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

Stephen Ziegler, PhD, JD

Disclosures

- Stephen Ziegler, PhD, JD
  - Drug & Health Policy Consulting, LLC – Owner
  - Mayday Pain & Society Fellow
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

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 to do something results in C, L, E
Preliminary Considerations

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

Ethics

- AMA Code of Ethics
- Code of ethics is a guide. Unethical conduct may = breach of professional conduct = investigation
- Classic ethical principles to guide decision making (not equal, internal conflict):
  - Do no harm – EOL, eg, (nonmaleficence)
  - Do what is best for patient (not society, family, etc) (beneficence)
  - Justice (societal concern? dialysis)
  - Respect for autonomy (EAR, epistemic humility, and PPI)
  - Trust: essential to therapeutic relationship. Distrust leads to less disclosure and noncompliance
Are You Treating Individual or Society?

- Treatment agreements and trust
  - Have you become an “unwitting agent” of government?
    - Martino’s Ethic of Under RX
- Indiana UDTs and the 4th Amendment
- 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

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

- Duty of care to Pt (do no harm, do in best interest)
- BUT duty of care to society (justice, fairness)
- AND duty of care in the law (legit med purpose)
- Knowledge and liability
- 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”? No Ostriches. Imputed knowledge
Good intentions by Govt creates dilemmas

- PDMP: Good idea in theory: Have you run yourself lately? Challenges:
  - Funding
  - Not universal (housing, rules, privacy, reporting, use)
  - Big brother is watching: Sigler et al
- Who wants to be investigated? Weinstein and race to the bottom
- France coordinated vs A) multiple threats in US, B) wide variation, C) lack of law enforcement coordination (MI)
- State Rx guidelines or rules (WA state push back on CME)
- Treatment agreements, may not be effective but NO just sign here!
- Pill mill legislation as an excuse?

Multiple GOVT Interventions: Paved with good intentions

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

- Abuse – dose dumping – routes of abuse
- Solution: ADFs
- ADF approaches, not mutually exclusive
  - Physical barrier (tamper resistant)
  - Aversion
  - Agonist/antagonist
  - Prodrug
- But ADFs are not without their own challenges . . .

ADF Dilemmas

- Is it the same? Some have extra material (original + tech)
- What about the cost to pharma industry?
- Insurance? New Orleans controversy
- Cost to your practice (phone)
- Cost to individual?
  - Why are you Rx? For patient or unknown 3rd party diverter?
  - Co-pays
  - Stigma
  - Effectiveness
  - Collateral and subsequent impacts for Rx to patient
Another Clinical Dilemma: Patient Deception

- Multiple forms of deception: How do you define?
- Difficult to detect on its face
- How far should we go to uncover “the truth?”
- Do we have a therapeutic responsibility to uncover information about the patient?
- Patient autonomy BUT deception could impact therapy (cause harm)
- Why would patients deceive?
- What do you do? San Diego detective
- Plan ahead, seek assistance (consults, Assn, etc)

Clinical Dilemma: Deception (cont’d)

- UDTs? Who answered the phone? Fire the patient?
- See, eg, Indiana State Med Assoc: “Legal, regulatory information and more at your fingertips on www.ismanet.org” (eg, Answers for Actions)
- Reasonableness, not perfection, and document
Another Clinical Dilemma: Opioid Refugees & High Dose

- What = high dose and who should decide?
- Treating opioid refugees – challenges with the inherited patient
- Opting out? See WA DOH memo
- Tapering. Whose interest is being advanced?
- Referral and follow up

Summary

- Risk management = effort at balance
- Clinical, ethical, legal conflicts
- Remain up to date
- Get help
- Document! Document! Document!
- 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

Jennifer Bolen, JD

Legal Issues in Pain Management:
Who is Watching the Fox?
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 – luo + sao.
  - 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 patient (living or not) against the HCP & it does not seem to matter that the patient:
  - 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 for . .

Use of Opioids

Opioid Selection, Dose, Chronicity

Ongoing Prescribing in the Face of Risk(s)

Ongoing Prescribing in the Face of Patient Reported, Perceived/Potential Contraindications for Use of Opioids
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

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