21A.216J Dilemmas in Bio-Medical Ethics
2005/3/16 (W), Week 7, Class 13

Readings

CK Francis. 2001. "Medical Ethos and Social Responsibility in Clinical Medicine." *Journal of Urban Health.* 78(1):29-45.
Marcia Angell. 1997. "The Ethics of Clinical Research in the Third World." *NEJM.* 337(12):847-849
Marcia Angell. 2000. "Investigators' Responsibilities for Human Subjects in Developing Countries." *NEJM*. 342(13): 967-969.
Peter Lurie and Sidney M. Wolfe. 1997. "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries." *NEJM.* 337(12): 853-856.
N. Yasemin Oguz. 2003. "Research Ethics Committees in Developing Countries and Informed Consent: With Special Reference to Turkey." *The Journal of Laboratory and Clinical Medicine.* 141(5):292-296.
National Bioethics Advisory Commission. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*: Executive Summary

Class Business

Book: Visiting issues eugenics, race, etc. *Killing the Black Body*

> "Implicit in the failure of the profession of medicine to advocate aggressively for equitable distribution of health care resources … majority (Francis 2001:37)

Marcia Angell. 1997. "The Ethics of Clinical Research in the Third World." *NEJM*. 337(12):847-849

- One of most 10 influential Americans in time magazine
- Conducting trials in general—are unethical to do placebo trials when known treatments already exist? Should be patient be put foremost?
    - Gawande—initial risks in the beginning—requires surgical practice; is not the same as drugs
    - Placebo arm of the trial could be ethical? Control arm v experimental arm
    - Test whether body therapy works on people suffering from depression; very interesting to work with population who is not receiving treatment and those that are not; the standard of care is that people receive meds
    - Contemporary example: breast cancer trial—if efficacious, the immediately put on the drug
    - Negotiating and weighing risks—irreversible or temporary
    - Gawande—perhaps everyone should be subject to same level of care

Marcia Angell. 2000. "Investigators' Responsibilities for Human Subjects in Developing Countries." *NEJM*. 342(13): 967-969.

- Vertical transmission of HIV—justification of what would normally occur in developing countries anyway. What about standard of care for developing

countries? Is it fair to give it to folk who might not normally be able to have access? Political, economic resources of the country
- Do you think that MDs/scientists should be responsible – who should be responsible for treating patients?
- Whether privilege is a right in the USA or not? Same ethics here as there? A hierarchy of value of who deserves treatment. A right for us, a privilege for them? Gratitude for participation?
- Bring up issues of informed consent. How much do people actually know? Access to scientific information.

Uganda study of STDs/HIV
- Participants with HIV were observed and not treated for up to 30 months;
- Personal confidential information v relationship with partner
- Question of power: men are spreading HIV; women don't have power to say no to men sexually
- Culture of machismo, optional male condom use? Women is more stable partner but may not have power to demand his condom use
- Sex workers especially
    - Professor gave free therapy service; one of the prostitutes; focused on one particular victim of violence, but what about other structural inequalities
    - Didn't have the power to say no to men when she had to make money
    - These countries are indebted to developed world, via WB, IMF, how are they going to pay for drugs
    - Issues of standards of care
- Viral load / HIV transmission rates information doesn't help Ugandans
- How there should be same standards in developing countries and developed countries—is it okay to outsource our research where there is no approach regulation, the population is more needy, there is no government survey?
- Injustice to patients there; injustice to patient here
- Research population abroad is different; the results may not be as relevant; hard to match them. And the other way around? A completely different population?
- Outsourcing trials to developing countries. Should transfer ethics as well. Capitalist pursuit of research ethics.
- Babies—thyroid glands—sudden infant death syndrome—real problem of studying the destitute was that when people are starving, it is reduced in size; bad science with transfer of conditions;
- To what extent do IRBs do their job? Informed consent doesn't work, because patient may not necessarily wish to raise voice to doctor
- Ethical to treat one disease and not another?

Peter Lurie and Sidney M. Wolfe. 1997. "Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries." ***NEJM*****. 337(12): 853-856.**
- To what extent do IRBs do their job? Informed consent doesn't work, because patient may not necessarily wish to raise voice to doctor
- Placebo control trials successful for preventing perinatal transmission; to find a cheaper drug for HIV transmission

- Found 18 studies for perinatal transmission
- Not all participants were provided with the drugs; differences in the studies; despite existence of IRBs and supposed standards of care
- Rather than give no treatment, is it okay to give shorter or lesser term of care as experimental arm?
    - Arbitrary setting of dosage
- Can research be done in more than one way, why not select one that minimizes loss of life? Should they be providing treatment if they can?
- Subjects are doing the USA a favor; why not return the favor to the subjects; the first world is benefiting more.
    - Developing country company makes a drug, tests it on those in the developing world, find that it works, but don't return anything to it—should they have receive anything in the long term?
    - Compensation for test subjects
    - Like employees—should pharma. subjects get compensations
- Who should be responsible for patient welfare …?

N. Yasemin Oguz. 2003. "Research Ethics Committees in Developing Countries and Informed Consent: With Special Reference to Turkey." ***The Journal of Laboratory and Clinical Medicine.*** **141(5):292-296.**

- IRBs in developing country—Research Ethics Committees (RECs)—created by pressure on Turkey
- Major scientific journals require REC approval first; developing countries didn't have their own standards and adopted those of the developed countries
- In Turkey family is smallest autonomous unit; idea of autonomous individual does not map onto their culture
- Not understanding autonomy—provided sense of western superiority
- Collective autonomy—based on their culture v information on individual
- Turkish society is presented as very paternalistic; patients never questioned authority of doctor
- Informed consent—lower literacy rates, REC more difficulty in validating informed consent
- Developing countries—inequities of medical care—their only way of care in Developing countries
- Question: should developing countries be forced to abide by same rules?
    - Yes, they should promote those kinds of committees; but leave some flexibility w/o imposing cultural western view?
- "We should apply our same ethics, same treatment… but they don't need to be held to same standards." Clinical trial ethics—universal v particular.
- As western medicine asserts its power/globalization on rest of the world and force creation of a new kind of individual
- Why is it okay to say that those Turks or other people have different standards, different morals? Can cultural ethicism can be taken to the extreme as well.
- Hierarchy of value of the person, how we view others

