

Ensuring Rights and Dignity in Ethical Practices of Clinical Studies with Vulnerable Group and Safeguarding Vulnerable Group Act (2006)

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ABSTRACT

Vulnerability in research refers to participants who cannot protect their interests, leading to an increased risk of harm. This manuscript explores the conditions making a group vulnerable, tools to reduce ethical violations, and the importance of ethical safeguards in research. Vulnerability may arise from inability to understand informed consent or from unequal power dynamics. Excluding vulnerable groups from research solely based on their status is unethical and can skew results. Special protection is needed for vulnerable populations, such as children, the elderly, or those with mental health issues, to ensure their rights and dignity are upheld in clinical trials. Ethical principles like informed consent, beneficence, and justice, as well as regulatory frameworks like the Declaration of Helsinki and Good Clinical Practice (GCP), ensure participant safety and research integrity. In the UK, the Safeguarding Vulnerable Groups Act (2006) further protects vulnerable individuals by regulating those who work with them. The paper emphasizes the importance of integrating ethical oversight, continuous risk assessment, and monitoring to prevent exploitation and ensure respect for vulnerable participants.

Keywords: Good clinical practice; Vulnerability; Participants; Ethical principles

INTRODUCTION

The word vulnerability stems from the Latin *vulnerare*, which means to wound. In the context of human subjects' research individuals or groups are vulnerable if they are unable fully and independently protect their own interests, either due to intrinsic characteristics (e.g., age or immaturity), or circumstances (e.g., illness, incarceration, or poverty) [1,2].

Different categories of vulnerability:

- Individuals who are physically frail due to age and co-morbidities, have several chronic diseases, or have disabilities.
- Individuals who are terminally ill or have diseases that are incurable.
- Individuals in critical circumstances Racial and ethnic minorities.
- Individuals that are homeless, nomadic, displaced, or refugees
- Individuals who are subject to an authoritarian regime,

members of the armed forces, and those who are confined or imprisoned (in nursing homes or other institutions).

- Individuals who are economically disadvantaged, are in low-resource communities, are unemployed or living in poverty, or are receiving social assistance or welfare benefits. Those who lack political clout, are branded, ostracized, or experience discrimination or social exclusion.

MATERIALS AND METHODS

Ethical considerations of clinical trials in vulnerable population

NDCT rules: New drug and clinical trial rules, 2019 are applicable from 19th march 2019, except chapter 4 (ethics committee for biomedical and health research), which came into force after 180 days [3-5].

Salient features of NDCT:

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- The Hon'ble Supreme Court of India received a Public Interest Litigation (PIL) in 2012 from a patient-centered NGO accusing government and non-governmental organizations of conducting clinical trials improperly. The Honorable Supreme Court stated on October 21, 2013, that clinical study approvals ought to be predicated on all pertinent safety and efficacy considerations, especially when weighing the risks against the benefits to the patients.
- The 59 Report of the Parliamentary Standing Committee on Health and Family Welfare on the operation of the Central Drugs Standard Control Organization (CDSCO) noted deficiencies in the regulation of clinical trials. It took MoHFW a long time to think through and finalize the rules. This delay was noted by the Supreme court, and in an order dated December 4, 2018, noted the Government's submission that the rules will be finalised within two months. When the court observed that two months may be too long a period, the Government assured the court that, if possible, the NDCT Rules could be finalised even before that. They were finally notified on March 19, 2019.
- The NDCT rules are applicable to, and regulate, all new drugs, investigational new drugs for human use, clinical trials, bioequivalence studies, bioavailability studies and ethics committees

General principles and regulations of clinical trials according to the NDCT rules:

- Together with the ethical committee, the sponsor and investigator share responsibility for the trial subjects' safety. The Third Schedule outlines the duties of the sponsor, investigator, and ethical committee.
- The clinical and animal toxicological data produced during the course of the drug development and clinical trial processes should be assessed to make sure they have an effect on the trial subjects' safety.
- Any clinical trial should have a clear and explicit primary goal, which could include evaluating pharmacokinetic and pharmacodynamic parameters, characterizing safety and efficacy exploratorily or confirmatorily, and designing the trial to yield the information that is needed. The clinical and animal toxicological data produced over the course of clinical trials and medication development should be assessed to ensure their impact for the safety of the trial subject.
- It includes: Approach design and analysis, development methodology, non-clinical and clinical studies.

Studies in special population: If pertinent to the drug's clinical profile and expected usage pattern, information supporting the drug's use in children, pregnant women, nursing mothers, elderly patients, patients with failure of the kidneys or other organ systems, and those taking certain concurrent medications must be submitted [6,7].

Geriatrics—If (a) The condition to be treated is characterized as an aging disease, then geriatric patients should be included in phase III clinical trials (and phase II trials, at the Sponsor's option) in significant numbers. (b) In cases where the elderly patient's reaction to the new medication (in terms of safety or effectiveness) differs from that of the non-geriatric patient [8].

Paediatrics: The timing of paediatric studies in the new drug development program will depend on the medicinal product, the type of disease being treated, safety considerations, and the efficacy and safety of available treatments. For a drug expected to be used in children, evaluations should be made in the appropriate age group. When clinical development is to include studies in children, it is usually appropriate to begin with older children before extending the trial to younger children and then infants.

If the new drug is for diseases predominantly or exclusively affecting paediatric patients, clinical trial data should be generated in the paediatric population.

If the new drug has a potential for use in paediatric patients—paediatric studies should be conducted. These studies may be initiated at various phases of clinical development or after post marketing surveillance in adults if a safety concern exists at various phases of clinical development or after post marketing surveillance in adults if a safety concern exists.

RESULTS AND DISCUSSION

CIOMS

The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization in official relationship with World Health Organization (WHO). It was founded under the auspices of WHO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949 [9].

Declaration of Helsinki

The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

Principles: The International Code of Medical Ethics states that "a physician shall act in the patient's best interest when providing medical care," and the WMA's Declaration of Geneva binds doctors with the words, "The health of my patient will be my sixth consideration."

Promoting and defending patients' health, rights, and well-being including those participating in medical research is the responsibility of the doctor. The fulfillment of this obligation is the focus of the doctor's expertise and conscience.

Research is the foundation of medical advancement, and investigations involving human beings are eventually required. Understanding illness causes, progression, and outcomes is the main goal of medical research using human subjects in order to provide preventative, diagnostic.

First, the LGBT community's champions or peer educators could receive education and awareness-raising. The prospective

community members would then better comprehend the information when they had given them to them.

Research among tribal population

Tribal populations should only be the subject of research if it is medicinal, diagnostic, or preventive in nature and will benefit the tribe appropriately.

Before accessing tribal territories, appropriate permission from the appropriate administrative authorities, such as the district collector or tribal welfare commissioner, should be obtained. Elders in the community, those who are familiar with the tribal people's local language or dialect, and suitable witnesses should all be consulted before obtaining informed permission.

Protection of vulnerability

The experimental procedure should be carried out just prior to the abortion or in other situations where it is obvious that the pregnancy will be terminated in order for research on fetuses that will be aborted to be ethically acceptable. It is important to reassure the investigator that the woman had enough time and opportunity to think through her choice. Decisions about the viability of the fetus or pregnancy termination should not be made by researchers (Figure 1).

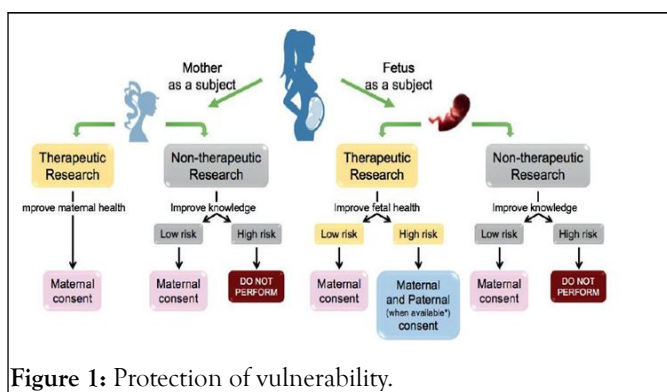


Figure 1: Protection of vulnerability.

Clinical studies involving expectant mothers. Procedures carried out to enhance the health of the mother or fetes are referred to as therapeutic research. Procedures that will advance scientific understanding are referred to as non-therapeutic research. High risk is identified when the consequences are substantial, severe, or irreversible for the mother, fetes, or subsequent kid, whereas low risk is defined as when the consequences are nonexistent or minimal. Both the mother's and the father's (if the father is present) consent are only needed when the fetal risk is significant.

Violated norms (DART trial):

- DoH §17: Investigations may not have been ceased in time after a negative risk/benefit balance for STI was identified.
- DoH §19: The population in which the research was carried out might not benefit from the results of the study, as tenofovir is not readily available in Uganda and Zimbabwe.
- DoH §22: Voluntary informed consent was obtained for each patient, but this may have been compromised by patients being desperate to get access to free treatment, and risks may not have been sufficiently explained.

- DoH §30/20: Post-trial access arrangements were unclear and apparently not described in the trial protocol. This would also effectively inhibit patients to leave the trial.

Outcome: The investigators of the DART trial denied lethal side effects of treatment interruption and ethical shortcomings in the trials. On 17-19 July 2006, the Office of AIDS Research (OAR) of the US National Institutes of Health (NIH) and the Treatment Action Group (TAG) held an international workshop to discuss the conduct of STI and intermittent therapy trials. A review of available evidence confirmed that some trial participants were at increased risk of adverse events, including death. It was concluded that STI trials cannot be recommended until the findings from past trials have been better understood (Figure 2).

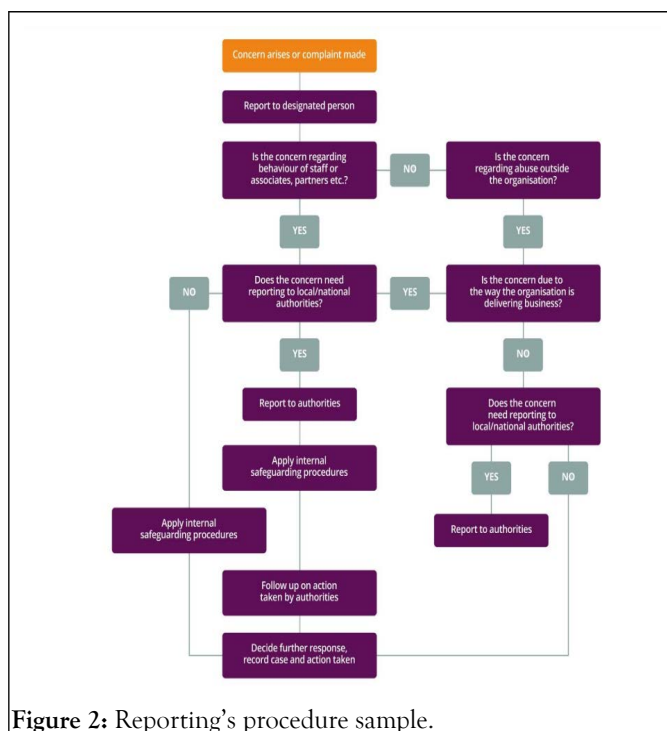


Figure 2: Reporting's procedure sample.

CONCLUSION

Vulnerability is key to protecting human subjects in research, with the term "vulnerable populations" introduced in the 1949 Nuremberg code, updated in the 2008 declaration of Helsinki, and the 1979 Belmont report. Excluding individuals solely because they belong to a vulnerable group is unethical and can bias results. However, researchers must provide extra protection for vulnerable populations.

The study should ensure participants fully understand the information provided and are selected or excluded for valid reasons, with no hidden agendas. This includes varying laws, regulations, and the need to consider individual patient beliefs for each case.

Although stricter regulations are needed, recent relaxations should not repeat previous errors. Enhancing safeguards for participants will benefit all parties and contribute to better public health outcomes.

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