Informed Consent for Psychiatric Outpatient Care

PGY3 Core
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Why is consent necessary?

• Patients do not give up the right to control what happens to their bodies when treated
• Physicians have a legal and ethical duty to obtain consent from patients/representatives
• General consent is part of the “Terms & Conditions” agreement patients sign
• BUT specific informed consent for the treatment being offered is also needed
• Failure to obtain informed consent is usually interpreted as negligence, rather than battery

www.risk.mednet.ucla.edu/MC1000.pdf
www.biotech.law.lsu.edu/cases/consent/Cobbs_v_Grant.htm

Key Conceptual Elements of IC

• Voluntariness
• Information (“disclosure”) vs
• Competency
• One-time event at start of treatment
• Ongoing process during care

Patients should be informed of

• Nature of the treatment offered
• Risks, complications, expected benefits
• Alternative treatments and their Risks/Benefits
• Their right not to consent
• Any research, personal, economic or other potential conflicts of interest that may exist
Legal Background

- Origins of Informed Consent
- Two standards you should know
  - “Reasonable Medical Practitioner”
  - “Reasonable Patient”

Salgo v Stanford University 1957

- Martin Salgo was a 55 yo male with compromised circulation to his lower extremities, who suffered spinal cord injury and paralysis following trans-lumbar aortography to evaluate aortic patency (in 1953). He claimed insufficient information was given to him about the procedure

  - “A physician violates his duty to his patients and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment”

Natanson v Kline 1960

- “Reasonable medical practitioner”
  - After a mastectomy for breast cancer, Irma Natanson underwent cobalt radiation tx, and had radiation-induced tissue necrosis (lung, ribs, etc), lost the use of her arm and hand (pianist), had non-healing wounds of her chest wall, and sued for negligence.
  - Upon appeal to the Kansas Supreme Court, she won and set a standard for reasonable medical practice

Natanson v Klein 1960

- Court held necessary elements of disclosure included
  - Nature of illness
  - Nature of proposed tx and likelihood of success
  - Risks of untoward outcomes
  - Availability of alternative modes of tx
  - Physician should disclose what a “reasonable medical practitioner” would disclose under similar clinical circumstances
  - Assumed consensus within the profession
Canterbury v Spence 1972

“Reasonable patient model”

- Post-op after a laminectomy for back pain, Jerry Canterbury fell off his bed when left unattended while voiding; he developed LE paralysis and incontinence
- Underwent 2nd spinal surgery with post-op problems of urinary incontinence, infection, prolonged hospitalization, work disabilities
- Sued successfully for malpractice, citing he was not fully informed of potential complications
- Communicate information that a reasonable patient would want to know

Informed Consent - Which Meds?

Riese v St Mary Hospital 1987

- Eleanor Riese was hospitalized voluntarily with dx of chronic schizophrenia; when she refused to take neuroleptic meds, her status was made involuntary
- Involuntary patients who receive treatment for symptoms of psychosis and severe mental illness must give informed consent
- Psychotropic agent defined as treatment for psychosis or significant mental illness and included “antipsychotic, lithium, and antidepressants”

Some issues with current laws

- Legal opinions several decades old, do not reflect current diagnoses or treatments
- Very narrow a scope of informed consent - benzodiazepines and anticonvulsants do not have standard advisement, yet do have significant liability
- CA Legislation concerns psychiatric inpatients
- Reform impeded by lack of consensus (patient advocacy, civil liberty, national support groups, local & national government)

Psychiatric Malpractice Claims

- 33% Incorrect treatment (antipsychotic to non-schizophrenic, psychotherapy without meds)
- 20% Attempted or completed suicide
- 11% Incorrect Diagnosis
- 10% Improper supervision
- 7% Medication error or drug reaction
- 5% Improper commitment
- 4% Breach of confidentiality
- 3% Unnecessary hospitalization
- 1% Improper conduct with patient

Resnick APA 1995
**Legal Suits of Uninformed Consent in Psychiatry**

- Common themes to legal suit
  - Tardive dyskinesia
  - Typical before atypical antipsychotic
  - Teratogenicity
  - Breast feeding
  - Amenorrhea
  - Rash

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**Informed Consent - Tips**

- **Standard advisement in spirit of the reasonable practitioner & reasonable patient models, representative of community**
- Patient oriented drug handbooks may be helpful
- Recognize that there may be community standard differences (university, VA, private, urban v rural practice)

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**Informed Consent - Tips**

- Written progress note documenting
  - Diagnosis and target symptoms
  - Discussion of Rx (i.e. FDA approved indication or off-label use)
  - Pregnancy / Breast feeding status
  - Include side effects if rare or discussed as community standard (i.e. MAO diet, mania induction, TD, rash, agranulocytosis)
  - State that patient's questions were answered, that risks/benefits/alternatives were discussed
  - Indicate if “Therapeutic Privilege” was exercised (full disclosure would pose harm to pt) (Cobbs v Grant 1972)
**Meds for Informed Consent**

- Typical Antipsychotics
- Atypical Antipsychotics
- Lithium
- Anticonvulsants
- Benzodiazepines
- Tricyclic Antidepressants
- Monoamine Oxidase inhibitors
- Selective Serotonin Reuptake Inhibitors
- Serotonin Norepinephrine Reuptake Inhibitors
- 5HT2 antagonists
- Bupropion
- Herbal Remedies

**FDA Boxed Warnings**

**Clozapine**
- Agranulocytosis (1.3% of patients)
- Seizures

**Valproate**
- Fetal neural tube defects (1%-2%)
- Hepatic failure (1 per 10,000 patients treated per year)
- Hemorrhagic pancreatitis (1 per 40,000 patients treated per year)

**Carbamazepine**
- Agranulocytosis (1.4 per 1 million patients treated per year)
- Aplastic anemia (5.1 per 1 million patients treated per year)

**Lamotrigine**
- Serious rashes (0.8 per 1000 monotherapy and 1.3 per 1000 adjunctive therapy in adult bipolar patients)

**Lithium**
- Toxicity close to therapeutic levels
- Teratogenesis
- Polyuria, Renal insufficiency
- Thyroid liability
- Acne

**Carbamazepine**

- Black Box
- Aplastic anemia (5.1 per 1 million pts/yr)
- Agranulocytosis (1.4 per 1 million pts/yr)
- Conduction Delay
- Cytochrome P450 induction
- Teratogenesis
- Dermatological
Valproate

- Black Box
  - Fetal neural tube defects (1%-2%)
  - Overall congenital malformations may be as high as 10%
- Hepatic failure (1 per 10,000 patients /yr)
- Hemorrhagic pancreatitis (1 per 40,000 pts / yr)
- Thromobocytopenia
- Hyperammonic encephalopathy in subjects with Urea Cycle Metabolic Disorders
- Polycystic Ovarian Disease?

Lamotrigine

- Black Box
  - Serious rashes (0.8 per 1000 monotherapy and 1.3 per 1000 adjunctive therapy in adult bipolar patients)

Typical / Atypical Antipsychotics

- Typical Antipsychotics
  - NMS
  - TD
- Atypicals
  - NMS
  - TD
- Clozapine Black Box
  - Agranulocytosis (1.3% of patients)
  - Seizure
  - Myocarditis
  - Respiratory and CV arrest

U.S. FDA Warning on Atypical Agents and Hyperglycemia / Diabetes Mellitus

- Epidemiologic studies suggest an increased risk of hyperglycemia-related adverse events in patients treated with atypical antipsychotics
- In some cases, ketoacidosis, hyperosmolar coma or death have been reported
- Patients who develop symptoms of hyperglycemia and those who have or are at risk for diabetes should undergo regular blood glucose monitoring

www.fda.gov/medwatch
U.S. FDA Warning on Atypical Agents and increased risk of mortality and CVAE

- This Black Box warning arose from post marketing surveillance and subsequent re-analysis of controlled data in elderly patients with dementia-related behavioral disturbances
- Absolute risk remains low but relative risk vs. placebo is increased (1.6-1.7 times greater)
- All cause mortality
  - Heart failure, sudden death, infectious
- Cerebrovascular Adverse Events (e.g., stroke, transient ischemic attack)

Antidepressants

- 2004 - FDA issued a Public Health Advisory, indicating the need for close monitoring of all patients treated for depression; a Talk Paper focused on antidepressants in children; and recommendations from meetings of the Psychopharmacologic Drugs and Pediatric Advisory Committees included
  - that a “black box” warning of increased risk of suicidality in pediatric patients be applied to all antidepressant medications
  - that they not be contraindicated in pediatric patients
- Update in labeling for all antidepressants in 10/2004
- 2005 - New patient and healthcare info sheets became available; a PHA and a new Talk Paper reiterated that adult patients should be closely monitored for suicidal thoughts or behaviors.
- Data from clinical trials continue to be studied (as of 2007) and NIH is supporting study specifically in this area.
- Preliminary STAR*D genetics data suggest specific variations in CREB1 may elevate risk in men (Perlis AGP 2007)
  http://www.fda.gov/cder/drug/antidepressants/

Antidepressant Class Labeling for Antidepressants and Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Insert established name] or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. [Insert established name] is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) [This sentence would be revised to reflect if a drug were approved for a pediatric indication(s). Such as, [Insert established name] is not approved for use in pediatric patients except for patients with [Insert approved pediatric indication(s)]. (See Warnings and Precautions: Pediatric Use)]

Serotonin Syndrome - ADs + Triptans

- SSRIs when used in combination with triptans (5HT receptor agonists) for migraine headaches
- Signs & symptoms include
  - Restlessness
  - Hallucinations
  - Loss of coordination
  - Tachycardia
  - Increased body temperature
  - Blood pressure lability
  - Hyperactive reflexes
  - Diarrhea
  - Coma
  - Nausea
  - Vomiting

www.fda.gov/cder FDA Advisory issued 7/2006
Persistent Pulmonary Hypertension in the Newborn (PPHN) & in utero exposure to ADs

- Chambers reported that PPHN was 6x more common in babies whose mothers took an antidepressant at wk 20 or later during gestation vs nonexposed infants (risk of 1-2/1000; Odds Ration 6.1 (CI 2.2-16.8)), based on a case-control method (N=1,213)
- After the 2006 NEJM report by Chambers’ group, the FDA issued an alert (July ’06) urging caution and vigilance
- Recent large studies in July 2007 NEJM by Louik et al (N=15,709; 1st trimester exposure) and Alwan et al (N=13,714; 1 mo pre- or 3 mo post-conception) concluded that there is not a significant relationship between early exposure to SSRIs as a class and birth defects; they caution that all meds may not be the same, but that the “specific defects implicated are rare and the absolute risks are small” (cf risks of untreated maternal depression)
  - SER & omphalocele odds ration 5.7 (CI 1.6-20.7; 3 exposed subjects)
  - PAR & RV outflow tract obstructions OR 3.3 (CI 1.3-8.8; 6 exposed)

Consent and Psychotherapy?

- Inform of costs, possibilities of negative transference, regression, depression, limitations on confidentiality?
- PRO ARGUMENT: as a valid medical treatment, therapists have the same obligations
- COUNTER ARGUMENT: Neither risks nor benefits of psychotherapy can be known at the outset of tx; disclosure may hamper progress
- Should discuss mode of therapy, R/B/A


Beahrs & Gutheil Am J Psychiatry 2001