SCITECH
RESEARCH ORGANISATION

Volume 4, Issue 1
June 14, 2016

Journal of Progressive Research in Social Sciences
www.scitecresearch.com

Regulations and Guidelines for Research are only a Starting Point to Ensure Ethical Research Practice

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Abstract

Ethical research practice is an umbrella term enlisting various aspects of research practices including clinical interventions, surveys, case-control and cohort studies, studies involving children and studies in developing countries. All the mentioned aspects vary in their conduction and use of ethics. According to some ethics, its rules and guidelines are just the starting point of the research. The following text clears out the doubts on the ethics and elaborates on the prominence of ethical practices in the prodigious field of research.

Keywords: Research ethics; Bioethics; Public health; Clinical trials.

Introduction

The term “bioethics” has been used since the year 1927 when Fritz Jahr, published an article entitle"Bio-Ethik: Eine Umschau ilber die ethischen Beziehungen des Menschen zu Tier und Pflanze" in the journal Kosmos. Later in 1970s Van Rensselaer Potter again used the term and elaborated on it. His book “Bioethics: Bridge to the Future” is one of the landmarks in the field of bioethics (Sass, 2007; Lolas, 2008). Fritz Jahrmodified the term many times and finally ended up with “global bioethics”(Whitehouse, 2003).Initially bioethics had major focus on doctor-patient relationship, organ transplants, genetics, reproductive biology, and resource allocation. The field of public health was paid little heed initially but a tangent towards public health ethics was observed in the mid-1990s. There was a massive increase in interest in population health and the numerous ethical dilemmas were faced by public health programs (Callahan & Jennings, 2002).From ethical point of view, public health activities could be described as teleological and consequentialist i.e. it is purposive and the steps and actions taken in due course has colossal impact on the consequences that follow (Childress et al., 2002).

According to the American Public Health Association, the 10 Essential Public Health Services are 1. Monitor health status to identify community health problems. 2. Diagnose and investigate health problems and health hazards in the community. 3. Inform, educate, and empower people about health issues. 4. Mobilize community partnerships to identify and solve health problems. 5. Develop policies and plans that support individual and community health efforts. 6. Enforce laws and regulations that protect health and ensure safety. 7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable. 8. Assure a competent public health and personal healthcare workforce. 9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services. 10. Research for new insights and innovative solutions to health problems (Lee, 2012).These essential services were considered pivotal guidelines to be followed.

Ethical Paradigm

Decades after the Universal Declaration of Human Rights we can still observe violation and exploitation of human rights (table 1) not only in developing countries but in the prospering industrialised nations as well. This plight explains the difficulty in achieving universal moral aspirations (Benatar, 2002).The public health ethics paradigm entails attempts to designate strength to the moral background of policies, practices, and actions, thus leading to formation of firm moral guidance. The public health ethics paradigm entails attempts to designate strength to the moral background of policies, practices, and actions, thus leading to formation of firm moral guidance. The duties of public health agents include analyzing new situations with general moral considerations in background and also considering auditing the resemblance and distinctions of upcoming scenarios from the prior cases that acquired a comparably settled moral consensus. (Childress et al., 2002).The list includes disclosure concerning the study, privacy, anonymity, confidentiality, fair treatment, protection from discomfort and harm, and self-determination. Amongst these respect for autonomy, beneficence, and non-

maleficence are the major component of the researcher-researched relationship and are called the principles of public health ethics. The principles were framed in 1970s by Tom Beauchamp and James Childress (Lee, 2012; Varmus & Satcher, 1997).The various events in the field of public health ethics have been outlined in table 2.

Table 1:- The Copious Events in the History of Public Health

Sr. No.	YEAR	EVENT	REFERENCE
	1840s	J. Marion Sims, the father of gynecology, carried out surgical experiments on enchained African women, without anaesthesia.	Sartin (2004)
	1874	Roberts Bartholow working in Good Samaritan Hospital, inserted needle electrodes into brain of Irish servant woman, Mary Rafferty.	Morgan (1982)
	1880s	A Hawaiian physician working at a hospital for lepers injected six girls under the age of 12 with syphilis.	Glantz (1998)
	1895	Dr. Henry Heiman deliberately injected four year old and sixteen year old mentally disabled boys with gonorrhoea as part of an experiment.	Glantz (1998)
	1896	Dr. Arthur Wentworth performed spinal taps on 29 young children to test the adverse effects of the procedure.	Glantz (1998)
	1908	Three Philadelphia researchers infected large number of children with tuberculin at the St. Vincent's House orphanage.	Hamill (1908)
	1909	F. C. Knowles deliberately infected two children in an orphanage with Molluscum contagiosum after an outbreak in the orphanage.	Morrow & Richards (1996)
	1911	Dr. Hideyo Noguchi injected 146 hospital patients including children with syphilis.	Lederer (1985)
	1913 to 1951	Dr. Leo Stanley executed a wide variety of experiments on hundreds of prisoners at San Quentin involving testicles of humans and animals.	Schultheiss & Engel (2003)
	1932-1972	The Tuskegee Syphilis Study observed the effects of untreated syphilis in 400 African American men. Researchers halted the treatment even after the availability of penicillin and didn't inform the study subject about it.	Thomas & Quinn (1991)
	1940	Two Nazi refugee scientists cautioned U.S.A. regarding nuclear weapons of Germany.	Bayly & Nelson (2009)
	1944-1980s	A secluded research was sponsored by the U.S. government on the effects of radiation on humans involving cancer patients, pregnant women, and military personnel without their notification.	Ara (2010)
	1956-1980	Few researchers executed hepatitis studies on mentally disabled children at the Willowbrook State School by intentionally infected subjects with the disease.	Goldby (1971)
	1950s-1963	The CIA performed a mind control research program administering LSD and kept the participants in oblivion.	Buckman (1977)
	1994	Roger Poisson fabricated and falsified data on 99 of the 1511 women in breast cancer clinical trials.	Weijer (1995)

Sr. No.	YEAR	Landmark	REFERENCE
1)	**1947**	The Nuremberg Code for research on human subjects was accepted.	Vollmann & Winau (1996)
2)	**1964**	World Medical Association, Helsinki Declaration. The ethical principles for research on human subjects were declared.	Williams (2008)
3)	**1960s/1970s**	Congress adopted the Animal Welfare Act in 1966 and adopted in 1970, 1976 and 1985.	Mendelson (1996)
4)	**1972**	The national media and Congress concentrated on the unethical research practices on human subjects even enlisting the Tuskegee study.	Fisher (2007)
5)	**1974**	Congress passed the National Research Act. This act authorized federal agencies to develop human research regulations.	Mowery et al., 2001
6)	**1979**	The National Commission issued The Belmont Report which comprehended principles of ethical research on human subjects.	Al-Khatib et al., 2001
7)	**1980**	Congress passed the Bayh-Dole Act, thus permitting researchers to patent the inventions developed using government funds.	Mowery et al., 2001
8)	**1981**	The DHEW made notable revisions of the federal human research regulations on human researches.	Gardner (1978)
9)	**1989**	The PHS formed two agencies, the Office of Scientific Integrity and the Office of Scientific Integrity Review.	Claxton (2005)
10)	**1991**	Revision of human research regulations took place. All the U.S. government agencies, excluding EPA, accepted "the common rule".	Guillemin & Gillam (2004)
11)	**1993**	Council of International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), announced the International Ethical Guidelines for Biomedical Research Involving Humans.	Levine (1993)
12)	**2004**	Agencies including NIH adopted the OSTP misconduct definition.	Parrish (2006)
13)	**2011**	The Office of Human Research Protections announced amendments to the Common Rule so as to improve the human subject protections and reduce the burden on the investigator.	Emanuel & Menikoff (2011)
	2010	Lancet retracted a paper published by Andrew Wakefield in 1998, it associated autism to the measles vaccine.	Chen et al., (2013)

Table 2:- The Laws, Definitions, Rules and Amendments in Human Research

Public Health Ethics Framework

In practising public health there is a need for an ethical framework because of two factors. Which are ?These factors include catering practical guidance for public health professionals and describing the defined values of public health. These values are different in applicable ways from values that define clinical practice and research (Kass, 2001). Few public health ethics framework has been portrayed in table 3.

Sr. No.	Principle of the Framework	Reference
1)	➢ Negative right to non-interference ➢ Positive right for improvement in public's health ➢ Social justice	Kass (2001)
2)	➢ Production of benefits ➢ Prevention of abuse, violence and harm ➢ Distribution of the burdens & benefits ➢ Producing maximal balance of benefits to harms ➢ Assurance of participation ➢ Respect of autonomy ➢ Protection of confidentiality ➢ Fulfilment of commitments ➢ Building & maintaining trust ➢ Disclosing information truthfully	Childress et al., (2002)
3)	➢ Individual liberty ➢ Non-discrimination ➢ Honesty & truthfulness ➢ Social duty	Upshur (2002)
4)	➢ Providing care ➢ Equity ➢ Individual liberty ➢ Privacy ➢ Trust ➢ Proportionality ➢ Solidarity ➢ Protection from harm ➢ Reciprocity ➢ Stewardship	Thompson et al., (2006)
5)	➢ Population-level utility ➢ Evidence ➢ Justice/fairness ➢ Beneficence ➢ Accountability ➢ Costs/efficiencies	Baum et al., (2007)

	➢ Autonomy ➢ Political feasibility ➢ Non-maleficence	
6)	➢ Interdependence ➢ Fundamentality ➢ Community trust ➢ Justice	Swain et al., (2008)
7)	➢ Respect for autonomy ➢ Beneficence ➢ Justice ➢ Non-maleficence	Jaffe & Hope (2010)
8)	➢ Human rights, critical determinants of health ➢ Assurance of good health of people by government.	Mann (1996)
9)	➢ Autonomy ➢ Confidentiality ➢ Equal opportunity for health resources ➢ Equity ➢ Solidarity and sociality	Petrini & Gainotti (2008)
10)	➢ Equality between citizens ➢ Autonomy as self-governance ➢ Protection of individual freedom ➢ Social contract on use of state power to advance welfare ➢ Health is important for a good life ➢ Health is defined by individuals ➢ Limiting liberty is acceptance only on prevention of harm ➢ Third-party participation in delivering public health	Baldwin et al., (2009)
11)	➢ Relational autonomy ➢ Relational social justice ➢ Relational solidarity	Kenny et al., (2010)

Table 3:- Different Frameworks and their Governing Principles

Different Aspects of Ethical Guidelines

Clinical trial

As stated by Jonas in 1965, that there should be no research conducted on patients unless they had a direct positive outcome on health. Likewise the primary expectation of the participants is improvement in terms of medical condition. Along with the benefit, the subjects must be explained the risks and negative side-effects thus completely explaining the risk-benefit ratio component (Emanuel et al., 2000). Informed consent procedure play a pivotal role as it reduces the sense of threat in the mind of subjects regarding allocation to placebo group and their on-going medication. The prevailing ethical approach to clinical trials attempts to view the clinical trials in a scientific experiment. According to the ethical guidelines they are aimed at producing knowledge that results in improvement in the medical care and treatment i.e. value

of research to society.Another consideration is ethic of subject selection, this aspect includes differentiation on the basis of gender, cast (excluding ethnographic studies) and region. It also explains medical condition of the patient-subject, in case of severe condition enrolment in a study should be thought twice definitely after considering the benefit of the patient from study (Kottow, 2009; Miller & Brody, 2003).A third requirement is related to the fair selection of the study population. This implies that groups selected for study should be related to the research question. Many times, participants are selected "by convenience" and not because research is focused on finding a solution to the problem of the group (Kopitowski, 2014).

A clinical trial (randomized) is considered to be ethical only in case of clinical equipoise (Miller & Brody, 2003).The point on which there is no predilection for treatment is known as equipoise. It neither means not knowing nor being uncertain, but it entails that there is no rational preference in all circumstances (Lilford & Jackson, 1995). In 1987 Benjamin Freedman brought an innovative way to view randomized trials ethics by promoting clinical equipoise rather than individual equipoise (Ubel & Silbergleit, 2011).

Developing Countries

When considering ethical issues in developing countries, there are many factors that affect the outcome of the study, these enlist poverty, endemic diseases, and a low level of investment in health care systems. These factors influence both the process of performing clinical trials and the selection of trials. One other process affected is informed consent, this process differs in developing countries according to local custom and culture. Sometimes issues like illiteracy and use of language other than local language might be other hindrance. One of the contentious issues in research design in the conduct of clinical trials in developing countries is regarding usage of placebo in the control group or receiving the same intervention which is usually followed in a developed country (Shapiro & Meslin, 2001; Varmus & Satcher, 1997). Literature states 15 studies conducted in the different developing nations. These studies examined the effectiveness of the anti-retroviral drug zidovudine in the preventing HIV transmission during pregnancy against a placebo. To match the standard of conduction of clinical trials of developed, use of placebos should be prevented as it is unacceptable to be used in US (Varmus & Satcher, 1997).

Studies involving children

The involvement of children in the field of research has been there from a long time. They act as active informants in most of the areas of clinical and non-clinical researches (Brostrom, 2012). Case laws state that there are three stages of childhood. In the first category there are children of tender age who do not have the competency to give consent to health care treatment. Second, the children under 16 years of age, the 'Gillick component', and these children are mature enough to give consent to most of the health care procedures (Allmark, 2003). The United Nations Convention on the Rights of the Child (UNCRC) in 1989 established children's rights to participation (Article 12) unambiguously and universally. The important aspects of involving children in research are ensuring that children are heard and protected. If children are involved in a study, the welfare of individual child is more substantial than the research study itself. MRS guidelines state that the children below the age of 16 years should be happy with the involvement in the study and there is necessity of parental consent for these children. Children should also be informed in the end that there are no wrong consequences of not involving in the research (Nairn & Clarke, 2012; Thomas & O'kane, 1998).

Conclusion

Cited literature and history suggests that guidelines and regulations though are a starting point in carrying out a research but their presence in the field of research related to human beings or animals is imperative for protection of the rights of every individual. In addition to this, research ethics is also counted eminent in recording and publishing of data.

Acknowledgment

The author would like to thank Mr. Salil Jain & Mrs. Parul Jain. The author reports no conflict of interest and state that it was a self-funded research.

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