ASSOCIATION OF RESEARCH ETHICS KNOWLEDGE WITH PREVIOUS RESEARCH EXPOSURE AND ACADEMIC QUALIFICATION AMONG FOOD AND NUTRITION GRADUATES IN PAKISTAN

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ABSTRACT

OBJECTIVES: To assess the knowledge and attitude regarding research ethics and its association with previous research exposure and academic qualification among food and nutrition graduate students of Pakistan.

METHODS: This cross-sectional survey was conducted from April-May 2016. A structured-questionnaire was e-mailed to food and nutrition students from different cities of Pakistan. The questionnaire had four parts; demography, prior exposure to research, knowledge and attitude regarding research ethics. Chi-Square test and Fisher's Exact test were applied to assess association and data were analyzed using Statistical Package for Social Sciences (SPPS) version 20.

RESULTS: The mean age of the participants was 28.964±7.985 years (range 21-59). A total of 280/400 (70%) respondents completed the questionnaire. Majority (91.1 %) of the participants was females and 60% had completed post-graduate education. About 96.4% participants reported prior involvement in research but only 21.4% had international publications. More than 80% of the respondents stated that they had knowledge about key concepts of research ethics but only 41.1% knew about Nuremberg Code and 42.9% about Helsinki Declaration. Scenario-based statements assessing attitudes had mixed results. Previous exposure to research, training in research ethics, international publications, application to research ethics committee (REC) and being a post-graduate was associated with knowledge of ethical principles ($p<0.05$).

CONCLUSION: Self-reported knowledge was good but students lacked correct attitude. Post-graduate students and those with research experience had better knowledge regarding research ethics.

KEY WORDS: Knowledge (MeSH); Attitude (MeSH); Research (MeSH); Ethics (MeSH); Students (MeSH); Ethics Committees, Research (MeSH); Codes of Ethics (MeSH); Helsinki Declaration (MeSH).

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INTRODUCTION

There is an increased need to conduct research in developing countries. Researches involving human participants need to be guided by fundamental ethical principles to ensure the protection of their rights, dignity and welfare.[1] To maintain ethical standards in health research and publication certain norms are laid down by various National and International Agencies. The Nuremberg Code[2] and Declaration of Helsinki [1] are the benchmarks in ethical standards followed worldwide for biomedical research and uniform requirements for manuscripts submitted to biomedical journals (formulated by International Committee of Medical Journal Editors) for publication in scientific journals.[3] Regardless of the existing guidelines for research ethics, the developing nations are not involved in the debate of ethics in health research. There is an increased need to develop local capacity in bioethics and research that promotes equity.[4] Previously knowledge of research ethics education has been assessed among new graduate students,[5] graduate students of basic medical sciences, clinical sciences, dentistry and public health,[6] and medical and dental post-graduate students in South India.[7]

Food and nutrition graduates are involved with human subjects for counseling, diet modification and research. They should have knowledge of research ethics as a responsibility toward achieving the highest standards of services. There is no research which has investigated the knowledge and attitude of food and nutrition graduate students toward research ethics in Pakistan. The present study was conducted with an objective to assess the knowledge and attitude regarding research ethics and its association with previous research exposure and academic qualification among food and nutrition graduate students of Pakistan.

METHODS

The current research was an online cross-sectional survey. The study was conducted at University of South Asia, Lahore, Pakistan. Data was collected and analyzed, and manuscript was prepared at the University. The questionnaire was e-mailed to food and nutrition graduate students located in different cities of Pakistan. Data collection took place between April-May 2016.

The entire population whose emails were available constituted the sample. The email addresses of the students were retrieved from a registered society of nutritionists and dietitians-

Pakistan Nutrition and Dietetic Society (PNDS). Universities offering food and nutrition programs were searched through the internet food and nutrition program and names of cities and provinces were used as key words. If the website displayed the email address of the Head, the questionnaire was emailed to head of departments and they were requested to circulate the questionnaire in their alumni. Besides this, social media sites like LinkedIn, ResearchGate were also used to reach the students. Snowball sampling technique was also employed and participants were requested to forward the questionnaire to other students. The questionnaires were emailed to 400 students and a total of 280 respondents completed the questionnaire. The response rate was 70 percent.

A self-administered structured questionnaire was made for the current research after review of literature.[1,2,8,9] It was piloted to rephrase ambiguous questions and eliminate unnecessary questions. Content and face validity was insured by consulting experts in the field. The 35 item questionnaire had four parts; demography, previous exposure to research, knowledge and attitude regarding research ethics. The demographic part had multiple options with an open ended blank stating others. The previous exposure to research and knowledge part had dichotomous options; yes and no. The attitude part had statement like "Research Ethics Committee (REC) is helpful and every institute should have REC" and participants had to select from Likert scale options, strongly agree, agree, neutral, disagree and strongly disagree.

Frequencies and percentages were calculated for responses. Chi Square test was applied to assess association and Fisher's Exact test was applied where cell frequency was less than 5. A p-value <0.05 was taken as significant and data were analyzed using Statistical Package for Social Sciences (SPSS) version 20.

Ethics approval and consent to participate

The study was exempted by Ethical Review Committee, University of South Asia, Lahore, Pakistan as it was an online survey and did not involve human trial. The questionnaire had an introduction stating the purpose of research and whoever consented completed the questionnaire. Names of the participants were not inquired and they were ensured of confidentiality of data.

RESULTS

The mean age of the participants was 28.964±7.985 years (range 21-59). Majority (71.4 %) of the participants were aged less than 30 years. Majority of the participants belonged to Lahore (57.4%), followed by Karachi (21.4 %), Faisalabad 5.4%, Islamabad 3.6 %, Dera Ismail Khan, Gilgit, Multan, Peshawar, Rahimyar Khan, and Sargodha 1.8%. Majority (91.1%) of the participants were females and 60% had completed post graduate education. About 57% specialized in food and nutrition and 17.3% specialized in food science and human nutrition. About one third of students had a monthly household income more than Rs. 100,000 (Table I).

Almost 96.4 % participants reported prior involvement in research but only 21.4% had international publications. Knowledge regarding key concepts of research ethics is evident from Table II. Participants had knowledge about informed consent (85.7%), voluntary nature of participation (98.2%), right to withdrawal (92.9%) and confidentiality (96.4%).

Table III shows attitudes towards research ethics. Positive statements like research ethic committee (REC) is helpful, research ethics as mandatory module, informing patients about aims, purpose, benefits and risks, anonymity and confidentiality scored better. Statements regarding use of deception and dissemination of results were mixed. Results of negative statements were mixed too. Only 52% answered correctly about Ethical Review (ER) being necessary for inter collaborative research. Forty-three percent disagreed that ER would delay research and yet 60% were of opinion it is necessary even after being approved from Advanced Board of Studies. Fifty-five percent disagreed that informed consent is only necessary when using biological samples and 40% disagreed that vulnerable groups can be included if guardian is not available for consent. 62% were against fabrication of data and 33% disagreed with the view that once enrolled participants have to complete the study.

Prior involvement in research was associated with knowledge of informed consent ($p=0.001$), program debriefing ($p=0.016$), Nuremberg Code ($p=0.006$) and Helsinki Declaration ($p=0.002$). Prior training in research ethics was associated with knowledge of voluntary nature ($p=0.029$), program debriefing ($p=0.002$), anonymity ($p=0.007$), beneficence ($p=0.028$), Nuremberg Code ($p=0.001$) and Helsinki Declaration ($p=0.001$) [Table IV].

International publications were associated with knowledge of informed consent ($p=0.001$), right to withdrawal ($p=0.047$), possible risks ($p=0.005$), Nuremberg code ($p=0.001$) and Helsinki Declaration ($p=0.001$). Applied to research ethics committee was associated with knowledge of informed consent ($p=0.001$), right to withdrawal ($p=0.001$), confidentiality ($p=0.015$), justice ($p=0.014$) and beneficence ($p=0.026$) as evident from Table V.

Academic qualification i.e. being a post graduate was associated with greatest knowledge regarding ethical principles. Being a post graduate was associated with knowledge of informed consent ($p=0.001$), voluntary nature ($p=0.002$), right to withdrawal ($p=0.002$), confidentiality ($p=0.001$), anonymity ($p=0.001$), justice ($p=0.021$), beneficence ($p=0.004$) and possible risks ($p=0.036$).

DISCUSSION

There have been numerous unethical practices in the past, therefore; international community has made several ethical guidelines or codes to protect rights of human subjects. In the current research the participants reported a good knowledge of ethics. But the present study indicated that graduate students had unsatisfactory

knowledge about various ethical guidelines such as Nuremberg Code and Helsinki Declaration. The reason behind this is that general research ethics is taught as a chapter in compulsory subject research methodology but health research ethics, history of unethical researches and development of Documents of Set of Ethical Principles i.e. Nuremberg Code, Belmont Report and Helsinki Declaration governing health and medical research are not taught.

Majority of the participants answered attitude based positive statements correctly. They agreed and understood the role and importance of Research Ethics Committee, program debriefing, anonymity and confidentiality. But mixed results were obtained regarding use of deception. The APA Ethics Code allows for its use when the benefits of using it outweigh the risks, participants cannot reasonably be expected to be harmed, there is no way to conduct the study without deception, and participants are informed of the deception as soon as possible. But according to Helsinki Declaration under no conditions deception can be used. Another attitude which received 44% neutral responses was importance of dissemination of results. Reason behind this could be that majority of students do not have good writing skills and scholarly writing is not mandatory and focused in a developing country like Pakistan. Responses on scenario based negative statements were also mixed. Only 33-60% could choose correctly from the given options. This means that as earlier stated good knowledge of ethical principles was just for namesake and they did not understand the concepts clearly, so the attitude based scenario statements confused them.

Those participants who had previous research involvement, training in research ethics and international publications had better knowledge of ethical principles, Nuremberg Code a

nd Helsinki Declaration. It was evident from the current research that academic qualification was associated with maximum knowledge of ethical principles. It was found so because post graduate students are more rigorously exposed to research methodology curriculum than graduate students. As Documents of Set of Ethical Principles are not taught in colleges, therefore, academic qualification was not found to be associated with knowledge of Nuremberg Code and Helsinki Declaration.

But it has to be understood that mostly graduate students work as nutritionists and dietitians in hospitals and have access to human subjects and are involved in nutrition interventions. Hence they should be well versed in research ethics. On campus or work cite training increases knowledge of principles of research ethics. A study by Brown and Kalichman[10] among graduate students in experimental sciences showed that training resulted in improved reports of knowing what to do if faced with an ethical dilemma. A study evaluating outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university concluded that the training improved participants' knowledge of principles of research ethics, international guidelines and regulations and operations of Institutional Review Boards (IRBs). Participants retained much of the knowledge acquired from the workshop one month after its completion.[11]

As previously suggested, curriculum in research ethics should be developed for university faculty;[9] in the same way there is a need to standardize the nutrition curriculum all over Pakistan and develop contextually relevant, in line with international standards of research ethics curriculum. Till the curriculum is developed and implemented a short course could be developed in light of Shroder-Back et al. ethics course in public health program. They have used case study and problem based learning approach for a 6-8 week short course.[12] Majority of the respondents were of the view that research ethics should be taught as a mandatory course. Therefore, training, short courses and revision of curriculum are mandatory to achieve the goal of improved knowledge and practice of research ethics among food and nutrition students.

Strengths and limitations

A major strength of this study is that it was the first survey to explore knowledge and attitude regarding research ethics among food and nutrition graduate students in Pakistan. The questionnaire was anonymous and participation was completely voluntary. It is hoped that anonymity assures honest responses. However, this feature could also impose a limitation that only those choose to answer who had good knowledge regarding research ethics.

CONCLUSION

Knowledge regarding key concepts of research ethics was commendable among food and nutrition graduate students in Pakistan. But knowledge regarding Documents of Set of Ethical Principles i.e. Nuremberg Code and Helsinki Declaration was inadequate.

TABLE I: DEMOGRAPHIC AND ACADEMIC CHARACTERISTICS OF THE PARTICIPANTS

Characteristics		%
Gender	Female	91.1
	Male	8.9
Degree	PhD	10
	M Phil	50
	M Sc (hons)/ MS	9
	M Sc/ BS	30.3
Specialization	Food & Nutrition	57.1
	Nutrition & Dietetics	16.0
	Food Science & Human Nutrition	16.0
	Community Health & Nutrition	3.5
	Public Health & Nutrition	5.3
	Human Nutrition	1.7
Household Income (PKR)	>100,000	33.9
	50,000-100,000	39.2
	<50,000	23.2

TABLE II: PREVIOUS EXPOSURE WITH RESEARCH AND KNOWLEDGE REGARDING ETHICAL PRINCIPLES

Variables		Yes (%)	No (%)
Previous Exposure with Research	Prior involvement in research	96.4	3.6
	Prior training in research ethics	53.9	46.1
	International publications	21.4	78.6
	Previously applied for approval from Research Ethic Committee	37.9	62.1
Knowledge Regarding Ethical Principles	Informed consent	85.7	14.3
	Program debriefing	80.4	19.6
	Voluntary participation	98.2	1.8
	Right to withdrawal	92.9	7.1
	Confidentiality	96.4	3.6
	Anonymity	91.1	8.9
	Justice	89.3	10.7
	Beneficence	83.9	16.1
	Possible risks	83.9	16.1
	Potential benefits	92.9	7.1
	Nuremberg Code	41.1	58.9
	Helsinki Declaration	42.9	57.1

Also students lacked correct attitudes towards ethical issues. As previous exposure with research and academic qualification was significantly associated with increased research ethics knowledge, it should be added in the food and nutrition graduate curriculum in Pakistan.

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REFERENCES

1. World Health Organization. Declaration of Helsinki. Bull World Health Organ 2001;79(4):373-4.
2. Nuremberg Code. Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law. Washington, D.C.: U.S. Government Printing Office. 1949;10(2):181-2.
3. Shah N. Ethical issues in biomedical research and publication. J Conserv Dent 2011;14(3):205-7.
4. Bhutta ZA. Ethics in international health research: A perspective from the developing world. Bull World Health Organ 2002;80(2):114-20.
5. Heitman E, Olsen CH, Anestidou L, Bulger RE. New graduate students' baseline knowledge of the responsible conduct of research. Acad Med 2007 Sep;82(9):838-45.

TABLE III: ATTITUDE REGARDING ETHICAL PRINCIPLES

ATTITUDE	SA (%)	A (%)	N (%)	DA (%)	SDA (%)
POSITIVE STATEMENTS					
1. Research ethic committee (REC) is helpful & every institute should have REC	60	36	4	0	0
2. Research ethics should be taught as a mandatory post graduate module.	44	52	4	0	0
3. Patients should be informed of aims and purpose of the research including risks and benefits.	59	35	4	2	0
4. Deception can be used when potential benefits outweigh the risks involved.	10	14	32	25	19
5. Ideally participant's identity should not be known to researcher and it should not be revealed to anyone outside the researcher or his staff.	31	50	13	6	0
6. There should be measures to protect patient data from being accidently exposed.	67	31	0	0	2
7. The study results should be disseminated and everyone should benefit from the contributions.	0	54	44	2	0
NEGATIVE STATEMENTS					
8. Ethical review of research by an research ethics committee (REC) is only necessary for international collaborative research.	9	28	11	31	21
9. Ethical review by an REC would delay research and make it harder for the researcher.	2	22	33	28	15
10. Ethical review of research by an REC is not necessary since it has passed advanced board of studies.	4	15	21	44	16
11. Informed consent is necessary only when using biological samples and presentation of data as pictures.	9	18	18	44	11
12. If no surrogate/guardian is available to give informed consent for vulnerable group they could still be included.	4	23	33	32	8
13. It is ok to fabricate data to improve outcomes of research as long as there is no harm to the participants.	4	30	4	29	33
14. We should tell the participants that once enrolled they have to complete the study.	13	41	13	24	9

KEY: SA= Strongly Agree; A= Agree; N= Neutral; DA= Disagree; SDA= Strongly Disagree

TABLE IV: ASSOCIATION OF PRIOR INVOLVEMENT IN RESEARCH & PRIOR TRAINING IN RESEARCH ETHICS AND KNOWLEDGE REGARDING ETHICAL PRINCIPLES

Principles		Prior Involvement in Research		p-value	Prior Training in Research Ethics		p-value
		No (%) n=10	Yes (%) n=270		No (%) n=129	Yes (%) n=151	
Informed consent	No	50	12.9	10.802 (0.001)*	15.5	13.3	0.290 (0.611)
	Yes	50	87.1		84.5	86.7	
Voluntary nature	No	0	1.9	1.000	3.9	0	0.029*
	Yes	100	98.1		96.1	100	
Right to withdrawal	No	0	5.6	1.000	7.8	3.4	2.706 (0.116)
	Yes	100	94.4		92.2	96.6	
Confidentiality	No	0	3.8	1.000	3.9	3.4	1.000
	Yes	100	96.2		96.1	96.6	
Program debriefing	No	50	18.9	5.833 (0.016)*	27.9	13.2	9.347 (0.002)*
	Yes	50	81.1		72.1	86.8	
Anonymity	No	0	7.4	1.000	11.6	3.3	7.225 (0.007)*
	Yes	100	92.6		88.4	96.7	
Justice	No	0	11.5	0.609	10.9	11.3	0.012 (0.914)
	Yes	100	88.5		89.1	88.7	
Beneficence	No	40	16.3	0.072	22.5	12.6	4.798 (0.028)*
	Yes	60	83.7		77.5	87.4	
Possible risks	No	0	11.5	0.609	15.5	7.9	3.250 (0.071)
	Yes	100	88.5		84.5	92.1	
Potential benefits	No	0	0	--	0	0	--
	Yes	100	100		100	100	
Nuremberg Code	No	100	55.2	0.006*	72.9	43	25.212 (0.001)*
	Yes	0	44.8		27.1	57	
Helsinki Declaration	No	100	52.9	0.002*	65.9	45.1	12.212 (0.001)*
	Yes	0	47.1		34.1	54.9	

*p-value<0.05

TABLE V: ASSOCIATION OF INTERNATIONAL PUBLICATIONS & APPLIED TO RESEARCH ETHICS COMMITTEE AND KNOWLEDGE REGARDING ETHICAL PRINCIPLES

Principles		International Publications		p-value	Applied to Research Ethics Committee		p-value
		No (%) n=220	Yes (%) n=60		No (%) n=174	Yes (%) n=106	
Informed consent	No	18.2	0	0.001*	23	0	0.001*
	Yes	81.8	100		77	100	
Voluntary nature	No	2.3	0	0.588	2.9	0	0.160
	Yes	97.7	100		97.1	100	
Right to withdrawal	No	6.8	0	0.047*	8.6	0	0.001*
	Yes	93.2	100		91.4	100	
Confidentiality	No	4.5	0	0.126	5.7	0	0.015*
	Yes	95.5	100		94.3	100	
Program debriefing	No	20.5	18.3	0.133 (0.436)	23.6	14.2	3.647 (0.065)
	Yes	79.5	81.7		76.4	85.8	
Anonymity	No	6.8	8.3	0.163 (0.686)	5.7	9.4	1.350 (0.245)
	Yes	93.2	91.7		94.3	90.6	
Justice	No	14.1	0	0.001	7.5	17.0	6.051 (0.014)*
	Yes	85.9	100		92.5	83.0	
Beneficence	No	19.1	10	2.743 (0.098)	13.2	23.6	4.984 (0.026)*
	Yes	80.9	90		86.8	76.4	
Possible risks	No	13.6	1.7	0.005*	8.6	15.1	2.804 (0.094)
	Yes	86.4	98.3		91.4	84.9	
Potential benefits	No	0	0	--	0	0	--
	Yes	100	100		100	100	
Nuremberg Code	No	64.5	28.3	25.192 (0.001)*	60.9	50	3.201 (0.074)
	Yes	35.5	71.7		39.1	50	
Helsinki Declaration	No	60	35	11.888 (0.001)*	58.6	48.1	2.934 (0.087)
	Yes	40	65		41.4	51.9	

*p-value<0.05

6. Osungbade KO, Ogundiran TO, Adebamowo CA. Research Ethics Education among Graduate Students of the University of Ibadan, Southwest Nigeria. Br J Med Med Res 2014;4(14):2736-49.
7. Janakiram C, Gardens SJ. Knowledge, attitudes and practices related to healthcare ethics among medical and dental postgraduate students in south India. Indian J Med Ethics 2014;11(2):99-104.
8. El-Dessouky HF, Abdel-Aziz AM, Ibrahim C, Moni M, AbulFadl R, Silverman H. Knowledge, awareness, and attitudes about research ethics among dental faculty in the Middle East: A pilot study. Int J Dent 2011; 2011: 694759. DOI: 10.1155/2011/694759. Epub 2011 Jul 3.
9. Kandeel N, El-Nemer A, Ali NM, Kassem H, El-Setouhy M, Elgharieb ME, et al. A multicenter study of the awareness and attitudes of Egyptian faculty towards research ethics: a pilot study. J Empir Res Hum Res Ethics. 2011 Dec;6(4):99-108. DOI: 10.1525/jer.2011.6.4.99.
10. Brown S, Kalichman MW. Effects of training in responsible conduct of research: A survey of graduate students in experimental sciences. Sci Eng Ethics 1998;4(4):487-98.
11. Ajuwon AJ, Kass N. Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university. BMC Med Ethics 2008;9(1):1-9.
12. Schröder-Bäck P, Duncan P, Sherlaw W, Brall C, Czabanowska K. Teaching seven principles for public health ethics: towards a curriculum for a short course on ethics in public health programmes. BMC Med Ethics 2014;15(1):1-9.

AUTHOR'S CONTRIBUTION

The sole author **AS** has made substantial contributions to the manuscript in terms of concept & study design, acquisition and analysis of data, drafting the manuscript & final approval of the version to be published.

Author agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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