

Bioethics and Human Advocacy: Ethical Principles of Clinical Research and Innovative Treatment Associated with Therapeutic Misconception

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Abstract:- This paper broadly deals with clinical research and innovative treatment to encompass studies or experiments performed on human beings for the purpose of producing wide-ranging knowledge related to human health or medical treatment. It is capable of producing huge benefits to the lives and healthiness of those who are ailing or potentially ill. It is the kingpin of medical progress and the only means of establishing the innovative treatments as secure and efficient. The medical practitioner's can report the outcome of their treatment practices on exacting patients but in the absence of well designed study, these results can lack predictive value.

Keywords:- Bioethics, clinical research; Innovative treatment; Controlled Trail's; Therapeutic Intervention.

I. HIGHLIGHTS

In Indian Context, the health indicators are already very poor, the concern of ethics and financial efficiency in the provisioning and delivery of services becomes difficult. In an effort to investigate this issue, this article first provides an outline of the field of ethics in clinical research, the health care sector in India and its facilities, the main institutional performers in clinical research and lastly, the key ethical issues concerning the different performers in clinical research and innovative treatment – the burgeoning pharmaceutical industry. In its conclusion, the article reports on the issues with a special emphasis on geographical locations and organizational settings.

II. INTRODUCTION

Clinical ethics is a practical discipline that provides a structured approach to assist physicians in identifying, analyzing and resolving ethical issues in clinical medicine. The practice of good clinical medicine requires some working knowledge about ethical issues such as informed consent, truth-telling, confidentiality, end-of-life care, pain relief and patient rights. Clinical research trails are the backbone of

modern medicine, making them the centre of medical innovation and scientific breakthrough. The increasing number

of clinical research trails carry out today is coordinated by rising controversies. These controversies encompass ethical concerns and conflicts of interest and are often addressed by media, in newspaper headlines undermining the confidence of many prospective participants and discouraging them from volunteering for a clinical trial. These highly exposed breaches of ethics and professionalism unconsciously affect the entire clinical industry.

Clinical research is defined as a division of healthcare science that establishes the protection and efficiency of medications, devices, diagnostic products and curing regimens intended for human use. This type of researches is also supportive in finding which approach mechanism is of paramount importance for certain illnesses. The idea of clinical trials follows strict scientific standards that protect patients and help produce reliable study results. A human service, research is defined as “a systematic investigation, including development, testing and evaluation designed to develop or contribute to generalizable knowledge. It is that component that narrows the definition and differentiates between a physicians who “systematically” searches for facts” to diagnose and treat a patient and a physician who analytically searches for essentials among a sample of patients with the objective of drawing conclusions about the effectiveness of a treatment across a larger population.

III. CLINICAL OPERATIONS

Clinical operations or trails are experiments or observations that are part of clinical research. Such eventual biomedical or behavioural research studies on human beings are designed to respond specific questions about biomedical or behavioural interventions. They comprise of new treatments such as providing fresh vaccines, drugs/ medicines, dietary plans and supplements and medical devices and known interventions that demand further revision and assessment. Clinical trials produce data on safety and efficacy. They are performed only after they have got the approval from health authority/ethics committee in the country where approval of the therapy is required. These authorities are responsible for selecting the risk/benefit ratio of the trial – their approval does not

indicate that the therapy is secure or efficient, only than the trial may be conducted.

Clinical operations provide a range of integrated services that cover the planning, management, execution and analysis of clinical trials. They provide therapeutic, regulatory and operational expertise consistently solves the challenges that arise during clinical projects. As per the professionalism is crucial when clinical operations are added to the blend. A medical practice requires a constant flow of personal and confidential medical information and financial data from patients, prayers and physicians to successfully perform appropriate services. A medical practice can have the best set of business policies and procedures and the commitment of professional standards allows the organization to carry out its business in the most effective manner.

IV. LEADERSHIP

Leadership is defined as the ability to persuade others. Any person who is not capable of influencing others due to the lack of integrity, trustworthiness and work ethics. This domain requires the medical practice to lead an environment that fosters teamwork, accountability and cooperation. It means the medical practitioners' work tough to foster excellence through governance, education and training through problem solving ability.

V. COMMUNICATION SKILLS

Communication is defined as the art of expressing and exchanging expressions through writing and speech. The medical profession requires both oral and written communication skills through delivering and while messaging.

VI. ORGANIZATIONAL AND ANALYTICAL SKILLS

For getting the better organizational skills it is important to have the organizational and analytical skills such as managing budgeting/ forecasting models, establishing benchmark, development of clinical pathways, negotiating and evaluation, this domain requires an orientation and mastery of organizational and analytical skills.

VII. PROFESSIONAL AND TECHNICAL KNOWLEDGE AND SKILLS

This aim of best professional and technical knowledge is to initiate the ability to apply specialist/technical knowledge and skills to achieve agreed work objectives. The following are the criteria for professional skills that:

- Encourages and/or ensures professional best practice.

- Knows, on the basis of professional/specialist/technical knowledge, the limitations of what can be concluded based on the information and facts available.
- Consults colleagues within profession to develop, test and refine ideas.
- Takes account of precedent, progress and trends when making recommendations.
- Offers guidance where necessary on the basis of professional/specialist/technical skills and experience.
- Makes links across professional/specialism and knows when to accept a multidisciplinary approach.
- Proposes practical courses of action which balance the professional/specialist/ technical view with what is pragmatic and attainable.
- Delivers efficient professional/specialist/technical skills and/or care.

VIII. INNOVATIVE TREATMENT AND CLINICAL RESEARCH

Innovative treatment and Clinical research is concerned with the experiments that are performed on human beings with the objective of producing extrapolate knowledge related to human health. These researches are focused on observational to physical, chemical or psychological intervention. Innovative way of treatment is more accurate to refer to the patients rather than participants as it features more medical care. The medical practitioner's modify their clinical practices in the light of what they learn from patients' experiences, experimentation with a new untested therapy. The fundamental aim of clinical research is to generate new knowledge for the advantage of future patients.

Mostly, the patients are vulnerable to misunderstanding the difference between research and innovative treatment. Even if the participants don't make this error they could hold unrealistic hopes of being cured by their participation. This mindset also known as "*therapeutic misconception*" deals with the participant's decisions about their participation are made solely with their benefit in mind. The researches that benefit the participants are known as therapeutic research; on the other hand all the participants are not directly benefitted from such researches are called as "*non-therapeutic research*". All researches involve procedures that are non therapeutic whereas all observational procedures are different from surgical procedures. Therapeutic research involves procedures that are identical to those used in innovative treatment and unlikely to benefit the participant. The World Medical Association's Helsinki Declaration was redrafted that refers physician's who combine research with medical care. But the issue whether the participant is benefitted and not expected to gain any benefit remains debatable. The ethical and regulatory question is whether the experiments performed on human beings for the purpose of producing generalisable facts particularly taking account of

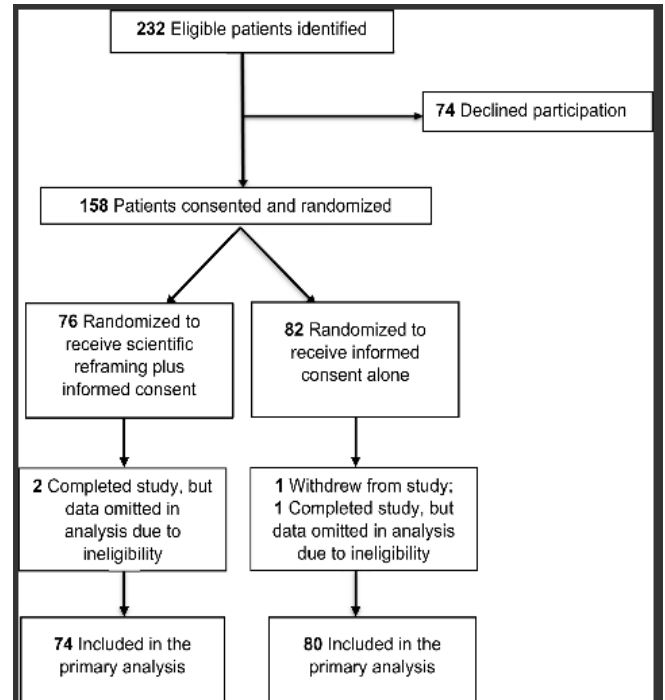
the potential for the therapeutic misconception capitulates any results.

The therapeutic misconception was first recognized by Appelbaum, Roth and Lidz in their influential 1982 research paper. The word was invented by their study, which observed the consent exchanges in 4 studies investigating treatment for psychiatric illnesses. Particularly, these learning have looked at different interventions, including medications, dose responses and social interventions; at least one used a placebo control. This prospective randomized trial conducted by Christopher, Truong et al. from 2015 to 2016 to test the efficacy of an informed consent intervention based on scientific reframing compared to a traditional informed consent procedure (control) in reducing therapeutic misconception among patients considering enrollment in hypothetical clinical trials modeled on real-world studies for one of five disease categories. Patients with diabetes mellitus, hypertension, coronary artery disease, head/neck cancer, breast cancer, and major depression were recruited from medical clinics and a clinical research volunteer database. The primary outcomes were therapeutic misconception, as measured by a validated, ten-item Therapeutic Misconception Scale (range = 10–50), and willingness to participate in the clinical trial.

IX. RESULTS

The results showed that out of 154 participants who were part of the study (age range, 23–87 years; 92.3% white, 56.5% female); 74 (48.1%) had been randomized to receive the experimental intervention. Therapeutic misconception was significantly lower ($p = 0.004$) in the scientific reframing group (26.4, 95% CI [23.7 to 29.1]) compared to the control group (30.9, 95% CI [28.4 to 33.5]), and remained so after controlling for education ($p = 0.017$). Willingness to participate in the hypothetical trial was not significantly different ($p = 0.603$) between intervention (52.1%, 95% CI [40.2% to 62.4%]) and control (56.3%, 95% CI [45.3% to 66.6%]) groups.

Therefore, it is evident that enhanced educational intervention augmenting traditional informed consent led to a meaningful reduction in therapeutic misconception without a statistically significant change in willingness to enroll in hypothetical clinical trials. Additional study of this intervention is required in real-world clinical trials.



Source: Pattison. D. Shaun. Medical Law and Ethics. South Asian Edition. Sweet and Maxwell. 2017.

X. PHASES OF RESEARCH ON MEDICINAL PRODUCTS

The research on medicinal products comprises of four phases. The Phase I trials also called as first-in human trials usually involves less participants and are designed to test the toxicity or dose of new drugs. The Phase II trials are designed to explore the short-term toxicity and therapeutic efficacy of a product on less participants suffering from the condition in question. And the last phase III trials are designed to confirm therapeutic efficacy.

XI. THE ETHICAL PERCEPTION OF CLINICAL RESEARCH

There are lots of ethical queries while performing Clinical research due to difference in viewpoints. The theoretical perception involving Utilitarianism and Communitarianism might be expected to take a more lenient approach towards clinical research than those focusing on the rights and interests of individuals

As per the research data, India has become a significant country for clinical trials of international pharmaceutical companies. Indian prospective for the enrollment of patients and decline of clinical trial has created the most attractive strategic imperative for global clinical trials. However, globally, there has been a concern about ethical and scientific implications of globalization of clinical trials to developing countries.

XII. THE ROLE AND VALIDITY OF CONSENT

The component of consent is one of the critical issues in medical treatment as the patient has a legal right to self-determination protected within Article 21 of the Indian Constitution. He can decline any treatment except in an emergency condition where the consent for treatment is not required. The consent attained should be legitimate but a doctor who treats without valid consent will be liable under the tort and criminal law. The law presumes the doctor to be in a dominating position, hence the consent should be obtained after providing all the necessary information. Consent, as an agreement poses a number of difficulties while determining during the time of consenting because when the person who is actually consenting should have the competence, voluntariness or information required for any obvious agreement to be treated as a valid consent. These complexities are supported by normative questions originated from law and moral theory. Therefore, consent removes the burden of a binding duty.

XIII. GUIDANCE AND THE REGULATORY CONTEXT

The international and national bodies have issued various guidelines on good research practices. The guidelines is as per Nuremberg Code that laid down 10 various principles for research on humans, started with the assertion that obtaining the participant's voluntary consent is "absolutely crucial". It is also mandatory that these experiments are designed to yield productive results based on the animal experimentation for avoidable sufferings and grievances that are terminable at the request of the participant. These principles formed the basis of Helsinki Declaration that was first adopted by the World Medical Association in 1964.

XIV. RESEARCH ETHICS COMMITTEE

The function of Research ethics Committee is to analyze the ethical satisfactoriness of research proposals and thereby perform as an independent defended sitting between the researcher and the prospective participant. The Clinical Trials Regulations require ethics committee to take into account various matters before approving any clinical trial. This include the trial designing, the anticipated risks and benefits, the sustainability of the protocol, all those involved in the facility, procedure for obtaining informed consent, the rationale for including any persons incapable of giving informed consent, the provision for giving compensation in case of death or injury. Moreover, these regulations also initiate criminal sanctions.

XV. CONCLUSION

Hence, for apparent advantages, global players view India as a favored destination for conducting clinical trials. The activity, in the long run, has the potential to help our citizens, professionals and society. However, our infrastructure and systems are not yet in the optimal state to meet this challenge. Indian policy makers, administrators and

professionals should initiate positive steps to ensure that this opportunity is exploited to its maximum potential.

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