

Medical research and ethics - Revisited

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ABSTRACT

Ethics in the medical research is known since many years; however, there have been new developments in this area recently. A phenomenal improvement in the health-care system, leading to increased life expectancy, and thereby, newer lifestyle and other health-related diseases has opened avenues for newer drugs and health-care technology. However, these have to be tried and tested in the context of the disease epidemiology, health-care delivery and of course, medical ethics. Monitoring and evaluation of the treatment regimes of well documented effective medicines is also required. This is the core of medical research. With the ever increasing concept of evidence-based medical system, and thereby, a rapid rise in the number of clinical trials; the role of medical ethics is potentially increasing to keep the patients' interest in mind. The physicians have to consider the health and positive outcome for the patients. This gives rise to conflicting roles and duties; however, physicians' role and patient commitment must supersede the role of researcher in such cases. The ethical principles, i.e. autonomy, beneficence, and justice apply not only to the physician but also to the medical researcher as well. To monitor the interests of the patients, the ethical review committee sees to it that the clinical trials are conducted with the correct "ethical" approach, giving due consideration to the informed consent process. Refining the regulations and guidelines, especially for individual studies is the core mechanism to strengthen the international medical ethics scenario. This has increasing importance in view of increasing funded research, research involving children, women and prisoners, research related to neurosciences, newer vaccines, organ and tissue transplant, and stem cell transplantation.

Key words: *Bioethics, Clinical trials, Research*

Medicine is an evolving science and is an area of constant research. Although lot of things are already known, many things are yet unknown in this context. Due to the phenomenal improvement in the health-care system, there is a significant increase in life expectancy owing to non-invasive methods of the diagnosis, newer drugs, and the unprecedented technological advances in the treatment. However, drugs which are working today, might not work tomorrow due to phenomena of resistance. Hence, there is the need of applied research for developing new drugs, tests, imaging techniques, surgical modalities, etc especially, due to ever-increasing novel health issues that were not so critical earlier [1]. There is now a need for newer drugs with better efficacy and lesser side effects for the treatment and control of emerging diseases. We need newer treatment regimes for improved outcomes of diseases. Research is needed not only for identifying these new treatments or drugs but also for new devices and surgical techniques. This has to be tried and tested in the context of the disease epidemiology and health-care delivery (health systems' research). It is well documented that acceptance to medication also depends on the medical sociology, culture and anthropology, laws (legal medicine), and ethics (medical ethics) [2,3].

Medicine differs from mathematics and physics in the way that medicine does not have any blanket principles. Although there are general guiding principles that may be valid, each patient is different and every patient is an individual entity in its own. Although it may work for the majority, it might not be valid or effective to treat all the patients. A doctor often experiments the treatments in case of those patient who may not respond to the routine medications. Thus, medicine is experimental. This is true even for the routinely accepted treatments, wherein the response to the same treatment by every individual may vary. Hence, monitoring and evaluation of the treatment regimes of well-documented effective medicines is also required. This is the core of medical research [2].

EVIDENCE BASED MEDICAL PRACTICE

Physicians need to be updated about all the changes that occur continuously in the medical world. They have to keep reading and improving their knowledge of clinical research, based on the results of medical research; termed as evidence-based practice. Individual professionals need to be informed, trained, and motivated to be on the lookout of and incorporate the latest

evidence into their daily work [4]. However, trying to inculcate the same changes in their practice requires a basic understanding of research and its methods [2,5].

PHASES OF CLINICAL RESEARCH

Clinical trials are the mainstay of medical research for the practicing physicians [6]. Before a new drug can be approved by government-mandated regulatory authorities, it must undergo extensive testing for safety and efficacy. A research hypothesis is first established, following which, laboratory studies and animal studies are done. After such an extensive exercise, the pharmaceutical company has to get its approval to study various aspects of the drug in human beings. Once approved, the drug has to pass through four phases. In phase I, the drug is tried on a small number of human beings who volunteer and are paid in return. This phase is done to determine dosage, to know how the body processes the drug (pharmacokinetics) and to know the side effects. In phase II trial, the drug is used in patients with a particular disease to determine whether the drug has any beneficial effect and to know the side effects. In phase III, marketing of the drug is done and the drug is finally introduced into the market to compare it with other drugs and/or placebo. After the drug is marketed, it enters into phase IV called post-marketing surveillance to look for very long-term side effects [6].

ROLE OF A PHYSICIAN VIS-A-VIS A RESEARCHER

Because of the ever-increasing concept of evidence-based medical system, there has been a rapid rise in the number of clinical trials, which entail finding and recruiting large number of patients, as per the statistical requirements of the trials. Keeping the patients' interest in mind, the physicians need to keep several potential problems at bay. This can be done by anticipating these problems and issues and trying to avoid them. A researcher is involved in the research in the first place; however, the role of a physician in the research is in stark contrast [5]. This is true in terms of the physician-patient relationship, even if the physician and the researcher are the same person. The researcher is involved only in generating new knowledge, while the physician needs to consider the health and positive outcome for the patients. This gives rise to conflicting roles and duties; however, physicians' role and patient commitment must supersede the role of researcher in such cases [5,7,8].

A potential issue in such cases is conflict of interest [9]. Participation in the medical research is a well-funded enterprise and physicians are sometimes offered considerable reward for participating. This includes monetary reward per subject enrolled, electronic items for data management, and sponsored conferences as well as authorship in publications of the results. These benefits may conflict with the physicians' duty to provide the best possible treatment to the patients. The patients may not be fully informed about their rights of taking part in the results and/or the right to take informed decision of participation in the research or clinical trial. The ethical principles of the physician, i.e., autonomy,

beneficence, and justice apply to the medical researcher as well. These need to be fully understood and duly followed by the physicians as well [10–12].

WHAT IS “THE ETHICAL” APPROACH?

There are broadly two approaches toward ethical issues: non-rational (does not mean irrational, meaning reflective use of reason in decision-making) and rational.

NON-RATIONAL APPROACHES

Obedience

This is a common way of making decisions on ethical issues; especially, by children and those who work with authorization structures (e.g. military, air force). They follow the rules or instructions of those in authority, whether they agree with them or not [7,13,14].

Imitation

It subordinates one's judgment about right and wrong to that of another person.

Feeling or Desire

It is a subjective approach to moral decision-making and behavior. It is variable from person to person and also from time to time in the same person.

Intuition

It is the immediate perception of the right way to act in a situation. It is entirely subjective.

Habit

It is an efficient method of moral decision-making. The advantage is that there is no need to repeat a systematic decision-making process each time a moral issue arises.

RATIONAL APPROACHES

Deontology

It involves a search for well-founded rules that can serve as the basis for making moral decisions. There are specific rules to be applied in specific situations.

Consequentialism

It bases ethical decision-making on an analysis of the likely consequences or outcomes of different choices and actions. The right action is the one that produces the best outcomes. One of the best-known forms of consequentialism is *utilitarianism* which

uses utility as its measure and defines this as “the greatest good for the greatest number.” Other measures include quality-adjusted life years or disability-adjusted life years.

Principalism

It uses ethical principles as the basis for making moral decisions. It helps to take decisions as per the situation, rules, and the consequences; helping to choose the right thing. In general, there are four principles; autonomy, beneficence, non-maleficence, and justice [15].

Autonomy

It requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination.

Beneficence

It is ethical obligation to maximize the benefit and to minimize the harm.

Non-maleficence

It means doing no harm or causing the least harm possible to achieve beneficial outcome.

Justice

It is an ethical obligation to treat each person in accordance with what is morally right and proper.

INFORMED CONSENT

It is the most important aspect in the medical ethics. It came into being; keeping in mind that due respect should be given to patients. In history, the first written consent was obtained by Dr. Walter Reed from the persons involved in his experiment [16].

Informed consent has four elements: disclosure, comprehension, voluntariness, and documentation [2].

Disclosure

Disclosure means informing/disclosing the purpose, details of the procedure, duration of the study, its risks and benefits including monetary gains as well as alternative options and that they can discontinue their participation at any time. Providing all these details may need significant time on the part of researcher, so time constraint remains an important challenge to the disclosure. In addition to time, language and sociocultural barriers can prove to be a challenge.

Comprehension

It is the information to enable a potential participant to make an informed decision about whether to participate in a study is the responsibility of the researcher. Challenges to the comprehension are language barriers, extreme of ages, psychiatric illnesses,

subjects with poor decision capacity or inability to fully comprehend, and inability to express one's choice.

Voluntariness

It is an agreement or willingness to participate without undue influence. The consent for participation in research should be free of coercion and free of undue influence. In addition to undue influence, power dynamics and gender inequalities are challenges to the voluntariness.

Documentation

It should be written documentation of the informed consent. This should include the study summary and rights of research participant and should describe the whole informed consent process. As per the new regulations from Drug Controller General of India, for clinical trials of new chemical entity or a new molecular entity involving vulnerable subjects, audiovisual recording of consent process must be done [17].

INFORMED CONSENT AS A “PROCESS”

Informed consent is not an isolated event; it is an ongoing dialog between the investigator and the research subject. The investigator has a responsibility to address the participants' concerns, to answer his questions, and to ensure that the patient has understood basic purpose of the study and study procedures.

Developments in Medical Research

Medical research ethics is an area of expertise which is fast evolving. It has also emerged as an area of debate over the past couple of decades. This is more so in case of transnational research collaborations, that is, research funded by institutions based in Europe and North America and implemented together with institutions in Latin America, Asia, Africa, and Eastern Europe. Transnational research often involves enrolling relatively poor study participants in less wealthy countries [18].

Concern regarding the ethics of medical science is not new. It is well known that the Nazis in Germany committed atrocities in the name of science and the African-Americans were denied treatment for syphilis in the Tuskegee trial [19]. Thus were born the ethical codes, namely, Nuremberg Code, the Declaration of Helsinki, and the Belmont Report [10]. The rising awareness about international human rights; rights based on the gender, prisoners, and the economic inequities have increasingly risen the public debate about science [20]. For the same reason, ethical review committees have come into existence to monitor the ethical part of the studies and the clinical trials.

Ethical Review Committee

It is of utmost importance now that each and every study is approved by an ethical committee. This committee oversees whether the

study is proposed and further conducted in an ethical manner and that it does not impinge on the ethical rights of the subjects or patients. It has different names in different countries such as Institutional Ethics Committee, Institutional Review Board, Ethics Review Board, and Research Ethics Board. Its responsibilities are to ensure a competent review of all the ethical aspects of the project proposals received by it in an objective manner, to look for the scientific soundness of the proposed research and its social value. The committee consists of 8–12 members from a multidisciplinary and multi-sectorial background [21]. A minimum of 5 persons are required to form a quorum to take a decision regarding research; especially, clinical trials [6].

Proportionate EC Review: Expedited/Full

Ethical review by the committee is subject to the type and nature of risks involved in the study. It should assess the risk and potential benefits of the research or trial. A balanced review is based on the “minimal risk concept” helping to decide whether a “full board review” or an “expedited review” is required. Minimal risk entails a condition where “The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”. [22]

The decision to conduct an expedited review may be made by the chair of the EC while keeping all members informed about the studies approved by expedited review. All clinical trials are initially subject to a full EC review, and usually, the continuing review of trials must be conducted by the full EC. ECs differ in their views about whether continuing reviews, protocol amendments or alterations, safety reports, and multicentric studies are acceptable for expedited review or not [6].

Guidelines for Research on Human Subjects

1. Ask an answerable research question.
2. Pay attention to the study design.
3. Choose your subjects without bias.
4. Enhance benefits and minimize risks.
5. Respect your subject's rights [6].

Approaches to Strengthening International Medical Research Ethics

The rising debate about medical research ethics can be answered by refining the regulations and guidelines, especially for the individual studies [23–26]. There is a felt need to build and expand the capacity of local and national bodies for monitoring the ongoing studies. This can be done more efficiently through ethics review committees and community advisory boards [12,25,27–32]. The existing codes have abstract and universal ethical principles which cannot be applied in all contexts for all the geographic areas. Therefore, local and national bodies can act as competent

independent specialist bodies in research-related decision-making; especially, in low-income settings [25,27,28,31].

There have been many improvisations in the arena of International Medical Research Ethics wherein, in India, it is now mandatory for all ethics committees which review and approve clinical trials to get registered with the Directorate General of Health Services and Central Drugs Standard Control Organization [33]. Under the Drug and Cosmetics Act, this central authority is responsible for the approval of new drugs, clinical trials in the country, laying down the standards for drugs, and control over the quality of imported drugs.

It is the responsibility of the investigator to report any untoward incidences such as adverse drug reactions (ADRs). The noxious effect of a drug when it is used in the recommended doses is an ADR; if the causal association is not proven, it is termed as an adverse event (AE). An AE or ADR leading to death, hospitalization or its prolongation, disability or incapacity is termed as a Serious Adverse Event (SAE). The ethics committee and regulatory body of the country are bound to uphold the ethical principles of the beneficence, justice, and non-maleficence in such cases. The principal investigator should report the SAE within 24 hours to DCGI, the sponsor, and the chairperson of the ethics committee. Ethics committees investigate and submit their report of SAE to the DCGI and accordingly, the compensation is decided by the DCGI [34,35]. Ethics committees are empowered to hold or stop the ongoing trials when felt necessary for the safety of study subjects. The ethics committees are also responsible for the monitoring the clinical trial sites periodically.

Clinical Trial Registration

Registration of trial before its initiation in publicly available trials registry (*viz.* Clinical Trials Registry of India) [36] has become mandatory in many countries. Free web-based access to the information about ongoing clinical trials is regarded as an important tool for the public. It also provides a complete picture of the past research, whether it was negative or successful (Cochrane registration or the Prospero website registration). This stands true for the systemic reviews also, which help in combining the results to come to one viewpoint or decision about the usefulness or the implementation of the drugs and medications. The ethics committee may be requested to monitor the compliance of the clinical trial registration according to the local regulations and policies.

Regulatory Authorities and Trial Registration

Since the late 1990s, drug regulatory authorities have put more emphasis on the need to publish essential information about the ongoing clinical trials on publicly searchable trial registries. This has been an explicit concern for those with life-threatening diseases, such as HIV/AIDS and cancer; since it would increase the possibility for the patients to identify trials for the participation. These diseases are worldwide, with the public health aspect being

more important and case based. US-FDA has made it mandatory to register phase II/III trials (not phase I), since the data implicates the application or introduction of the new drugs. Each trial must be registered before its onset, and there is a penalty system in place for the non-compliance.

Scientific Journals and Trial Registration

Since 2004, the International Committee of Medical Journal Editors has set up a policy enforcing the registration of the interventional trials (phases II-IV) in an accepted public trials registry to be considered for the publication in its journals [36]. The policy became mandatory in July 2005. The registration must take place before starting the patient enrolment. This policy has been extended to include phase I trials. However, only a few journals have adopted this policy. Most of the medical journals do not mention the policy in their instructions to the authors [6].

Unresolved Issues

There are certain aspects of the medical science which do not get a general consensus. In areas such as genetics, neurosciences, newer vaccines, organ and tissue transplant, and stem cell transplantation, there are no readymade answers for the questions arising. However, there have been some guidelines framed for the stem cell research and research in the children, recently [13,23,26]. Despite all these potential problems, the medical research is a valuable and rewarding activity for the physicians and medical students as well as for the research subjects themselves. These results when extrapolated have greater rewarding results for the general public. Every level, the individual or the committee, do face their own individual issues and problems. These need a case-based resolving approach [14]. A rising concern is the need for soft skills while interacting with the subjects; at the same time not encroaching on their ethical rights [37].

There is not much funding for the research-oriented work, and where it is there, they may sometimes be led by conflicts of the interest. Furthermore, there is inequity in the research health funding and diseases afflicting more than 90% of the world's population get <10% of the global funding for the research. This disparity of more spending on diseases affecting the rich rather than poor countries is known as "the 10/90 gap" [38].

CONCLUSION

Medical Science is ever evolving and so medical ethics also needs to be flexible and open to change and adjustment, as indeed it has been for quite some time now. However, we hope that its basic principles will remain in place; especially, the values of compassion, competence, and autonomy, along with its concern for the fundamental human rights and its devotion to the professionalism.

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