Review Paper

Ethics Dumping and India's Unfortunate History

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ABSTRACT

The practice of researchers in a high-income country exploiting research participants from a low-and-middle-income country (LMIC) due to the relatively less stringent laws and ethical restraints that would otherwise prohibit the same to be carried out in their own home country is referred to as ethics dumping. Historically, there are several instances of ethics dumping internationally, which was a lot more widespread before the Declaration of Helsinki of 1964 and the Universal Declaration of Bioethics and Human Rights. This article aims to look at a few prominent and historic examples of unethical research conducted internationally and critically analyze a few instances of ethics dumping in India. Ethics dumping, unfortunately, persists even after the targeted country or community institutes regulations to prevent exploitation. This can be attributed to a lack of appropriate implementation of the laws, cultural and communication barriers, and a gap in the knowledge amongst the native population and the local researcher or contact persons recruited. The exploitation is oftentimes disguised as health aid from philanthropic organizations contributing to global health which has in many instances resulted in uninformed trials and studies conducted on vulnerable populations, ultimately leading to human rights violations. As future healthcare professionals, it is important that published medical literature recognizes this dark and unfortunate chapter of modern medicine, as only this can help create awareness and mould healthcare students and professionals into proponents of ethical research who will hopefully shape the future of clinical research based on sound ethical principles.

Key words: ethics dumping, unethical, LMIC, human rights, violation.

Introduction

Ethics dumping refers to the unethical practice of independent researchers or organizations in a high-income country exploiting a medium or low-income country to conduct research, harnessing the relatively less stringent laws and ethical restraints that otherwise prohibit the same to be carried out in their own home country. There may be several compelling impetuses for ethics dumping to occur, more often, intentionally, than otherwise. For instance, ethics dumping could be in the form of taking advantage of a country's ambiguous laws and regulations or taking advantage of the lesser required economic resources to conduct research.

In another instance, ethics dumping could be disguised as an altruistic act in the form of providing relief to vulnerable populations who otherwise may not have access to research interventions and in the process, there is a compromise on ethics.

Role of the European Commission

The term 'ethics dumping' was coined by The European Commission in 2013. More recently, the Code of Conduct for Research for Horizon 2020, the research fund of The European Commission, which extends to all research projects funded by the European Union was revised to include clear guidelines to aid researchers in identifying and mitigating the sometimes unintentional and obscure instances of ethics violation. Examples include the necessary employment of translators to ensure valid consent; the maintenance of confidentiality and safety, complying with local and national laws when research on sensitive issues, like the health of homosexual individuals or sex workers, are conducted in countries where it is still illegal [1]. Despite the institution of better guidelines in the European Union, the vast majority of high-income countries are yet to adopt similar policies, which exposes low and middle-income countries, with a large proportion of vulnerable population, to unethical research practices.

International Instances of Ethics Dumping

Ethics dumping is not an entity that has only recently come into existence. Instead, it has only recently been identified and defined with a global consensus to eradicate its prevalence. The infamous Tuskegee trial conducted in the 1900s, where illiterate black men with tertiary syphilis were diagnosed and left untreated, is an excellent example of taking uninformed consent and failing to provide follow-up and standard care, leaving the patients untreated merely for research purposes [2]. Another well-known example, the International Genomics Research trial compared the genome of indigenous San people from Namibia with South African people which was published without prior permission from San leadership. It revealed information claimed as private and discriminatory by San leadership [3]. Another case is that of a study on health-seeking behaviours undertaken by a non-governmental organization (NGO) in an African village pertaining to female genital mutilation. The rural female participants were uninformed about the research as the NGO was primarily involved in providing humanitarian aid. As a result, the study publicly revealed details about illegal female genital mutilation, disregarding safety, socio-cultural norms, and subsequently contributed to stigmatizing their culture [4].

The Indian Cervical Cancer Trial

The World Bank estimates that nearly 75% of the world's population and nearly 62% of the world's poor reside in low-to-middle-income countries (LMICs), like India [5]. India is home to nearly 1.38 billion [6]. A significant majority of India's population lacks access to basic necessities like education and healthcare. More often than not, they are unaware of their basic human rights, especially in the context of receiving healthcare of the highest attainable standard [7]. India has thus inevitably fallen prey to several rather conspicuous attempts of ethics dumping which has cost innocent lives and warranted the institution of new guidelines and re-evaluation of existing protocols and laws surrounding clinical research on human subjects conducted or funded by a foreign body in India.

The Indian Cervical Cancer Screening Trial can be likened to the Tuskegee Trial. This trial, which ran between 1998 and 2015, was a clustered randomized control trial (CRCT) conducted in Mumbai, Osmanabad, and Dindigul in India, to study the sensitivity and specificity of using inexpensive methods of screening like 'direct visual inspection with acetic acid' for detection of precancerous or cancerous cervical lesions [8].

The trials were funded by the National Institution of Health (NIH) of the United States of America and the Bill and Melinda Gates Foundation. A total of 374,000 women were recruited, of which 141,000 women were assigned to the non-screening control arm. While cytology from a Pap smear was and is the gold standard for cervical cancer screening, the participants in the control arm did not receive the established standard of care protocol, i.e., screening by Pap smear, which was possibly because of its limited access. They were only dispensed with health education to identify the signs and symptoms of cervical cancer and information on the available treatment for the same. They were followed up frequently to assess the trial proportion who had developed cervical cancer and subsequently died. These participants did not receive any form of treatment with 254 participants dying from the control arm and 208 from the screening arm [8].

The trials had apparent flaws in their study design with there being alleged deficiencies in the consent form provided in Marathi, the regional language spoken by the majority of the trial participants. It omitted important information on further tests and interventions rendering the consent invalid, as cited by the Office of Human Research Protections (OHRP), United States of America's investigation into one of the three trials. Furthermore, there seemed to be a lack of maintenance of a standard of care throughout the trial. Finally, the trial recruited women from socio-economically disadvantaged backgrounds like homeless women and slum-dwellers who are already at an increased risk for developing pre-cancerous lesions that go undetected and eventually invasive cervical cancer which ultimately bears significant mortality [8]. The participants in the control arm were thus denied basic human rights to avail the highest possible standard of care which was life-saving, as they were left in the dark about not getting any treatment. This trial has since garnered significant criticism, with even an offered refute to the above ethical arguments [9].

The Indian HPV Vaccination Trial

In 2009, The Programme for Appropriate Technology in Health (PATH), an American non-profit, and the Bill and Melinda Gates Foundation funded a 3.6 million HPV vaccination trial, with GlaxoSmithKline and Merck & Co supplying the vaccines in India in order to extend its reach in the Global South. This was to ultimately prove its importance and efficacy to be added to the universal immunization schedule. The trial recruited 24,777 adolescent girls from the states of Andhra Pradesh and Gujarat, predominantly from local tribal communities, the majority of whom were illiterate and their parents/guardians, for the most part, were also incapable of providing consent [10].

The trial was brought to a halt in 2010 when 7 deaths within the trial were reported. Post-mortem examinations were not conducted with trial investigators claiming the cause of most deaths unrelated to the trial (malaria, suicide, etc.). This was met with criticism and later prompted a government inquiry into the nature of the conduct of the trial, the possibility of ethics dumping by exploitation of vulnerable populations, and the relatively lesser stringent laws surrounding clinical trials in India. The Indian Council of Medical Research (ICMR) and the Drug Controller General of India (DCGI) came under heavy scrutiny for their role in the approval and regulation of the trial [11].

This trial not only took advantage of vulnerable minors from rural communities, by failing to obtain valid consent, with a school headmaster consenting on behalf of the study participants in one instance, it also failed to constitute a functional central ethical review board and a system for reporting adverse drug reactions [11]. This resulted in the violation of their basic human rights prohibiting exploitation and allowing dignity and health to all.

Ethical Quandaries of Ethics Dumping, Instituted Guidelines and its Mitigation

It is apparent that the practice of ethics dumping violates all four pillars of bioethics- with participant autonomy compromised and beneficence in question. Such practices are thus maleficent and a gross injustice to unguarded populations.

The 18th World Medical Assembly adopted the Declaration of Helsinki in 1964, which outlines recommendations guiding doctors for clinical research. Since then, with 9 amendments, the latest being 2013, The Declaration has been an authoritative source of reference for ethical principles to be followed in medical research involving human subjects. It was the first document accepted by the medical fraternity wherein they laid out the non-negotiable ethics-appropriate practices, the concepts of freely given informed consent and right to withdraw it anytime, and the explanation of risks and benefits of the proposed intervention. Above all, it stressed that the health of the patient was a physician's utmost responsibility [12].

Today, this Declaration has expanded to state that it is the foremost duty of the researchers to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. It adds that human subject research has to be justified by its potential preventive, diagnostic or therapeutic value, and vulnerable populations must be involved only when it is not possible otherwise and the said people benefit from it, and appropriate compensation and treatment must be provided to participants if they are harmed. Finally, everyone

involved in such research has ethical obligations to register it with national authorities, publicly share the study protocol to allow third-party scrutiny, and publish the findings, whether positive, negative or inconclusive [13].

Ethics Dumping also violates many Articles within the Universal Declaration of Bioethics and Human Rights (UDBHR). With the most pertinent being the exploitation of vulnerable population (Article 10) which is a violation of human rights, and hence human dignity (Article 3), the failure in many instances of ethics dumping to obtain valid consent, thereby undermining autonomy (Article 7&8) and in many cases the breach of confidentiality (Article 11) [14].

To avoid negligence, The Indian Good Clinical Practice Code (GCP), by the Central Drug Standard Control Organisation states guidelines for researchers to ensure the safety and protection of the population's rights, that researchers, individuals or organisations, have to strictly adhere to [15].

The four-value framework proposed by the Global Code of Conduct (GCC) includes Fairness, Respect, Care, and Honesty to be implemented for carrying out research in resource-poor settings. It emphasizes the role of the local ethics committee to reduce exploitation and ensure no harm and equal participatory roles at all the stages of the sanctioned project in case of collaborative research projects [16].

Conclusion

It is thus important that healthcare students, healthcare professionals, and policymakers alike, to sensitize ourselves to the possibilities of overt unethical research practices like ethics dumping. We must educate ourselves and subject future collaborative research proposals and ongoing clinical research to strict scrutiny to warrant upholding the current laws and guidelines to ensure scientifically robust and ethically sound research. It is also our duty to inform potential candidates of clinical research about the objectives, possible benefits and harms of their participation. Furthermore, they need to be made aware of their human rights, and that individuals organizing human subject research have the moral and legal responsibility of upholding those. This may be a possible option of remediation against potential exploitation. The only concrete fail-safe against a repeat of the Tuskegee trials is an investment by ethicists, policymakers and the existing medical fraternity to create an upcoming generation of professionals who have the principles of ethics instilled in them in their formative years of medical education.

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