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COMPENSATION, VULNERABILITY, AND ETHICAL EROSION IN CLINICAL TRIALS IN INDIA

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ABSTRACT

The concept of compensation is generally regarded as an ethical principle in clinical trials as it protects the research participants who undertake the risks of biomedical research. In developing countries like India, where people have limited access to healthcare facilities and socio-economic disparities prevail, compensation may play an insignificant role for justice and more as an alternative of real and meaningful informed consent. Similar ethical gaps can be seen in the governance of clinical trials in India. This paper critically examines the functioning of compensatory frameworks in situations where economic, structural vulnerability and power imbalances prevail. By citing various international perspectives, this paper contends that while formula-based compensation is suitable and procedurally effective, it has the capacity to drift away from ethical attention from voluntarism and precaution towards post-injury remedy. In such circumstances, compensation may reinforce the structural challenges of informed consent rather than making them good. The paper further argues that compensation cannot be the sole base for ethical protection in clinical research but must be based on such principles that gives importance to informed consent, institutional accountability, and substantive justice for vulnerable populations which forms the core of any ethical clinical trial.

Keywords: Compensation, Clinical Trials, Informed Consent, No-Fault Compensation, Marginalized Community, India.

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1. Introduction

Human participation plays a significant role in advancing new aspects of medical science and developing innovative treatments. Behind every medicine we consume, there is a human volunteer who has endured the risk involved in clinical trials. Such a person deserves utmost protection and his rights are to be safeguarded during the entire trial process and even after its completion if there are any adverse effects. Therefore, in this regard, compensation becomes indispensable. It is not a charity; rather it is a means through which trial related injuries are recognised and given due regard by the trial institution. Compensation reinforces the principle of justice as it ensures fair distribution of benefits and research burdens among participants. However, in situations where there are socio-economic complexities, restricted access to healthcare facilities, and limited choices, compensation as an ethical principle becomes complex. It may act more as an incentive that influences participants decisions and less as redressal for injury suffered.

When human volunteers assume that participation in such clinical trials will yield free medical benefits or financial aid that would otherwise remain unavailable, the thin line between voluntary informed consent and necessity-driven participation is blurred. This raises a critical yet important question: “does compensation protect participants in true sense, or is it a way to compensate for deeper structural failures in taking consent and providing care?” In India compensation models for clinical trials have become a significant tool to protect participants from any injuries related to the trials. Following a huge public outcry and media scrutiny, the Indian government made significant amendments in the regulatory frameworks governing clinical trials by strengthening protections for research participants and creating effective formula-based compensation model.[1]

This paper focuses on India’s no-fault compensation model and critically points out the ethical challenges faced in its effective implementation. Drawing references from best international practices, the paper inquires whether the framework relating to compensation can truly safeguard participants in contexts where consent is highly influenced by doctor-patient relationship, family or community compulsion. It concludes that compensation cannot meet ethical responsibilities as a standalone solution, unless it is studied together with true and meaningful informed consent, recognition of individual autonomy, protection of vulnerability, and supervising institutional accountability and transparency.

2. Compensation, Consent, and Ethical Tensions in Clinical Trials:

Compensation is considered as one of the most important aspects of clinical trials. It has two main purposes: firstly to reward participants for taking part in such trials, and secondly, to redress any harm suffered by them during such participation. Monetary benefits such as travel expenses, payments for loss of wages or any other inconvenience, and non-monetary benefits such as free medical benefits and related care are also provided to the research participants.[2]

In developing countries like India, marked by social, economic vulnerabilities, limited health literacy, therapeutic misconception, and other structural influences, compensation often plays a dual role. It may act as a tool valuing human life as well as on the other hand, it often reduces human participants contribution to a standardized criterion. It can also serve as a powerful incentive that can influence participation, particularly in situations where taking part in research study makes them get access to free medical care or other beneficial treatments which may otherwise remain inaccessible to them. In such circumstances, consent may not be a fully voluntary decision; rather it may be the reflection of constrained alternatives. This leads to a significant ethical issue as to “whether compensation is a tool to safeguard participant protection or it a narrow means to compensate for systemic restrictions on individual’s autonomy”.

When the principle of compensation becomes a key factor in moulding participants’ decisions, the emphasis may shift from giving due recognition to the quality of informed consent to addressing harm only after it has occurred. In doing so, compensation may mean responding

to harm, rather than taking precautions at the very beginning, thereby shifting the approach from preventive to a reactive model of compensation focussing mainly on post-harm redressal.

3. India's No-Fault Compensation Framework in Clinical Trials

India has adopted a no-fault compensation framework for clinical trials, under which participants are entitled to compensation for trial-related injury or death without the need to prove negligence or fault on the part of the researchers or sponsors. This approach establishes a paradigm shift from traditional
fault-based liability models and reflects an effort to prioritize participant protection within the governance of clinical research. Under this framework, the primary responsibility for providing compensation and medical benefits rests primarily on the trial sponsor, thereby strengthening institutional accountability for research-related harm. The development of this framework is closely tied to public concerns about unethical trial practices, participant safety, and the lack of compensation when liability is hard to prove. As a result, regulatory changes were introduced to strengthen participant protection, promote consistent compensation decisions, and rebuild public trust in clinical research. In this context, the no-fault model acts as a corrective tool to ensure that participants are not left without any resort in case of any injury suffered during trial.

The New Drugs and Clinical Trials Rules (The NDCT Rules) 2019, requires informed consent forms (ICFs) to clearly state compensation provisions as an essential part of the information given to participants.[3] Additionally, the guidelines laid down by the Indian Council of Medical Research [4], the Indian Good Clinical Practice guidelines[5],and the directives from the Drugs Controller General of India (DCGI) provide reimbursement for injuries, disabilities, or deaths related to trials, including medical costs covered by the sponsor.[6] A unique aspect of India's compensation model is that it is characterised by the use of a standard formula and pre-determined criteria to determine the level of compensation in the event of injury, disablement or death. Factors considered for calculating compensation typically include the severity of the adverse event, the participant's health condition at enrollment, and the connection between the trial and the harm suffered. Ethically, the no-fault approach reduces procedural hurdles and allows faster access to medical care and financial aid, especially for participants who may not have legal options to seek remedies.

As discussed earlier, in Indian clinical settings characterised by socio-economic vulnerability, the compensation model appears to align with the 'principles of justice, beneficence and non-maleficence,' however, while the framework addresses harm only after it occurs, it leaves unresolved questions about how risks are communicated, understood, and voluntarily accepted before participation. Compensation thus functions as a safety net but does not inherently guarantee participant autonomy.

4. Regulatory Framework Governing Clinical Trial Compensation in India

In recent times, India has emerged as the preferred favourable destination in the global pharmaceutical market. This increasing role of India has led to greater regulatory scrutiny of participant protections, particularly in respect to compensation in the 'event of trial-related injury or death'. At the same time, the country's socio-economic diversity, the unequal access to healthcare and the limited awareness of rights represent challenges for the effective implementation of compensation mechanisms uniformly and meaningfully. If we look at the earlier regulatory framework, Rule 122-DAB and Schedule Y of the Drugs and Cosmetics Rules, 1945, provided that participants suffering trial-related injury or death were given financial compensation, in addition to medical care, and the sponsors had the primary responsibility to provide such relief. In cases of serious adverse events (SAEs), decisions on compensation were taken after recommendations from expert committees and the final amount was decided by the DCGI.[7] However, the framework suffered from severe ambiguities and implementation challenges which eventually led to the introduction of the NDCT Rules, 2019.

The New Drugs and Clinical Trials Rules 2019, marked a significant development in India's compensatory landscape by consolidating and integrating compensation obligations within an evolving regulatory framework for clinical research. Chapter VI, Rules 39-43,covers provisions relating to 'compensation for injury or deaths arising from clinical trials and bioavailability or bioequivalence of new or investigational drugs'.[8] Under these Rules, sponsors are required to provide free medical treatment for trial related injuries till the point the injury becomes unrelated to the trial.[9] In addition to this, sponsors are required to submit an undertaking to the Central Licencing Authority (CLA) promising to compensate in all eligible cases.[10] The rules also lay down strict timelines for reporting SAEs. Once an investigator becomes aware of such an event, he must notify the same to the sponsor, ethics committees, and CLA within the timelines set forth in the Rules for the timely determination and payment of compensation, wherever applicable.[11] The amount of compensation is determined on the basis of a formula as laid down in the Seventh Schedule of the Rules[12]. Additionally, the Ethics Committees (ECs) play an advisory role by assessing causality and making recommendations regarding compensation. However, CLA makes the final decision and once the compensation amount is assessed, the sponsor is bound to pay the victim or his family the requisite amount within the specified timeline without any failure or delay.[13]

Altogether, India's compensatory framework is appreciable as it shows a real effort to protect participants' rights by ensuring that they receive appropriate medical treatment and financial compensation in the event of any injury or death during the trial. However, this no-compensation and standardized formula-based compensation model is not without flaws. When looked at India's diversified research environment, this framework fails to address several ethical issues relating to voluntarism, true and meaningful informed consent, and structural coercions. These concerns may hardly be visible to us, but they remain truly significant in clinical trials taking place in India.

5. Ethical Concerns regarding Clinical Trial Compensation Practices in India

Although after having such a structural compensatory framework for clinical trials in India, serious ethical concerns still persist. The success of such frameworks cannot be judged solely on the basis of present regulations or standardized formulas but must be assessed within the social environment where such trials occur and the participants give their voluntary consent.

A primary ethical concern is structural vulnerability. Participants in India come from various social and economic backgrounds, often having limited or no access to basic healthcare amenities which compels them to take part in such trials with the hope of getting free medical or financial benefits. In such circumstances, compensation acts more as an incentive and less as a safeguard and this blurs the line between 'voluntary consent and participation driven out of necessity'. Voluntary participants, including vulnerable groups, sometimes may be at risk because their decisions are influenced by various financial aspects.[14]

The formula-based approach used in calculating compensation amount is also one of the ethical issues. Though such a formula is used to ensure uniformity and foreseeability, in practice, the assessment of risk and nature of injury differs from the amount of awarded compensation calculated by ethical committees and clinical trials sponsors. So, it is often seen quite a lot of inconsistencies and negligence in the equal treatment amongst different clinical trial participants. Additionally, reducing serious human injuries to computable factors, such as age, the nature of risk, or loss of wages, raises serious concern. The problem lies in the over emphasis on monetary measures as a means of redressing harm. Such an approach makes us believe that mere monetary values can sufficiently cover the full extent of injury. However, when such harm is reduced into some numericals, the non-economic aspects of a person's life such as lost childhood, psychological trauma, loss of self-worth, long lasting sufferings, and the social and family burdens all remain unnoticed and unvisited. Another ethical issue which is of great concern is the delays and discrepancies in the payment of compensation amounts. Past records reveal that there lies a big dichotomy between trial-related deaths and awarded

compensation amounts. During the phase from 2005 to 2012 the total number of deaths that India recorded among clinical trial participants was 2,868 and only 89 were considered as trial-related, while compensation was given to only 86 people. The compensation amount varied widely from ₹55,000 to ₹4,200,000, neglecting the uniform assessment condition. The vital discretion about compensation was always left with the ethics committees, the sponsors, and the investigators, which generally led to several fallacies.[15] These contradictions prompted the Supreme Court of India to issue directions to the regulatory authorities to come up with safety measure guidelines and the enforcement of the rights of the clinical trial participants.[16] Although the new NDCT Rules, 2019, introduced major changes in the compensatory framework, inconsistencies continue due to poor management of data, improper handling of documents relating to adverse events, and hurdles faced in tracking participants, delay in assessments of causality and providing appropriate relief. Additionally, even when compensation is paid to the victims, the amounts usually tend to be low, varying from ₹1.5 lakh to ₹3 lakh.[17] This drawback undervalues justice for affected participants and also raises strong critical questions relating to the importance of human life. The quality of informed consent also becomes questionable. Although the NDCT Rules, 2019 mandates the full disclosure of study details including the risks, benefits, compensation provisions in the informed consent forms, participants fail to fully understand their rights or the legal recourse to claim compensation. Illiteracy, language barriers, power imbalances, and therapeutic misconceptions further lessen the value of informed consent from "a vital ethical commitment to a mere procedural and technical formality". All these ethical concerns highlight that compensation is seen as an alternative for institutional accountability, shifting the focus from preventing harm to managing its after consequences. Compensation amounts cannot mend structural flaws like inadequate supervision,
weak compliance, insufficient insurance coverages, unreported adverse drug events, [18-19] or procedural maladministration. And so, delayed payments and unclear responsibilities often make the sponsors struggle to provide adequate compensation.[20] This issue becomes particularly complex when an unborn child suffers injury because of the participation of his parents in the study. While compensation guidelines in this regard do exist, determining whether the injury is in direct relation to the trial can be difficult. Thus, there is an urgent need to establish clear and definite standards in this regard.[21] It can therefore be stated that, when monetary compensation replaces preventive safeguards, clinical trials become ethically and fundamentally weak.

6. Judicial initiatives in Clinical Trial Compensation

The Indian judiciary has moulded the regulatory framework governing clinical trials to a large extent. As discussed earlier, in the early 2010s, the Supreme Court of India heard many Public Interest Litigations (PILs) relating to the conduct of unethical practices of clinical trials in India including inadequacy of compensation practices by the sponsors.[22] In cases like Swasthya Adhikar Manch v. Union of India,[23] and Rahul Dutta v. Union of India,[24] the Supreme Court severely criticized the government for being negligent and allowing poor unregulated clinical trial practices in India that has threatened the value of human lives. This prompt and timely intervention by the Apex court led the Indian government to make several changes in the regulatory framework which effectively tried protecting the constitutional and human rights of the clinical trial participants. Several amendments were also introduced in the compensatory framework highlighting the ethical responsibilities of investigators, sponsors and Ethics Committees to protect vulnerable participants, ensure accountability for research-related harm, and promote the true quality of informed consent, especially in contexts characterized by structural vulnerability and power imbalances.[25] Further, in the case of Jacob Puliyel v. Union of India,[26]the Supreme Court prioritised participants' welfare over scientific or commercial interests. Meanwhile, in Common Cause v. Union of India,[27] the court recognised the need of independent ethical bodies in overseeing the ethical governance of clinical trials in India. In recognising the participants rights and awarding them due

compensation for medical negligence and poor medical services, the consumer forums have also played an important role. This can be seen in the case of Dr Durga Nursing Home v. K Dhanasekaran,[28] where lapses in monitoring,storage, and emergency facilities attracted medical liability. If we compare judicial developments in other countries like the United States and the United Kingdom, we find that both the countries observe similar ethical standards, despite having different compensation models. By analysing both the countries remarkable judgements such as the Canterbury v. Spence,[29]In re: Zyprexa Products Liability Litigation[30], Montgomery v. Lanarkshire Health Board,[31]and A and Others v. National Blood Authority and Another,[32] it can be seen that both the countries emphasize on ethical principles such as informed consent, beneficence, justice, risk disclosure, adequate compensation amount, institutional responsibility, accountability and transparency in clinical settings. All the cases along with the country's perspectives affirm that compensation should rarely be seen as a remedial tool and more as a broader institutional responsibility of care and justice.

7. Conclusion

From the above discussions made so far, it can be concluded that compensation in clinical trials works as an important safeguard in protecting participants' rights and dignity. However, compensation alone or having a standardized mathematical formulae in calculating adequate compensation does not ensure ethical protection until and unless it is backed by effective informed consent. Although the recent NDCT Rules,2019, establish clear obligations of sponsors towards clinical trial participants, issues such as delay in payments, inadequate causality assessment, failure in timely reporting of adverse events, the vulnerabilities of participants do exist. Furthermore, compensation can be a tool to alleviate pain and suffering, it can in no way be a means to compromise with autonomy, informed consent and preventive supervision. Although India's compensation model reflects a positive shift towards participant protection, its true success depends on its practical implementation particularly in the context of socio-economic complexities. Formula based calculations can prove to be great on paper and may aim for uniformity, but they are often calculated on the basis of the subjective assessments made by the sponsors and investigators, thereby overlooking the broader social and non-economic consequences of harm.

Final Reflections

When viewed from the perspective of ethical governance of clinical trials, compensation should be regarded as an essential part of such governance and not merely as a financial relief. The focus should be not only in paying the participants but also in preventing harm before it occurs through improving transparency in assessing trial risks, ensuring timely reporting of adverse events, strengthening supervision by Ethics Committees, and ensuring accountability for protocol violations or negligence. Additionally, establishing Alternative Dispute Resolution (ADR) forums like arbitration or mediation can play a great role in providing the victim families a quicker and less adversarial way to obtain compensation. Therefore, towards the end it can be concluded that when compensation is effectively implemented alongside preventive safeguards, transparency and accountability, and a true commitment towards participant welfare, it can move beyond technical formalities and prove as a powerful tool in achieving ethical justice in clinical trials in India.

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