Opioid Treatment Agreements:

Opportunities, Challenges, and Ethics Issues

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Disclosures

- I have no relevant conflicts of interest to disclose

Objectives

1. Describe the role of opioid treatment agreements and the components of a standard document.
2. Discuss ethical concerns raised about opioid treatment agreements, including possibilities of coercion, stigmatization, abandonment, and harm to the doctor-patient relationship.
3. Demonstrate how use of an opioid treatment agreement can support respect for persons by improving informed decision-making.
4. Discuss the patient health and public health justifications for the surveillance and monitoring of opioid pain medications.

Case

Mrs. Balm is a 62 year old cancer survivor. She has had neurotoxic chemotherapy, radiation and surgery as part of her treatment, which led to chronic pain. She had been on morphine 15 mg, 4 times a day, for 10 years, since finishing her cancer treatment.

Due to insurance issues, she changed primary care practices 2 years ago to your clinic, and her new team attempted to get her off opioids.

After trying many other medications with limited benefit and increased cost and side effects, morphine 15 mg 4 times a day is restarted. She signs an Opioid Treatment Agreement with her provider. Initially, she reports much improved function.

After 6 months, you review her chart, and see that she has called for early refills 4 of the 6 months, and called once to request a new prescription because she "lost" her medication. You also notice there are notes of some angry calls she has left the nursing staff when requested to come in for a routine urine drug screen. What will you do? What are your concerns?

2011 Institute of Medicine Report:
Relieving Pain in America:
A Blueprint for Transforming Prevention, Care, Education, and Research

Underlying principles for report:

- Pain management is a moral imperative
- Chronic pain can be a disease in itself
- The value of comprehensive treatment
- The need for interdisciplinary approaches
- The importance of prevention
- Wider use of existing knowledge
- Recognition of the conundrum of opioids
- Collaborative roles for patients and clinicians
- The value of a public health and community-based approach

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Pain is a public health problem

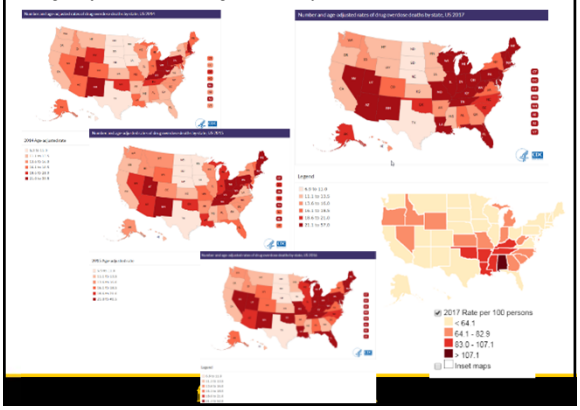
- Affects at least 100 million American adults (not including people in long term care facilities, the military, or prison)
- High costs to society
- Reduces quality of life
- Comprehensive and interdisciplinary (e.g., biopsychosocial) approaches are the most important and effective ways to treat pain
- Such care is difficult to obtain because of structural barriers – including financial and payment disparities
- A cultural transformation is needed to better prevent, assess, treat, and understand pain

Opioid Epidemic

- In 2013, more than 16,000 people died from an opioid overdose, and nearly 2 million abused or were dependent on prescription opioids
- From 1999 to 2017, nearly 218,000 people have died in the United States from overdoses related to prescription opioids
- Overdose deaths involving prescription opioids were five times higher in 2017 than in 1999
- In 2017, prescription opioids were involved in more than 35% of all opioid overdose deaths
- 46 people die every day from overdoses involving prescription opioids
- Current estimates are that somewhere between 0.7 – 6% of patients treated with opioids develop addiction

Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov.
Center for Disease Control and Prevention, Prescription Drug Overdose Data http://cdc.gov/overdose/data
Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017. Morb Mortal Wkly Rep. ePub: 21 December 2018

Age-adjusted rates of drug overdose by state, 2014-2017, and Rx Rate



Opioid Treatment Agreements

- Terminology – Opioid Treatment Agreements (OTA) or Patient-Provider Agreement (PPA) or Opioid Contracts
- Role – to explicitly state roles and responsibilities, risks and benefits, how drugs should be refilled and stored, use of tests and restrictions, along with consequences
- Goal – to improve outcomes, reduce opioid misuse and abuse, improve patient education, reduce risk of overdose

Opioid Treatment Agreements

- From Iowa Code:

g. Pain management agreements. A physician who treats patients for chronic pain with controlled substances shall consider using a pain management agreement with each patient being treated that specifies the rules for medication use and the consequences for misuse. In determining whether to use a pain management agreement, a physician shall evaluate each patient, taking into account the risks to the patient and the potential benefits of long-term treatment with controlled substances. A physician who prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain shall utilize a pain management agreement if the physician has reason to believe a patient is at risk of drug abuse or diversion. If a physician prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain and chooses not to use a pain management agreement, then the physician shall document in the patient's medical records the reason(s) why a pain management agreement was not used. Use of pain management agreements is not necessary for hospice or nursing home patients. A sample pain management agreement and prescription drug risk assessment tools may be found on the board's website at www.medicalboard.iowa.gov.

(downloaded 5/15/19 from the IAC's Chapter 13 STANDARDS OF PRACTICE AND PRINCIPLES OF MEDICAL ETHICS: https://www.legis.iowa.gov/docs/iac/rule/06-06-2018.653.13.2.pdf)

Iowa Medical Board sample Pain Management Agreement

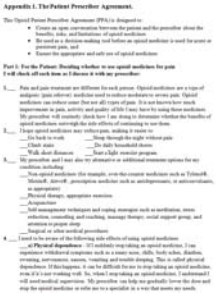
1. **PURPOSE:** The purpose of the Pain Management Agreement (Agreement) is to prevent misunderstandings about certain controlled medications you will be taking for pain management. This is to help both you and your physician (provider) to comply with the law regarding controlled medications. I understand that this Agreement is essential to the trust and confidence necessary in a physician/patient relationship and that my physician undertakes to treat me based on this Agreement.

2. **VIOLATION:** I understand that if I break this Agreement, my provider will stop prescribing these pain control medications, and may terminate my care. In this case, my provider may choose to taper me off of my medications, or discontinue medications and prescribe medication to treat the withdrawal symptoms. This choice will be made my provider.

3. **COMMUNICATION:** I will communicate fully with my provider about the character and intensity of my pain, the effect that my pain has on my daily life, and how well the medications are helping to relieve my pain.

https://medicalboard.iowa.gov/sites/default/files/documents/2017/11/pain_management_agreement_2012_.pdf

Patient Prescriber Agreement. Pergolizzi et al



Pergolizzi JV, Curro FA, Col N, et al. A Multicentre evaluation of an opioid patient-provider agreement. Postgrad MedJ 2017; 93: 613-617

Evaluation of a Patient Provider Agreement

- FDA Safe Use Initiative Opioid PPA Working Group
  - Developed a PPA and tested it for acceptability, education, bias, and feasibility of incorporating it into a clinical visit
  - 14 providers at urban centers, 117 patients
  - 89% of patients felt it was neutral, 97% "easy to understand," and 88% said it was "just right" in length
  - 84% of providers said it could be administered in < 10 min
  - 59% of providers said it did not change therapeutic relationship, and 33% said it had a positive impact

Pergolizzi JV, Curro FA, Col N, et al. A Multicentre evaluation of an opioid patient-provider agreement. Postgrad MedJ 2017; 93: 613-617

Should OTAs be applied universally?

- Concerns include:
  - There are no universally agreed upon standards
  - The patient may not understand the language
  - Formal contracts may intimidate rather than empower
  - The physician-patient relationship could be altered by stigmatization, mistrust, and coercion
  - It is not clear whether they are effective in reducing opioid misuse and abuse

Ethical issues - concerns

- Stigmatization
  - Patients with chronic pain often already feel stigmatized, and requiring that they sign a form makes some feel as though they are perceived as deviant
  - Differentiating between malignant pain and non-cancer pain
- Coercion
  - If a patient has no choice but to sign in order to have their pain treated, is that a meaningful choice?
  - Will patient-centered discussions be replaced by forms?
- Abandonment
  - A patient's violation of the agreement does not eliminate the clinician's ethical duty to care for the patient, but many are dismissed due to violations
  - Will OTA lead to discrimination against patients who are more complex, challenging, or vulnerable, allowing clinicians to dismiss patients who need care?

Richard Payne, "Opioid Treatment Agreements Repurposed – But Who Monitors the Monitors?" Hastings Center Report 47, no. 3 (2017): 36-37; and "A Rose by Any Other Name"
JL Starrels, et al, "Systematic Review: Treatment Agreements and Urine Drug Testing to Reduce Opioid Misuse in Patients with Chronic Pain." Annals of Internal Medicine 152, no 11 (2010): 712-20

Ethical issues - concerns

- Lack of efficacy
  - In a systematic review, only weak evidence was found to support the use of opioid agreements in 2010, and other reviews have found insufficient evidence to support
- Who does an OTA benefit?
  - An individual patient
  - Clinicians
  - Healthcare systems
  - Society

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Ethical issues - arguments in favor

- Utilitarian
  - In order to minimize the risk of addiction and abuse (greater good), some who have pain for which opioids are efficacious and who do not abuse them may go untreated or may feel stigmatized
  - There is limited evidence on the efficacy of opioids for chronic pain, so is there a great risk to undertreatment?
- Public health
  - Justification for surveillance and monitoring to improve public health provides the ethical basis (rather than direct benefit to the patient)

Joshua B. Rager and Peter H. Schwartz, "Defending Opioid Treatment Agreements: Disclosure, Not Promises," Hastings Center Report 47, no. 3 (2017): 24-33

Ethical issues - arguments in favor

- Clinical ethics
  - **Autonomy / Respect for persons** - disclosure of the requirements allows a patient to make an informed decision about whether to accept the treatment along with the limitations to their individual freedom
  - **Primacy of patient welfare** – allowing benefit where possible, while minimizing harms by discussing risks with all patients and using other treatments in those not felt to be safe candidates for opioid use
  - **Justice** – providing the same process for all patients who meet certain criteria, thus decreasing discrimination

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Ethical issues – Virtues

- Wisdom
- Judgment
- Courage
- Honesty
- Social intelligence
- Fairness
- Prudence
- Forgiveness
- Hope

Impact of Opioid Stewardship

- Urine drug tests, pill counts, and pharmaceutical monitoring do have evidence for identifying abuse and diversion – and may be part of an overall Opioid Stewardship program that an OTA can disclose and make applicable in a more just way
- States that have implemented policies with tighter restrictions and monitoring, have seen decreases in deaths due to opioid overdoses

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