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

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Disclosures

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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 Pt deception
- Describe the concept of “high dose” as it applies to opioid pharmacotherapy, inherited patients, and apply new strategies to turn challenges into opportunities to improve patient care

Risk Management

- Risk management = principle of balance
- Managing risk = perfection?
- Majority Pts not problem, notorious 6%?
- Govt intervention in RM (state, fed)
- Good intentions; Intended & unintended impacts Sigler et al
- Foreseeable? Yes. Remedial? Rarely
- Hydraulic pressure=do something! = C, L, E dilemmas
Hydraulic pressure

- Korematsu
- Great cases, like hard cases, make bad law... because of... some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment. These immediate interests exercise a kind of hydraulic pressure which makes what previously was clear seem doubtful, and by which even well settled principles of law will bend.[emphasis added]
  - Justice Holmes (dissenting in *Northern Securities Co. v. United States*, 193 U.S. 197 (1904))
- The Power of the Narrative

Preliminary considerations

- K
- Treatment agreement (Not a K)
- Informed Consent (distinct, on-going)
- Individualized treatment vs Govt one-size-fits-all?
- Practice of med: Fund moral enterprise
- Relief of P & S ancient duty of HCPs
- Is the government acting unethical?
Ethics

- AMA Code of Ethics
- Code of ethics is a guide. Unethical conduct may = breach of professional conduct= investigation
- 4 Classic ethical principles to guide decision making (not equal, internal conflict):
  - Do no harm – EOL, e.g. (Non-maleficence)
  - Do what is best for patient (Not society, family, etc) (Beneficence)
  - Justice (Societal concern? Dialysis)
  - Respect for autonomy (EAR) (nulla actio impunita?)
- Trust- essential to therapeutic relationship. Distrust = less disclosure

Rx brings a mix of challenges (C, L, E)

- Duty of care to Pt
  - Respect for autonomy
  - Do no harm
  - Do what is in their best interest
- BUT duty of care to society
  - Justice, fairness
  - Follow the law (legit med purpose)
Ethical dilemma? Can we talk?

- Swear you are not the government?
- Run criminal history on your patients?
  — Let’s consider

Is the government encouraging unethical behavior?

- Rich (2000): The message that has been sent and clearly received by physicians is that their primary responsibility is to help regulators prevent drug diversion, not to effectively manage the pain of their patients
- Have you become an “unwitting agent” of government?
  - Martino’s Ethic of Under RX
- Treatment agreements, trust, and reduction of harm.
  — Another uninformed government mandate OR Opportunity for real dialogue but NO: “just sign here”
Government’s solution: Make it illegal

- California v Robinson, 370 U.S. 660 (1962)
- Crime: to be addicted to narcotics” (status/condition)
- C, L, E concerns?
- Non-disclosure, 8th Amendment, Justice
- Indiana mandatory UDTs.
- 4th Amendment, Respect for autonomy, Whose interests are being advanced?

Are you an HCP or policeman?

- Dr. Feelgood (A case scenario) - Netflix
- Evidence of legitimate treatment
- Out of state patients
- Refugees?
- Sanctioned by state medical board
- Knew some were diverting (defined)
- Not your problem?
Knowledge and imputed knowledge

- If know, or should have known Rx being diverted, duty clear (William Hurwitz).
- But how far should we be expected to go to uncover “Misuse or abuse”? Running criminal histories appropriate (clinically, ethically, legally)? Why?
- No Ostriches. Imputed knowledge

Good intentions by Govt creates dilemmas

- PDMP: Have you run yourself lately? Good idea in theory BUT . . .
  - Funding
  - Not universal (housing, rules, privacy, reporting, use)
  - Big brother is watching: Sigler et al
- Lack of coordination in U.S. = multiple threats & wide variation. cf France
- State Rx guidelines or rules misinterpreted (WA MEMO)
- Pill mill legislation as an excuse to opt out?
- Check out this email excerpt . . .
Rumor Based Medicine or emerging issue?

- A pain clinic, claiming compliance with DEA and CDC requirements for opiate reduction, have scheduled all patients (1000) for interventions and reduced all to 45 MED no matter their diagnosis or payor source.

- Refusal to 'go along' is resulting in discharge without referral.

- “I am thinking of sharing your email with my orthopedic colleagues, the ones who have discharged all their opioid patients. What bothers me much more is that at least once a day I see a patient who has been well managed for years on opioids who has been discharged by his or her primary care doctor, often with no referral. One patient almost died from going into withdrawal. What bothers me is that the doctors are blatantly lying to their patients, claiming they can no longer prescribe because of the governor's new rules. Having written the original rules and having consulted on [them], I know that is a lie, and it saddens me that doctors can be so un-ethical.”

FDA and ADFs

- FDA: History of risk management
- Package inserts (1970, oral contraceptives)
- Success: Thalidomide – restricted distribution system –
- ADF’s the new flavor of the month?
- How many have heard of ADF’s? Indiana, e.g., 844 IAC 5-6-2 Definitions
Emerging Risk Management Tool: 
Abuse Deterrent Formulations

- FDA: Opioids with abuse-deterrent properties are tablets or capsules that are designed to deter abusers from crushing them into a powder for swallowing, snorting or injecting to create a faster, more intense high.
- Different technological approaches by pharma industry
  - Physical barrier (Tamper resistant)
  - Aversion
  - Use of Agonist & Antagonist
  - Prodrug (conversion in GI tract)
- ADFs are not without their own challenges . . .

ADF Challenges: Good idea in theory

- Is it the same? Some have extra material (original + tech)
- What about the cost to pharma Industry? Unchartered territory and may not receive AD label
- Cost to Insurance? New Orleans controversy
- Cost to your practice (phone)
- Cost to Individual?
  - Co-pays
  - Stigma
  - Effectiveness
  - Collateral and subsequent impacts for Rx to patient
Clinical Dilemma: Patient deception

- What do patients lie about? (Is there a top ten list)?
- Are all deceptions the same?
- 50/50 accuracy
- Patient autonomy BUT deception could impact therapy (cause harm)?
- Detecting via UDTs? Who answered the phone? Fire the patient?

Tips

- Plan ahead
- Seek assistance (consults, Assn, etc)
  - See, eg, Indiana State Med Assoc: “Legal, regulatory information and more at your fingertips on www.ismanet.org” (e.g. Answers for Actions)
Clinical Dilemma: Opioid Refugees & High Dose

- Opting out = opioid refugees
- What concerns do you have about inherited pts?
- What = high dose?
- Calculating MED – fraught with danger (see CDC)
- Who should decide what = high dose?
- Tapering? Whose interest is being advanced?
- Referral and follow up

Summary

- Risk Management = Effort at balance
- Reasonableness, not perfection
- Small percentage = problem acute, chronic
- Screening can be valuable
- Govt efforts can be unethical – create C,L,E conflicts
- Need help? Get help
- Document! Document! Document!
  — Documentation (consistent with good care)
- And finally. . .
Become a voice for change

- A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient
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 – too + too.
  - 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
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)  Treatment Agreement  Periodic Review and Monitoring  Consultations and Referrals  Documentation, Documentation, Documentation  Comply with all other controlled substances laws and regulations

Informed Consent

27

28
## Reasonable*? Steps to Prevent*? Abuse and Diversion

**Think: Initial and Ongoing Risk Monitoring**

<table>
<thead>
<tr>
<th>Visit Frequency, Control of Drug Supply, and Use of PDMP</th>
<th>Drug Testing</th>
<th>Behavioral and Medical Risk Evaluation Tools</th>
<th>Use* of Consultations and Referrals</th>
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## Individualized Care, Well-Documented

**Think: Justify each treatment very carefully; Well-documented rationale for**

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<tr>
<th>Use of Opioids</th>
<th>Opioid Selection, Dose, Chronicity</th>
<th>Ongoing Prescribing in the Face of Risk(s)</th>
<th>Ongoing Prescribing in the Face of Patient Reported, Perceived/Potential Contraindications for Use of Opioids</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.
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