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Original Article

Dental Researchers' Knowledge about Helsinki Ethical Principles at Mansoura University In Egypt

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Abstract

Objectives: The present study was conducted to assess the knowledge level of dental researchers at Mansoura University of Egypt.

Subjects and methods: Participants of this cross-sectional study were recruited from the Faculty of Dentistry at Mansoura University using a well-structured, self-administered, close-ended questionnaire based on the Declaration of Helsinki ethical principles. After providing informed consent, 496 dental researchers participated in the study.

Results: Study tool validation revealed content validity indices of 0.88 and 0.86, the internal consistency of the questionnaire items was 0.87. All study participants emphasized the importance of research ethics committees, while 93.5% were aware of the research ethics committee at their institution. The most followed ethical guidelines at the researchers' institutions were the Declaration of Helsinki principles. The participants' knowledge level about the Declaration was 0.65. Participants' qualifications had the greatest impact on their knowledge level (beta= 0.15 at p = 0.05).

Conclusions: The participants' knowledge level was above average, and researchers' qualifications showed the highest impact on their knowledge level followed by the place of work.

Keywords: Deceleration of Helsinki. Dental, Researchers. Mansoura University. Egypt

Introduction

Research is defined as "gathering of data, information and facts for advancement of knowledge in a systematic manner that follows rigid standard protocol [1]." To protect humans from harm and enable their autonomy, several treaties and declarations have been established, including the Nuremberg Code (Code et al., 1982), the Declaration of Helsinki (DH) (World Medical Association, 2013a), the European Union Convention on Human Rights and Biomedicine (Alghanim, 2012), the Convention on Human Rights and Biomedicine (the Oviedo Convention) (Nys,

2006), and various guidelines promulgated by the Council for International Organizations of Medical Sciences." The most comprehensive and pioneering guidelines are the Nuremberg Code and the DH (Guraya et al., 2014). In 1964, the World Medical Association (WMA) adopted the DH during the 18th General Assembly. The DH, which is regularly reviewed and revised, is a set of ethical guidelines applied to research on human subjects, including research on identifiable human materials and data, and is widely regarded as authoritative (Emanuel, 2013; Williams, 2008). In 2013, the latest update of the DH was released, which included new paragraphs and the rearrangement into specific sections. The latest version of the DH included the following 10 principle areas (World Medical Association, 2013b): 1) risks and burdens vs. benefits, 2) protection of vulnerable groups and persons, 3) need for sound scientific inquiry, 4) review of research protocols by research ethics committees, 5) privacy and confidentiality, 6) obtaining informed consent, 7) use of placebos, 8) post-trial provisions, 9) research registration and publication of results, and 10) use of the unproven interventions in clinical proactive."

Several studies demonstrated insufficient ethics capacity among investigators from different countries of the Eastern Mediterranean region (Abdur Rab & Mamdouh, 2004; Abou-Zeid et al., 2006). In Egypt, most of the research ethics committees (RECs) use international research ethics guidelines to review protocols, including the Council for International Organizations of Medical Sciences, the Islamic Organization for Medical Sciences, the DH, and the Belmont Report, which is rarely used.

The Faculty of Dentistry at Mansoura University is one of the oldest faculties of dentistry in Egypt and attracts dental researchers from different nations seeking postgraduate degrees. According to a PubMed search, limited research is available concerning dental researchers' knowledge of guidelines and regulations governing the proper conduct of research involving human subjects. Therefore, the present study aimed to determine the knowledge level of dental researchers at Mansoura University of Egypt. To fulfill this aim, a questionnaire was developed and validated based on DH principles, knowledge levels among participants of different sex, experience, qualifications, job titles, nationality, and place of work were compared, and the impact of demographic characteristics on participants' knowledge level was evaluated.

Subjects and Methods

Study design, location, and duration

This cross-sectional study was conducted at Mansoura University, Faculty of Dentistry between February 2022 and April 2022.

Study population

Students enrolled in postgraduate degrees as well as staff members and assisting staff in Mansoura University between 2015 and 2022, were included in the study. Researchers who were not present at the time of the study or discontinued their postgraduate programs were excluded.

Ethical approval and participant consent

The study protocol was approved by the Ethical Committee at the Faculty of Dentistry, Mansoura University (# A33080622). An introductory paragraph in the questionnaire was written to inform study participants about the aim and specific objectives of the research, as well as to obtain their consents. All participants were informed that their participation was voluntary and that they had the right to withdraw from the study at any time without penalty. Additionally, participants were informed that their identities would be kept anonymous and confidential. Subjects' responses were only accessed by the

research investigators and data were dealt with as aggregate rather than individual scores.

Instrument development

A committee of 3 experts in the field of public health and dental public health (an associate professor and a professor in dental public health (DPH), and a professor in public health) engaged in the formulation and development of the English questionnaire items based on the latest update of the DH published in 2013. Twenty-five statements were generated based on the 37 Helsinki ethical principles. Seven items were related to the general principles of the Declaration, one item covered the general principles and the research ethics and committee together, one item focused on vulnerable groups and individuals, seven items covered informed consent, four items focused on scientific requirements, and one item each focused on post-trial provisions, research registration and publication, dissemination of results, unproven interventions in clinical practice, use of placebos, and risks, burdens, and benefits. The questionnaire was divided into two sections. The first section concerned demographic data of the participants and included sex, years of experience, nationality, place of work, last qualification, and job title. The second section consisted of 27 items; items 1 and 3 were not related to the Declaration topics, while the remaining 25 items covered the 10 areas of the DH. The first 15 items were in the form of multiple-choice questions, while the remaining 12 items were in the form of a 3-point Likert scale (1-agree, 2-disagree, 3-no opinion).

Multiple responses to the items were accepted, as instructed at the beginning of the questionnaire. Some questionnaire items had one correct response (items # 2, 5, 6, and 11), while other items had two (items # 1, 4, 7, 8, 9, and 10) or three (item # 3, 12) correct options. A pilot study was conducted using 125 dental researchers by sending the questionnaire link via WhatsApp messages. Researchers who participated in the pilot study were refrained from participation in the study. The questionnaire was generated on Google Form. (https://docs.google.com/forms/d/e/1FAIpQLSc99q2vS2swzpP2jkctWaUBB5kcSFZqfXlT0-_pvN0VkLOQJg/viewform?usp=sf_link).

Sample size calculation

According to Osborne and Costello (Osborne & Costello, 2004) (2014), the required sample size for study tool validation is not absolute, owing to the variety of tools and the differences in their item numbers. The known guidelines for the respondent-to-item ratio are 5:1, 10:1, 15:1, or 30:1 (Pedhazur, 1997). As our target group was not large enough (934), we used a respondent-to-item ratio of 5:1. The scale contained 25 items; thus, the accepted final sample size for validating the questionnaire items was 125 researchers. For measuring the knowledge level using the validated tool, all dental researchers in the college were invited to participate in the study.

Instrument validation

To estimate the content validity, the questionnaire was evaluated by 13 expert jurors in the scientific research field, including a professor in DPH, 3 associate professors in DPH, an assistant professor in DPH, 4 professors in Pediatric Dentistry, 2 professors in oral biology, and 2 professors in bio-dental material. The experts evaluated the relevance and clarity of each questionnaire item using a 3-point ordinal scale (1: not relevant or clear, 2: partially relevant or clear, 3: relevant or clear). The experts could modify some items if needed and their suggestions for editing were considered in the final form of the questionnaire. The content validity index (CVI) was measured at the item level (I-CVI), expert level (E-CVI), and scale level (S-CVI) (Almanasreh et al., 2019).

Reliability was assessed in the form of internal consistency. To test reliability, the questionnaire was completed by 125 dental researchers. Internal consistency was examined by Cronbach's α reliability

coefficients. A Cronbach's α value of 0.50–0.70 is acceptable, and 0.70 or higher shows good homogeneity among the items (Bolarinwa, 2015).

Measurement of participants' knowledge

Data about dental researchers' knowledge was collected through the well-structured, close-ended, self-administered questionnaire, which was created on Microsoft Forms (Office 365) after measuring its validity and reliability and incorporating suggested edits. The questionnaire was sent to postgraduate students as well as staff members and assisting staff through their official mail. The starting date for sharing the questionnaire link was February 2, 2022, and the link was available to participants until April 25, 2022. The participants were notified about the questionnaire through mail and WhatsApp messages at the beginning of the sharing time. Gentle frequent reminders were sent to potential subjects to secure a higher response rate.

Statistical analysis

Data collected through the Microsoft Form were downloaded in a Microsoft Excel sheet and analyzed using Statistical Package for Social Science (IBM SPSS) program version 20. Descriptive statistics were used to summarize information obtained from study participants, including means, standard deviations, frequencies, and percentages. Non-parametric tests, including Mann–Whitney and Kruskal–Wallis tests, were used to demonstrate differences between variables with abnormal distributions. Pearson correlation and regression analyses were conducted to investigate factors influencing knowledge level about the DH among study participants. Cronbach's α reliability test was performed to measure the internal consistency of the questionnaire. $P \leq 0.05$ was considered statistically significant.

Results

The CVI and internal consistency results are shown in Table 1. Relying on experts' opinions and pilot testing, the scale CVI was 0.88 and 0.86 for relevance and clarity, respectively. The internal consistency of the questionnaire items, as measured by Cronbach's α coefficient, was 0.87.

496 out of 934 dental researchers (staff and assisting staff as well as postgraduate students) filled in the questionnaire with response rate 53.1%. The study cohort consisted of 66.3% (n = 329) females. Most participants (86.7%) were from Egypt. Concerning years of experience, 38.7% of the participants worked in the dental field for more than 12 years. The contributions of participants holding bachelor's and Ph.D. degrees were similar (41.9%, and 38.7% respectively). The response rates were 53.1% for academic staff members (assistant professors, associate professors, and professors), 9.7% for general dental practitioners (G.D.P.), and 51.6% for supporting and non-supporting staff members (instructors, demonstrators, and specialists). Most participants came from academic institutions (87.1%), and 12.9% of participants came from the Ministry of Health (MOH) (Table 2).

As shown in Table 3, 100% of study participants emphasized the importance of RECs, and 93.5% of participants were aware of the RECs at their institutions. Regarding ethics guidelines in the participants' institutions, DH principles constituted 37.3%, followed by Good Clinical Practice guidelines (9.7%). Surprisingly, 40.1% of our researchers did not know the following ethical guidelines in their institutions.

The relationship between study participants' knowledge about the DH and their demographic characteristics was summarized in Tables 4 and 5. The participants presented an average knowledge level about DH principles (0.65). Females and males exhibited relatively similar knowledge levels (0.68 and 0.67 for females and males, respectively).

Egyptians and researchers from other nationalities also exhibited similar knowledge levels (0.67 vs. 0.69, respectively). A statistically significant difference was found between the mean knowledge score of participants from Academic Institutions and the MOH (0.72 vs. 0.66, respectively; p = 0.003).

Researchers holding doctorates exhibited higher mean knowledge scores (0.76) than researchers with master's (0.67) or bachelor's degrees (0.61), (p = 0.001). Significant differences in knowledge were found between qualification degrees (bachelor vs. master's degree, p = 0.000 and Ph.D. vs. master's degree, p = 0.000). Significant differences in knowledge were also found between the three levels of experience (p = 0.000). The mean knowledge scores were higher for researchers with more than 12 years of experience after graduation (0.70) compared with the knowledge scores of researchers with 1–6 years of experience.

Table 6 summarizes the correlation between participants' knowledge level and study variables. A significant positive linear correlation was detected between researchers' knowledge level and their qualifications (p = 0.000). Place of work and job title were negatively associated with knowledge level (p = 0.000). Sex, nationality, and years of experience were not significantly associated with the researchers' knowledge level.

The linear regression model incorporated the three predictors of knowledge (R^2 = 0.07, F = 7.97, p = 0.000). As shown in Table 9, participants' qualifications showed a significant positive regression weight, indicating that researchers with higher coding on this scale were expected to have higher knowledge levels, after controlling for the other variables in the model. According to the qualification codes (1 = Bachelor, 2 = Master, and 3 = Ph.D.), Ph.D. holders exhibited higher knowledge levels. However, place of work was negatively associated with knowledge levels (coded as 1 = Academic Institute and 2 = MOH). Thus, participants from academic institutes had better knowledge levels. Lastly, qualification had the highest effect on the dependent variable of knowledge level followed by the place of work (Beta = 0.15 and −0.13, respectively) (Table 7).

Discussion

In Egypt, the Medical Research Ethics Committee (MREC) of the National Research Center was established in 2003 to review medical research and safeguard the dignity, rights, safety, and well-being of research participants. The regulatory rules of the MREC are based on the DH and WHO regulations (Gillett, 1994). Despite these regulations, Alahmad et al. (2012) showed that no special ethical guidelines are used in Egypt; only medical documents containing an abstract chapter concerning clinical research were available. Another study conducted by Matar and Silverman (2013) demonstrated the lack of national guidelines in Egypt, as mentioned by all REC chairs who stated that "they received little to no guidance from the MOH and lamented about the lack of national research ethical guidelines in Egypt."

Recently (2021), a Clinical Research Law was enacted by the Egyptian parliament and approved by the Egyptian president to regulate clinical research conducted on humans (Samir Abdelhafiz et al., 2021). The law endorsed the establishment of a supreme council to review the ethics of clinical research. This council was entrusted with following up on the implementation of the provisions of the law and taking the necessary actions if violations of any provisions occurs (Samir Abdelhafiz et al., 2021).

Table (1): Content validity indices and reliability of the study tool

Content validity index (CVI)	**I-CVI**	Relevance	0.69–1.00
		Clarity	0.77–1.00
	E-CVI	Relevance	0.63–1.00
		Clarity	0.78–0.89
	S-CVI	Relevance	0.88
		Clarity	0.86
Cronbach's α Coefficient		0.87	

Table (2): Distribution of Study Characteristics among Study Participants

Participants' characters (total = 496)		Number	Frequency
Gender	Male	167	33.7
	Female	329	66.3
Nationality	Egyptian	430	86.7
	Others	66	13.3
Years of experience	1 to <6 y	160	32.2
	6 to <12 y	144	29.1
	≥12 y	192	38.7
Qualifications	Bachelors	208	41.9
	Masters	96	19.4
	Ph.D.	192	38.7
Job title	General dental practitioner	48	9.7
	Supporting & non-supporting staff	256	51.6
	Academic staff members	192	38.7
Place of work	Ministry of Health	64	12.9
	Academic institution	432	87.1

Table (3): Research Ethics Committees And The Followed Ethical Guidelines Among Participants' Institutes

The items		Number	Frequency
Do you think the presence of Ethics Committee is essential?	Yes	496	100
	No	0	0
Is there a research ethics committee in your institution?	Yes	464	93.5
	No	32	6.5
If you need to know medical research ethics on human subjects, which guidelines do you prefer best?	Helsinki Declaration	185	37.3
	Nuremberg Code	32	6.5
	Good Clinical Practice	48	9.7
	Belmont Report	0	0
	Common Rule	0	0
	Any others	32	6.5
	Not aware of any	199	40.1

Table (4): Relationship of The Covered Areas in The Helsinki Declaration to Participants' Sex, Nationalities, Place of Work, and Qualifications

Demographic characters		General principles	Informed consent	Use of placebo	Vulnerable groups	Research protocol	Post-trial provision	Research registration	Un**proven** intervention	Risk, B and benefits	Total mean knowledge
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Overall		0.73 (0.20)	0.57 (0.22)	0.29 (0.46)	0.34 (0.48)	0.78 (0.27)	0.87 (0.34)	0.63 (0.49)	0.66 (0.47)	0.94 (0.23)	0.65 (0.18)
Sex*	**Male**	0.73 (0.14)	0.65 (0.19)	0.35 (0.48)	0.25 (0.44)	0.85 (0.19)	0.88 (0.32)	0.58 (0.49)	0.66 (0.48)	0.94 (0.43)	0.67 (0.14)
	Female	0.76 (0.18)	0.56 (0.20)	0.29 (0.45)	0.42 (0.50)	0.79 (0.26)	0.91 (0.29)	0.70 (0.46)	0.69 (0.46)	0.63 (0.47)	0.68 (0.14)
	p-value	0.007	0.000	0.09	0.001	0.02	0.89	0.04	0.72	0.16	0.36
Nationality*	**Egyptian**	0.84 (0.13)	0.69 (0.23)	0.44 (0.50)	0.19 (0.39)	0.84 (0.18)	0.91 (0.29)	0.78 (0.42)	0.59 (0.50)	0.96 (0.19)	0.69
	Others	0.78 (0.12)	0.57 (0.16)	0.27 (0.45)	0.45 (0.50)	0.79 (0.26)	0.85 (0.36)	0.64 (0.48)	0.72 (0.45)	0.97 (0.18)	0.67
	p-value	0.007	0.001	0.098	0.03	0.18	0.17	0.02	0.11	0.32	0.12
Place of work*	**MOH**	0.78 (0.13)	0.58 (0.15)	0.24 (0.43)	0.46 (0.50)	0.78 (0.27)	0.84 (0.37)	0.59 (0.49)	0.67 (0.47)	0.96 (0.19)	0.66 (0.14)
	Academic I.	0.80 (0.10)	0.60 (0.24)	0.46 (0.50)	0.27 (0.45)	0.84 (0.20)	0.92 (0.27)	0.85 (0.36)	0.76 (0.43)	0.98 (0.15)	0.72 (0.13)
	p-value	0.20	0.90	0.000	0.02	0.22	0.15	0.000	0.21	0.71	0.003
Qualification**	**Bachelor** [a]	0.82 (0.15)	0.55 (0.14)	0.43 (0.51)	0.43 (0.50)	0.68 (0.32)	0.86 (0.35)	0.50 (0.47)	0.57 (0.49)	0.62 (0.35)	0.61 (0.12)
	Master [b]	0.74 (0.11)	0.60 (0.14)	0.41 (0.49)	0.32 (0.47)	0.84 (0.17)	0.88 (0.33)	0.49 (0.04)	0.71 (0.46)	0.91 (0.29)	0.67 (0.14) [a,c]
	Ph.D.[c]	0.81 (0.10)	0.62 (0.24)	0.50 (0.50)	0.50 (0.50)	0.88 (0.19)	0.83 (0.38)	0.83 (0.38)	0.83 (0.38)	0.43 (0.46)	0.76 (0.13)
	p-value	0.000	0.37	0.000	0.000	0.000	0.02	0.000	0.17	0.003	0.001

Total mean knowledge score was calculated by computing the mean of the included items of the questionnaire, it was rated from 1.

ac: Pairwise comparison of qualifications at $p < 0.05$

*: Differences between study variables were assessed using the Mann–Whitney non-parametric test

**: Differences between study variables were assessed using the Kruskal–Wallis non-parametric test

Table (5): Relationship Between Covered Areas in Helsinki Declaration and Participants' years of experiences and job titles

Demographic characters		General principles	Informed consent	Use of placebo	Vulnerable groups	Research protocol	Post-trial provision	Research registration	Un**proven** intervention	Risk, B and benefits	Total mean knowledge
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Years of experience	1 to <6 y [a]	0.78 (0.17)	0.54 (0.19)	0.20 (0.40)	0.60 (0.49)	0.65 (0.38)	0.60 (0.49)	0.60 (0.49)	0.80 (0.40)	0.98 (0.04)	0.64 (0.20)
	6 to <12 y [b]	0.74 (0.11)	0.60 (0.14)	0.41 (0.49)	0.32 (0.47)	0.84 (0.17)	0.88 (0.33)	0.62 (0.49)	0.71 (0.46)	0.91 (0.29)	0.67 (0.14) [a]
	≥12 y	0.84 (0.08)	0.61 (0.20)	0.25 (0.44)	0.38 (0.49)	0.84 (0.18)	0.98 (0.43)	0.75 (0.44)	0.63 (0.49)	0.97 (0.01)	0.70 (0.09) [a, b]
	p-value	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.08	0.001	0.000
Job title	G.D.P. [c]	0.83 (0.14)	0.57 (0.16)	0.10 (0.30)	0.60 (0.49)	0.73 (0.31)	0.80 (0.40)	0.60 (0.49)	0.60 (0.49)	0.98 (0.12)	0.65 (0.14)
	Supporting staff	0.74 (0.11)	0.60 (0.14)	0.41 (0.49)	0.32 (0.47)	0.84 (0.17)	0.88 (0.33)	0.62 (0.49)	0.71 (0.46)	0.91 (0.29)	0.67 (0.14) [c]
	Staff members	0.79 (0.06)	0.62 (0.30)	0.67 (0.48)	0.11 (0.03)	0.92 (0.12)	0.98 (0.01)	0.97 (0.22)	0.99 (0.05)	0.95 (0.24)	0.78 (0.09) [c]
	p-value	0.13	0.29	0.000	0.000	0.000	0.000	0.000	0.000	0.21	0.000

Total mean knowledge score was calculated by computing the mean of the included items of the questionnaire, it was rated from 1.
Differences between the study variables were assessed using the Kruskal–Wallis non-parametric test
a, a-b: Pairwise comparison between different groups of years of experiences at $p < 0.05$
c: Pairwise comparison between different groups with varying job title at $p < 0.05$

Table (6): Correlation Between Participants' Knowledge Level and Study Variables

Study variables	Pearson Correlation (r)	p-value
Sex	0.02	0.71
Nationality	0.06	0.27
Years of experience	0.05	0.33
Qualifications	0.22	0.000
Place of work	-0.20	0.000
Job title	-0.22	0.000

Table (7): Linear Regression Analysis for Participants' Knowledge Level Predictors

Predictors	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	Std. Error	Beta		
Qualifications	0.03	0.01	0.15	1.94	0.05
Place of work	−0.04	0.02	−0.13	−1.93	0.05

Dependent variable: Overall participants' knowledge scores
Predictors: qualification which was coded as 1: Bachelor, 2: Master, 3: Ph.D. Place of work which was coded as; 1: academic institutes, 2: MOH

Mansoura University is listed as a growing university in the Shanghai Index 2021 and was ranked between 701 and 800 (Gate, 2022). A REC was established at the Faculty of Dentistry at Mansoura University in 2017. Since this date, 806 proposals for master's or Doctorate theses and scientific articles were approved by this committee. The rules and regulations of the committee were established according to the general rules of Mansoura University.

Participants' knowledge about RECs

In the current study, almost all participants reported the importance of ethics committees; 93.5% confirmed the presence of these committees at their institutions, while 70.3% correctly responded to the exact functions of these committees. Additionally, 37.3% preferred the DH as a source of ethical guidelines.

According to Janakiram & Gardens (2014), 79% of dental postgraduates were aware of ethics committees at their institutions. However, these researchers did not know about the function of these committees; this result was consistent with those of several studies conducted elsewhere (Hariharan et al., 2006; Brogen et al., 2009; Hern., 1990). Ravindran and Kandhimadhi devi (2020) reported that a majority of participants (86.6%) in their study believed that research on human subjects must be controlled by the ethics committee. However, 29.2% of their participants believed that the medical ethics committee would delay research and make research more difficult for the researcher.

Moreover, Mallela et al. (2015) demonstrated 96.2% accurate knowledge among their participants about institutional RECs; 76% responded that these committees are helpful and 68% classified RECs as needed. Additionally, Tarboush et al. (2020) demonstrated 94% and 80% agreement on the role of RECs in overseeing the ethical aspects of research to protect the welfare of research subjects.

In contrast, Hariharan et al. (2006) demonstrated that 36.1% of their students believed that ethics committees often caused delay in research processing. This is consistent with the findings reported by El-Dessouky et al. (2011) in Saudi Arabia (44%), Reddy et al. (2013) in South India (26%), Gopinath et al., (2014) in India, (31%), Ravindran and Kandhimadhi devi (2020) in South Kerala (29.2%), Mohammad et al. (2011) in Aligarh, India, and Mallela et al. (2015) in North India (20%). Given that all research projects need the approval of ethics committees, this finding suggests that the process of obtaining this approval should be accelerated.

Participants' knowledge about the Declaration of Helsinki

The present study revealed an average knowledge level about DH ethical principles with a total mean score of 0.65. This finding could be explained by the discrepancy in the undergraduate curricula regarding teaching ethical principles. In addition, even in postgraduate courses, no courses specifically taught medical ethics, except for a postgraduate degree in DPH.

The knowledge level in this study was higher than the level reported by Hadir et al. (2011), who revealed an overall knowledge score of 40.2%. On the other hand, Bayoumy et al. (2020) presented an overall participant mean knowledge score of 7.68. Moreover, Tarboush et al. (2020) reported an understanding level of research ethics of 62%. Despite these scores, misconceptions about major ethical principles persisted in their study. In a similar study, Çorman Diner et al. (2020) demonstrated that only 31.7% of their participants had adequate knowledge about the DH. Chopra (2019) reported a lower rate regarding the importance of ethics knowledge among their participants and showed that their study participants got their ethics knowledge from different sources than the international guidelines; sources included reading, the internet, and experts. This finding was consistent with Janakiram & Gardens, (2014) who showed that their participants obtained their ethics knowledge from different sources, including the internet, newspapers, undergraduate training, or work experience. Furthermore, Ravindran and Kandhimadhi devi (2020) reported that 36.7% of postgraduates had good knowledge, 46.9% had fair knowledge, and 16.3% had poor knowledge. Mallela et al. (2015) showed that only 34.8% of the respondents displayed knowledge about the DH.

In contrast to our findings, 52.2% and 81.2% of participants of two studies conducted in Sri Lanka revealed poor knowledge score (Amarasinghe & Weerasinghe, 2018 and Ranasinghe et al., 2020; respectively). Jalal et al. (2018) demonstrated that only 4% of their participants knew about the detailed content of the DH, which they attributed to gaps in curricular training regarding medical ethics. Torabi et al. (2021) showed that 12.1% of study participants knew about the DH, and Hariharan et al. (2006) reported that very few respondents in their study were aware of the DH. Adhikari et al. (2016) demonstrated that 85% of their participants were unaware of the DH. Finally, Nithin et al. (2014) demonstrated a knowledge gap about research ethics among their participants.

Association between sex, years of experience, and participants' knowledge

Our results did not reveal significant differences in participants' knowledge between males and females; however, significant differences in knowledge according

to years of experience were detected. Consistent with this finding, Janakiram & Gardens (2014) demonstrated that sex was not associated with participants' knowledge about ethics. In a study conducted by Torabi et al. (2021), females displayed a higher mean knowledge score (7.69) than males (7.03) but the difference was not significant (p = 0.077). Moreover, Tarboush et al. (2020) did not detect any significant association between correct answers about the DH and the participants' sex. However, Jalal et al. (2018) reported that female participants had higher knowledge (1.65 times odds) scores about medical ethics than the scores of male participants. Increased years of experience also significantly impacted knowledge levels in that study.

Impact of the place of work and qualifications on participants' knowledge

Correlation and linear regression analyses examining the relationship between knowledge about DH principles and proposed predictors revealed significant linear correlations between knowledge levels and qualifications and place of work. The number of published articles increases with increasing academic rank, leading to more frequent exposure to RECs and journal guidelines. Furthermore, staff members in academic institutions can easily transfer the culture of medical ethics regarding research among peers and friends, which may account for the difference in knowledge between MOH and academic institutions. In agreement with our finding, Nithin et al. (2014) showed that professors had higher knowledge levels than lecturers (38% vs. 14%, respectively). Recently, Çorman Dinçer et al. (2020) reported sufficient knowledge about the DH in 64% of professors, 36% of associate professors, and 38.1% of assistant professors. Also, Jalal et al. (2018) also showed that higher job title levels correlated with knowledge levels. In contrast to our finding, Janakiram & Gardens (2014) showed that student seniority did not impact participant knowledge about ethics. Additionally, Tarboush et al. (2020) did not detect any significant association between answering ethics questions correctly and academic rank (lecturer, assistant professor, associate professor, or professor).

Conclusion

Based on our results, we conclude that the level of knowledge about DH was above average. Among background variables, qualifications showed the highest impact on participants' knowledge followed by their place of work. Additionally, years of experience and job titles were significantly associated with knowledge level.

Conflict Of Interest

The authors did not have any conflict of interest

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