Ethics & Confidentiality

David Kan, MD, MRO

San Francisco VA Medical Center
UCSF Department of Psychiatry

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Overview

- **Ethics**
- **Confidentiality**
  - Federal Rules
  - Adolescents
  - Electronic Activities
  - Tarasoff
- **Special Issues (Time Permitting)**
  - Malpractice
  - Driving and Substances
  - Opiate Treatment Program Specific Issues
  - Diversion control

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Ethics

- **Beneficence**
  - Promoting well-being of others
- **Non-Maleficence**
  - First do no harm *(Primum non nocere)*
- **Autonomy**
  - Right to self-determination
- **Justice**
  - Balancing societal and individual needs

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Ethics in Addiction Treatment

- **Informed Consent**
- **Competence and established theory**
- **Confidentiality**
- **Duty to Protect**
- **Maintaining Boundaries**
  - Self-Disclosure
  - Touch, Sexual Boundaries
- **Supervision**
- **Honoring Diverse Values**
  - Ethnic, linguistic, gender, sexual orientation

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Patient-Physician Relationship Defined

"a consensual relationship in which the patient knowingly seeks the physician's assistance and in which the physician knowingly accepts the person as a patient."

QT, Inc. v. Mayo Clinic Jacksonville, 2006 U.S. Dist. LEXIS 33668 (N.D. Ill. May 15, 2006)

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Patient-Physician Relationship Defined

- **Fiduciary relationship**
- **Begins By**
  - Contract for benefit of patient OR
  - Affirmative Act on part of MD
- **Ends With**
  - Mutual Consent
  - MD Fired
  - Services no longer needed

Physician Duties

- **Provide Treatment to Standard of Care**
- **Can deny care if:**
  - Ethically Inappropriate
  - Medically ineffective
  - Moral or Religious objectionable to MD
  - Outside of expertise
  - Panel is full and no capacity to treat
  - In non-emergent situations:
    - Unruly or noncompliant

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Ref: http://www.physiciansnews.com/law/202.html

Physician Duties

- **Consultants**
  - Specific occasion or service
  - Ensure patient does not expect further service
  - Define scope of illness to be treated
- **Emergencies (EMTALA) – "No Dumping"**
  - Duty for hospitals and MDs to treat
    - Regardless of ability to pay
    - Medical Screening
    - Medical Stabilization

Common Standard of Care

"Dr. Krantz referred you to me? I was going to refer you to Dr. Krantz."

"to do what a reasonable physician would do with the same or similar patient under the same or similar circumstances"

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Abandonment

- **No proper notice of withdrawal**
- **Ample opportunity to seek alternative care**
- **Cannot abandon patient in crisis**
- **Prevention**
  - Establish Practice Polices (no-shows, behavior, non-payment)
    - Verbal or Written
  - Written Termination – Certified with Return Receipt
    - Date relationship will end
    - Summarize status of care and further care needed
    - All patients treated equally
  - Document Referrals

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Abandonment

- **Patient being treated for pain**
- **Declares self addicted**
  - Early rx refills, “lost” prescriptions
  - Multiple drugs on UDS
- **Refuses referral to opiate treatment program**
- **Refuse to prescribe?**
- **What now?!**

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Non-Discrimination

- **Section 504 of the Rehabilitation Act of 1973**
  - If receiving federal funding: Patient cannot be denied services solely on disability
- **Americans With Disabilities Act of 1990**
  - Broader protections
  - Physical impairment that substantially limits one or more major life activities
  - A record of impairment
  - Regarded as having an impairment
    - Contagious disease – *Bragdon v Abbott (USSC 1998)*

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Informed Consent

- **Competent**
- **Voluntary (not coerced)**
- **Information**
  - – Nature of treatment
  - – Risks/Benefits of treatment
  - – Alternatives with their risks/benefits including risks/benefits of no treatment

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Exceptions to Informed Consent

- **Emergencies**
- **Therapeutic Privilege**
  - Information would cause harm
- **Waiver by Patient**
- **Incompetence**
  - Need substitute decision maker
- **Case Example**
  - UDS when collecting U/A without specific consent
  - Legal? Ethical?

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Ethics Summary

- **Ethics has special meaning and application in addiction medicine**
- **Know your role**
  - Do what is best for your patient
  - You have protection
- **Inform your consent process**

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Confidentiality

"Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret."

Oath of Hippocrates
5th Century B.C.
(460-377 B.C.)

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The HIPPA in the Room

- **Governs protected health information**
  - Electronic, Written, or Oral

- **Who's Covered?**
  - Health Plans
  - Most Health Care Providers
  - Health Care Clearinghouses

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Confidentiality/Privilege

- **COnfidentiality**
  - Clinician's Obligation to keep information secret
- **PRivilege**
  - Patient's Right to bar information access

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Confidentiality/Privilege
Addiction Treatment

- **Medical Information**
- **Psychiatric Information**
- **Drug and Alcohol information**
  - Requires separate subpoena AND judges order
- **Each has own levels of protection**

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Federal Confidentiality Law
42 CFR § 2.12

- **Applies if:**
  1. Individual, program, or facility is federally assisted
     (tax exempt, federal funding, tax-deductible donations, medicare)

  AND

  2. ANY of three conditions are met
     - 1. Individual or program holds itself out as providing addiction diagnosis, treatment or referral
     - 2. Is a staff member at general medical facility identified as a provider of addiction diagnosis, treatment or referral
     - 3. Any unit at general medical facility holds itself out to provide addiction diagnosis, treatment or referral

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Federal Confidentiality Law
42 CFR § 2.12

- If #1 and #2 is met, federal confidentiality laws apply

- Absent federal jurisdiction, state authority applies

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Federal Confidentiality

- **Consent Form**
  - Name of program or person permitted to make disclosure
  - Name or title of individual or organization receiving disclosure
  - Name of Patient
  - Purpose of disclosure
  - How much and what kind of information
  - Patient Signature
  - Date of Signature
  - Statement that consent is subject to revocation at any time to the extent that the program has already acted on it
  - Expiration date, event, or condition

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Federal Confidentiality

- Consent required when purpose of disclosure is *not* for "treatment, payment, or health care operation."
- Patients must receive copy of consent.
- Program must retain record of consent for six years from expiration date.

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Federal Confidentiality Exceptions

- **Crimes on program premises or against program personnel**
- **Child Abuse Reporting**
- **Medical Emergencies**
  - Information limited to medical emergency
- **Subpoenas and court-ordered**
  - Patient must sign consent to respond to subpoena unless court order issued

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Federal Confidentiality

- **Qualified Service Organizations**
  – Business associate agreement needed
- **Accreditation Bodies (Joint Commission)**
  – Considered extension of program
- **Research**
  – Even more rules

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Federal Confidentiality

- **Patient rights**
  – Request restriction of uses and disclosure
  – Right to access PHI
- **Denial of Patient Access to PHI**
  – Therapeutic Privilege – would cause harm
  – Research
  – Reference to another person
  – Request by representative
  – Patient has right to appeal

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Federal Confidentiality

- **Right to amend PHI**
  - 60 day limit
  - Can deny request if:
    - Information is accurate and complete
    - Did not create information
    - Must notify of denial reasons
- **Accounting of Disclosures**

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Federal Confidentiality

- **Administrative Requirements**
  - Complaints about privacy practices
    - 180 day statute of limitations from knowledge of breach
  - Designated privacy official
  - Training
  - Policies and Procedures
  - Sanctions

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Federal Confidentiality

- **Information security**
  - Locked or secure
  - Administrative, technical, physical safeguards

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Adolescent Issues

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Confidentiality/Privilege Addiction in Minors

- **Family Educational Rights and Privacy Act of 1974**
  - Prevents universities from sharing most student information.
  - Allows them to contact parents if a child's health or safety is at risk.
  - In 1998, amended to give universities permission to notify parents anytime a student under 21 had any alcohol or drug violation.

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Confidentiality/Privilege Adolescents

- **Adolescents do not have legal status of adults unless legally "emancipated minors"**
- **Rules differ from state to state**
  - Variables
    - Age
    - Stage of cognitive, emotional, social development
    - Payment
  - >1/2 of states permit adolescent SA treatment without parental consent
  - Parental notification issues
  - California – must disclose minor info if under state law

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Adolescent Federal Confidentiality

- **Written consent for disclosure generally required**
- **Exceptions**
  - Emergencies
  - Child Abuse
  - Lack of capacity to consent

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Federal Confidentiality in Minors

- **A minor must always sign consent form to release information to his parents or guardian**
- **Some states require additional parental consent before providing treatment**
  - Then both parent and patient signatures are necessary
  - In California (Cal.Family Code § 6929(b)(f))
    - 12 or older can consent to treatment
    - Under 18, parent can still consent for opposing child

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Adolescent Confidentiality Case Example #1

- **Mother brings 16 y/o son to ER.**
- **UDS + for heroin – son is regular user**
- **Can MD share test results?**
- **The potential conflict:**
  - States allow drug abuse information to be shared with parents when deemed appropriate
  - Federal law needs written consent

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Adolescent Confidentiality Case Example #1

- **Is provider bound by federal confidentiality law? (Must meet both criteria)**
  - 1. Is there federal assistance – most hospitals are - YES
  - 2. Does provider meet <u>any</u> of 3 criteria for addiction treatment program?
    - 1. Hold itself out as addiction treatment program? – NO
    - 2. Is MD's primary function addiction dx, tx, or referral? – NO
    - 3. Does unit at general medical facility hold itself to be addiction dx, tx, or referral? - NO
  - Therefore, State Law applies
    - *Disclosure may be permitted under state law*

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Adolescent Confidentiality Case Example #2

- **Private Non-Profit provides drug counseling to teens**
- **Father calls asking if daughter is receiving treatment**
- **The potential conflict:**
  - States allow drug abuse information to be shared with parents when deemed appropriate
  - Federal law needs written consent
- **Can program disclose daughter is client?**

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Adolescent Confidentiality
Case Example #2

- **Is provider bound by federal confidentiality law? (Must meet both criteria)**
  - 1. Is there federal assistance – most hospitals are - YES
  - 2. Does provider meet <u>any</u> of 3 criteria for addiction treatment program?
    - 1. Hold itself out as addiction treatment program? – yes
    - 2. Is provider's primary function addiction dx, tx, or referral? – yes
    - 3. Does unit at general medical facility hold itself to be addiction dx, tx, or referral? – N/A
  - Therefore, Federal Law applies – *minor written consent needed prior to disclosure*

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Electronic Transactions

- **Administrative safeguards**
  - Access
  - Designated Privacy Officials
  - Tracking
  - Training
- **Physical safeguards**
  - Workstations
  - Flashdrives, portable media
- **Technical safeguards**
  - Data integrity
  - Encryption
  - Malware
  - Passwords
  - Auto Logoffs

E-Mail Issues

- **Secure Servers and Encryption**
- **Warnings needed**
  - The information contained in this message may be privileged and confidential. If you are NOT the intended recipient, please notify the sender immediately with a copy to hipaa.security@ucsf.edu and destroy this message.
- **Not Recommended for Highly Sensitive Information**
  - Mental Health, Substance Abuse, HIV/AIDS
- **Informed Consent**
  - Responsiveness, security

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E-mail Issues: Informed Consent

- **Example:**
  - I will be happy to respond to your query but to do so via email you must provide your consent, recognizing that email is not a secure form of communication. There is some risk that any protected health information that may be contained in such email may be disclosed to, or intercepted by, unauthorized third parties. I will use the minimum necessary amount of protected health information to respond to your query.
  - If you wish to conduct this discussion via email, please indicate your acceptance of this risk with your email reply. Alternatively, please call my office to arrange a phone conversation or office visit.

Rationale for Exceptions to Confidentiality

Balance between

Patient's Right to Privacy

<u>and</u>

Competing societal interest

e.g., public safety

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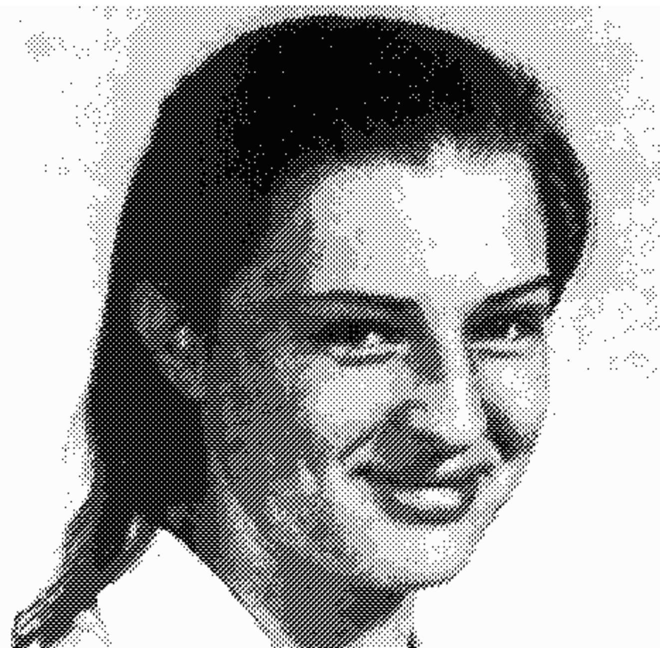
Tarasoff

- **Tarasoff v. The regents of the University of California, 1976**
- **Facts:**
  - Prosenjit Poddar and Tatiana Tarasoff
  - Started dating
  - Mr. Poddar unfamiliar with mores of America became depressed and saw psychologist, Dr. Moore.



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Tarasoff

- **Facts:**
  - Mr. Poddar revealed intent to get gun and kill Tatiana.
  - Psychologist asked UCPD to hospitalize.
  - Poddar was discharged.
  - Poddar moved into Tarasoff house.
  - Tatiana returned from vacation.
  - Tarasoff was stalked and killed.

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Tarasoff

- **Facts:**
  - Lawsuit was filed for failure to warn.
  - Case dismissed by trial and appellate court citing lack of duty to 3rd party.
  - California Supreme Court overturned.

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Tarasoff

"When a therapist determines…that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to *protect* the intended victim against such danger. The discharge of this duty may require the therapist to take one or more of various steps. Thus, it may call for him to warn the intended victim, to notify the police, or to take whatever steps are reasonably necessary under the circumstances." – Tarasoff v. UC Regents

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Tarasoff in Addiction Case Example

- Female pt. struggling with alcoholism
- Went to brief detox program but relapsed to drinking
- Pt. takes care of two toddlers and often brings them to clinic
- "I never drink when I'm taking care of kids, only after their father gets home."
- She is usually tremulous but sober in clinic

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Tarasoff in Addiction
Case Example

- Patient shows up one day drunk with toddlers
- She has driven to clinic and intends to continue drinking when she goes home
- What should you do?

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Tarasoff in Addiction

- **Call police to bar patient from drunk driving**
- **Call report to CPS and follow with written report.**
  – Downloadable form: *http://www.ag.ca.gov/childabuse/pdf/ss_8572.pdf*
- **Notify children's father, if possible.**

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Tarasoff in Adolescents

- Rules apply equally to adolescents

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Confidentiality Summary

- Two part test as to whether federal standards apply
- Know your state regulations.
- In Adolescent cases: Is parental consent/ notification necessary required?
- Tarasoff means duty to *protect.*

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Special Issues

- Malpractice
- Opiates and Driving
- OTP Specific Issues
- Diversion Control

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Malpractice 4 D's

Dereliction of **D**uty
Directly leading to
Damages

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Malpractice

- **DUTY**
  - Is this your patient?
  - If someone is not your patient you cannot be sued for negligence.
  - Physicians can still choose whom their patients will be.
  - Some exceptions

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Malpractice

- **DERELICTION**
  - A breach or violation of the standard of care is a necessary element
  - What is Standard of Care?

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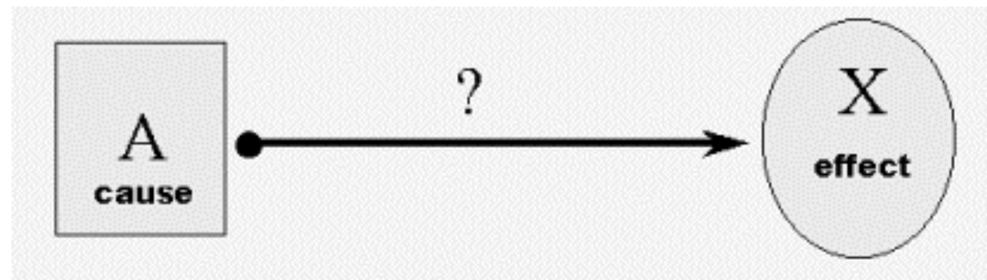
Malpractice

- **DIRECTLY**
  - The breach of the standard of care must directly cause injury to the patient.
  - Aka: “proximate cause”



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Malpractice

- **DAMAGE**
  - Must be injury to the patient that can be proven
  - Injury must have **directly** resulted from substandard care.

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Statute of Limitations

- **Clock starts after discovery of the harm. (One year in most States; two in CA.)**
- **Example:**
  - Patient treated for pain for one year.
  - Leaves practice
  - Treated for addiction three years later.
- **Longer statute of limitations, if plaintiff can prove:**
  - Fraud
  - intentional concealment, or
  - presence of a foreign body with no therapeutic or diagnostic purpose.

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Negligence

- **54 y/o presents with lumbar radiculopathy with history of alcohol dependence.**
- **Prescribed physical therapy, Morphine SR**
- **Overdoses**
- **Drug Screen shows:**
  - BAL – 0.92
  - + for methadone, morphine, clonazepam, alprazolam

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Negligence

- Documentation of needle tracks
- Drug Testing
- Benzos - Lateral Nystagmus

Negligence Case Example

- **Patient is being dispensed at OTP**
- **Nodding, smells of alcohol**

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Contributory Negligence

e.g., in North Carolina:

- **Plaintiff has contributed to bringing about the harm.**

- **Any amount of contributory negligence bars recovery by the plaintiff.**

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Comparative Negligence

e.g., in California:

- The allocation of responsibility for damages incurred between plaintiff and defendant
- The reduction of the damages recovered by the negligent plaintiff in proportion to his or her fault

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Types of Errors

- Errors of fact - **UNFORGIVING**
  - Failure to obtain relevant data, e.g., past records, ask appropriate questions.
- Errors of judgment - **FORGIVING**
  - Acted in good faith and exercised requisite care in obtaining necessary information and arriving at diagnosis and treatment.

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Good Practice
General Recommendations

- **Consult, Consult, Consult**
  - Reasonable physician with similar patient, similar circumstances
  - Consultation meets this test
- **Document, Document, Document**
  - Best defense
  - Never alter records – whack credibility
    - Addendums okay
  - Standard of Documentation ≠ Standard of Care

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Good Practice
General Recommendations

- **Protocols and Procedures**
  - Diversion Control
  - Consents
- **Contact Risk Management or Loss Prevention.**
  - Prior to bad outcome!
- **NEVER talk directly to plaintiff's attorney.**
- **Be honest with your attorney.**
- **All communications go through your attorney.**

"Tarzan hate frivolous lawsuits."

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Res Ipsa Loquitor

"The thing speaks for itself"

- No Expert Testimony
- Burden of Proof on Defendant
- Rare in Psychiatry

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Four Elements of *Res Ipsa Loquitor*

1. Harm rarely occurs in the absence of negligence.
2. Situation under the sole control of the defendant physician.
3. Plaintiff did not contribute to bad result.
4. Only the defendants have access to information about what happened.

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Res Ipsa Loquitor Example

- Dentist with addiction to anesthetic gasses
- Leaves part of needle in jaw of patient
- Patient develops pain and needs surgery
- Dentist obviously at fault
- "The thing speaks for itself."

Mens Rea

- Latin for “guilty mind”
- Primarily criminal
- Malpractice – equated with recklessness
- Accused foresaw but failed to stop behavior and thus, took risk of causing damage
- Greater foreseeability, the greater the recklessness
- Example prescribing opiates to opiate addict

Prima Facie

- Party with burden of proof has to produce Prima Facie evidence for case to move forward
- Making or building a case
- Does not have to be conclusive or irrefutable
- Used to determine whether case can move forward
- Example: Patient overdoses, was on methadone, plaintiff sues for negligence

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Legal & Liability Concerns - Criminal

Drugged Driving (DUI)

1. Laws that require the drug to render driver "incapable of driving safely."
2. Laws that require the drug "to impair the driver's ability to operate safely, or require driver to be under influence of intoxicating drug."
3. Per se laws that make it criminal offense to have drug(s) in one's body while driving.

Laws Vary State by State

Legal & Liability Concerns

- **California Law (CVC 23152)**
  - It is *unlawful* for any person who is *addicted* to the use of any drug to drive a vehicle.
  - It is *unlawful* for any person who is *under the influence* of any alcoholic beverage or drug, **or** under the **combined influence of any alcoholic beverage and drug**, to drive a vehicle.
  - These subdivisions ***SHALL NOT APPLY*** *to a person who is participating in a narcotic treatment program* approved pursuant to Article 3 (commencing with Section 11875) of Chapter 1 of Part 3 of Division 10.5 of Health and Safety Code
  - Opiate Replacement itself is not PER SE impaired driving

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OTP Legal & Liability Concerns - Civil Liabilities

- **Negligence Lawsuits by Injured Parties against:**
  - Patients
  - OTP

- **Defending Liability for Patients**
  - Demonstrate **legal** use of methadone
  - Confirm patient was **stabilized** on dose
  - No impairment of functioning [1,2]
    - Cognitive, Psychomotor

1. Lenne et al, "The effects of the opioid pharmacotherapies methadone, LAAM and buprenorphine, alone and in combination with alcohol, on simulated driving." Drug Alcohol Depend. 2003 Dec 11;72(3):271-8

2. Baewert, et al: "Influence of peak and trough levels of opioid maintenance therapy on driving aptitude." Eur Addict Res. 2007;13(3):127-35

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Induction Issues

- **How Much is Too Much?**
  - Methadone
    - **Cannot** lever dose to amount/type of drug used
    - Federal/State limits on 1st day
    - Don't forget long half-life (8-59hrs)
    - Most methadone deaths happen during induction in non-tolerant pain patients
    - Untreated opiate withdrawal **itself** is almost never fatal

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Induction Issues

- **How Much is Too Much?**
  - Buprenorphine (2-32mg q day)
    - Safer profile due to partial agonist
    - Less clinical experience
    - Caution with benzodiazepine / sedatives
    - Also long half-life
    - Illegal to use short acting opiates in context of opiate treatment (either detox or induction)
    - AGAIN – Untreated opiate withdrawal **itself** is almost never fatal.

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Narcotic “Contracts”

- **FSMB Model guidelines recommend**
  - Use in “High Risk” groups (Controversial)
  - Urine/serum medication level monitoring
  - # and Frequency of refills
  - Reasons for discontinuation of therapy
- **More descriptive of patient-MD relationship**
- **Not Legally Binding**
  - No room for negotiation
  - No Refills - but who is covering?
- **Think of it as piece of documentation**

Universal Precautions

- **Ask ALL patients about hx of addiction**
- **Careful prescribing**
- **ID misuse**
- **Structured opioid therapy**
  - Shorter rx, UDS, tapering
- **Referral to methadone/buprenorphine treatment**

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Medication Callback/Recall

- **At SFVAMC ORT:**
  - Random call backs at least 2x a year
  - Bring in methadone, narcotics, benzos
  - Submit urine toxicology
  - 24-hour notice
  - Prefer to call back in first week of prescription
  - Substantial reduction in diversion of VA prescribed medication
  - DOJ CURES/PAR

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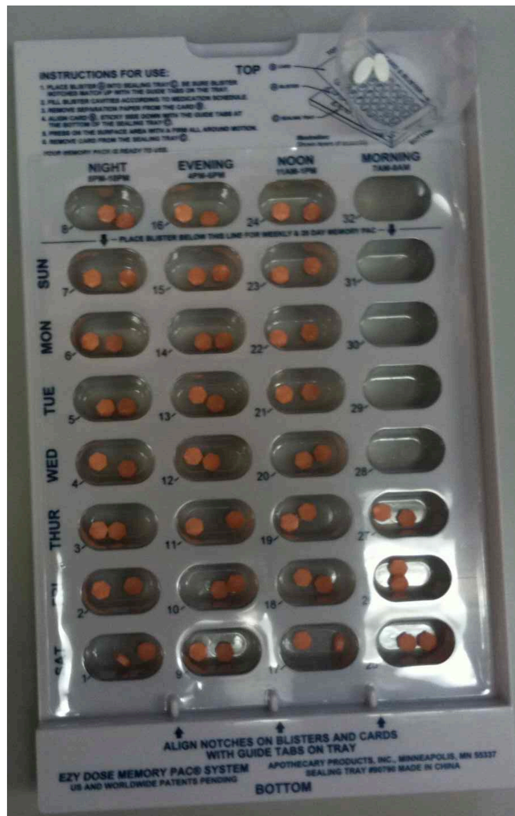
Blister Packing

- At SFVAMC ORT since 2006
- Long history at nursing facilities
- Certain pharmacies will do for you



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Blister Packing

- **Tamper-Evident**
- **~$0.30-40 per pack**
- **Single pill - 90 seconds to fill a month supply**
- **Outcomes:**
  - Improved patient satisfaction
  - Improved medication adherence
  - Decreased medication diversion
  - Quicker Call-Backs

Special Issues Summary

- **Document, Document, Document**
  - Nobody likes a lawsuit but your best offense is a good defense
- **Anticipate and plan for sticky situations**
  - SOPs, Policies and Procedure
- **Memorize the legal terms**
  - They will be on the test
- **OTPs**
  - Heavily scrutinized but defensible
- **Universal precautions for diversion control**

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