Ethics: Bioethics (Fall2014)

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Bioethics: Born in Scandal

By way of introduction . . .

- *Repo! The Genetic Opera*

- Are there limits to what someone can freely and voluntarily consent?
  - Should some options not be offered?

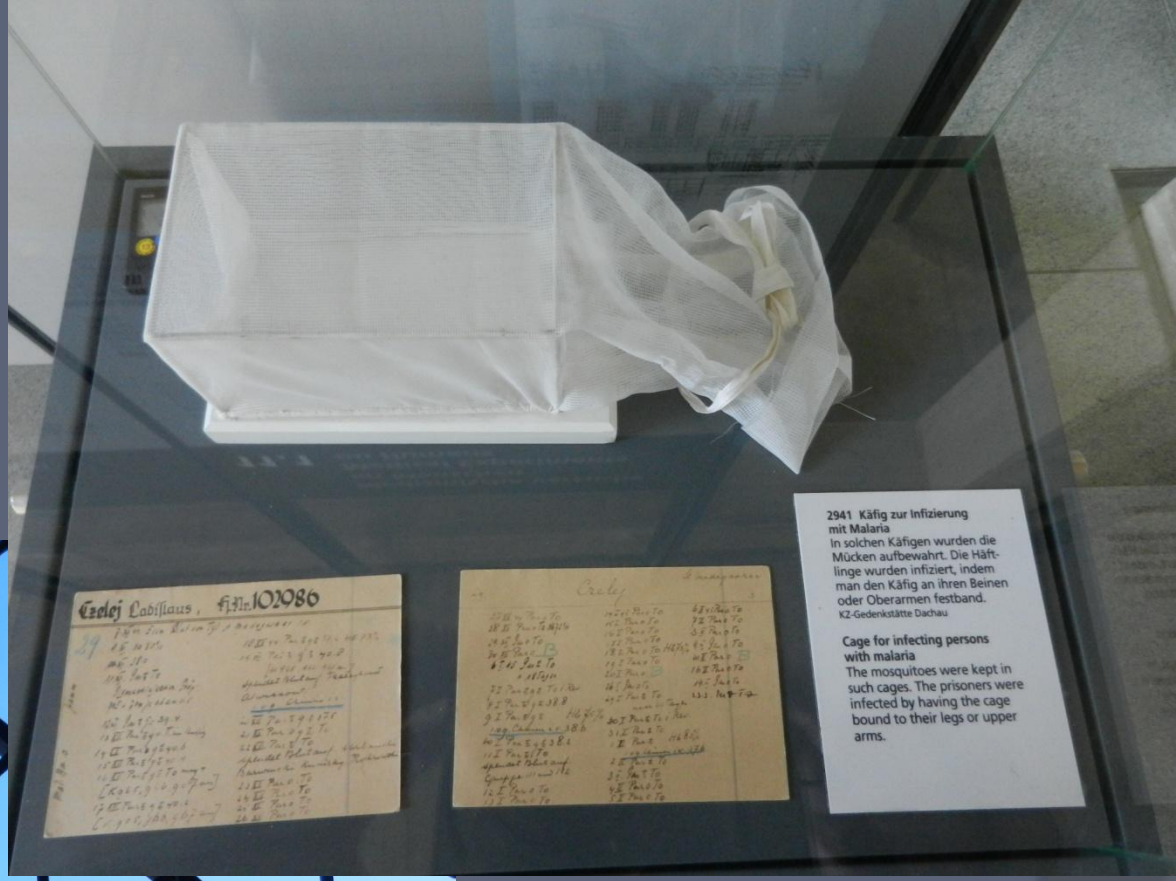
- Given the asymmetric power relation between physicians or researchers on the one hand and patients or subjects on the other, how can free, voluntary, and informed consent be obtained?

Why Might Informed Consent Pose Problems for Researchers and Doctors?

- Extra time, resources, approvals…
- Might not receive enough volunteers for important research
- If subjects are allowed to back out of research and refuse their previously acquired data, then some research will never achieve a high enough "n" for useful results.
- The "good of the state" or the good of the many might be really urgent.
- **Initial thoughts on the rights of research subjects in competition with the good of science, the good of the many?**

Nazi Experiments & Nuremberg

Dachau Concentration Camp



Used for malaria experiments on prisoners

Doctors' Trial & Nuremberg Code

- **Does the Hippocratic Oath sufficiently cover the moral obligations of physicians/researchers towards research subjects? If not, why not?**
  - *Primum non nocere*
  - "Hippocratic ethics, even when supplemented with informed consent, tend to submerge the subject's autonomy into what the physician-investigator thinks is best for the subject" (Shuster 1439)

- **Different aims and moral priorities of physicians and researchers – different models of relationship needed**

Doctors' Trial & Nuremberg Code

- **If a research protocol is presented to an Institutional Review Board, and the research seems to be methodologically flawed or offers little in the way of useful scientific knowledge, should the IRB refuse to approve it? Even if the subjects will be put at minimal risk?**

- Andrew Ivy admits: "the right of the research subject to withdraw from an experiment may not always exist" when "subjects had already been infected, or in dangerous experiments" (1439)
  - **Does this mean that these types of research should be morally prohibited?**

Tuskegee Syphilis Study

Tuskegee Syphilis Study (1932-1972)

Penicillin became available in **1947**

- **If researchers believe that they are conducting a "study in nature" as passive observers, is informed consent morally unnecessary?**
  - **What might be problematic about the "study in nature" assumption? (Keeping in mind racist attitudes of researchers in this case…)**

- "you have gotten a great deal of treatment for bad blood […] THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT" (Brandt 758)
  - **Is deception ever justifiable in recruiting or retaining research subjects?**

- Inducements: "free treatment", burial expenses, "getting better medical care than they would under any other circumstances" (760)
  - **Even if the subjects had given consent with these inducements offered, would you have moral qualms with soliciting their consent in the first place?**

Willowbrook Hepatitis Study

Willowbrook Hepatitis Study (1956-1971)

- "On these disease-ridden wards, the line between treatment and experimentation seemed to vanish. A researcher could select his disease and enjoy substantial freedom to experiment, believing that he was serving both society and the residents" (Rothman & Rothman 750)
  - **Is it morally problematic for the therapy-research line to be blurred, given concerns about informed consent and the physician/researcher-patient/subject relationship?**
- **What are some moral concerns about the consent form given to parents of children at Willowbrook?**
- **Do the lack of nonhuman hosts and the high rate of contagion justify Krugman's methods?**

Concerns about Acquiring Informed Consent

- From vulnerable populations: prisoners, children, the cognitively disabled…
  - **Do you think these individuals can ever truly consent to research? What if it is non-therapeutic and offers no direct benefit to the subject?**
- In certain contexts: prison, psychiatric institutions, wartime
  - **What are some of the key moral concerns about conducting research in these contexts?**
- When many of the harmful side effects are unknown/uncertain
  - **How should researchers handle this type of situation in the consent process?**
- Incentivizing vs. reimbursement vs. no monetary award/gift
  - **How might the promise of money raise concerns about informed consent and autonomous decision-making?**

Imagine the Scenario

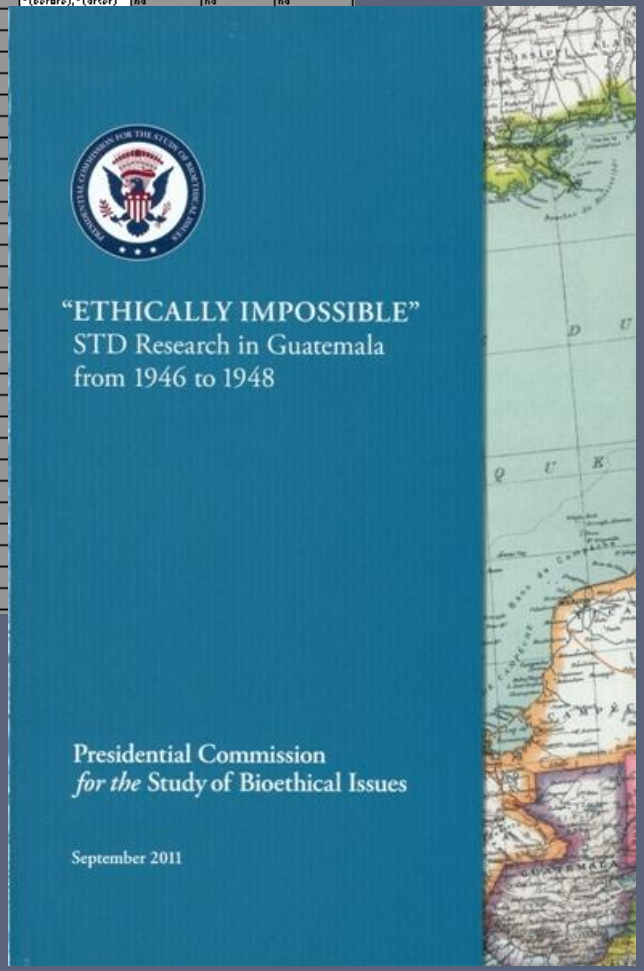
- There is a proposed study that could potentially lead to the eradication of a (non-lethal but prevalent) sexually transmitted infection. The research design calls for a large infected group that can be tested and re-tested at regular intervals, and they cannot find volunteers in their local community.

  - **If the most efficient and reliable results could be obtained by infecting adults through deception, would it be justified? Does the type of deception matter? What if they consented to the research but not to the possibility of deception?**

  - **What if the adults were a poor, uneducated population in a developing country? What if they gave a general consent?**

Guatemala STD Research

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	Unique Line Number	PCSBI #	Source	PCSBI HSPI Archives	Experiment Number	Date	Subject Age	Subject Sex	Subject Numb	Additional Population Descriptio	Sulfa Urin	Gonorrhea +/-	Gonorrhea Test	Gonorrhea Sugars	Syphilis +/-
2	7106	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000003	nd	2/11/1947	18	F	nd	nd	nd	nd	culture	nd	nd
3	7107	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000003	nd	2/13/1947	18	F	nd	nd	nd	nd	culture	nd	nd
4	7108	CSW-0001	Notebook 1: Daily Laboratory Recor	CTLR_0000004	nd	2/15/1947	18	F	nd	nd	nd	nd	nd	nd	nd
5	7176	CSW-0001	Gonorrhea Experiment #1	CTLR_0001742,	nd	6/1946, 8/1946, 11	18	F	nd	nd	nd	nd	nd	nd	nd
6	7621	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000133	nd	7/30/1947	nd	F	3	nd	nd	gram neg diplococci	nd	nd	nd
7	7622	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000191	nd	9/25/1947	nd	F	3	nd	nd	-(before), -(after)	nd	nd	nd
8	7623	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000192	nd	9/26/1947	nd	F	3	nd	-	-(before), -(after)	nd	nd	nd
9	7624	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000195	nd	9/27/1947	nd	F	3	nd	nd	-	nd	nd	nd
10	7625	CSW-0002	Notebook 1: Daily Laboratory Recor	CTLR_0000201	nd	10/2/1947	nd	F	3	nd	nd	nd	nd	+---	nd
11	7626	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000236	nd	11/18/1947	nd	F	3	nd	nd	-(after)	nd	nd	nd
12	7627	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000237	nd	11/19/1947	nd	F	3	nd	nd	-(before), -(after)	nd	nd	nd
13	7628	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000258	nd	12/8/1947	nd	F	3	nd	nd				
14	7629	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000260	nd	12/9/1947	nd	F	3	nd	nd				
15	7630	CSW-0002	Gonorrhea Experimentr - Military	CTLR_0001942	nd	1/20/1948	nd	F	3	nd	nd				
16	7631	CSW-0002	Gonorrhea Experimentr - Military	CTLR_0001952-	nd	1/21/1948	nd	F	3	nd	nd				
17	7633	CSW-0002	Gonorrhea Experimentr - Military	CTLR_0001924-	nd	1/28/1948	nd	F	3	nd	nd				
18	7632	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000308	nd	1/28/1948	nd	F	3	nd	nd				
19	7634	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000374	1	6/28/1948	nd	F	3	nd	nd				
20	30163	CSW-0002	Gonorrhea Experimentr - Military	CTLR_0001912-	nd	6/29/1948	nd	F	nd	nd	nd				
21	7635	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000374	1	6/29/1948	nd	F	5	nd	nd				
22	7636	CSW-0002	Notebook 2: Daily Laboratory Recor	CTLR_0000388	nd	7/3/1948	nd	F	5	nd	nd				
23	7637	CSW-0002	Gonorrhea Experimentr - Military	CTLR_0001970-	nd	9/25/1947 and 9/2	nd	F	5	nd	nd				
24	7638	CSW-0002	Notebook 4: Guatemala Journal St	CTLR_0000552	22	9/25+26/1947	nd	F	5	nd	nd				
25	7639	CSW-0002	Gonorrhea Experiment 9-26	CTLR_0001859	nd	Sept. 26	nd	F	5	nd	nd				
26	8275	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000103	nd	7/11/1947	nd	F	nd	nd	nd				
27	8276	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000159	nd	8/21/1947	nd	F	nd	nd	nd				
28	8277	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000181	nd	9/18/1947	nd	F	nd	nd	nd				
29	8278	CSW-0003	Notebook 1: Daily Laboratory Recor	CTLR_0000195	nd	9/27/1947	nd	F	nd	nd	nd				
30	8279	CSW-0003	Notebook 2: Daily Laboratory Recor	CTLR_0000219	nd	10/16/1947	nd	F	nd	nd	nd				
31	8280	CSW-0003	Notebook 2: Daily Laboratory Recor	CTLR_0000222	nd	10/27/1947	nd	F	nd	nd	nd				
32	12857	CSW-0004	Notebook 1: Daily Laboratory Recor	CTLR_0000120	nd	7/17/1947	nd	nd	nd	nd	nd				
33	13329	CSW-0004	Notebook 1: Daily Laboratory Recor	CTLR_0000157	nd	8/19/1947	nd	F	nd	nd	nd				
34	13328	CSW-0004	[CSW-4, CSW-10, CSW-7]	CTLR_0001544	nd	8/31	nd	F	nd	nd	nd				
35	13327	CSW-0004	[CSW-4, CSW-10, CSW-7]	CTLR_0001547	nd	8/31/1947	nd	F	nd	nd	nd				
36	13334	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000032	nd	4/9/1947	nd	F	nd	nd	nd				
37	13335	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000138	nd	8/4/1947	nd	F	nd	nd	nd				
38	13336	CSW-0005	Notebook 4: Guatemala Journal St	CTLR_0000537	16	8/4/1947	nd	F	nd	nd	nd				
39	13337	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000140	nd	8/6/1947	nd	F	nd	nd	nd				
40	13338	CSW-0005	Notebook 1: Daily Laboratory Recor	CTLR_0000143	nd	8/8/1947	nd	F	nd	nd	nd				



Presidential Commission Report

Daily Show on the U.S. apology...

Questions? Comments?