ORIGINAL ARTICLE

INDEPENDENT REVIEW OF RESEARCH PROPOSALS FROM ETHICAL POINT OF VIEW IN PAKISTAN

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Background: Ethics is a part of subject philosophy and gained importance in research after the Nuremberg Code that led to Helsinki's Declaration on research ethics. In most developed countries stringent measures are taken to implement ethics in research. Awareness is on the rise in developing countries too. **Methods:** This cross-sectional part of mixed methods design of study is part of a PhD thesis. Data was collected from medical institutions including medical colleges, medical universities, dental colleges, and teaching hospitals of Pakistan. Questionnaires were developed, and final version was adopted after pretesting. Questionnaires were sent via registered post. **Results:** A total of 78 institutions responded. Out of 78, 48 (61.5%) were in public sector and 30(38.5%) in private sector. Seventy-four (94%) had institutional review boards. The numbers of members ranged from 1 to 15 with 40(54%) having number of members from 3 to 7. Out of 74 with IRBs, 17(23%) had members from community, 11(15%) had religious scholars and 8(11%) had members from legal background. Sixty-four (86.5%) responded that they had time frames for research proposal processing that ranged from one to 26 weeks (6.2±5.6) **Conclusion:** It is concluded that most of the medical institutions where research is conducted and approved through deficient research ethical boards in terms of their constitution. Research ethics is not a priority area for most of the institutions. Representation of society at large is missing. National action is required at government level.

Keywords: Institutional Review Boards; Research Ethics; Ethics Committees; Constitution of IRBs

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INTRODUCTION

The term 'ethic' has been associated with much depth and broadly involves moral principles that is concerned with human behaviours.[1] Philosophers, over a period of time have been explaining ethics based on approaches, principles, and casuistry. The theories and principles, however, converge to achieve the same objectives.[2]

The theories include: deontology, consequentialism, and virtue ethics. Deontology is a system of ethical analysis propounded by Immanuel Kant that bases the correctness of one's actions on fulfilling the duties of the person acting as such. Individuals have moral obligations to others. By fulfilling those obligations, they act and on the contrary acting unethically. In simple words deontology means what is good is good and what is bad is bad. Consequentialism is a system of ethical analysis, close to John Stuart Mill explanations that bases the correctness of one's actions on the consequences of the action. Other words used with different connotations but the same outcome are teleology and utilitarianism. In virtue-based approach, to be ethical is to cultivate in oneself appropriate character traits, such as honesty, altruism, courage, and perseverance, and also to work to create such character traits in others. These theories of normative ethics demonstrate that they are more complementary than contradictory. Most people find it more useful to consider all three perspectives while dealing with ethical dilemmas.[3]

A medical man encounters ethics in clinical situation while dealing with patients, in public health, and research in health setups mostly involving human beings. The distinction between research ethics and clinical ethics is important for many reasons. The most important is that, when dealing with a patient in a clinical situation, providing the best possible care for that patient is the primary goal of the practitioner. In the research setting, the individual patient is participating in the project for the benefit of others. Participating in research may not be beneficial for the patient rather may be a cause of harm. Those overseeing the research projects have specific ethical obligations that are different from clinical situations.[4]

The history of research ethics is closely associated with the political situations and conflicts spread over the pages of history. The world was shaken by the Nazi experimentation (World War II) under state sanctions. This led to Nuremberg Code in 1947, which envisaged that nobody shall be subjected to experimentation without his/her consent. It culminated into Declaration of Helsinki in 1964.[5] The infamous Tuskegee Syphilis Study (USA; 1932–1972) led to Belmont Commission which produced a comprehensive document known as The Belmont

Report published in 1979. The American President Bill Clinton tendered a state apology to the survivors and families of victims of Tuskegee Trials.[3]

The Declaration of Helsinki developed by the World Medical Association, clarified and interpreted the principles of research ethics in the light of the Nuremberg Code. This international effort, first published in 1964 and updated a dozen times since, acknowledged the relevance of clinical research as an important societal strategy for improving human welfare.[6]

Advancement in understanding of ethics and continuous scrutiny by media and civil society have led to the establishment of Institutional Review Boards (IRBs) that have representation of people upon whom research is carried out. IRBs were established to protect the rights and welfare of human subjects of research. The duties of IRBs include reviewing the research protocol and the informed consent document to ensure an acceptable level of risk to subjects in the larger interst of humanity and a complete process of informed consent.[7]

Institutional Review Boards should have the scientific expertise to judge the merits and weaknesses of the research projects they review. IRB members rely on the regulatory definition of research, which emphasizes the purpose directing the activity in question. Some of them see IRBs as a bothersome obstruction to be overcome. The IRBs may at times be required to have contact with the investigator and the project beyond reviewing paperwork. Protection of the subjects of research may occasionally require the IRB to monitor the processes. This may include direct or disinterested party monitoring of the projects.[8] In fact implementation of the Belmont Report principles led to institutional review boards (IRBs) that protect individual research participants through confidentiality, informed consent, and oversight.[9]

In developed countries IRBs work under guidelines but these guidelines are also under continuous scrutiny. In one article they are spelled out as: 1) social or scientific value of research, 2) scientific validity, 3) fair subject selection, 4) favourable risk-benefit ratio, 5) independent review, 6) informed consent, and 7) respect for enrolled subjects.[10] Medical journals have the duty to ensure that research articles conforming to ethical standards and IRBs approval are published. In the United States, five medical journals were studied and found deficient in reporting ethical approval. Ethical approval was reported in 97% cases of randomized controlled trials (RCT), but in the case of other study designs it was not up to the mark.[11]

In Pakistan we encounter different milieu. A review by Hyder *et al* reveals that literature pertaining to health ethics is scarce in Pakistan with very little authorship by Pakistani health professionals. Most of the available Pakistani literature pertains to clinical practice ethics. The authors have pleaded for the resurrection of Pakistan Journal of Ethics.[12] In another study by it is concluded that adherence to principles of ethics in medical practice is inadequate in Pakistan. The authors have suggested that bioethics be incorporated in undergraduate and postgraduate medical curricula and efforts were needed to be made to make people aware of their rights.[13]

This study is a part of PhD thesis that includes mix methods of research. In the present article quantitative analysis of data pertaining to IRBs in medical institutions is presented and discussed.

MATERIAL AND METHODS

This cross-sectional, part of the larger study with mixed methods design, was conducted after obtaining ethical approval form Health Services Academy, Quaid e Azam University Islamabad. Data was collected from 1st April 2015 to 31st March 2016.

Questionnaire was developed and pretested before adopting a final version. Questionnaires were sent to all medical colleges, medical universities, dental colleges and teaching hospitals registered with Pakistan Medical & Dental Council (PM&DC). Keeping the data confidential was assured and is ensured in reporting results. Most of the institutions did not respond, who were sent the questionnaires again. Requests to complete them were also made through phone calls. A lot of institutions did not respond at all even after making repeated requests.

The variables in the study included: type of institution, whether public or private, province, presence of IRBs, and constitution of IRBs besides asking for their comments through open ended questions. Data was analysed descriptively using SPSS version 20.0.

RESULTS

Seventy-eight institutions responded out of total 145 who were contacted through registered post. Province wise breakup is given in Table 1. Pakistan comprises 04 provinces and a federal area. Provinces are Punjab, Sindh, Khyber Pakhtunkhwa (KPK) and Balochistan in order of population and number of medical institutions. Response of the only medical institution in Balochistan could not be obtained.

Table-2 shows institutions by type. Response rate of universities awarding medical degrees was better than other institutions. There were 48 (61.5%) institutions in public sector and 30 (38.5%) in private sector. Presence of institutional review boards (IRB) was reported in 74 (94.4%) cases. It was learned through phone calls that most of the institutions that did not respond lacked existence of IRBs. The numbers of members in the IRBs in

various institutions ranged from 1 to 15. Forty (54%) institutions had members from 3 to 7.

`Institutions were enquired to respond to the constitution of IRBs. Most of the boards were 58 (78%) had presence of their own employees on the board. Out of 74 institutions having IRBs 17 (23%) institutions had members from community, 11 (15%) had religious leaders, and 8 (11%) had legal advisors on the board. Institutions were asked whether time frame was given for review process of research proposals. Out of 74, 64 (86.5%) answered in affirmative. Responding further to a query about the length of the time period it was reported that it ranged from one week to 26 weeks with a mean of 6.2±5.6 weeks. Twenty institutions reported a time frame of 20 weeks. Fifty-eight institutions replied that they used some guidelines to examine research proposals. They were further requested to provide those guidelines. Twelve of them attached the guidelines which were WHO guidelines for research.

A section of the questionnaire was reserved for comments. Many questionnaires were received with comments. Some of the comments are reproduced as following in table-3.

Table-1: Respondent medical institutions by province

Province	Number	%
Federal	4	5.1
Punjab	38	48.7
Sindh	23	29.5
KPK	13	16.7
Total	78	100.0

Table-2: Institutions by type

Type of Institution	Number	%
Medical College	45	57.7
Medical University	10	12.8
Teaching Hospital	15	19.2
Dental College	7	9.0
Others	1	1.3
Total	78	100.0

Table-3: Comments by the respondents

"Awareness of principles of ethics, publication ethics is required."
"Awareness seminar/symposium. Introduction to bioethics topic/subject in curriculum."
"Competent skilled personnel should oversee research activities. Every institution should have their independent IRB and EC."
"Ethical issues to be highlighted at graduate and postgraduate levels of medical education."
"Ethical review committees should be constituted by the health secretary."
"Facilitation by institutions. Promotions to be linked with research performance."
"Train faculty on research ethics. Few lectures in undergraduate syllabus on research ethics shall be added."

DISCUSSION

Research ethics is largely an ignored subject especially so in the developed countries like Pakistan. The present study is a part of a larger project of a PhD thesis wherein mixed study design is employed.

Medical teaching institutions like medical colleges, universities awarding medical degrees, dental colleges and teaching institutions were included in the study besides interviewing other key informants. Results pertaining to ethical boards is reported in the instant study.

Response of the institutions was poor, and it was revealed that most of the institutions especially teaching hospitals were reluctant to respond because of either non-existence of such committees or boards, or lack of understanding of the process. A study by Ibrar *et al* supports it.[14] Another study supports our version that constitution of most of the boards do not have proper representation as per the World Health Organization guidelines.[15]

A few institutions which, in most cases are universities take care of the notion that representation of those segments is important upon which research is to be carried out.

The basic aim of such boards is to review the articles whether they are technically and ethically sustainable for implementation and monitoring. This task is supposedly done by the professional bodies having representation of communities, religious segments and legal experts. The comments in our study show that respondents see a role for the government. In Pakistan there is a National Bioethics Committee (NBC) with no connections with the institutions where research is carried out. The role of NBC came almost to a halt when 18th amendment in the Constitution of Pakistan made Health a provincial matter.[16] Pakistan Medical Research Council (PMRC) is also a government regulatory body with limited scope. There is no central registry or such bodies at provincial levels.

Comments received during data collection showed emphasis on educating medics at undergraduate level as well as holding of seminars, symposiums and courses in ethics at later stages of profession.

The results of the study have the limitations of lack of response on part of the institutions as well as poor understanding of the subject. These aspects are addressed in the qualitative part of the study in the thesis report.

CONCLUSION & RECOMMENDATIONS

In conclusion it is reported that most of the medical institutions where research is conducted have deficient research ethical boards in terms of their constitution. Research ethics is not a priority area for most of the institutions. Representation of society at large is missing. It is recommended that government and professional bodies work in unison to make amends to the situation.

Conflict of Interest: None

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