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

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Disclosures

- Stephen J. Ziegler, PhD, JD
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  - Mayday Pain & Society Fellow
    - Balanced policies
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 these challenges into opportunities

Risk Management

- Efforts to minimize harm and ensure approp access
- Management of risk = perfection?
- Most not a problem, but the notorious 6%?
- Abundance of approaches state and federal
- Intended, unintended consequences (negative impact on patient care)
- Foreseeable, but remedial too?
Preliminary considerations

- K
- Cf Treatment agreement = tool BUT NOT a K (unequal bargaining power, deficits)
- Separate from IC, but Indiana mixes? 844 IAC 5-6-5 Physician discussion with patient; treatment agreement
- As to actual Tx, pain individualized -- do what is right
- What = “right”? 
- Practice of med: Fund moral enterprise, relief of P & S ancient duty of HCPs

Ethics

- Medical board of California: Code of ethics is a guide. Unethical conduct may amount to a breach of professional conduct which the BD will investigate
- AMA. See, e.g., http://www.ismanet.org/legal/ethics.htm
- Classic ethical principles to guide decision making (do no harm, do what is in the patient’s best interest, justice, and respect for autonomy)
- Ranking, conflicts BTW 4 principles, conflict law
- Informed consent (on going), epistemic humility and PPI
- Trust- essential to therapeutic relationship
  — Distrust leads to less disclosure and non-compliance
  — No blind trust
Individual vs Society vs Government?

- Who are you treating? The individual, society, both?
  - 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

Shared and Balanced

- In Rx, it is a mix of challenges (CLE)
- Duty of care to Pt (do no harm, do in best interest)
- Duty of care to society (justice, fairness)
- Duty of care in the law (legit med purpose)
- Conflict is the foundation of balance
- If know, or should know, Rx being diverted, duty clear (No Billy)
- But how far should we be expected to go to uncover “Misuse”?
Multiple GOVT Interventions: Paved with good intentions w/multiple CLE challenges

- PDMP: Good idea in theory, challenges though
  - Funding
  - Not universal (housing, rules, privacy, reporting, use)
  - Triplicate Rx program + unintended negative impacts
- Licensing (historical, dance with who you brought- not best at self REG: Indiana unlawful but unethical? 844 IAC 5-2-8 Peer reviews
- State Rx guidelines and rules (Common: Pt Eval & screening, Tx plan, IC, Periodic review, consults, complete medical records, regulatory compliance, exit strategy)
- Treatment agreements (not same as IC) – No “just sign here” discuss!
- Pill mill legislation (opting out excuse)

Multiple GOVT Interventions: Paved with good intentions

- Prosecutions of prescribers – multiple forums –
  - Not all investigated the same – and race to the bottom?
- FDA: History of risk management
  - Package inserts (1970, oral contraceptives)
  - Thalidomide – restricted distribution system - success
  - 2007 Amendments > FDA REMS authority (e.g., med guide EASU (training, setting), Comm plan, eval—BUT lost opps
    - Label changes (ceiling, upscheduling)
    - ADFs and the government’s push
Emerging Risk Management Tool: Abuse Deterrent Formulations

- Abuse – dose dumping – routes of abuse
- Solution: ADFs – different technical approaches
- Indiana, e.g., 844 IAC 5-6-2 Definitions
- Approaches, not mutually exclusive
  - Physical barrier
  - Aversion
  - Agonist/Antagonist
  - Prodrug
- Created legal, ethical, and clinical challenges

Dilemmas

- Is it the same? Some have extra material (original + tech)
- What about the cost to pharma Industry?
- Insurance?
- Practice (on the phone)
- Individual?
  - Why Rx? For patient or unknown 3rd party diverter?
  - Co-pays
  - Stigma
  - Effectiveness
  - Collateral and subsequent impacts for Rx to patient
Clinical Dilemma: Patient deception

- Multiple forms of deception: How do you define?
- Difficult to detect on its face
- Patient autonomy BUT deception could impact therapy (cause harm)
- Why would patients deceive?
- What do we do? San Diego detective.
- Plan ahead, seek assistance (consults, Assn, etc)
- UDTs? Who answered the phone? Fire the patient?
- “Legal, regulatory information and more at your fingertips on www.ismanet.org” (e.g. Answers for Actions)

Clinical Dilemma: Deception (cont’d)

- How far should we go to uncover “the truth?”
- Do we have a therapeutic responsibility to uncover information about the patient?
- Does it depend on the info we seek?
- It is about them or us?
- Act on appropriate info (Cf. Billy), and beware of the ostrich (imputed knowledge)
- Reasonableness, not perfection, and document
Clinical Dilemma: Opioid Refugees & High Dose

- What = high dose and who should decide?
- Treating opioid refugees – challenges with the inherited patient
- Opting out
- 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 – lao + 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 aberrant-behavior, including the patient’s use of marihuana (medical or not)

The “Government” Is More Aggressive These Days (cont’d)

- Willing to use the patient (living or not) against the HCP and 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

- 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 (cont’d)

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