Reinventing Pain Care: The Antidote to the Worst Man-Made Epidemic in Modern Medical History

-Pain, Pain Management, and the Opioid Epidemic-

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Gary M. Franklin, MD, MPH
Research Professor
Departments of Environmental Health, Neurology and Health Services
University of Washington

Medical Director
Washington State Department of Labor and Industries

Co-chair
Agency Medical Directors’ Group
"To write prescriptions is easy, but to come to an understanding with people is hard."

-- Franz Kafka, "A Country Doctor"
“We can’t solve problems by using the same kind of thinking we used when we created them.”
The worst man-made epidemic in modern medical history

- Over 200,000 deaths
- Many more hundreds of thousands of overdose admissions
- Millions addicted and/or dependent
- Spillover effect to SSDI*

“Pharmaceutical heroin”

- Opiates can depress breathing by changing neurochemical activity in the brain stem, where automatic body functions are controlled.
- Opiates can change the limbic system, which controls emotions, to increase feelings of pleasure.
- Opiates can block pain messages transmitted through the spinal cord from the body.
ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154

Portenoy and Foley
Pain 1986; 25: 171-186

- Retrospective case series chronic, non-cancer pain
- N=38; 19 Rx for at least 4 years
- 2/3 < 20 mg MED/day; 4> 40 mg MED/day
- 24/38 acceptable pain relief
- No gain in social function or employment could be documented
- Concluded: “Opioid maintenance therapy can be a safe, salutary and more humane alternative…”

By 2006 over 10,000 WA citizens in public programs were on >/= 100 mg/day MED
By the late 1990s, at least 20 states passed new laws, regulations, or policies moving from near prohibition of opioids to use without dosing guidance.

- WA law: “No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed.” (WAC 246-919-830, 12/1999)

Laws were based on weak science and good experience with cancer pain: Thus, no ceiling on dose and axiom to use more opioid if tolerance develops.

- Pain as the 5th vital sign-HCAHPS pain satisfaction survey
WA State has led on reversing the epidemic

- 2007-AMDG Guideline was first U.S. guideline with a dosing threshold (120 mg/day MED in 2007, updated 2010, substantial update 2015)
- 2010-1\textsuperscript{st} report of clear association of high doses with overdoses (Dunn, Von Korff et al, Ann Int Med 2010; 152: 85-92)
- 2010 WA legislature-repeals old, permissive rules and establishes new standards-ESHB 2876-and DOH rules for all prescribers-MD, DO, ARNP, DPM, DDS)
- 2011-UW Telepain-Dr Tauben et al
- 2015-Expanded AMDG opioid guideline-highly consistent with CDC guideline

Franklin et al, Natural History of Chronic Opioid Use Among Injured Workers with Low Back Pain-Clin J Pain, Dec, 2009

• 694/1843 (37.6%) received opioid early
• 111/1843 (6%) received opioids for 1 yr
• MED increased sign from 1st to 4th qtr
• Only minority improved by at least 30% in pain (26%) and function (16%)
• Strongest predictor of long term opioid use was MED in 1st qtr (40 mg MED had OR 6)
• Avg MED 42.5 mg at 1 yr; Von Korff 55 mg at 2.7 yrs
Evidence of effectiveness of chronic opioid therapy

Enduring adaptation produced by established behaviors
Addiction criteria may be different for pain patients on chronic opioids

For the illicit drug user:

• Procurement behaviors

For the pain patient – much more complex:

• Continuous opioid therapy may prevent opioid seeking
• Memory of pain, pain relief and possibly also euphoria
• Even if the opioid seeking appears as seeking pain relief, it becomes an adaptation that is difficult to reverse
• It is hard to distinguish between drug seeking and relief seeking

responding to the EVIDENCE: morphine equivalent dose RELATED RISK

### Risk of adverse event

<table>
<thead>
<tr>
<th>Dose in mg MED</th>
<th>&lt;20 mg/day</th>
<th>20-49 mg/day</th>
<th>50-99 mg/day</th>
<th>≥100 mg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Ratio</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
</tbody>
</table>

- **Risk of adverse ± overdose event** increases at >50 mg MED/day
- **Risk increases greatly at ≥100 MED/day**

2007: WA State AMDG initially recommends 120 MED threshold dose
2009: CDC recommends: 120 mg/day MED
2012: CT work comp: 90 mg/day MED
2013: OH State medical Board: 80 mg/day MED
2013: Am College Occ. & Environ Med: 50 mg/day MED
2014: CA work comp: 80-120 mg/day MED
2016: CDC 50 mg/day MED yellow flag; 90 mg/day MED red flag

Courtesy G. Franklin 2014
Early opioids and disability in WA WC. Spine 2008; 33: 199-204

- Population-based, prospective cohort
- N=1843 workers with acute low back injury and at least 4 days lost time
- Baseline interview within 18 days (median)
- 14% on disability at one year
- Receipt of opioids for > 7 days, at least 2 Rxs, or > 150 mg MED doubled risk of 1 year disability, after adjustment for pain, function, injury severity
Risk/Benefit of Opioids for Chronic Non-Cancer Pain
-Franklin; Neurology; Sept 2014-Position paper of the AAN-
Opioids should not be used routinely for the treatment of routine musculoskeletal conditions, headaches or fibromyalgia*

*WA DLI opioid guidelines, 2013
http://1.usa.gov/1nYlarL
AMDG Mission Statement

The Agency Medical Directors’ Group (AMDG) mission is to maximize the value, quality, safety, and delivery of state purchased health care.

AMDG Goals

AMDG members collaborate across state agencies to accomplish the following goals:

1. Identify and assess ways to improve the quality of healthcare delivered to Washington citizens,
2. Promote the cost-effective purchase of health care services, and
3. Simplify the administrative burden for providers in Washington’s health care financing and delivery systems.

“These goals support RCW 41.05.013 on coordinating state purchased health care programs and policies.”

AMDG Priorities

The AMDG’s medical directors and senior policy makers focus available resources on the following priority areas that provide immediate and long-term benefits for Washington’s health care delivery system:

1. Protect public health: by advancing initiatives and programs that keep people safe and improve their health.
2. Purchase high value care: so public funds are used wisely for high quality care.
3. Implement evidence-based best practices: by using research to produce policies and guidelines on clinical topics that affect everyone.
4. Coordinate state health care coverage and purchasing: to make efficient use of resources.
5. Support and integrate healthcare reforms: that affect all Washington citizens.
Part I – If patient has not had clear improvement in pain AND function at 120 mg MED (morphine equivalent dose), “take a deep breath”
  • If needed, get one-time pain management consultation (certified in pain, neurology, or psychiatry)
Part II – Guidance for patients already on very high doses >120 mg MED
Guidance for Primary Care Providers on Safe and Effective Use of Opioids for Chronic Non-cancer Pain

- Establish an opioid treatment agreement
- Screen for
  - Prior or current substance abuse
  - Depression
- Use random urine drug screening judiciously
  - Shows patient is taking prescribed drugs
  - Identifies non-prescribed drugs
- Do not use concomitant sedative-hypnotics
- Track pain and function to recognize tolerance
- Seek help if dose reaches 120 mg MED, and pain and function have not substantially improved

http://www.agencymeddirectors.wa.gov/opioiddosing.asp
MED, Morphine equivalent dose
Open-source Tools Added to June 2010 Update of Opioid Dosing Guidelines

- Opioid Risk Tool: Screen for past and current substance abuse
- CAGE-AID screen for alcohol or drug abuse
- Patient Health Questionnaire-9 screen for depression
- 2-question tool for tracking pain and function
- Advice on urine drug testing

**OPIOID DOSE CALCULATOR**

<table>
<thead>
<tr>
<th>Opioid (oral or transdermal)</th>
<th>Mg per day</th>
<th>Morphine equivalents</th>
</tr>
</thead>
<tbody>
<tr>
<td>codeine</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>fentanyl transdermal (in mcg/hr)</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>hydrocodone</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>hydromorphone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>methadone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>up to 20mg per day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 to 40mg per day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41 to 60mg per day</td>
<td>50</td>
<td>500</td>
</tr>
<tr>
<td>&gt;60mg per day</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>morphine</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>oxycodone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>oxymorphone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>TOTAL daily morphine equivalent dose (MED) =</td>
<td>520</td>
<td></td>
</tr>
</tbody>
</table>

CAGE, “cut down” “annoyed” “guilty” “eye-opener”

http://www.agencymeddirectors.wa.gov/opioiddosing.asp#DC
### Summary of 2015 Interagency Guideline on Prescribing Opioids for Pain

**All pain phases**
- Use non-opioid therapies, such as behavioral intervention, physical activity and non-opioid analgesics.
- Avoid opioids if the patient has significant respiratory depression, current substance use disorder, history of prior opioid overdose or a pattern of aberrant behaviors.
- Assess and document function and pain using a validated tool at each visit where opioids are prescribed.
- Don’t prescribe opioids with benzodiazepines, carisoprodol, or sedative-hypnotics.

<table>
<thead>
<tr>
<th>Acute phase (0–6 weeks)</th>
<th>Perioperative pain</th>
<th>Subacute phase (6–12 weeks)</th>
<th>Chronic phase (&gt;12 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check the state’s Prescription Monitoring Program (PMP) before prescribing.</td>
<td>Evaluate thoroughly preoperatively: check the PMP and assess risk for over-sedation and difficult-to-control pain.</td>
<td>Don’t continue opioids without clinically meaningful improvement in function (CMIF) and pain.</td>
<td>Continue to prescribe opioids only if there is sustained CMIF and no serious adverse events, risk factors, or contraindications.</td>
</tr>
<tr>
<td>Don’t prescribe opioids for non-specific back pain, headaches, or fibromyalgia.</td>
<td>Discharge with acetaminophen, NSAIDs, or very limited supply (2–3 days) of short-acting opioids for some minor surgeries.</td>
<td>Screen for comorbid mental health conditions and risk for opioid misuse using validated tools.</td>
<td>Repeat PMP check and UDT at frequency determined by the patient’s risk category.</td>
</tr>
<tr>
<td>Prescribe the lowest necessary dose for the shortest duration.</td>
<td>For patients on chronic opioids, taper to preoperative doses or lower within 6 weeks following major surgery.</td>
<td>Recheck the PMP and administer a baseline urine drug test (UDT) if you plan to prescribe opioids beyond 6 weeks.</td>
<td>Prescribe in 7-day multiples to avoid ending supply on a weekend.</td>
</tr>
<tr>
<td>Opioid use beyond the acute phase is rarely indicated.</td>
<td></td>
<td>Don’t exceed 120 mg/day MED without a pain management consultation.</td>
<td></td>
</tr>
</tbody>
</table>
When to discontinue
- At the patient’s request
- No CMIF
- Risks outweigh benefits
- Severe adverse outcome or overdose event
- Substance use disorder identified (except tobacco)
- Aberrant behaviors exhibited
- To maintain compliance with DOH rules or consistency with AMDG guideline

Considerations prior to taper
- Help the patient understand that chronic pain is complex and opioids cannot eliminate pain.
- Consider an outpatient taper if the patient isn’t on high-dose opioids or doesn’t have comorbid substance use disorder or other active mental health disorder.
- Seek consultation if the patient failed previous taper or is at greater risk for failure due to high-dose opioids, concurrent benzodiazepine use, comorbid substance use disorder or other active mental health disorder.

How to discontinue
- Taper opioids first if patients are also on benzodiazepines.
- Unless safety considerations require a more rapid taper, start with 10% per week and adjust based on the patient’s response.
- Don’t reverse the taper; it can be slowed or paused while managing withdrawal symptoms.
- Watch for unmasked mental health disorders, especially in patients on prolonged or high-dose opioids.

Recognizing and treating opioid use disorder
- Assess for opioid use disorder and/or refer for a consultation if the patient exhibits aberrant behaviors.
- Help patients get medication-assisted treatment along with behavioral therapies.
- Prescribe naloxone (especially if you suspect heroin use) and educate patient’s contacts on how to use it.

Special populations
- Counsel women before and during pregnancy about maternal, fetal, and neonatal risks.
- For children and adolescents, avoid prescribing opioids for most chronic pain problems.
- In older adults, initiate opioids at 25–50% lower dose than for younger adults.
- For cancer survivors, rule out recurrence or secondary malignancy for any new or worsening pain.

Check out the resources at www.AgencyMedDirectors.wa.gov
- Free online CME
- Opioid Dose Calculator
- Videos from Primary Pain Care Conference
Washington Unintentional Prescription Opioid Deaths
1995 – 2015
44% sustained decline

Source: Washington State Department of Health
Unintentional Opioid Overdose Deaths
Washington 1995-2014

Source: Washington State Department of Health, Death Certificates
Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse

Data are plotted as a function of the decade in which respondents initiated their opioid abuse.

Figure Legend:
Rise in Heroin Deaths

- Rise started well before ANY regulation
- Occurring in all states, most of which have done no regs
- Main rise in heroin deaths in 18-30 year olds
- Main increase in prescription opioid deaths in 35-55 year age groups

Compton WM, Jones CM, Baldwin GT. Relationship between nonmedical prescription-opioid use and heroin use. NEJM 2016; 374: 154-163
Reducing acute/subacute opioid prescribing

AKA Preventing the next cohort of our citizens from becoming another “lost generation”

NGA 1. Prevent future dependence, addiction and overdose among our citizens

- Repeal permissive 1999 “model” pain language
- Adopt and operationalize the CDC guidelines via:
  - Setting new prescribing standards through state licensing boards
  - Leveraging public health care purchasing programs (e.g. Medicaid)
- Foster strong collaboration across public program at the highest level of state government and among leaders in the medical community
4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.
Second key to prevention: Protect our children and teenagers

• For patients ≤ 20 years, limit Rx’s to no more than 3 days (or 10 tabs) of short acting opioids for acute use
  • Dental extractions (56 million Vicodin 5 mg/year) and sports injuries at emergency department/urgent care
    ➢ NSAIDS or Tylenol preferred

• Could be implemented with system changes (eg, EMR “hard stops” or mandatory informed consent after 3 days)
Risk of prolonged opioid use increases by 1% per day after just 3 days—Martin, in preparation
NGA 2. Optimize capacity to effectively treat pain and addiction

- Deliver coordinated, stepped care services aimed at improving pain and addiction treatment
  - Opioid overdose case management
  - Cognitive behavioral therapy or graded exercise to improve patient’s functioning and ability to self manage their pain
  - Medication-assisted treatment (MAT) for patients with opioid use disorder - eg, increase regional capacity via Vermont spoke and hub method
- Increase access to pain and addiction experts for primary care via telepain (mentor consultation service)
- Incorporate these alternative treatments for pain and care coordination into payer contracts (e.g. Medicaid)
NGA 3. Metrics to guide both “state-of-the-state” and provider quality efforts

- Use a common set of metrics
- Start with public programs
- Establish a process for public/private implementation (e.g. WA statutory, governor appointed “Bree Collaborative”)
- Use metrics to notify outlier prescribers
Dentists and Emergency Medicine Physicians were the main prescribers for patients 5-29 years of age.

5.5 million prescriptions were prescribed to children and teens (19 years and under) in 2009.

Source: IMS Vector® One National, TPT 06-30-10 Opioids Rate 2009
Opioid use for third molar extractions by oral/maxillofacial surgeons

53 third molar extractions/month

4436 practicing OMFS (80%)

2.8 million third molar extractions/year with 20 tabs hydrocodone

56 million tabs hydrocodone/year
Mieche et al, Pediatrics, Nov 2015: Prescription opioids in adolescence and future opioid misuse

• Prospective panel data from the Monitoring the Future Study

• N=6220 surveyed in 12th grade and followed up through age 23

• Legitimate opioid use before high school graduation is independently associated with a 33% increase in the risk of future opioid misuse after high school. This association is concentrated among individuals who have little to no history of drug use and, as well, strong disapproval of illegal drug use at baseline.
Early opioids and disability in WA WC. Spine 2008; 33: 199-204

- Population-based, prospective cohort
- N=1843 workers with acute low back injury and at least 4 days lost time
- Baseline interview within 18 days (median)
- 14% on disability at one year
- Receipt of opioids for > 7 days, at least 2 Rxs, or > 150 mg MED doubled risk of 1 year disability, after adjustment for pain, function, injury severity
Claims With Opioid Prescriptions Within 6 to 12 Weeks of Injury

Percent claims with opioids within 6 to 12 weeks since injury

Percent of claims with opioids

- Moving Average
- Baseline within 6 to 12 weeks since injury

Data as of date: 7/3/2016

Report run date: 8/5/2016
The Mercier-Franklin Opioid Boomerang, 1991-2015 WA Workers Compensation

Projected Percent of Loss and Percent of Claims
Claims with Opioids Compared to All Claims

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<thead>
<tr>
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<tbody>
<tr>
<td>1991</td>
<td>54%</td>
<td>59%</td>
<td>64%</td>
<td>69%</td>
<td>74%</td>
</tr>
<tr>
<td>2009</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td>2010</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>2012</td>
<td>54%</td>
<td>54%</td>
<td>54%</td>
<td>54%</td>
<td>54%</td>
</tr>
<tr>
<td>2015</td>
<td>24%</td>
<td>24%</td>
<td>24%</td>
<td>24%</td>
<td>24%</td>
</tr>
</tbody>
</table>

Projected Percent of Claims With Opioids by Accident Quarter
The State of US Health, 1990-2010
Burden of Diseases, Injuries, and Risk Factors*

- Years lived with disability 2010
  - Low back pain      3.18 million YLD
  - Major depressive disorder     3.05 million YLD
  - Other MSK disorders       2.6 million YLD
  - Neck pain                    2.13 YLD
  - Anxiety disorders        1.86 million YLD
  - Diabetes (#8)             1.16 million YLD
  - Alzheimers (#17)          .83 million YLD
  - Stroke (#23)                 .63 million YLD

*JAMA 2013; 310: 591-608
THANK YOU!

For electronic copies of this presentation, please e-mail Laura Black

ljl2@uw.edu

For questions or feedback, please e-mail Gary Franklin

meddir@u.washington.edu