

concerns (9) calls for heightened sensitivity and caution in design and execution of CHIM trials, even erring on the side of overprotection in the early trials lest we stumble at the starting post. The obvious benefits that may flow from such trials should inspire a concerted effort, drawing from our expertise and commitment to good research to create a durable model that could work for other LMIC regions as well.

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Law and ethics in consensual harm

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Abstract

In recent times there has been an emerging interest in conducting Controlled Human Infection Model studies in low-and-middle-income countries, in which healthy human beings are infected with weakened pathogen strains under controlled conditions. These volunteers are monitored closely so that cures and prevention methods can be developed for the disease. Such studies call into question the legal sophistry of taking consent to harm a person by justifying it for the greater good or advancement of science. This paper analyses the law on the subject and the ethics of obtaining consent to harm another human being as in the context of Controlled Human Infection Models.

Introduction

Controlled Human Infection Model (CHIM) trials are conducted on healthy human beings, who are intentionally infected with a disease (the infectious organism could be close to wild-type

pathogens, adapted or attenuated from wild-type, with less or no pathogenicity, or genetically modified in some manner) (1), in a controlled environment, so that science can trace the path of the infection, and what is happening at the molecular and cellular levels, and find the best time for medical intervention, develop a cure and/ or preventive methods against the infection (2). History has been marked by experiments similar to CHIM trials for diseases like small pox (3), dengue, malaria, influenza, tuberculosis, typhoid, etc. While the WHO guidance document states that it would be inappropriate to carry out CHIM trials for diseases that are virulent or even use an attenuated organism for those that have a high fatality rate, or a long uncertain period of latency, it does speak of the necessity for CHIM trials in a very few circumstances and the caution with which the trials should take place (1).

One justification often given for conducting CHIM trials is that they accelerate the development of vaccines or treatments, by using fewer financial and human resources than in clinical trials (4). But, can the use of fewer resources be enough of a justification to intentionally harm another human being? What about the obligations of the researcher “to do no harm” (non-maleficence) to research participants? Can we for the sake of the advancement of science harm healthy human beings? Such acts do, to some extent, violate Article 32 of the Universal Declaration on Bioethics and Human Rights that states “the interest and welfare of the individual should have priority over the sole interest of science or society” (5).

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Do individuals have a right to submit themselves to harm, even though it may be in a controlled setting and pose minimal risk? Can the safeguard of informed consent for intentional harm, or for taking on such a risk of harm, nullify the harm-doing? This article examines the law relating to consent to harm, an issue raised by CHIM trials.

The harm principle

John Stuart Mill, in his philosophical treatise *On Liberty*, said, "It is not the duty of the law to concern itself with immorality as such. It should confine itself to those activities which offend against public order and decency or expose the ordinary citizen to what is offensive or injurious" (6). Public perceptions of what actions or omissions should be restricted, criminalised and punished change from time to time, and have been debated and discussed over the years. For instance, most people may agree to criminalise murder, theft, and the sexual abuse of children, whereas most would oppose restrictions on members of a particular caste or community from living in a particular geographical area, or restricting the religion one may profess, while some may even want to bring their own sense of morality into the law and may want restrictions on bigamy, private use of pornography, etc (7). There is a distinction between laws designed to prevent harm and those used to enforce moral values, "or those with morality having to do with rights and those having to do with ideals" (7), like the protection of autonomy and respect for people.

Joel Feinberg, according to Michael Bayles, in a critique of moral limits of the criminal law, rejected legal paternalism that placed the well-being of persons above their autonomy, protecting them from even voluntarily accepted harm (8). According to Feinberg, the law should be used for the protection of particular values, like personal autonomy and respect for persons (7). His central question was whether choices made by people were voluntary or not, and he recommended a complex set of factors to gauge this: (a) the more risky the conduct the greater the degree of voluntariness required, if it is to be permitted; (b) the more irrevocable the risk of harm, the greater the degree of voluntariness required, if it is to be permitted (8). He also stated that judgements of voluntariness will vary depending on background assumptions, and the contexts and purposes of the judgements (8). Feinberg's harm principle argues that wrongdoing is nullified by consent, as in the case of euthanasia and gladiatorial battles, but the criminal law can be invoked where it is difficult to determine the genuineness of consent (7). How do we measure the genuineness of consent? In CHIM trials, participants may be informed and consent may be voluntary, but, whether it is genuine or not is not measured. People may enter trials not only for altruistic reasons, there could be other compelling factors that are not measured and often ignored while determining the genuineness of consent.

Magnitude of harm

Consent to being harmed does not mean that the magnitude of permitted harm can be severe. If the harm inflicted is

irreversible, or leads to death or spread of disease, consent would be irrelevant (9). Those who believe that the magnitude of harm can set a limit to consent endorse the view that if the aggregate harm done to a person exceeds a certain magnitude and is greater than the good, it should not be allowed (10). If such a view is considered, then it may be permissible—with the consent of a person—to do more good than harm, but below a certain magnitude (10). Sometimes it may be permissible to harm a person with their consent, for the sake of good done to another person, as when rescuing another person.

However, the "wrongness" of harming a person with consent is derived from the fact that it is morally wrong for a person to consent to being harmed herself/ himself to a certain degree for the sake of a certain goal (10). Some people also believe that we have moral demands that are irreducible to the demand to protect and promote goodness, ie, it is wrong to harm a person as a means to a greater good; and that is so *even though* harming a person may promote the greater good (10). Respect for the autonomy of others does not permit the harming of a person as a means to a greater good in all circumstances (10). CHIM trials therefore would not be permissible, even though Phase I clinical trials for drugs maybe permissible. The distinction between the two is that in the former actual harm is intended; and in the latter, there is a risk of harm that maybe unintentional.

Consent to bodily harm

The moral, ethical questions that arise are: whether consent to harm can be a defence to an act that would otherwise amount to criminal wrongdoing? Also, whether consent overrides *prima facie* wrongdoing, or if consent is vitiated by it?

Crimes of rape, sexual assault, medical interventions, etc, require that the victim did not consent; for if there was consent, then the action would be rendered lawful. Consent needs to be given by a person with the capacity to consent ("adult of sound mind"), and could be expressed, or implied, genuine—in the sense that the person giving consent comprehends the nature of the act, and consent is not vitiated by fraud, misrepresentation, mistake, coercion, undue influence, etc. Consent has been described as a defence to a charge of assault, but, in one sense, it is the failure of the prosecution to prove beyond reasonable doubt one of the elements of an offence (*viz* the absence of consent) (10).

Case law

As a matter of public policy, a person cannot consent to being harmed by an unlawful action. Thus, if two people agreed to have a fist fight, whether in public or private, that could inflict actual bodily harm, their consent would not be recognised in law, and their actions would be unlawful (11). There are certain exceptions, such as the sport of boxing (11), reasonable medical interventions (where if there is no consent it could incur criminal liability) (10), body piercing and tattooing (12), rough and undisciplined horseplay (13) and more recently in India, passive euthanasia (14).

The courts have also weighed the possibility of consent to risk of unintentional bodily harm, as in a game of rugby where a player was punched in the face fracturing a jaw, and though physical contact involving the use of force was necessary in the game, public policy imposed limits on the violence to which a rugby player can consent and force used outside the course of the game would lead to conviction (15). Courts have considered the issue of consent or genuine belief (where there was no consent) to acquit persons who jokingly tossed two schoolboys in the air and allowed them to fall on the ground, causing grievous bodily harm (13), and where in jest some officers tried to ignite fire resistant suits, leading to serious burns, although it was not intended (16).

Thus, certain acts that caused harm unintentionally, or under a genuine belief that it would not cause harm, have been looked upon by the courts leniently. However, Feinberg's principle of autonomy that allowed a person to consent to harm without rendering it an actionable wrong (8), was not supported by the majority in the judgment of *R v Brown* wherein the House of Lords held that since actual bodily harm was intended and caused, consent was irrelevant (17).

In *R v Dica* the court held that consent to risk can be a defense, though, it was stated that, once a person has knowledge of the risk of transmission of a disease, s/he is unlikely to consent (18).

With regard to CHIM trials, though consent is taken, intended harm is inflicted on a healthy person, who may develop the disease contained in the injected pathogen, even though it may be in a "controlled" setting, with treatment available. The probability of any healthy person getting the disease should be irrelevant as actual harm is intended to be caused and the participant is observed till s/he develops the disease, or to a point where s/he is likely to develop the disease. Infecting another for the sake of science seems offensive, against all principles and guidelines of conducting ethical trials and is "harm", as the harm or risk of harm could not possibly benefit the person in any manner (other than the compensation payable).

Duty

Moral duties have correlative rights. Thus, just as there is a duty not to harm, there is a correlative right not to be harmed (9). The question that arises is whether such a right can be waived. Each person has a duty to protect and promote well-being. Absolute rights cannot be waived, because in harming one's own self the right is violated (9). Even if suicide is no more a criminal offence, it does not mean that society has accepted or consented to the practice of suicide, it has only de-criminalised it, but is yet concerned with the person with suicidal tendencies and needs to reach out to the person to prevent harm to the self.

In clinical trials, it is the duty of the researcher not to harm even though there is consent. It is not just a legal duty, but also a moral and ethical duty. Hence, for the sake of advancement of science, would it be justifiable for a researcher to cause harm,

albeit in a controlled setting, to healthy volunteers consenting to harm? Would it not be tantamount to a breach of duty, especially of a researcher (or doctors) to save life, to prevent harm, to reduce pain and disease, to make people healthier – not sick? But, the argument can well be stated that in order to reduce disease in the population, research needs to be conducted on a few people willing to take the risk of minimal harm for the greater public good.

Medical research involves potential benefits and harms, and only such research ought to be undertaken where the benefits outweigh the harms. Research takes place on both healthy humans and patients who are required to voluntarily enter a clinical trial upon understanding the nature of the trial, the risks and benefits, etc. Some trials are termed to pose "no more than minimal risk", that would imply risks that are encountered in daily life and not anything additionally (19). Even in such trials there are risks of potential harm that could be physical, psychological, economic, social and legal harms (9). Further, problems with regard to the process of consent, such as therapeutic misconception, conflict of interest, difficulties of communication, etc, (9) are known and continue, despite regulations and guidelines. Violation of the consent process has the potential not only for harming the participant, but also vitiating the trial, and compromises on voluntariness.

Criminal law and consent

Consent forms an important part of all clinical trials on human participants. The requirement under the law and in all guidelines on clinical trials is that informed consent needs to be taken, where the participants are informed about the risks and benefits of the trial, availability of alternative treatments, known risks and the possibility of unknown risks, etc. The main difference between CHIM trials and phase I – III clinical trials is that in the latter there are risks of harm (that may or may not occur), whereas, in the former there is intentional harm, though it is controlled and perhaps managed. It is not just a risk; it is actual harm when one intentionally infects a healthy person with a disease.

Criminal law and public health laws contain many provisions that criminalise negligent and malignant spread of disease dangerous to life. Under section 269 of the Indian Penal Code (IPC) (20), "Whoever unlawfully or negligently does any act which is, and which he knows or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or with fine or with both." Section 270, IPC, penalises the malignant spread of the infection that attracts a punishment of two years. Diseases like chicken pox, cholera, diphtheria, enteric group fevers, influenza, pneumonia, leprosy, measles, plague, poliomyelitis, relapsing fever, scarlet fever, small pox, tuberculosis, typhus, yellow fever, etc, are listed as "dangerous diseases" in the public health laws and municipal laws of the States¹ (20), that empower the State governments with the power to contain their spread. CHIM trials may be conducted for such diseases termed as

dangerous diseases in law, and that could then invoke clauses concerning unlawful, negligent or malignant spread of diseases dangerous to life.

There are other provisions in the IPC such as those that criminalise voluntarily causing hurt, grievous hurt, or performing acts that endanger the lives and personal safety of others (20: ss 319-23, 336) that could probably be of some relevance to CHIM trials. The IPC defines the term “voluntarily” where a person is said to cause an effect voluntarily when it is caused by means which s/he knew or had reason to believe to be likely to cause it (20: s 39) and defines “injury” to denote any harm illegally caused to a person, in mind, body reputation or property (20: s 44).

A necessary element in order to invoke the criminal law is *mens rea* (guilty mind), the knowledge and intention to harm. On the face of it, CHIM trials have all these elements that could invoke the criminal law against the researchers, even though the true intention is the advancement of science. However, the exception of consent could be a defence for the researcher. Criminal law also shows leniency towards acts done in good faith, or those not intended or known to cause harm or injury, or done without criminal intent to cause harm (20: ss 81, 87, 88, 92, 95). The explanation given in law is that it is a question of fact in a particular case, whether the harm to be prevented or avoided was of such a nature and so imminent as to justify or excuse the risk of performing the act with the knowledge that it was likely to cause harm (20: Expl. to s 81). In CHIM trials, though the exceptions in criminal law could come to the rescue of the researchers, they may also need to justify the imminent need to incur the risk of performing an act that is likely to cause harm.

Taking informed consent prior to enrolling a person in a CHIM trial would have to stand the test of whether a person can consent to being harmed (which the court in *R v Brown* has said would be irrelevant, and harm would be measured); and of how much knowledge the consenting participant had of the harm that would be inflicted. Further, after knowing the extent of harm, was the consent voluntary, and free from any undue influence, misrepresentation, etc, and informed. If we follow Feinberg’s principle, then the participant’s autonomy and consent to enter the trial would supersede what he called the paternalistic role of law that would prevent harm even to consenting adults. The magnitude of the harm would also need to be measured to make consent relevant in CHIM trials.

Another important aspect for consideration is that despite the moral autonomy to decide what should be done to one’s own body, there are certain restrictions on self-harm, which necessarily limit what others may do even if consent to harm was obtained (9).

Compensation

The WHO guidance document states that the information gained should clearly justify the risks to human participants and that “it is essential that challenge studies be conducted

within ethical framework in which truly informed consent is given”(1:p3).

But, is informed consent enough to allow CHIM trials? There does not appear to be much documentation on the amount of compensation given to healthy participants to enroll for CHIM trials. Providing a good amount of compensation would be justified in one sense, as a healthy person would be taking a grave risk of being infected with a disease that would probably have some short term and even some long-term adverse effects on her/his health. But, in another sense, would providing high compensation be an undue inducement for persons to take the risk of harm? What is the true meaning of respect and dignity of the individual human participant, who agrees to be harmed and to take the risk of harm for the sake of science and is then forced to battle with temporary or reversible harm or permanent harm?

Conclusion

Constitutional morality respects every human being and seeks to provide all persons with the means to lead healthy and dignified lives. The right to life and liberty guaranteed under Article 21 of the Constitution of India includes the right to health that includes the highest attainable standard of health. Autonomy of individuals needs to be respected and self-harm may be allowed in certain exceptional situations, such as in the case of euthanasia.

Research experiments on humans have been stained by scandals and violations of the rights of participants. The small pox trial in 1796 (21), the Nazi trials that included freezing experiments, hypothermia trials, twin experiments, wound experiments, tuberculosis experiments, etc. where involuntary participants were forced to undergo the torturous experiments (22) have led to the development of ethical principles in conducting human trials. Could such trials be justified had informed consent been taken and if they were voluntary?

By allowing CHIM, are we reinforcing the paternalistic nature of science and slowly moving back in time? In a country like India, where we know that medicine and healthcare are still highly paternalistic, and consent is just a routine procedure (where it is not absent), where poverty is rampant, hand-picked persons can give ethical approvals and money can buy anything (even research participants), can we allow CHIM with our eyes wide open to the possible consequences in this country? Clinical trial participants are unable to seek redress for their grievances; justice is not seen to be provided to the victims of clinical trials, with cases pending for years and no respite to participants. There is no comprehensive law that protects the rights of clinical trial participants, (with the exception of providing compensation for trials conducted for new drugs); and it is well known that most participants enroll in clinical trials not only for altruistic reasons but also to earn some money that would provide for their families.

The question, therefore, is not whether we should carry out research or not, but how much we have learnt from the

past, and what safeguards we have brought in to protect participants in research. Are we, in a developing country like India, getting induced to perform CHIM studies, seeking to help build a healthcare infrastructure? In the name of controlling diseases by understanding their progress and developing vaccines, are we just looking for easy ways to prevent diseases, rather than concentrating our efforts on hygiene and sanitation, providing nutrition and food to those in need? There does not seem to be any imminent need to conduct CHIM trials in India. The scarce resources need to be optimally utilised to strengthen primary healthcare and the social determinants of health that are the fundamental and basic rights of all humans.

It is important to set a high threshold if we are to protect the cardinal rights to autonomy, dignity and wellbeing of individuals. We also need to reconsider the sophistry of consent that allows harm and do a reality check on not just the magnitude of the harm but also the voluntariness of informed consent.

Note

¹ State Municipal Council Acts like the Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965, s. 237; Tamil Nadu District Municipalities Act, 1920; Madras Public Health Act, 1939; Travancore Cochin Public Health Act, 1955; Goa, Daman and Diu Public Health Act, 1985 with Rules 1987.

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Public engagement in the context of a CHIM study

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Abstract

Public engagement especially in new and contested areas of medical research is an essential ethical requirement. It helps to build trust, to embed ethical discourse in public beliefs and values and widen the accountability and the governance of biomedical research. Historically, ethical codes resulted from public protest following unethical medical research practices. Unethical

practices do continue to a certain extent, primarily among unempowered communities. The need for public awareness, public deliberation and public advocacy are even more important in a country like India, where “research” is not understood, where paternalism on the part of the health professional, and the non-questioning attitude of the patient/participant have been customary, followed in recent times, by mistrust and an expectation of corruption in the public mind when dealing with a healthcare set up.

CHIM studies carry various levels of unknowns. There are challenges of public non-comprehension of the need for being “infected”; of families and communities being at risk; of possible high levels of compensation being offered as inducements; of other public health / preventive measures being supplanted. It is important for researchers and regulators in India, not to rush into

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