Risk Management: Safe Prescribing Practices in Mental Health

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Objectives
• Identify the elements of malpractice
• Describe a case where a mental health prescriber was sued for malpractice
• Discuss what went wrong in the cases
• Explain the Drug Enforcement Administration's cautions for prescribers of controlled substances
Case #1: Suicide after Rx for Prozac

- 15-year-old girl presented at CHC 2 days after ER visit with complaints of nausea, abdominal pain and vomiting
- NP wrote Rx for anti-nausea med and Prozac for "depression"
- Patient was to RTC in 1 month
- Patient hanged herself 3 weeks later but lived with brain injury for 3 more years

Case #1: Suicide after Rx for Prozac

- Family sued the NP, claiming the FDA had issued a warning regarding Prozac increasing suicide risk in adolescents
- NP argued the suicide was related to break-up with boyfriend and argument with father
- Court awarded the family $3,459,902

Elements of malpractice

- Duty of care
- Breach of the standard of care
- Injury
- Causal relationship between the breach of the standard of care and the injury
Definition: Standard of care

- The caution that a reasonable person in similar circumstances would exercise in providing care to a patient
  Common law definition; i.e. case made law

Lessons learned from this case

- What is the standard of care?
  – Prozac approved for adolescents with major depression and/or obsessive compulsive disorder, but not for minor depression
  – Use depression scale
  – Consider referral for major depression
- Where to find warnings?

Additional complication in this case

- NP wrote for Prozac on a prescription pre-signed by a physician
- The physician was prosecuted for pre-signing prescriptions
Pre-signing prescriptions

• “All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.”

21 CFR, Section 1306.05

Case #2: NP lowered dose of antipsychotic with disastrous result

• 49-year-old woman was attacked by a patient while at work in a mental health clinic
• Patient had a history of schizophrenia, violent behavior, noncompliance with medications and involuntary commitment. She was assessed during her last hospitalization as a moderately high danger to others

Case #2: NP lowered dose of antipsychotic with disastrous result

• Patient released to care of community clinic
• NP had not fully reviewed pt's history and lowered the dose of antipsychotic because the pt did not like taking medications
• Injured worker sued the clinic
• Parties settled for $5.5 million
  – Injuries to worker: Wounds to hands, arms, face, eyes, torso, heart, lungs, liver, bowels, buttocks and vagina, from butcher knife
Lessons learned from this case

• What is the standard of care?
  – For lowering of dose?
  – For obtaining and reading medical record?

• If you are the expert in this case, what will you say?

Considerations when thinking about lowering antipsychotic dose

• Likelihood of psychotic relapse
• SSRI discontinuation syndrome
• Antipsychotic discontinuation syndrome
• Anticholinergic withdrawal reaction
• Withdrawal dyskinesia
• Rebound dystonia
• Potential for adverse events related to abrupt discontinuation
  – Dizziness, lightheadedness, nausea, tremors, etc.

Pre-signing prescriptions

Cases 3 & 4:

A physician in Georgia was criminally prosecuted and served eight months in federal prison for pre-signing prescription blanks so that, on his day off, the nurse practitioners he worked with could refill prescriptions for chronic pain patients.

A physician assistant in GA was sentenced to 41 months in prison for giving out pre-signed prescriptions while physician away for a week.
Prescribing without conducting and documenting an evaluation

Case 5:
- A 60-year-old man, divorced and living alone for the first time, complained of “feeling down” and requested some pills advertised on TV
- A physician assistant, after talking to the man for approximately 10 minutes, prescribed Prozac
- Two weeks later, the patient received a critical letter from his daughter
- After he read the letter, he shot himself

Prescribing without conducting and documenting an evaluation

- The patient’s family sued the PA for failing to assess the man for suicidal ideation and failing to refer to a psychiatrist
- The plaintiff’s expert testified that the PA had not practiced the “standard of care” when she failed to evaluate the depth of the patient’s depression by administering a depression inventory and failed to make an appropriate referral
- The PA’s notes included neither a depression inventory nor a statement that she had offered a referral

Standard of care: Conduct and document an evaluation

- If you don't document, and something goes wrong, your malpractice defense will be difficult
- Drug Enforcement Administration looks for a “recurring concomitance of condemned behavior” when deciding whether to prosecute for drug trafficking
  - Among the condemned behaviors
  - “No physical examination documented”
Prescribing without conducting and documenting an evaluation

Cases 6 & 7:

NP prescribed large number of opioids without documenting work-up. Charged with drug trafficking and under disciplinary action by Board of Nursing

MD prescribed large numbers of opioids without documenting work up. Prosecutors called it a “pill mill.”

MD sentenced to 30 years in prison without parole

How to reduce risk of prescription errors

• Read the law of your state on prescribing, at least once a year
• Read the DEA’s web site on responsibilities of prescribers, at least once a year
• Read the PDR or Epocrates entry before prescribing a medication
  – Discuss side effects, interactions, precautions with patient
• Document Rx’s written, transmitted verbally or refilled

Read the laws of your state

Pennsylvania

A CRNP may prescribe and dispense a drug relevant to the area of practice of the CRNP from the following categories if that authorization is documented in the collaborative agreement (unless the drug is limited or excluded under this or another subsection):

(1) Antihistamines.
(2) Anti-infective agents.
(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids if originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy.
(4) Autonomic drugs…
Prescribing CDS without a DEA number

Case 8:
NP who did not have a DEA number prescribed a scheduled drug, not realizing it was scheduled. A pharmacist reported her to the DEA. DEA agents came to visit at her practice. The DEA let it drop, after she explained that she simply was ignorant of the law. However, her employer was embarrassed and fired her.

Prescribing CDS for a relative

Case 9:
NP wrote a prescription for an a controlled analgesic for her husband for low back pain. A pharmacist noted the last names of patient and clinician matched, and reported the NP to the Board of Nursing and the NP’s employer. The NP’s employer fired her.

Prescribing scheduled medications for pain

- Cancer-related pain
- Acute, short-term non-cancer pain
- Chronic non-cancer pain
  – Here is where the risk lies
There are no hard guidelines on prescribing controlled substances

- FDA doesn’t issue any such guidelines
- Boards of Nursing don’t issue any guidelines
- Nursing associations don’t issue any guidelines
- Pain societies do issue some guidelines

DEA expects clinicians to

- Prescribe appropriately (for a “legitimate medical purpose”)
- Make reasonable efforts to prevent abuse

Usually, detecting patients with risk of abuse is not this simple
Common characteristics of drug abuser (from the DEA)

• Unusual behavior in the waiting room
• Assertive personality, often demanding immediate action
• Unusual appearance - extremes of either slovenliness or being over-dressed
• May show unusual knowledge of controlled substances and/or gives medical history with textbook symptoms OR gives evasive or vague answers to questions regarding medical history

Common characteristics of drug abuser (from the DEA)

• Reluctant or unwilling to provide reference information. Usually has no regular doctor and often no health insurance
• Will often request a specific controlled drug and is reluctant to try a different drug
• Generally has no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation
  • http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm#resp

DEA’s “recurring concomitance of condemned behavior”

• Used street slang rather than medical terminology for the drugs prescribed
• No logical relationship between the drugs prescribed and treatment of the condition allegedly existing
• Wrote more than one prescription for same drug at one visit
  – United States v. Rosen, 582 F.2d 1032, 1035-1036 (5th Cir. 1978).
Mistakes clinicians made

- Failed to respond to patient behaviors
- Poor documentation of referrals
- Failed to justify continued use of pain medication
- Increased pain medication without rationale
- Gave the patient whatever he/she wanted
- Failed to investigate anonymous telephone tip
- Used benzodiazepine + opioids without rationale
  - Source: Bolen, J., attorney, at American Academy of Pain Management 2008 and 2010

NP prescribed oxycodone to man who sold pills through younger brother to high school students, one of whom overdosed

Make reasonable efforts to prevent abuse/diversion from the outset

- Face-to-face interview
- Perform and record a thorough H&P before Rx
- Obtain old records and history
- Inquire about prior experience with recreational drugs
- Try a course of non-opioid analgesics first
Make reasonable efforts to prevent abuse/diversion from the outset
- Tell the patient the Rx is a “trial” rather than a commitment to opioid therapy
- Get informed consent for opioid treatment
- Stay within dosage ranges recommended in the professional literature
- Re-evaluate weekly at first
  - Initial Rx may be for 1 week supply

When prescribing long-term (more than a month) for chronic non-cancer pain
- Reevaluate monthly at first, then Q 3-6 months
  - If the pain is not resolving, refer the patient to a pain specialist for a consultation
  - Consider psychiatric evaluation for comorbidity
- Trust but verify (corroborate patient report)
  - Urine drug screens
  - Pill counts
  - Work monitor

Follow up visits should include assessment of 4 A’s
- Analgesia (scale 1-10) compared with prior visit
- Activities of daily living (Driving? Cooking? Walking the dog?)
- Adverse effects
- Aberrant drug-related behaviors (Asks for early refill? Insists on a specific drug in specific quantity? Lost the pills?)

If the patient is worse, do something about it
Red flags – Stop and reconsider the prescription when

- Early refill requests
- Specific request for a particular drug
- Claim that certain drugs do not help
- Reluctant to change medications
- Drug screens negative for prescribed drug
- Claims that drugs were lost
- Anonymous tip
- Obtains drugs from multiple providers
- Uses more than one pharmacy

Urine drug screens

- Purpose:
  - Confirm that the patient is taking what you prescribed (7.5% of patients test negative)
  - Determine whether the patient is taking other drugs
- Know what the test you ordered detects

Pill counts

- Prescribe a 28-day supply
  - Correlate refill schedule with your schedule in clinic
- Schedule pill count on day 21
  - You’ll know how the patient is doing while having enough time to adjust before the Rx runs out
Consider setting up a work monitor

- Corroboration of patient self-report
  - Is patient impaired at work?
- Will need patient’s permission to relax confidentiality

Documentation

- Document your rationale for doing what you are doing
- Document your sources (such as journal article) if prescribing outside accepted parameters
- If deferring a physical, document the reason why
- If patient says drug was lost, get the statement about what happened in writing, get patient to sign and get it notarized

Treatment agreements/contracts

- Controversial in pain management
  - Pros:
    - A means of extricating yourself
    - Studies show they reduce opioid misuse
  - Cons:
    - May damage patient/clinician bond
    - Have been used against physicians
      - Case: MD had a contract – no early refills. MD violated the contract repeatedly by giving the patient an Rx “one more time.” Pt. sued the MD for promoting addiction
Possible terms of treatment agreement

- Patient will fill Rx’s at one pharmacy only
- Patient will seek Rx’s from one clinician only
- Patient will request refills at least 72 hours prior to need for the new Rx

How to terminate a patient

- “I cannot continue to prescribe for you because I don’t want to harm you”
- Don’t terminate in the middle of an acute episode of illness
- Give 30-day notice
- You need not offer a replacement clinician, though some experts say you should

Prepare yourself to prescribe opioids

- Read and understand
  - The clinical guidelines on prescribing
  - Your state’s laws on prescribing controlled substances
- Utilize the state’s drug monitoring web site
- Create policies for your practice
  - Evaluate thoroughly before prescribing
  - Take reasonable steps to prevent abuse/diversion
  - Prescribe only for legitimate medical purposes and in the usual course of professional practice
Prescribing program maintenance

- Look at your process with a critical eye once a year
- Perform internal peer review
- Perform chart audits

Describe 3 things a NP should always do when prescribing

- Document prescriptions written, transmitted verbally or refilled
- Inform the patient of precautions and possible side effects
- Ask yourself: Do I need a second opinion on this?
  - Order a consultation when prescribing opioids and...

Order a consultation when prescribing opioids and

- Patient’s pain is not well controlled
- Multiple symptoms require management
- Patient unable to care for self and caregivers are inconsistent, strained, or burned out
- Clinician suspects medication abuse
- Patient with history of abusing medications
- There are psychiatric diagnoses or symptoms
10 Federal laws on prescribing CS

1. No refills on Schedule II
2. May issue multiple prescriptions for 90-day supply of Schedule II medications with “fill dates”
3. Schedule II Rx’s must be in writing and signed by the practitioner

10 laws on Rxs for CS

4. In emergency, a Rx for Schedule II may be telephoned to pharmacy, with written Rx sent within 7 days
5. Prescription must be dated and signed on the date issued (no post-dating)
6. Rxs for Schedules III-V may be written, transmitted orally or faxed

10 laws on Rxs for CS

7. No Federal limit on the number/amount of CS prescribed
8. No expiration date on Rxs for Schedule II
9. Schedule III Rxs expire 6 months after date written. There may be 5 refills within the 6-month period
10. Signature stamps are not legal
DEA policy

- An agent of a prescriber may not call in Schedule II CS on behalf of the prescriber, even in an emergency
- DEA recommends that prescribers designate their agents, in writing
  - I, ___, hereby authorize ___ to act as my agent only for the following limited purposes:

Resources

- State-by-state opioid prescribing policies
- DEA