INFORMED CONSENT, PSYCHOPHARMACOLOGY & PREGNANCY

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This book examines the role of psychopharmacological treatment in a range of disorders that may be encountered during pregnancy, including major depressive disorders, anxiety disorders, bipolar affective disorder, schizophrenia, eating disorders, and substance abuse. The natural history of each condition pre- and post-partum is analyzed, and the evidence for the efficacy of drug treatments, evaluated. Special attention is paid to the potential dangers of different treatment options for both mother and fetus, covering risks of malformation, pregnancy and obstetric risks, neonatal risks, and possible long-term consequences. The risks of not treating a particular condition are also analyzed. On the basis of the available evidence, management guidelines are provided that additionally take into account non-pharmacological options. Closing chapters consider the value of complementary and alternative medicine and ECT and explore future research directions.
Patient Presentations

- First episode of illness in pregnancy.
- Relapse of a pre-existing illness during pregnancy.
- Chronic illness complicating pregnancy.
As A Minimum: Every Time Without Exception

- Careful & considered psychiatric assessment.
- Discuss this evaluation with your patient.
- Make an active, not passive decision to continue currently prescribed medications. But beware “knee jerk reactions”.
- Be clear in your rational for prescribing any and all medications.
- If there is diagnostic / therapeutic uncertainty consider second opinion from a PMH specialist.
- Ensure that a process of obtaining informed consent is followed.
Risks need to be Considered

- ‘Caught between a teratogenic hard rock and a clinical hard place’
  
  (Cohen 1989)

- The welfare of both mother and foetus need to be considered.

- Who has the greater ‘right’?

- Risk:Benefit Analysis.

- Be aware of Clinical Guidelines and be able to state clearly why you are stepping outside of these if you are. (e.g. NICE, RANZCP, Beyond Blue etc.)
Risk:Benefit Analysis

- Risk to the Mother of treatment
- Risk to the Mother of non-treatment
- Risk to the foetus of treatment
- Risk to the foetus of non-treatment

A risk:benefit analysis applies to a specific patient within a particular mental health scenario.

The comparison point is not the well, un-medicated woman next door.
Risks for the Foetus

- Teratogenic Risk
- Obstetric Complication Risk
- Risk for the Neonate
- Risk of negative long-term neurodevelopmental or other health outcome
Informed Consent

- Doctrine that aims to philosophically, ethically and legally preserve a patient’s right to self-determination.

- A process whereby a clinician secures the authorization of their patient to follow a particular course of medical management, having disclosed to the patient the important features and risks of that course, together with the features and risks of any alternative course open to the patient so that the patient’s decision can be regarded as relevantly informed.
History First

- It’s a story of Transformation.
- Patient inclusion in the decision making process once considered to be ill advised, now it is mandatory.
- Beneficence Model: maximal physician discretion
- Autonomy Model: emphasis on patient involvement
The history of the concept of informed consent is also the history of the nature of the doctor patient relationship and discloses a shift in the focus of control from one to the other.
Beneficence Model

- Endured till mid last century
- Hippocratic Tradition was enough
- Doctors were encouraged to have authority over their patients
- Consent to treatment came from the very act of consulting a doctor
- Benjamin Rush / John Gregory – improved medical outcomes come from greater patient understanding through sharing in their doctor’s wisdom
Autonomy Model

- AMA (1980) changed this ethic
- Right to self determination arose in the context of litigation.
- Emergence of Moral Theory
- The right to protect bodily integrity
- The term ‘informed consent’ first appeared in a legal context in 1957

(Salgo v Leland Stanford Junior University Board of Trustees 1957)
• It has been asserted that the initial imperative to seek consent for medical treatment emerged in the early 20th century as a response to law suits rather than a moral imperative to respect patient autonomy. (Will JF. A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making. Part II: The Autonomy Model. Chest 2011; 139 (6). 1491-1497)

• “True consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available.” (USA - Canterbury v Spence 1972)
Informed Consent

- Considered to be given when a patient agrees to a proposed treatment based on their participation in a risk: benefit analysis.

- In Perinatal Psychiatry a mother acts as an agent that authorizes the acceptance of risk on behalf of the unborn.

- The unborn has varying levels of legal rights across jurisdictions. (Conception in Ireland, Birth in Australia, etc?) But...

- Remember: patients have the legal right to make bad decisions.
The Law

- Negligence – “to not pick something up”. Common Law / an area of Tort Law.
- Harm caused by ‘carelessness’ without ‘intent to harm’.
- Proving a case of negligence that has resulted in harm potentially entitles the claimant to compensation.
The Laws of Negligence

- **Bolan Principle**: contemporary medical standards.
  
  (Bolan v Friern Hospital Management Committee 1957, Sidaway v Board of Governors of Bethlehem Royal Hospital 1985) – e.g. U.K. & India & Malaysia etc.

- **Sufficiency**: notional standard of a reasonable person.
  

- **Subjective Element**: the particular patient. – Australia
  
  (Rogers v Whitaker 1992)
This is Important

- Was the medical intervention standard practice? (Bolan Principle).

- Would a reasonable person in the patient’s position, if warned of the risk, be likely to attach significance to it? (Objective Limb)

- Was the medical practitioner aware that the particular patient, if warned of the risk, would be likely to attach significance to it? (Subjective Limb)
Medicine Vs The Law

- Medicine – $p$ value < 0.05 = proof
- Law – ‘more likely than not’ = proof
  
i.e. 51% vs 49%
Things Change

- What is speculative at one point in time may become established fact at another. (i.e. Intellectual Disability & Autism with Sodium Valproate)

- What is established fact at one point in time may become speculative or disproven at another. (i.e. PPHN and SSRIs).

- Estimates of risk can go both up and down over time. (i.e. Risk of Ebstein’s Anomaly with Lithium)

- Local Laws Evolve.
It has been the complaint of the medical profession that while the law has imposed a set of mandatory requirements it has made no attempt to inform as to how compliance with those requirements can be achieved.
It’s Actually Good Practice

However, informed consent should not be seen as onerous compliance with minimum legal requirements, but as a means of ensuring good communication with patients which is positively beneficial in its own right, through increasing patient understanding, managing expectations, improving compliance and fostering a sense of empowerment and control.
Ego = \frac{1}{\text{Knowledge}}

“More the Knowledge, Lesser the Ego, Lesser the Knowledge, More the Ego...”

-Albert Einstein.
In this territory there is absolutely no space for Ego.
Guidelines for Obtaining Informed Consent

- Explain diagnosis and proposed treatment and natural course of illness.
- Is proposed treatment standard practice?
- Explain proposed treatment & alternatives.
- Establish competence to agree.
- Involve the father (not legally required but good practice).
- Detail the risk: benefit analysis.
- Establish patient understanding.
- Vital question: Is there anything else you may wish to know and what are your particular concerns?
- Seek a decision and authorization.
- Documentation.
General Principles

Disclosure of risks involves:

- The nature of the risk (what is it?)
- The magnitude of the risk (how big is it)
- The probability the risk might materialize (how likely is it?)
- The imminence of risk materialization (when will it happen?)
Obtaining Informed Consent is a Process, not a Moment

- Allow time for questions.
- Whenever possible separate the assessment from the prescribing – allow time for a patient to consider your opinion and advice.
- Allow time for questions again.
- Patient’s rarely remember everything you say (20 – 60% retained). (Kessels RPC. Patients’ memory for medical information. Journal of the Royal Society of Medicine 2003; 96 (5): 219-222)
- And their memory can be incorrect for many reasons if things go wrong.
Beware the Consent Form

- In a case of negligence it rarely offers any protection. All it proves is that a process occurred and does not demonstrate ‘what’ occurred.
• Minimal effective dose. Emphasis need to be on *Effective* not *Minimal*. Beware half treatment – double risk exposure.

• Never forget Psychotherapy.

• Various guidelines (NICE, RANZCP, WFSBP, CANMAT etc.) often not helpful in pregnancy. All suggest avoiding first trimester exposure (but remember previous slide!) – the litigations lawyers love this one – “but you stepped outside of established guidelines doctor!” You need to be able to say why.
Essentially

- Never offer false re-assurances.
- Educate regarding pros and cons of both treatment and non-treatment.
- Reveal that we cannot advise with 100% certainty. For many medications any comfort with prescribing in pregnancy comes from the absence of negative data rather than the presence of positive data.
- A risk free situation does not exist.
- Informed Consent is a process, not a moment.
- Monitor Carefully (mental state, obstetrically and neonatally)
- Document well.
Did I remember to say?

DOCUMENT WELL.
THANK YOU
and... Book Depository $68