The Medical Stasi: Is Risk Management for Controlled Substances Destroying the Provider-Patient Relationship

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Disclosures

- Jennifer Bolen, JD
  - None
- Douglas Gourlay MD
  - None
- Stephen Ziegler, PhD, JD
  - None
Learning Objectives

- Explain the challenges of risk management in the use of controlled substances from clinical, ethical, and legal perspectives
- Describe the uncertainties associated with current risk management tools and dealing with patient deception
- Describe the concept of “high dose” as it applies to opioid pharmacotherapy, inherited patients, and apply new strategies to turn these challenges into opportunities

Introduction

- Today, we have the opportunity to explore some of the key clinical, ethical, and legal issues from the perspective of 3 thought leaders in their fields
  — Stephen Ziegler PhD, JD – Moderator & ethical perspectives
  — Douglas Gourlay, MD – Clinical perspective
  — Jennifer Bolen JD – Legal perspective
Introduction

- Pain & Rx problem in America
- Multiple governmental interventions (REMS). Have they harmed or helped patients and the therapeutic relationship? What if there was a lack of, or conflict in, evidence about the efficacy of these interventions?
- High dose therapy and inheriting patients
- Patient deception

Ethical Foundations

- Ethical conflicts in and between clinical medicine and law
- 4 principles of medical ethics (gives us a start)
  - Autonomy
  - Nonmaleficence (do no harm)
  - Beneficence (do the best, be the best, patient welfare)
  - Justice/fairness
Individual vs Society vs Government?

- Practice of medicine does not exist in a vacuum
- Who are you treating?
  - Individual or society?
  - Have you become an “unwitting agent” of government?
    - Martino’s Ethic of Under RX
    - Do you need the truth? Can you handle the truth?

Clinical Dilemmas

- If we have no solid evidence that REMs accomplishes their intended goals but we have some evidence of unintended costs, what should we do?
  - Treatment agreements, UDTs, ADFs
  - Medical futility and conscientious objectors in the War on Drugs
- Opioid refugees: inheriting the person in pain. What if someone else lit the fuse before you? Who decides what is an “unacceptably high dose of opioids?”
- Does a patient have a fundamental right of nondisclosure of certain/any aspects of their lives? If so, what if any exceptions are there?
Clinical Dilemma I: REMS

• Is there any evidence in the literature to suggest that our REMs efforts reduce morbidity or mortality? – NO
  — Specifically, does urine drug testing improve outcomes?
    • In the patient population seeking treatment for drug/alcohol problems our current thinking is “if you don’t monitor, you can’t manage”
    • Does this apply to the pain management population?
  — If UDT is used in this context, should it be a ‘clinical’ requirement or a regulatory requirement?
    • Does it matter? – YES

Clinical Dilemma I: REMS (cont’d)

• Does it matter who requires the test? – Probably YES
  — If the prescriber requires the test, the results may ultimately undermine, rather than support, the clinical relationship
  — If the government requires the test, the therapeutic alliance isn’t threatened
    • The clinical dyad can work together to deal with this requirement
      — The clinical dyad is threatened when the clinician is asked/told to do things (order a UDT etc) that may uncover information that challenges this dyad
    • The pretest probability of useful information coming from these tests might be very low – in a SUD population, it is very high
Clinical Dilemma I: REMS (cont’d)

▪ What if the patient doesn’t want this help? Do we have a right or obligation to confront our patients?
  – Is this consistent with the concept of “readiness to change”?
  – Does this promote or diminish the therapeutic alliance?
  – Is there really patient-centered UDT?
    ▪ In the context of substance use treatment – YES
    ▪ In the case of chronic pain management? – Not so clear

Clinical Dilemma I: REMS (cont’d)

▪ Can we ignore the government involvement this problem?
  – Congressional intervention in 2000 with the Decade of Pain Control and Research
  – Approval of yet another opioid medication to add to the vast array of medications on the market
  – Approval of generic versions of low cost, high potency opioids
Clinical Dilemma II: Opioid Refugees

- What = high dose and who should decide?
- Treating your current patients
- Treating opioid refugees – challenges with the inherited patient

Clinical Dilemma III: Deception

- When we order a HgA1c, we do it because we KNOW it can be useful in optimizing glycemic control and so, improve clinical outcomes
  - But hyperglycemia isn’t illegal – we don’t challenge patients and threaten discontinuation of therapy because of an abnormal result
  - In this case, the therapeutic alliance is preserved and probably strengthened by the test and subsequent efforts to optimize glycemic control
Clinical Dilemma III: Deception (cont’d)

▪ Recently, the courts seem to expect prescribers to know when their patients are being untruthful
  — Hindsight is always 20/20 – especially in court
▪ What should a reasonably prudent clinician be expected to know?
  — When what we think we know and what is really going on becomes obviously discrepant, the answers are easier than when the first sign of problems is a DEA investigation

Clinical Dilemma III: Deception (cont’d)

▪ Our first duty is to our patient
  — What happens when the patient suffers from a condition that causes them to lie?
    * Primum non nocere
▪ How far should we go to uncover “the truth?”
  — Do patients have the right to not disclose everything about their lives?
  — Do we have a therapeutic responsibility to uncover information about the patient?
    If so... at what cost?
Clinical Dilemma III: Deception (cont’d)

- In the context of prescribing controlled substances, a prudent clinician has a certain duty of care
  - This duty is not only to the patient but also to the system
    - We are trained to exercise reasonable caution in the prescription of controlled substances
      - The concept of “balance” between therapeutic availability and regulatory control is key – prescribers are an important part of this
        » If you KNOW that the drugs are being misused, our duty is clear
        » But how far should we be expected to go to uncover misuse?
          - UDT? PDMP? Criminal background checks?

Clinical Dilemma III: Deception (cont’d)

- In clinical care, we (the prescribers) should know certain things
  1. We are required to give the patient acceptable instructions on how to use medications we prescribe
  2. We should also inquire/document how the patient says they are using these medications – if other than above
  3. We need to appreciate that patients may be using medications other than ‘as prescribed’ – they could be lying
Clinical Dilemma III: Deception (cont’d)

- As clinicians, we can really only know the first 2
  - What the patient is actually doing is beyond our ability to know
- If the judiciary are taking the position that
  - “...because the patient could be lying – we should prescribe controlled substances – as if they were lying until we have incontrovertible proof to the contrary” we are in deep trouble!
    - This incontrovertible proof is rarely available
    - Risk is also dynamic – it must be continuously evaluated
    - The extent to which this evaluation must reach – is the debate!

Summary

- Ethical, legal, and clinical conflicts continue
- What is best for the person you are treating?
- Remain up to date
- Document! Document! Document!
- Become a voice for change
The “Government” Is More Aggressive These Days

- Willing to use experts who are:
  - NOT currently practicing medicine
  - Willing to testify that you, the prescriber, MUST EXHAUST ALL evidence-based conservative treatments BEFORE using opioids!
  - And it gets worse…

- Willing to put the practice of using opioids on trial, instead of the actions of the individual defendant/practitioner by focusing on:
  - Opioid dosing, even if clearly within the FDA drug label.
  - Chronicity of prescribing, even in the face of documented benefit.
  - Combination opioid prescribing – lao + soa.
  - Reported pain levels instead of function.
  - Total dosage units based on all opioid prescriptions written over a period of time.
  - Consequences associated with patient (Pt) aberrant-behavior, including the patient’s use of marihuana (medical or not).

- Willing to use the Pt (living or not) against the HCP & it does not seem to matter that the Pt:
  - Lied to the practitioner.
  - Died of other causes, so long as there opioids in their system at the time of death.
  - Also has a responsibility in the physician-patient relationship.
LEGAL STANDARD: A prescription for a controlled substance is valid ONLY IF:

- Meets all technical requirements
- Dated properly, DEA#, Sig, Proper Fill Instructions, Signature, and some pharmacies insist on diagnosis on face of Rx.

Legitimate Medical Purpose

- Usual Course Professional Practice
- Reasonable Steps to Prevent Abuse and Diversion

Valid CS Rx

**Legitimate Medical Purpose**

Think: Patient General Medical and Pain Specific History

- Diagnostics
- Diagnosis
- One or more generally* accepted Indications for the Use of a CS
- Well written treatment plan with treatment goals
Usual Course of Professional Practice

Think:
Licensing Board Rules, Guidelines, and the “standard of care”

Risk Evaluation (Behavioral and Medical) and Informed Consent

Treatment Agreement  Periodic Review and Monitoring  Consultations and Referrals  Documentation, Documentation, Documentation  Comply with all other controlled substances laws and regulations

Reasonable*? Steps to Prevent*? Abuse and Diversion

Think: Initial and Ongoing Risk Monitoring

Visit Frequency, Control of Drug Supply, and Use of PDMP  Drug Testing  Behavioral and Medical Risk Evaluation Tools  Use* of Consultations and Referrals
Individualized Care, Well-Documented

Think: justify each treatment very carefully; well-documented rationale . . .

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<th>Use of Opioids</th>
<th>Opioid Selection, Dose, Chronicity</th>
<th>Ongoing Prescribing in the Face of Risk(s)</th>
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Conclusions

- The prescription drug problem in America is very real
  - But it is a multidimensional problem requiring multidimensional solutions
  - The moral imperative to “do something” shouldn’t excuse poorly thought out policies or implementation of policies which invariably have both intended and unintended consequences
  - The war on drugs, as applied to this problem is adversely impacting both patients and practitioners alike
    - The government must not expect clinicians to read the minds of our patients – to expect otherwise is to hold us to an impossible standard
References

- Doust J, Del Mar C. Why do doctors use treatments that do not work? BMJ 2004; 328 (7438), 474.
- Fishman SA. Universal Precautions and Distrust. Pain Med; 2006; 7(2) 212.

References

- Rich BA. The war on drugs versus the war on pain: surviving two perfect storms. Pain Manag 2012; 2(6).:523-6
References