



# **Involuntary treatment of children**

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# Background

- Code of Hammurabi
- Hippocrates
- Herophilus (335-280 B.C.)
- Avicenna (980 – 1037)
- English common law – liability for deviation from professional custom of consent<sup>1</sup>
- Edward Jenner (1749-1823) - Study of cowpox/small pox without informed consent
- Walter Reed (1851-1902): First informed consent in a clinical trial; yellow fever in Cuba

1. Slater v Baker & Stapleton, 95 Eng Rep 860 (KB 1767)





## The Hippocratic Oath

I swear by Apollo Physician and Asclepius and Hygieia and Panacea and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art — if they desire to learn it — without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but to no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. Similarly I will not

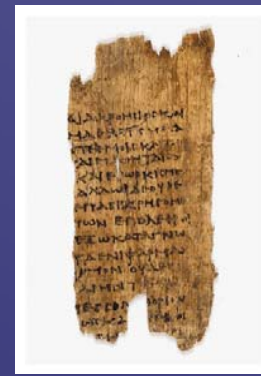
give to a woman an abortive remedy. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself holding such things shameful to be spoken about.

If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.





# Historical failures, landmarks

- Holocaust pharmaceutical trials (forcible)
- Tuskegee Syphilis Studies (uninformed)
- Nuremberg Code
- Declaration of Helsinki, 6<sup>th</sup> revision
- Federal regulations





# Involuntary treatment: What ?

- Treatment/care
- Absent informed
- Consent

Salgo v. Leland Stanford Jr. , University Board of Trustees, Stanford University Hospitals, 154 Cal.App.2d 560 , 1957





# Informed Consent



- **Medical** consent and **informed** consent
- Informed consent **process** and the informed consent **form**,
- Explanation of the **condition(s) and management option(s)** including alternatives, reasonably foreseeable risks and discomfort, reasonably expected benefits
- Risks and benefits of **alternatives**, including no treatment or procedure
- Make sure subject **understands**, has opportunity to ask questions to better understand
- **Consent form** be written in easy to understand language, avoid medical jargon, explain all necessary medical terms
- **Subject does not speak English** – consent in patient's language/read/explain via translator and with witness



# Human act: modifiers

- Ignorance – vincible and invincible
- Concupiscence – signifies frailty or proneness to evil, includes love, hatred, joy, grief, desire, aversion, horror, hope, despair, courage, anger, fear - lessens voluntariness
- Fear
- Violence
- Habit





# Patient's rights vis à vis custodian

- Patient and Family: Cruzan v. Director, MDH, 497 U.S. 261 (1990)
- Patient and State: Sell v. U.S., 539 U.S.166 (2003)
- Baby Doe cases
- Mrs. Schiavo - Florida
- Comparator 1: the Hippocratic Oath and emphasis on autonomy, patient rights
- Comparator 2: the Geneva Declaration and emphasis on humanitarian concepts





# Standards: Jurisdictional variations

- Municipal, state, national and international laws
- Most state courts base right to refuse treatment on common law right to informed consent<sup>1,2</sup>
- State courts rely on state constitutions, common law, state statutes for guidance<sup>3</sup>
- Right to die legislation: Federal, state
- International law and codes complement U.S. state or federal law when silent
- Confusing: ABA, AMA, AARP, insurers continue to lobby for, and propose harmonizing legislation

1. In re Storar, 52 N.Y. 2d 363, 438 N.Y.S. 2d 266, 420 N.E. 2d 64, 2. Belchertown State School v. Saikewicz, 373 Mass. 728, 370 N.E. 2d 417, 3. Conservatorship of Drabick, 200 Cal. App. 3d 185, 245 Cal. Rptr. 840



# Questions

- What is treatment, what is care, what is diagnostic?
- What is information, and when is it adequate?
- How is consent manifested (expressed or implied)?
- Whose consent is needed?
- When, if ever, is involuntary treatment justified?
- What is the right to refuse treatment?
- When may a patient halt ongoing treatment?
- Advance directives and forgoing treatment





# Clinical scenarios

- › Pediatrics, neonatology
- › Psychiatric care
- › Geriatrics
- › Surgery
- › Palliative care
- › Detainee/prisoner care
- › Clinical trials





# Children/Pediatrics

- Informed Consent
- Parental Permission
- Assent of the child

Pediatr. 95:314-317





# Voluntariness in an act: Requirements

- Derived from Latin word *voluntas*, meaning it is a willed act
- For voluntariness to be present: Knowledge and freedom to act in the agent
- **Knowledge** in intellect of what one is about and what this means, does not have to be pain-stakingly slow, can be quick
- **Freedom** - an act that the will can do or leave undone
- **Types of voluntariness**: Direct v. indirect, perfect v. imperfect, actual v. interpretative ...





# Indirect voluntariness: Agent, Act, Reason

- **Agent:** able to foresee the ill-effect, free to refrain from doing that which is the cause of the ill-effect and morally bound not to do that which is the cause of the ill-effect
- **Act:** When may one perform an act, from which flow 2 effects, one good, one bad? - **intention** of the agent must be honest in directly intending the good effect and merely permit the bad as a side issue
- **Reason** must be sufficiently grave calling for the act in its good effect, good effect outweigh the bad





# Emancipated minor

- Usually age 18 years – age of majority
- Emancipation may also be determined by self-supporting and/or not living at home, marriage, military service, support oneself, pregnant or parent, declared to be emancipated by court
- Varies by jurisdiction
- States give decision making authority to some un-emancipated minors who have capacity to make decisions (mature) OR are seeking treatment for certain specific conditions, e.g. sexually transmitted diseases, pregnancy, drug and alcohol abuse





# Assent of children

- Depends on age, maturity and mental state of child
- Verbal assent in <7 year olds
- Simple 1 page assent in 7-12 year olds
- Informed consent form >12 year olds
- Adolescents  $\geq 14$  may have decision-making skills for making informed health decisions
- Confidentiality and privacy – in 14 and older involve parent at times after appropriate discussion with adolescent vs. parental consent or notification may be required by law





# Children: Research

- For research purposes no concept of emancipation, except if the minor has a life threatening condition for which no good standard therapy is available and research proposed holds the possibility of benefit
- Fetal research – no exemptions from Investigational Board review, research must be of no more than minimal risk OR directed at the welfare of mother or fetus
- Under Oklahoma state law research using fetal tissue from induced abortions is illegal





# Case Review

- 28 year old Jehovah's Witness pregnant female patient with vaginal bleeding and placental abruption
- 30 week preterm infant delivered by Cesarean Section, birth weight 1650 grams, Apgar Score 2 and 5
- Infant was intubated, IV fluids started, placed on mechanical ventilation
- Infant's condition assessed as critical by pediatrician
- Transferred by air transport to nearest Neonatal Intensive Care Unit





# Case Review

- Infant has an initial hematocrit of 28% and baby was on life support
- Parents informed about the risks and benefits of blood transfusion – they refuse blood transfusions for the infant because of their religious beliefs
- Court order obtained and infant was transfused
- 2 additional transfusions after court-orders
- Infant's care was optimal, parents were happy with outcome and baby becomes a happy, healthy toddler
- Family sues – their rights and those of their child were violated





# Issues Review

- Consent – indirect via agent
- Is the involuntary treatment justified?
- Whose consent is needed?
- Was there a right to refuse treatment, self vs. another?
- Ignorance vs. information, vincible vs. invincible
- Human act modifiers: fear, habit?





# Ethical Issues: Resolution

- Case management or multidisciplinary conference
- Counseling
- Psychiatric consultation
- Hospital-based ethics committee
- Court ordered interventions/formal judicial interventions





*Thank you!*

