

*Review Article*

## **Ethics in Public Health Research and Clinical Research**

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**Abstract:** Research conducted with ethical values is the need of modern world and great benefit to the society in general and human beings in particular. Clinical research basically focuses on improving human health individually by improving current trends, methodologies and identifying innovative methods of treatment. Public health research is mainly concerned with the health of the entire populace. No standard rules can be formulated for conducting any form of research ethically; however following some basic ethical values can assure ethical conduct of research. In any research study whether that is public health research or clinical research, the importance is need to be to recognize an ethical standard that respects individual's autonomy and community's wellbeing. Ethical values in research studies can be achieved by requiring individual's and community's collective collaboration for the protection of individuals autonomy, dignity and wellbeing.

**Keywords:** clinical research, public health research, bioethics, autonomy, justice

**Introduction:** Research has been defined as an activity that is designed to test a hypothesis for the conclusions to be drawn for the development of new treatment and knowledge. Research promises great blessings of Science to human beings but, great care should be taken to ensure that it should not violate human dignity. For this purpose the researchers are ethically and morally bound to respect human life and people's autonomy. Research ethics aims to achieve fundamental objectives of how we ought to act in any situation or scenario, and to provide strong

reasons and justification for doing so. Research ethics plays an important role, striving to make possible that any research study is conducted after following the due ethical procedures<sup>1</sup>.

**Discussion:** There is no standard way of organizing the ethics of public health, clinical practice and biomedical science. There are Some basic ethical concerns that are focused for both types of research whether that is public health research or clinical research to be ethical, the study design must be scientifically sound, it should have sufficient power to test the hypothesis etc. Although these distinguishing characteristic concerns are often captured under the broad umbrella term of bioethics, sometimes bioethics is presented as the equivalent of medical ethics or in contrast to population level bioethics or public health<sup>1</sup>.

Public health research ethics object of concern is the whole populations, not individual human being, concerning to maximize welfare of the whole population. Public health research ethics follows a consequentialist approach that is promoting public health by seeking to improve good health and to avoid bad health outcomes of overall population. Promoting public health involves a high degree of commitment to the deterrence of disease focusing mainly on preventive aspect, involves diagnosing and treating illnesses, with all the attendant clinical services that those activities require. Public health addresses the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes. On the other hand, clinical research refers to the subset of individual human subject's research that focuses on improving well-being and human health, normally by identifying better methods to treat, or prevent individuals from diseases. The potential expected benefits of clinical research are only expectations based on hypothesis, but the risks and burdens of clinical research are present in the current study participants<sup>2</sup>.

Public health research ethics has a broader spectrum than clinical research ethics, public health research is, as what we do as a society collectively to guarantee better conditions for people of society to be fit and healthy. The field of public health is concerned with disease prevention and health promotion throughout the society. Unlike clinical research, public health research is less interested in clinical interactions between health care professionals and the individual patient, and it is more interested in developing broader strategies to prevent diseases<sup>2,3</sup>.

In bio medical and clinical research ethics, much emphasis is placed on autonomy, the freedom of the individual human being but, in public health research ethics the focus is on the overall public. For public interest some measures might cause minor infringements of a person's freedom but, that is to achieve significant benefits for a large number of people<sup>3</sup>.

Two theories of ethical perspective have commonly been cited in the literature of public health research ethics and clinical research ethics. The duty based deontological theory of Immanuel Kant and the consequences based utilitarian theory of Jeremy Bentham and John Stuart Mills. Kantianism or deontological theories hold that individuals should not be treated just as mere means to an end and that some actions are judged right or wrong regardless of the results and consequences. Deontological theories based on duty provide robust support for defending research subjects as an individual and whole community of people of individuals; it strongly focuses individual's autonomy and respect. Its great deal of focus is based on duty which asks for autonomy, individual respect and risk benefit ratio despite of consequences that may be great but, as far as these matters are concerned, it has to be followed in any and every case of clinical research ethics and other fields of life<sup>4</sup>.

On the other hand for the benefit of community and public health research ethics the utilitarian theories focuses to maximize beneficial consequences regardless of any harm to individuals. The principle of utility requires aggregate or collective benefits rather than individual benefits to be maximized from study participants to the future population. It balances the current risks and potential harm to individual's autonomy and individual respect with the benefits for future population. From a utilitarian perspective, based on utility the principle of utility is the ultimate ethical principle of concern that is focused to derive all other principles. Utilitarian theories provide strong justification and support for public health research programs such as obligatory vaccination programs for the safety of public health particularly children and the drinking water fluoridation of public water sources and public water supply system, which may be of no benefit or even harm to some individuals in that specific population or society<sup>2, 4</sup>.

As it is broadly understood, that public health research is concerned with promoting and protecting the health of populations. Public health research is mainly concerned with the health of the whole population as an aggregate, rather than the health of individuals. Public health research emphasize on the prevention of diseases and promotion of overall public health. In developing effective interventions it interacts with behavioral, social, biological, environmental and economical factors<sup>4</sup>.

The foundation of public health research ethics is social justice contributing to the society. Balancing individual's liberty and autonomy has been the main ethical issue in public which is not addressed due to its broader scope for society that causes inequality. On the other hand the fundamental ethical concern raised by clinical research ethics is whether and when it can be acceptable to expose some individual to risks and burdens for the benefit of others. The answer to this question depends crucially on the benefits to future population, and their relationship to those who are being currently exposed to the risks participating in the current research study<sup>2, 4</sup>.

In clinical research ethics, risk and benefit ratio is assessed focusing on the current patient. To asses, whether to harm someone for the future benefits of others or for future population is ethically and morally acceptable or not, while public health research ethics assess risk and benefits ratio for the benefits of future population and society as whole. From clinical research ethics perspective the issues will probably remain even after having a valid inform consent from the participant as inform consent does not remove the associated risks but only a procedure to be followed. The participant may face some risks due to new intervention, the risks which may not be avoided even after testing has occurred in the laboratory, and in animals<sup>5, 6</sup>.

Clinical research ethics concerns with the issue of therapeutic misconceptions, the distinction between clinical care and clinical research which arises between researcher who is the physician and the participant who is the patient for the physician participating in that research study. In any clinical research the patient sometimes participates in the research study due to his physician involved in that study. Sometimes the patients misconceive the research as the treatment. The inquiry of how to discriminate between research and treatment is still a grey area that is to be focused. On the other side in public health research ethics the issue of therapeutic misconception may not be of great deal but still cannot be totally neglected, there are fewer chances of

therapeutic misconceptions that still remain. Some people worry that doctors conducting randomized controlled trials studies confront situations of dilemma in clinical research ethics; on the grounds that offering patients access to a trial in which they have a high chance of receiving placebo or no treatment seems to involve the doctor in prescribing and recommending treatment of suboptimal nature to his own patient<sup>5, 6</sup>. In any research study whether that is public health research or clinical research, it is important to recognize an ethical standard that respects individual's as well as community's autonomy. It can be achieved by requiring individual's and community's collaboration to protect against exploiting vulnerable populations, to ensure fair terms of cooperation, and to minimize potential misunderstandings about the research<sup>5, 7, 8</sup>.

**Conclusion:** The four basic ethical principles of justice, beneficence, nonmaleficence and respect for individual's autonomy can be used as a scaffold for ethical decision making in any form of research. These principles ensures individual's and community's dignity, researchers obligations to individual and community, avoiding and disclosing conflicts of interest, minimizing risks and providing benefits, privacy and confidentiality that all are the fundamentals of every research study.

**Acknowledgement:** The authors would like to acknowledge the generous support and guidance of Dr. Arshi Farooqui, Aga Khan University Hospital, Karachi, Pakistan.

**Competing interests:** The authors declare that they do not have any competing interests.

**Funding:** The Authors declare that the current study was not funded

**Authors' contributions:** All authors have contributed substantially to the conception and design of the manuscript. Muhammad Waseem Khan is the 1<sup>st</sup> and corresponding author. Afrasiab Khan Tareen, and Imrana Niaz Sultan are 2<sup>nd</sup> authors and they have contributed equally. Muhammad Waseem Khan has critically revised the manuscript. All authors have read and approved the final manuscript.

**References:**

1. Kalantri, SP. Ethics in clinical research. *Indian Journal of anesthesia* 2003; 47(1): 30-32.
2. Beauchamp T, Childress J. *Principles of biomedical ethics*. Oxford University Press, 5th edition, New York; 2001.
3. Krebs J. The importance of public-health ethics. Special theme – Ethics and public health: *Bulletin of the World Health Organization* 2008; 86 (8).
4. Coughlin, SS. Ethical issues in epidemiologic research and public health practice. *Emerging Themes in Epidemiology* 2006, 3:16.
5. Kevin, P et al. Disclosure of Financial Relationships to Participants in Clinical research. *N Engl J Med* 2009; 361(9): 916–921.
6. Khan MW, Sultan IN, Khan A, Khan MB. Issues of research ethics and clinical ethics in developing world, Possible Solution: a way forward. *Bangladesh journal of Bioethics* 2012; 3(3):12-15.
7. Buchanan DR, Miller FG. A Public health perspective on research ethics. *J Med Ethics* 2006; 32:729-733.
8. Khan MW, Khan SZ, Khan A, Sultan IN. Standard of Care in Clinical Research Involving Human Subjects: A Perspective from Developing World. *Bangladesh journal of Bioethics* 2014; 5(2):68-72.