Danielle Bromwich Lecture

Key Points

- Need for international medical research: 10/90 gap, ten percent of health research is dedicated to 90% of global disease burden (diseases that adversely impact world's poorest countries)--> lack research on tropical infectious disease and lack of research on improving access to effective treatments
- HIV and AIDS- most affected in Africa, focused on perinatal HIV transmission--treatment is variable in some areas even though there is treatment --> problem is complexity of regimen of AZT
- “Medical research aims to generate knowledge that will hopefully, in turn, lead to improvements in medical practice”.

    - Animals are first used to experiment with these new medications, and then they graduate to the human bodies.
    - While informed consent of these human volunteers is considered an ethical requirement, there are certain standards that must be met by the volunteers and researchers for the consents to be considered valid, for example the volunteers need to be able to understand and be somewhat literate so they know what they are agreeing to and they must consent voluntarily.
- The researchers also need to disclose all of the information about the research being conducted without omitting small but important details that might change the minds of the volunteers if they learned.
- These rules are for the protection of the rights of their volunteers because many times, these volunteers get taken advantage of because of their low socioeconomic background and their lack of ability to fully comprehend the risks of research.
- This can generally be attributed to language barriers but sometimes volunteers simply have a hard time understanding what the research entails. However, research in developing countries in general can be seen as unethical.
- The need for international medical research however…as Prof. Annas quoted, "…can't do studies ethically in a country where there is no basic health care. You can tell a person there that this is a research, but they hear they have a chance to get care or else refuse their only good chance at care. How can you put them in that position and then say they are giving informed consent?" (24)

- But there is a lack of research on tropical infectious diseases and on improving access to their effective treatments
- The spread of HIV and AIDs in sub-Saharan Africa very high- lack of education about its transmission
- Very expensive costly treatment and its complexity can discourage its usage
- What about when individuals from a certain background don't value the opportunity to make decisions for themselves? Is there a need to obtain individual informed consent?
    - Informed consent can benefit volunteers indirectly because of the ways it influences the behavior of researchers by making them more aware and sensitive towards the volunteers.
- Randomized control trials- neither researcher or subjects know which group belongs to what tests so eliminate placebo effects- observed that people will experience some level of improvement when they believe they are receiving an effective treatment (whether or not they are)
- Active controlled trials- compares a test drug to an already established drug that has been used successfully for the same condition- is the new drug better than the existing drug? But it doesn't tell how much better
- While not all trials pose significant risks to subjects- cant assume that the risks of treatment are less than non treatment.
- Principles of clinical equipoise- means that there is genuine uncertainty in the expert medical community over whether a treatment will be beneficial

- Must be a significant degree of uncertainty about the net "therapeutic merits of interventions to be compared"
- Exploitation- advantageous use of something or someone- " an individual labors more than is strictly necessary to meet his or her own needs
- The ethical challenge of treating HIV women is balancing the need to develop effective and affordable treatment using these African women without exploiting them because those who "volunteer" in research risk individual rights/ and rising side effects for the benefit of others
- Lots of neglected tropical disease like dengue fever that there isn't a lot of research- very little incentive because you wont make money back or profit
- WHO's controversial solution: learn from 076 and proposed randomized controlled trials
- Controversy: women forced into study by offered nothing at all or shorter simpler AZT regimen (similar to Tuskegee case)
- Medical research ethics: produce knowledge but not designed to benefit individual research participants
- Clinical equipoise: exists when there is genuine uncertainty about superior treatment
- Standard care: members of control group ought to be given standard of care for condition being studied
- Another study in Boilvia (Surfaxin) concerning respiratory distress syndrome, FDA has four approved surfactants, approach mothers and randomized trial

Points of Synthesis

- I wonder where Professor Bromwich obtained her statistics from. For example, when she says approximately 1,000 HIV-infected babies born every day in Africa, is this number used to persuade people the significance of this research? This ties back into the first reading of the semester, *Wisdom of Whores*. Data can be manipulated to favor the researcher's study. Although the intentions may be good, is this ethical? We must also consider data manipulation when the intentions of the research aren't necessarily with good intentions.
- Healthcare system of developing countries need to improve, but our country isn't doing any better. Therefore, how are we going help developing countries if our healthcare system is the worst in the developed world? The Commonwealth Fund compared the US and other European countries in terms of healthcare, and inevitably the United States' health system was ranked last. This reminds me of a video I watched in a management class last year about healthcare systems around the world. Citizens in the US suffer greatly from healthcare costs compared to other countries around the world, such as France, Italy, and Singapore. Insurance companies add onto this hardship because many companies won't accept people who are not already healthy due to costs. This issue of rising medical expenses puts patients who need critical operations performed in great lifelong debt.
- I wonder who exactly participates in these researches if there is burden, risk, and certain requirements. Would most of the participants be of a particular crowd? Are the participants desperate and have nothing else to lose? If it is a win-win situation for both parties, yet the study may not be ethical, then does standard care still apply if these participants are still willing and eager to participate? My

questions of contractual agreement still come to mind because there is still uncertainty that the participants fully understand what trial they are participating and the risks of it.

- Active controlled trials compares a test drug to an already established drug that has been used successfully for the same condition- is the new drug better than the existing drug? But it doesn't tell how much better. I don't believe subjecting volunteers to the probability of side effects when this new drug is not needed- don't fix what's not broken