Opioid Prescribing: Ethical and Legal Considerations

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Objectives

1. Discuss ethical considerations in pain management
2. Review updates to Hawaii state law regarding opioid prescribing requirements
3. Integrate ethics, law, and clinical practice into a framework for safer opioid prescribing

Disclosure

- No conflicts to disclose
- I am not a lawyer
  - Nothing should be construed as legal advice
- I am not a bio-ethicist
  - Lessons from the trenches
- Focus on the practical

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Core ethical principles

- Autonomy
- Beneficence
- Nonmaleficence
- Justice

Autonomy

- Each patient has a right to consent to treatment consistent with his/her
  - ➢ Values
  - ➢ Goals
  - ➢ Life plan
- Expressing autonomy requires
  - ✓ Decision-making capacity
  - ✓ Informed consent

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Core ethical principles, cont'd

Beneficence: Actions are intended for the good of the patient

Nonmaleficence: Avoidance of harm to the patient

Justice: Fair and equitable treatment for all patients

Balancing Ethical Principles

Autonomy: What does/would the patient choose?

Beneficence: What does the most good for the patient?

Nonmaleficence: Does the burden or risk exceed the benefit?

Justice: Are patients treated equally and fairly?

Are resources equitably distributed?

Additional ethical principles

Veracity: truth telling

Fidelity: non-abandonment

Approach to ethical challenges

- Seldom a “right” vs “wrong”
- Focus on collaboration
  - Among patient, family
  - Balance autonomy with other imperatives
- It’s no fun alone!
  - Colleagues bring welcome perspective and objectivity
  - May better protect all parties
  - Guidelines and other resources useful

Autonomy in Opioid Prescribing

- Respect for autonomy mandates <u>informed consent</u>
- Physician obligation to inform re:
  - ✓ Treatment options/alternatives
  - ✓ Associated risks
  - ✓ Potential consequences

Expression of Autonomy Requires Capacity

- Consider the patient's ability to
  - ✓ Communicate a choice
  - ✓ Understand the relevant information
  - ✓ Appreciate a situation and its consequences
  - ✓ Reason rationally
- Intoxication or withdrawal may impair capacity

Common Autonomy Pitfall

- Patient may accept or decline offered treatments
- However autonomy does not mandate provider to prescribe
  - Antibiotics for common cold?
  - Opioids for chronic non-cancer pain?

Beneficence in Opioid Prescribing

- Beneficence: Patients are entitled to compassionate and effective care

Nonmaleficence in Opioid Prescribing

- Nonmaleficence: Providers are committed to safe care
- Thoughtfully balance risks
- If opioids are prescribed
    - Acute pain: short course (eg days not weeks or months)
    - Chronic pain: low dose trial of short-acting agents monitoring closely for functional improvement and adverse effects
    - Consider naloxone

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Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores
(30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

https://www.cdc.gov/drugoverdose/pdf/PDO_Checklist-a.pdf

Nonmaleficence and Fidelity

- Caution regarding
  - Misapplication of CDC guidelines (eg to surgical pain, cancer pain, sickle cell crisis)
  - Inflexible limitation of dose/duration
  - Abrupt opioid discontinuation
  - Overly rapid opioid weaning
  - Discharge/abandonment

D Dowell et al, NEJM, 2019

Nonmaleficence

HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

After increasing every year for more than a decade, annual opioid prescriptions in the United States peaked at 255 million in 2012 and then decreased to 191 million in 2017.[1] More judicious opioid analgesic prescribing can benefit individual patients as well as public health when opioid analgesic use is limited to situations where benefits of opioids are likely to outweigh risks. At the same time opioid analgesic prescribing changes, such as dose escalation, dose reduction or discontinuation of long-term opioid analgesics, have potential to harm or put patients at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

Risks of rapid opioid taper

- Opioids should not be tapered rapidly or discontinued suddenly due to the risks of significant opioid withdrawal.
- Risks of rapid tapering or sudden discontinuation of opioids in physically dependent[a] patients include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, and thoughts of suicide.[1] Patients may seek other sources of opioids, potentially including illicit opioids, as a way to treat their pain or withdrawal symptoms.[1]
- Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, HHS does not recommend abrupt opioid dose reduction or discontinuation.

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Urine Drug Screening: Ethical Considerations

- Informed consent advised
- Promotes trusting relationship
- Used for safety, not to be punitive

Hawaii Opioid Legal Update

Recent Legislation in Hawaii

- Act 217 (July 2015): Medical Amnesty
- Act 218 (July 2016)
  - Limited Schedule II opioids to 30 day supply
  - Mandated Prescription Drug Monitoring Program (PDMP) *registration*
  - Allowed PDMP delegates
- Act 68 (June 2016): Expanded access to opioid antagonists

Recent Legislation in Hawaii

- Act 66 (July 2017):
  - Required policy and procedure for informed consent for opioid therapy
    - Effective July 1, 2018
    - DOH has provided a template (available online)
    - Qualifying patients:
      1. More than three months of therapy
      2. Concurrent benzodiazepine therapy or
      3. > 90 mg morphine daily equivalent

Recent Legislation in Hawaii

- Act 66 (July 2017):
  - Initial concurrent opioid and benzodiazepine prescriptions limited to 7 days except for
    - Post-op pain
    - Chronic pain
    - Substance use or opioid dependence
    - Cancer pain
    - Hospice or Palliative Care

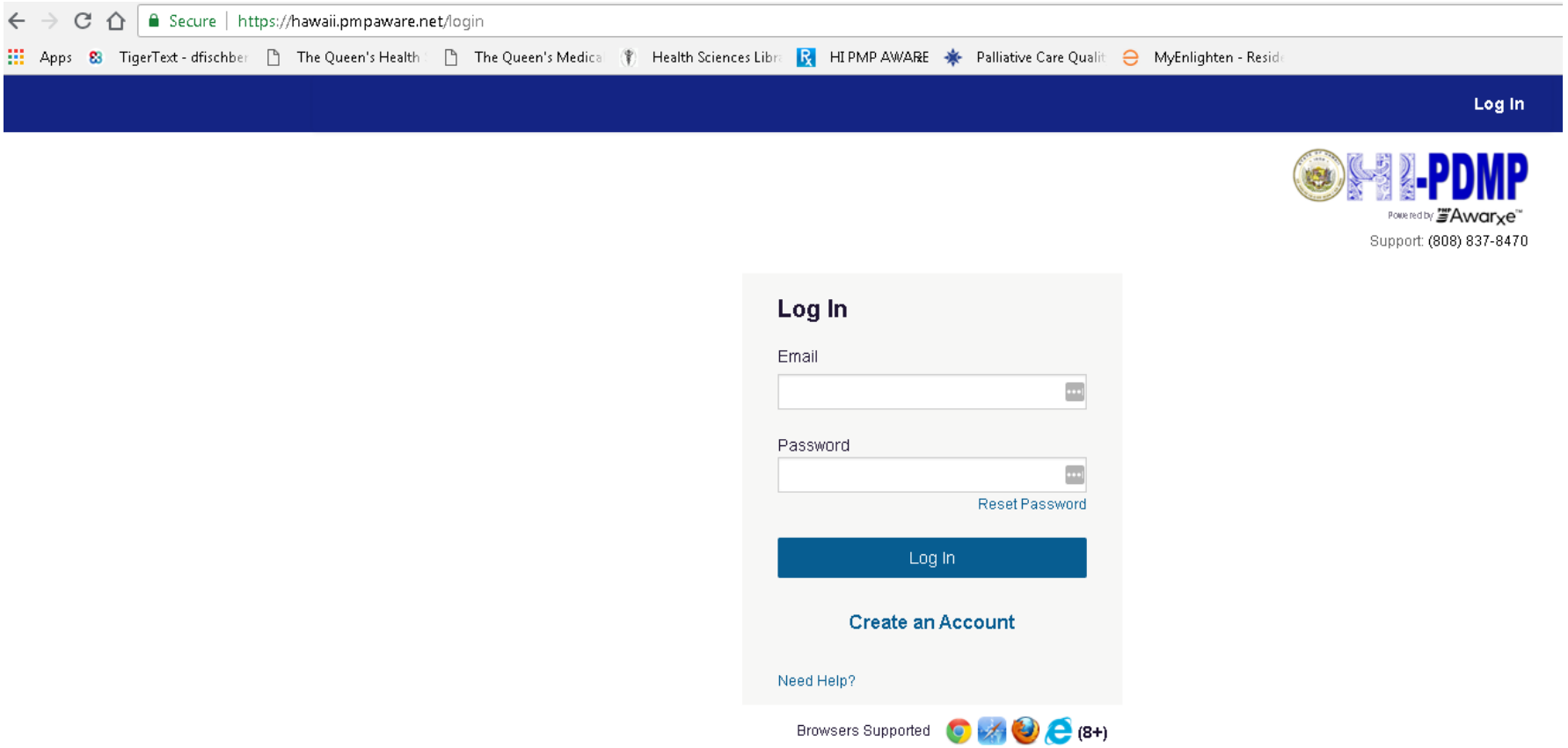
Recent Legislation in Hawaii

- Act 151 (July 2018):
  - Effective August 1, 2018
  - Mandated opioid warning label
  - “Caution: Opioid. Risk of overdose and addiction.”

Recent Legislation in Hawaii

- Act 153 (June 2018):
  - Effective July 1, 2018
  - Mandated provider *query* PDMP prior to prescribing any schedule II, III, IV meds except
    - ➢ Quantities of 3 days or less prescribed in an emergency situation
    - ➢ When PDMP not operational

Hawaii Prescription Drug Monitoring Program



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Mahalo

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