through with a program to address this issue. Such programs may include the following:
      - 12-step program and securing a sponsor
      - Individual counseling
      - Inpatient or outpatient treatment
      - Other: _____
2. I understand that in the event of an emergency, this doctor should be contacted and the problem will be discussed with the emergency room or other treating physician. I am responsible for signing a consent to request record transfer to this doctor. No more than 3 days of medications may be prescribed by the emergency room or other physician without this doctor's approval.
3. I understand that I will consent to random drug screening. A drug screen is a laboratory test in which a sample of my urine or blood is checked to see what drugs I have been taking.
4. I will keep my scheduled appointments and/or cancel my appointment a minimum of 24 hours prior to the appointment.
5. I understand that this doctor may stop prescribing opioids or change the treatment plan if:
   a. I do not show any improvement in pain from opioids or my physical activity has not improved.
   b. My behavior is inconsistent with the responsibilities outlined in #1 above.
   c. I give, sell or misuse the opioid medications.
   d. I develop rapid tolerance or loss of improvement from the treatment.
   e. I obtain opioids from other than this doctor.
   f. I refuse to cooperate when asked to get a drug screen.
   g. If an addiction problem is identified as a result of prescribed treatment or any other addictive substance.
   h. If I am unable to keep follow-up appointments.

_____ _____
Patient Signature Date Physician Signature Date

YOUR SAFETY RISKS WHILE WORKING UNDER THE INFLUENCE OF OPIOIDS:

You should be aware of potential side effects of opioids such as decreased reaction time, clouded judgment, drowsiness and tolerance. Also, you should know about the possible danger associated with the use of opioids while operating heavy equipment or driving.

SIDE EFFECTS OF OPIOIDS:

- Confusion or other change in thinking abilities
- Problems with coordination or balance that may make it unsafe to operate dangerous equipment or motor vehicles
- Breathing too slowly – overdose can stop your breathing and lead to death
- Nausea
- Sleepiness or drowsiness
- Vomiting
- Constipation
- Aggravation of depression
- Dry mouth

THESE SIDE EFFECTS MAY BE MADE WORSE IF YOU MIX OPIOIDS WITH OTHER DRUGS, INCLUDING ALCOHOL.

RISKS:

- Physical dependence. This means that abrupt stopping of the drug may lead to withdrawal symptoms characterized by one or more of the following:

Runny nose	Difficulty sleeping for several days
Diarrhea	Abdominal cramping
Sweating	'Goose bumps'
Rapid heart rate	Nervousness

- Psychological dependence. This means it is possible that stopping the drug will cause you to miss or crave it.
- Tolerance. This means you may need more and more drug to get the same effect.
- Addiction. A small percentage of patients may develop addiction problems based on genetic or other factors.
- Problems with pregnancy. If you are pregnant or contemplating pregnancy, discuss with your physician.

PAYMENT OF MEDICATIONS:

State law forbids L&I from paying for opioids once the patient reaches maximum medical improvement. You and your doctor should discuss other sources of payment for opioids when L&I can no longer pay.

RECOMMENDATIONS TO MANAGE YOUR MEDICATIONS:

- Keep a diary of the pain medications you are taking, the medication dose, time of day you are taking them, their effectiveness and any side effects you may be having.
- Use of a medication box that you can purchase at your pharmacy that is already divided in to the days of the week and times of the day so it is easier to remember when to take your medications.
- Take along only the amount of medicine you need when leaving home so there is less risk of loosing all your medications at the same time.

I have read this document, understand and have had all my questions answered satisfactorily. I consent to the use of opioids to help control my pain and I understand that my treatment with opioids will be carried out as described above.

_____ _____
Patient Signature Date Physician Signature Date

http://www.lni.wa.gov/ClaimsIns/Files/OMD/agreement.pdf. Accessed March 2010.

Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients With Chronic Paint

- **Background:** Experts recommend opioid treatment agreements and urine drug testing to reduce opioid analgesia misuse, but evidence of their effectiveness has not been systematically reviewed.
- **Purpose:** To synthesize studies of the association of treatment agreements and urine drug testing with opioid misuse outcomes in outpatients with chronic noncancer pain.
- **Data Synthesis:** Of 102 eligible studies, 11 met inclusion criteria; 6 were in pain clinics and 5 were in primary care settings. Four primary care studies examined multicomponent strategies that included interdisciplinary support. All studies were observational and rated as poor to fair quality. In 4 studies with comparison groups, opioid misuse was modestly reduced (7% to 23%) after treatment agreements with or without urine drug testing. In the other 7 studies, the proportion of patients with opioid misuse after treatment agreements, urine drug testing, or both varied widely (3% to 43%).
- **Conclusion:** Relatively weak evidence supports the effectiveness of opioid treatment agreements and urine drug testing in reducing opioid misuse by patients with chronic pain. Further research on effective ways to monitor and reduce opioid misuse is needed, especially in primary care settings.

What are the elements of practice that payers should be encouraging prescribers to do?

Universal Precautions need to recognized as integral component

SBIRT, mental health assessment,

Adiction consultatons

Urine drug monitoring

Reviewing prescription monitoring program data,

Addiction consultations

- If men were angels, no government would be necessary.
  - James Madison

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

Cost of UDT?

- POCT: Revenue per test varies from insurer to insurer
  - Medicare Was $20.05 now 8.25.
  - Avg. 3rd party 64.47 (0-145.05)
    - 1/3 pay
  - WC: 84.40 (0-644)
    - 40% pay
  - Referred Testing
  - $855-1442
    - Based on EOB's provided by patients
  - Average based on sample of 144 patients: $1155.05

Cost of UDT?

- Something to think about:
- Average based on sample of 144 patients: $1155.05

- `4 million patients on LOA
- 4,000,000*1155= $4,620,000,000
- 4 times/year= $18,480,000,000

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PMPs

- A number of states with prescription monitoring programs
- PMP's of different qualities and capabilities
  - CT: realtime data from all pharmacies in State
    - 2 week lag; methadone clinics don't participate
    - Does not 'see' neighboring states
  - NY: 2-4 weeks to get some data

Colorado Prescription Drug Monitoring Program Survey

- Survey conducted by AAPM to identify value to physicians in the state of Colorado
- Participants identified from database of pain, primary care and ER physicans.
- Goal: feedback to Co legislature to continue funding.

3. Did you find the CO PDMP helpful?

- Yes 422 97%
- No 153%
- **Total 437 100%**

4. Has the CO PDMP affected your decision to prescribe opiates or sedatives to a patient?

- Yes 423 96%
- No 164%
- **Total 439 100%**

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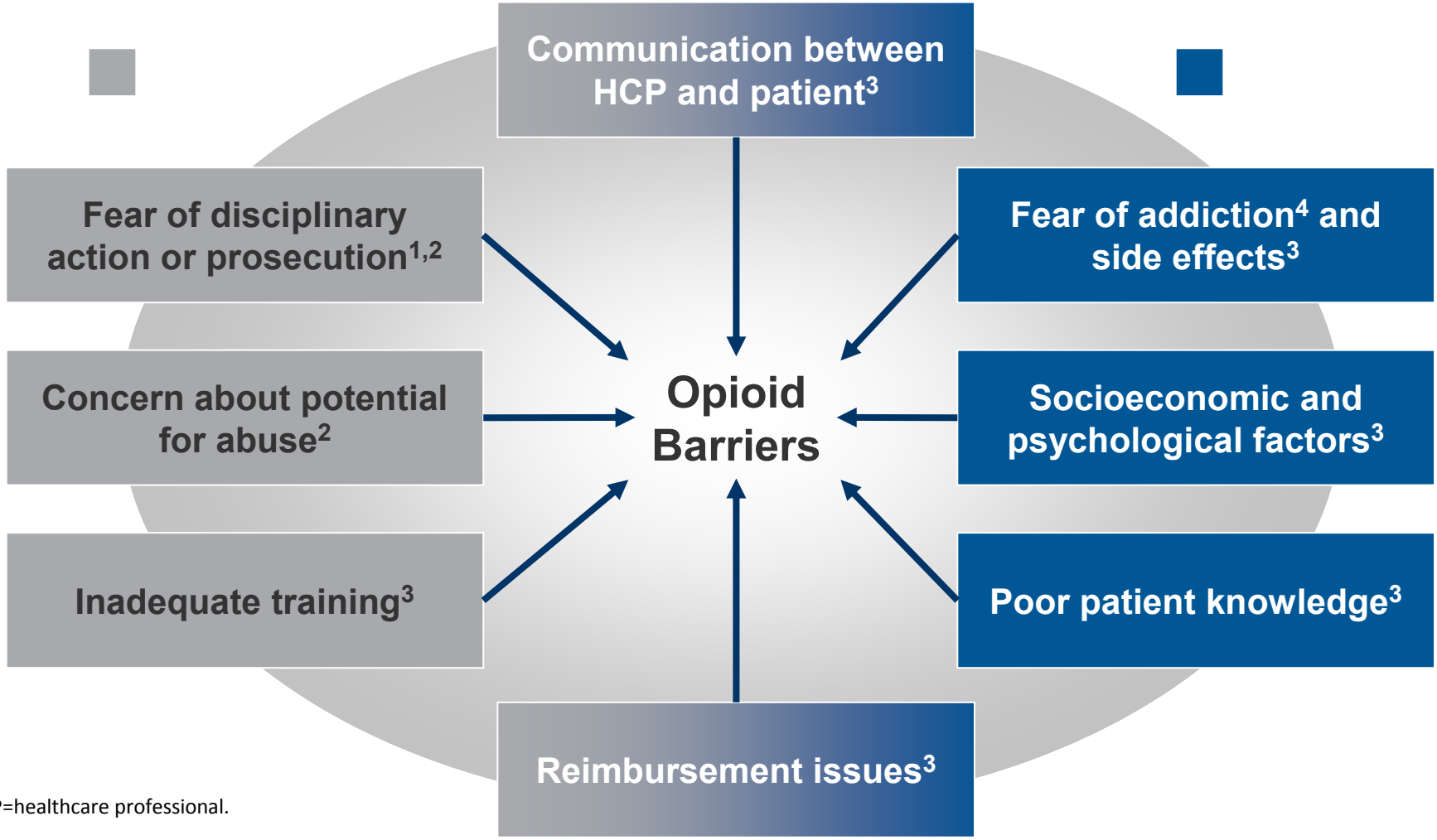
Multiple Barriers Exist to Opioid Utilization



HCP=healthcare professional.

1. Richard J, Reidenberg MM. *J Pain Symptom Manag.* 2005;29(2):206-212.
2. Gilson AM, et al. *J Pain.* 2007;8(9):682-691.
3. Glachen M. *J Am Board Fam Pract*. 2001;14(3):211-218.
4. McCracken LM, et al. *J Pain*. 2006;7(10):726-734.

How often is the payer a barrier to safe opioid prescribing practice?

- Uncertain
- “Physicans follow green…”
- 1/3 physicians do not accept Medicare
  - Certain regions at 50%
- Approximately 50% do not accept Medicaid
  - Likely greater number in provate practice vs, employed physicians

Impact of reduced Reimbursement for UDT and physician testing

- Sermo posting
- 18 physicans responded
  - 2/3 don't do UDT in office
  - Of those who currently do UDS, the majority will continue to do so, despite likely reduction in revenues. However, 6% said they will stop.

Impact of increased Cost to patient?

- In February 2002, the Department of Veterans Affairs (VA) increased copayments from $2 to $7 per 30-day drug supply of each medication for many veterans. We examined the impact of the copayment increase on lipid-lowering medication adherence.
- ***The copayment increase adversely affected lipid-lowering medication adherence among veterans, including those at high coronary heart disease risk.***

Doshi et al (*Circulation.* 2009;119:390-397.)

Ambulatory Care Copayments and Hospitalizations among the Elderly

Amal N. Trivedi, M.D., M.P.H., Husein Moloo, M.P.H., and Vincent Mor, Ph.D.

N Engl J Med
Volume 362(4):320-328
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The NEW ENGLAND JOURNAL of MEDICINE

Ambulatory Care Copayments and Hospitalizations among the Elderly

- *Background* When copayments for ambulatory care are increased, elderly patients may forgo important outpatient care, leading to increased use of hospital care.
- ***Conclusions Raising cost sharing for ambulatory care among elderly patients may have adverse health consequences and may increase total spending on health care*.**
- Amal N. Trivedi, M.D., M.P.H., Husein Moloo, M.P.H., and Vincent Mor, Ph.D.

Identifying and Managing Abuse and Diversion: it is not Cheap.

- Assessing risk and aberrant behaviors
- Performing scheduled and random UDTs
- Utilization of PMPs
- Assessing stress and adequacy of pain control
- Developing good communication with pharmacists
- Receiving input from family, friends, and other patients

Case Study: Opioid Renewal Clinic

What is the impact of a structured opioid renewal program?

- Primary goal: reduce oxycodone SA use to 3% of opioids
- Setting
  - Primary care
  - Managed by nurse practitioner and clinical pharmacist
  - Philadelphia VA pain clinic
- Structured program
  - Electronic referral by PCP
    - Signed Opioid Treatment Agreement
    - UDT
  - Support from multidisciplinary pain team: addiction psychiatrist, rheumatologist, orthopedist, neurologist, and physiatrist
  - Multimodal management
    - Opioids
    - NSAIDs and acetaminophen for osteoarthritis
    - Transcutaneous electrical stimulation (TENS) units
    - Antidepressants and anticonvulsants for neuropathic pain
    - Reconditioning exercises

Wiedemer NL, et al. *Pain Med*. 2007;8(7):573-584.

Opioid Renewal Clinic

Conclusions

- A structured, multispecialty program for opioid management in chronic noncancer pain patients can successfully implemented in a primary care setting
  - Standardized documentation
  - OTAs
  - UDTs
  - Frequent visits
  - Patient education

Wiedemer NL, et al. *Pain Med*. 2007;8:573-584.

Can This Approach Realistically Be Used in Other Settings?

- Hospital
- Substance abuse/pain treatment center
- Emergency department
- Why/why not?

Conclusion

Editorial JAMA

- **Chronic Noncancer Pain Management and Opioid Overdose: Time to Change Prescribing Practices**
  - A. Thomas McLellan, PhD; and, Barbara J. Turner, MSEd, MD, Executive Deputy Editor
    - *January 19, 2010 vol. 152 no. 2 123-124*

- *It is easy to suggest time-consuming, unreimbursed approaches to improve the safety of opioid prescribing without specifying how they can be incorporated into already overburdened clinical settings.*

- *Frankly, we do not know how to increase clinical diligence without additional work, time, or money, although technology can facilitate some of these suggested practice changes.*
- *The threat to patient safety is too great to allow current pain management and opioid-prescribing practices to remain as they are.*

- *Dunn and colleagues' data show the need to assess the risk for opioid misuse, provide close oversight, dose judiciously, and continually reevaluate the benefit of these potentially risky drugs.*
- *Smarter, more responsible practices are the only hope to avoid tragic, avoidable deaths.*