International solutions to unethical medical or scientific experimentation on human subjects

Question presented

Do mandatory vaccination programs constitute unethical human experimentation as vaccines are not duly tested before being injected and there is a complete absence of informed consent?
What are the various modes of redress against this policy of mandatory vaccination in international law?

Brief Answer

In the international arena, most documents relating to ethics in human experimentation are merely declaratory. They do not create any binding legal rights or obligations that may be enforced by individuals affected by violations of the rules contained therein. Since they do not confer rights, they also do not provide for any means of redressal for egregious violations of the principles. Typically, these documents are very highly regarded and are of significant importance as they have helped in shaping policies on medical human research on a national level.
However, the International Covenant on Civil and Political Rights creates legally binding obligations on the member states, and the Optional Protocol to the Covenant also provides individuals an effective means of redressal.

Outline

The following international documents and texts either expressly prohibit human experimentation without the informed consent of the test subjects or contain provisions that may be interpreted to prohibit such experiments. The following list also details any redress mechanisms provided by these documents.

Nuremberg code- 1947

1. Article one of the Nuremberg Code provides “the voluntary consent of the human subject is absolutely essential.” It further explains what voluntary consent connotes.
2. The United States is a signatory to the Nuremberg code. However, in the international fora, the Nuremberg code does not create any binding obligations or provides for a mechanism to enforce rights by individuals. Although not binding, the code is considered an authoritative source of domestic law in the United States.

Universal Declaration of Human Rights, 1948

1. The UDHR is a universal declaration adopted by the United Nations General Assembly in 1984. Although the declaration by itself is a non-binding instrument, that is, is does not create legal rights or obligations, it is considered to reaffirm human rights existing in customary international law. It is also considered the most basic document under international human rights law.

2. Some states and scholars do recognize that the rights enshrined in the UDHR are nothing but reiterations of customary international law. However, the United States has maintained that the document does not create any binding rights or obligations. Sosa v. Alvarez-Machain, 542 US 692, 735 (2004).
3. The UDHR does not expressly contain any provisions relating to human experimentation but Article 5 states that "no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment." This provision is broad enough to encompass a prohibition on medical or scientific experimentation with human subjects without informed consent.

Helsinki Declaration, 1964

1. The Declaration of Helsinki, issued by the World Medical Association in 1964, is the fundamental document in the field of ethics in biomedical research and has influenced the formulation of international, regional, and national legislation and codes of conduct. It is a comprehensive international statement of the ethics of research involving human subjects. It sets out ethical guidelines for physicians engaged in both clinical and nonclinical biomedical research.
2. The declaration contains specific provisions regarding the necessity of seeking informed consent from the test subjects. It states that "participation by individuals capable of giving informed consent as subjects in medical research must be voluntary." It further explains what this informed consent entails.
3. In 2008, the FDA eliminated all references to the declaration and its subsequent revisions. It instead ruled that compliance with the Good Clinical Practices (GCP) of the International Conference of Harmonization (ICH) is sufficient.

International Covenant on Civil and Political Rights, 1966

1. The ICCPR is another key document in the International Bill of Human Rights. The covenant contains binding legal obligations, but it is not a self-executing instrument, that is, the provisions of the covenant are enforceable only if the ratifying state has enacted domestic law to enforce the provisions.
2. Article 7 of the ICCPR expressly provides that "no one shall be subjected without his **free consent** to medical or scientific experimentation."
3. The United States is a party to the covenant, but it considers itself bound by article 7 to the extent that `cruel, inhuman or degrading treatment or punishment' means the cruel and unusual treatment or punishment prohibited by the Fifth, Eighth, and/or Fourteenth Amendments to the Constitution of the United States.
4. Optional Protocol One to the ICCPR permits the United National Human Rights Committee to receive and act upon individual complaints received alleging violations of the covenant by a state. The conditions for bringing a complaint to the UNHRC under the optional protocol one of the ICCPR are as follows-
    a. The country against which the complaint is sought to be brought must have ratified the optional protocol;
    b. the State party must have recognized the competence of the Committee monitoring the relevant treaty to receive and consider complaints from individuals.

(source: https://www.ohchr.org/EN/HRBodies/TBPetitions/Pages/IndividualCommunications.aspx#againstwhom)

5. Usually, exhaustion of domestic remedies is a pre-condition to bringing the complaint. (The complainant should also detail the steps taken to exhaust the remedies available in the State party against which the complaint is directed, that is steps taken before the State party's local courts and authorities. The requirement to exhaust domestic remedies means that the claims must have been brought to the attention of the relevant national authorities, up to the highest available instance in the State concerned. If some of these remedies are pending or have not yet been exhausted it should also be indicated, as well as the reasons for it.)
6. US has not ratified the two optional protocols relating to communications to the UNHRC.
7. The United States has accepted the competence of the UNHRC to receive communications only by state parties under Article 41 of the covenant. It has declared that it accepts the competence of the Human Rights Committee to receive and consider communications under article 41 in which a State Party claims that another State Party is not fulfilling its obligations under the Covenant. It should be noted that this article allows only complaints made by state parties; not individuals of the states (Article 41 (1)(a)). The optional protocols deal with individual communications.
8. In 1992, the United States summarized its position on non-consensual human experimentation to the U.N. Human Rights Committee in fulfillment of its reporting requirements under the ICCPR. It stated that "non-consensual experimentation is illegal in the U.S. Specifically, it would violate the Fourth Amendment's proscription against unreasonable searches and seizures (including seizing a person's body), the Fifth Amendment's proscription against depriving one of life, liberty or property without due process, and the Eighth Amendment's prohibition against the infliction of cruel and unusual punishment."

American Convention on Human Rights, 1969

1. This is a legally binding treaty of the western hemisphere aimed at consolidating the human rights obligations on member states.
2. Article 5 of the Convention provides for the right to humane treatment. It states that every person has the right to have his physical, mental, and moral integrity respected.
3. The United States has not ratified the convention and thus is not bound by the provisions therein.
4. The Convention established the Inter-American Commission on Human Rights and the Inter-American Court of Human Rights. The following procedure must be followed to bring complaints under this convention:
    - Individuals who believe that their rights have been violated must first lodge a complaint with the Commission and have that body rule on the admissibility of the claim.
    - If the case is ruled admissible and the state deemed at fault, the Commission will generally serve the state with a list of recommendations to make amends for the violation.

- Only if the state fails to abide by these recommendations, or if the Commission decides that the case is of particular importance or legal interest, will the case be referred to the Court.
- The presentation of a case before the Court can, therefore, be considered a measure of last resort, taken only after the Commission has failed to resolve the matter in a noncontentious fashion.

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Research, 1979

1. The Belmont Report was prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.
2. it is considered as a historic document reiterating the basic rules for the protection of human subjects.
3. This document is not an international convention conferring any legally binding rights with redressal mechanisms for violation of those rights.
4. The Basic Principles include the principle of "respect for persons". This includes providing the test subjects adequate information to make a considered judgment Informed consent is an application of the general principle of respect for persons. Informed consent requires three elements- information. Comprehension and voluntariness. In short, proper, complete, and accurate information has to be given to the test subjects, in an easy to understand the matter, and the consent to participate in the research has to be taken voluntarily, without coercion or undue influence by persons in authority.

International Ethical Guidelines for Biomedical Research involving Human Subjects, 2002

1. These international guidelines have been issued by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO).
2. These guidelines particularly elaborate on the obligation of medical researchers to seek the informed consent of the test subjects and the kind of information is to be disclosed to the test subjects for the consent to be "informed". They also lay down added protections and considerations when test subjects are vulnerable groups such as women and children.
3. These guidelines are merely intended to serve as models in defining national policies on medical research and do not create any legally binding obligations by themselves. Since they do not create any such legal rights or obligations, they do not provide for any source of redress in case a nation state violates any of the rules contained therein.

UNESCO Universal Declaration on Bioethics and Human Rights, 2005

1. Upon being mandated by its Member States to draw up a declaration setting out fundamental principles in the field of bioethics, the UNESCO unanimously adopted by acclamation the Universal Declaration in 2005.
2. The Universal Declaration constitutes a non-binding instrument in the eyes of international law. Yet, it is a valuable document as all for the first time in the history

of bioethics, all States in the international community are solemnly committed to respect and to implement the basic principles of bioethics, set forth within a single text.

3. The Declaration provides that "Any preventative, diagnostic and therapeutic medical intervention is only to be carried out with prior, free and informed consent of the person concerned, based on adequate information."

Possible international fora

1. **International Court of Justice**

Only states can bring claims against other states to the ICJ for internationally wrongful conduct pursuant to Article 36, Statute of the International Court of Justice. Individual claims will have to be espoused by the state concerned.

2. **International Criminal Court**

Individuals can be prosecuted before ICC for "crimes against humanity". However, the US is not a party to the convention submitting to the jurisdiction of the ICC. The US has expressed its strong opposition toward the ICC.

3. **United Nations Human Rights Committee**

Under the various UN human rights instruments, actions can be brought by nationals of a state against their state for breach of the provisions therein. As explained above in the context of the ICCPR, the United States has not ratified any optional protocols accepting the right of individuals to approach the UN HRC for violations of the treaty provisions.
Further, the UN HRC can only recommend a course of action that may be taken by the violating state. The state is under no obligation to enforce the recommendations of the committee, nor are there any practical sanctions for not complying with the committee's recommendations. In most cases, the action is almost with no practical effect, however, it may be a useful method to get public attention to the issue.

4. **US District Courts**

- Alien Tort Statute 28 USCS § 1350.

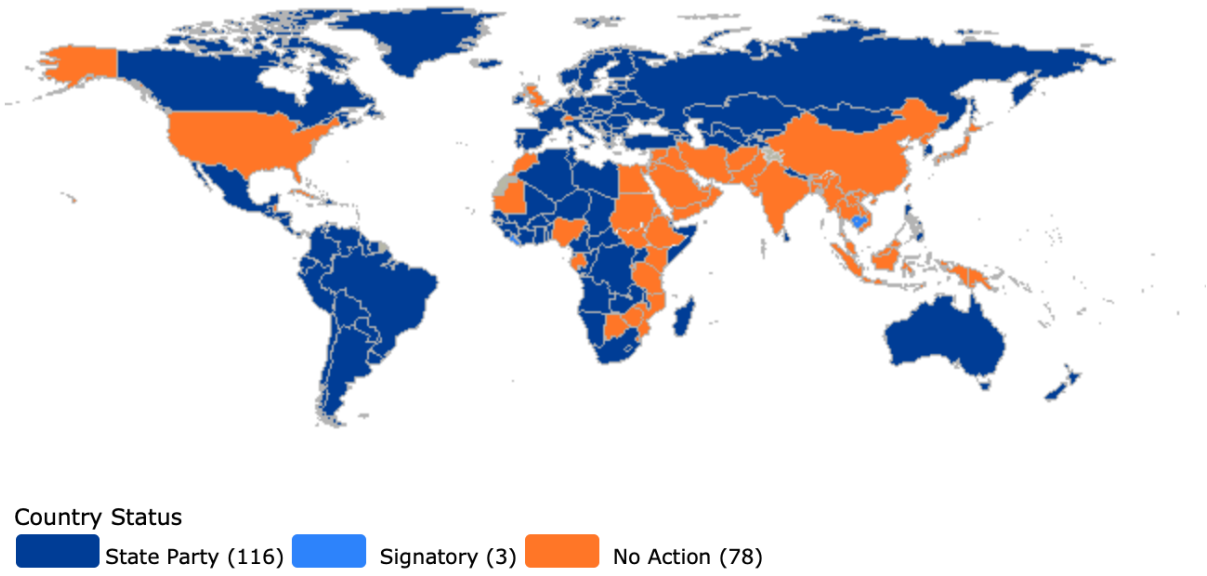
Under this statute, the district courts have original jurisdiction of any civil action by **an alien** for a tort only, committed in violation of the law of nations or a treaty of the United States.

Observations

The United Nations Human Rights Committee appears to be the best forum to bring an action for two reasons– first, it is the only international organization that recognizes the ability of individuals to bring human rights violation claims in the international arena and second, it is one of the strongest mechanisms to mobilize public opinion. Even though, its recommendations do not bind the state against which the recommendations are made but it certainly is a very strong forum to get public attention to this issue.

To file a complaint at the UNHRC, it should be brought under the ICCPR alleging a direct violation of Article 7 since the ICCPR is the only legally binding treaty that provides for redressal mechanisms.
We can nevertheless make use of all other international documents that do not provide for redressal mechanisms. They can be used to show an international consensus on the necessity of “free consent” and also the content of the free consent obligation.
As a reminder, to bring individual complaints under the ICCPR before the UN HRC, both states –that of the national and the state against which the complaint is sought to be brought– should have ratified the Optional Protocol of the ICCPR accepting the UN HRC’s jurisdiction to accept individual communications. Another pre-condition is the exhaustion of domestic remedies, as was explained above.

Below is a map of nations that have ratified the Optional Protocol:



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