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Editorials

Tuskegee: could it happen again?

The Tuskegee Syphilis Study is often paired with the horrific Nazi experiments as the prime examples of what happens when powerless subjects, the state's coercive power, racism, and medical research are unmoored from ethical concerns. In the Tuskegee study, over 400 African-American men with late stage syphilis were never told they were in a 40 year long (1932–72) experiment sponsored by the United States Public Health Service to study "untreated syphilis in the male Negro". The men were not directly offered treatment, even though they were told that the aspirins, tonics, and rubs were to help cure their "bad blood". With the support of community based physicians and nurses, the local standard of "no care" in Alabama's "black belt" became an orchestrated reality, even after penicillin became widely available in the late 1940s. The medical uncertainty over how to treat late stage syphilis and the desire to hold on to the subjects became the cover for the deceit that was perpetuated at Tuskegee. The government supported physician/scientists who ran the study went on to greater fame in their careers; although there was a lawsuit, no one was ever legally punished for what was done.

The ethical systems put in place after World War II and after the outcry over Tuskegee did change the regulations that supposedly now govern human subject research. Governmental regulating bodies, institutional review boards, data and ethics monitoring committees, and ethics courses were established or strengthened to obviate the possibility of a reoccurrence of abuses of this magnitude. Informed consent and an emphasis on the rights of the subject, not just the duties of the doctor, have become central to our ethical beliefs and to internationally promulgated standards.

British physician Thomas Percival's 1803 guide on medical ethics that claimed "beneficent deception" where "if men do not perceive it an injury to be deceived, there is no crime in false speech about such matters" no longer governs our notions of informed consent or ethical behaviours. We have returned, at least at the rhetorical level, to Claude Bernard's 19th century admonition that "the principle of medical and surgical morality, therefore, consists in never performing on man an experiment which might be harmful to him to any extent, even though the result might be highly advantageous to science, that is, to the health of others".

But nearly 30 years after the Tuskegee study was exposed and four years after an apology on behalf of the United States federal government from President Bill Clinton was finally tendered to the remaining survivors and their families, the international health care community's hope that it could never happen again is fading fast. We live in the age of the globalisation of research where international and multicentre trials are becoming the norm, where huge sums of money can be made or lost as a result, and where professional reputations and careers are built on grant getting ability. Moral statements from international medical bodies, over-worked governmental regulators, and quickie courses on ethics in our health science schools and for continuing education credit may no longer be enough to protect us from the modern day equivalents of what happened in Tuskegee. The mounting evidence suggests it is time to consider that the moral and institutional structures we put in place may no longer be strong enough to hold back an abusive tide.

Consider what a recent series in the *Washington Post* reported. A drug company begins a clinical trial of a new drug in Nigeria in the midst of a meningitis epidemic, but does not provide the usual standard of care when a subject's condition worsens. Even though there is another group of international physicians nearby providing treatment, the patient dies. Placebo trials on HIV vertical transmission take place in Thailand, the Ivory Coast, and Uganda even though zidovudine (AZT) is given in the West to HIV positive pregnant women. The infants born to these women in the placebo arm develop AIDS. Local doctors and nurses in Eastern Europe, Latin America, Asia, and Africa are rewarded with money, trips, and other research positions as they enrol illiterate patients in questionable circumstances, with little informed consent, and under coercive governmental support in more and more international drug company sponsored trials. In China, ill informed "subjects" are donating their blood for genetics testing and are promised free medical care that never arrives.

Questionable documentation from these kinds of studies increasingly forms part of the basis for new drug applications to governmental regulatory bodies in the West where the drugs are approved and then marketed. Are we ethically still in a small country town in mid-20th century Alabama? Or has it just moved outside the borders of the

United States? Is this what the globalisation of health care research has come to mean?

Few would argue that no human research should be done. Henry Beecher, the renowned American physician who authored the 1966 landmark paper on ethical failures in medical research, declared "The well-being, the health, even the actual potential life of all human beings born or unborn, depend upon continuing experimentation in man. Proceed it must; proceed it will". But as it proceeds, we cannot expect that the solution to the ethical dilemmas encountered will appear either *dues ex machina* or from historical precedent. Historical precedent itself is too easily made into a false god to whom prayers are useless.

To make sure Tuskegee does not reappear in our newspapers bearing the name of a town in Swahili or Mandarin will take political will, a commitment to justice, and a fair assessment of the reality of health care in an international context. We will have to gain a more sophisticated understanding of what is possible in situations where patients have few choices, where national per capita health care expenditures are less than what a western teenager can spend on her or his music collection, and where AIDS and other epidemics are endemic.

In the last year, international medical groups and bioethics commissions and councils in both the United Kingdom and the United States have issued advisories on international research. Responding to concerns over the HIV transmission trials, representatives of the World Medical Association last October approved revisions in the Declaration of Helsinki (the guidelines for biomedical research on human subjects) to condemn use of placebos in trials where known treatments are available. In the United Kingdom, the Nuffield Council on Bioethics has just completed a four month period of asking for comments on its paper on "the ethics of clinical research in developing countries". They suggested the need for new "intermediate" guidelines between the broad principles articulated through international tribunals and the practical realities in often poor and desperate countries. In the United States, the National Bioethics Advisory Commission in October has asked that treatment be offered subjects after research is completed, even if such drugs are not available in the host country. In each of these suggestions we can see reflected the efforts to not repeat what happened at Tuskegee: the failure to treat, the willingness to accept "community" standards, the linkage between a higher power and local health personnel, and the underlying racism that devalues subjects' lives away from the metropolitan centres.

All of these efforts are important turning points in our understanding of medical science's responsibilities toward subjects. They highlight the difficulties in situations where coercion, illness, and poverty are rife and researchers can cover their own efforts with a seemingly humanitarian gauze. Organised consumer groups, the government, and health professional organizations have to be willing to demand other changes. We need serious sanctions against those who violate these new rules and principles. We should link new drug approval at the governmental level to evidence of treatment provided to the subjects. We must place more educated consumers on review boards to question seemingly scientific decisions and to watch for violations of informed consent. We ought to be considering tying international law on human rights abuse to medical research.

Without our commitment to such elemental justice, the next Tuskegee is surely now being planned. And the new drugs appearing on our shelves may be manufactured from more than a different kind of "bad blood".

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