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Knowledge and views of parents regarding ethical aspects of medical research among their children in Jordan

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Abstract

Objectives Appropriate ethical framework should be considered when research involves children. The purpose of this study was to investigate parental knowledge and views regarding the ethical aspects of participation in medical research involving their children.

Methods A cross-sectional survey was conducted at different areas in Jordan. The questionnaire was administered to the parents using a face-to-face interview.

Key findings A total of 2000 questionnaires were collected from Jordanian parents, and 72.4% of them were knowledgeable. Parents with Bachelor's degree (OR = 1.33; 95% CI = 1.05–1.68; $P = 0.016$) and monthly income >1000 JD (OR = 2.12; 95% CI = 1.50–2.98; $P < 0.001$) indicated better knowledge. In contrast, parents with comorbidity were found to be less knowledgeable (OR = 0.60; 95% CI = 0.44–0.82; $P = 0.001$). The majority of parents agreed on that different factors such as permission of partner and involvement of healthcare professionals could affect their children's participation in medical research. Interestingly, three quarters of parents (76.3%) were willing to let their children participate in research to help others.

Conclusions These findings highlighted that parental educational level and high monthly income were predictors of good ethical research knowledge, which was opposed by parental comorbidity. Further investigations of other perspectives influencing the decision-making process of children participation in research, including children and paediatricians, are highly recommended.

Keywords children; ethical aspects; knowledge; parents; research participation; views

Introduction

Paediatric patients are those who are younger than 18 years old.^[1] They are vulnerable study participants, and their disease management requires several ethical and research considerations.^[2] Thus, conducting research involving children is a moral duty. Children and adults do not have the same cognitive abilities; hence, there is a significant reliance on parents and/or guardians in making children's health-related decisions. Information provided to this age group should be tailored to their developmental stage to accommodate their limited capabilities and experiences.^[3,4] Children do not have the legal capacity to give 'consent' to participate in medical research; instead, they can provide 'assent' after being fully informed by researchers who provide them with adequate material that suits their age.^[5] Different guidelines have been released by the European member states regarding the participation of children in research. Importantly, parental permission (signed consent) is always required, with children who are younger than 18 years.^[6] The main components and principles of consent that are generally acceptable in Western countries are also applied to other countries including Islamic regions. Generally, researchers decide whether to obtain assents and/or consents based on the onset of puberty^[7]; however, legal ages that mandate obtaining assents and/or consents may vary by geography, culture and legislative history in different countries.^[5]

Despite that, medical research among children in low-income countries is highly needed. Conducting research that meets the international standards in such areas is challenging. This is due to different reasons such as high prevalence of different diseases, poverty, weak infrastructure, unfamiliarity with medical research, lack of hospital documentation and poor regulations regarding paediatric research in developing countries.^[8] Previous studies have

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been conducted to assess the attitudes of parents and their children on paediatric research.^[9–16] Such studies have adopted qualitative methods, where they involved small number of participants and relied on parents who had already agreed to enrol their adolescents in research. Some quantitative studies have measured parental understandings and factors affecting their children's participation in specific clinical research areas such as anaesthesia/ surgery,^[17,18] leukaemia trials^[19] and ICU research.^[20] In the context of cultural background in Jordan and surrounding Arab countries, the current study aimed to investigate parental knowledge and views of ethical aspects regarding their children's participation in medical research. To the best of the authors' knowledge, this is the first study in Jordan and the Middle Eastern region that have examined this issue.

Methods

Study design and questionnaire development

A cross-sectional survey was conducted at different areas in Jordan. A convenience sample was approached in this study, in which participants were selected from public places such as shopping malls and clubs. The ethical approval to conduct this research was granted by the institutional review board in Jordan University of Science and Technology (study number 21/106/2017).

There was no adequate instrument available in the literature to cover all aspects of interest in this study. Therefore, researchers developed a questionnaire targeting parents by considering what has been published in this field. The questionnaire consists of three sections that address different themes: (i) parental knowledge about ethical aspects of research; (ii) parental views of factors that affect their children's participation in research studies; and (iii) parental attitudes towards research participation for the benefit of others. A final section was included to collect demographic data related to each respondent. One parent (mother or father) of at least one child was included in this study. Implied consent was obtained as long as the participant was willing to participate, and his/her data were de-identified.

A group of researchers has reviewed the content of the administered questionnaire for face validity (i.e. whether the questionnaire at the face assessment measured what it was supposed to measure) and content validity (i.e. whether the measured items covered all aspects of interest). In addition, piloting of the questionnaire was conducted on a small number of parents ($n = 50$). Feedback from the pilot phase was used to improve the clarity of questions, and the data were not included in the final analysis. The questionnaire was originally written in English and the semistructured interviews with the participants were conducted in Arabic language by a trained researcher to ensure consistent method of data collection. Two independent researchers have carried out forward translation from English to Arabic then backward translation from Arabic to English and reported a high match percentage between the two drafts.

All items in the questionnaire were formatted as closed-ended questions. The knowledge section consisted of 11 items that had three possible answers (correct, incorrect and

I don't know). The views section consisted of six statements with a 5-points Likert scale (ranging from 'strongly agree' to 'strongly disagree'), and the attitude section consisted of three statements with a 5-points Likert scale (ranging from 'Definitely willing' to 'Definitely not willing'). The internal consistency of each of the relevant sections in the designed questionnaire was tested using the Cronbach's α (alpha) measure. In the present study, the results ranged between 0.63 and 0.78 which indicated good reliability.

Statistical analysis

Following data collection, responses were coded and entered into Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA; version 20). Descriptive statistics were used to summarize the data for the entire sample. Continuous variables were presented as median (interquartile range), while categorical variables were presented as numbers and percentages. Univariate analyses using Mann–Whitney U -test (for continuous variables) and chi-square test (for categorical variables) were conducted to assess possible factors that could influence the level of knowledge (dichotomized as knowledgeable and non-knowledgeable). In order to determine factors that were independently associated with the knowledge of parents, binary logistic regression (LR) analysis adjusted for possible confounders (age and gender) was performed using the default 'Enter method'. It is also called 'forced entry' method where all independent factors in a block are entered into the regression model equation in a single step. All variables with $P < 0.05$ on univariable analysis were included in the LR model. Odds ratio (OR) values and their 95% confidence intervals (95% CI) were calculated. Statistical significance was set at P value < 0.05 . The answers to 11 different questions of knowledge for each participant were labelled as categorical variables using a cut-off point for cumulative scores of correct answers. A participant was categorized as knowledgeable if the sum of the scores was > 6 (out of 11) and non-knowledgeable if the sum of the scores was ≤ 6 (out of 11). In order to create a dichotomous variable for the knowledge, all respondents who gave the wrong answer or stated 'don't know' were coded 'incorrect'.

For the purpose of data analysis, we restricted response options for the views and attitudes sections. For example, we combined both 'strongly agree' and 'agree' as one category and both 'strongly disagree' and 'disagree' as one category. In addition, participants who answered 'definitely not willing' and 'probably not willing' were labelled as having not willing attitudes and subjects who answered 'probably willing' and 'definitely willing' were regarded as having willing attitudes.

Results

Demographics

In this study, a total of 2000 questionnaires were collected from Jordanian parents. More than half of participants were female and the median age was 37 years old. Most parents had monthly income of ≤ 1000 Jordan Dinar (JD; 1 JD = 1.41 US Dollar). Importantly, around 60% of

participants had a Bachelor's degree and 10% of participating parents reported a comorbidity. Demographic details of study participants are presented in Table 1.

Knowledge of parents on ethical aspects of participation in medical research among their children

In the present study, 72.4% ($n = 1448$) of parents were knowledgeable and the mean number of correct answers was 7.73 ± 2.3 (range 1–11). Approximately 13% ($n = 262$) of participants answered all questions correctly. An overview of the questionnaire items and responses is presented in Table 2. Statement number one 'your child participation in research study is voluntarily' was the one that was addressed correctly by most respondents (87.3%; the correct response was 'true'). On the other hand, statement number four 'You cannot withdraw from the research if you agreed to participate' was the one with the lowest rate of correct responses (52.2%; the correct response was 'false'). When the parents were asked about the source of information for their knowledge about research participation, healthcare professionals were the most commonly reported source (35.1%) followed by the Internet and social media (26%), whereas around the tenth of participants did not report any source of information (10.6%).

As shown in Table 3, the results of univariate analysis revealed that participants' comorbidity, level of education and monthly income were significantly associated with the knowledge of parents ($P < 0.001$). The results of multivariate analysis adjusted for possible confounder (age and gender) indicated that parents who had Bachelor's degree (OR = 1.33; 95% CI = 1.05–1.68; $P = 0.016$) and with monthly income >1000 JD (OR = 2.12; 95% CI = 1.50–2.98; $P < 0.001$) were independently associated with a better knowledge. In contrast, participants with comorbidity were significantly found to be less knowledgeable about ethical aspects of research participation (OR = 0.60; 95% CI = 0.44–0.82; $P = 0.001$).

Table 1 Demographic details of the study participants

Characteristics [†]	All participants ($n = 2000$)
Gender	
Male	877 (43.9)
Female	1123 (56.2)
Age (years) [‡]	37 [30–45]
Number of children [‡]	3 [2–4]
Parents with comorbidity	218 (10.9)
Having child with comorbidity	54 (2.7)
Level of parents' education	
School education	745 (37.3)
Bachelor degree	1255 (62.8)
Monthly family income	
<500 JD	768 (38.4)
500–1000 JD	862 (43.1)
>1000 JD	370 (18.5)

[†]All data expressed as n (%) of parents unless otherwise indicated.

[‡]Data described as median [interquartile range].

Table 2 Overview of knowledge statements

Items in the questionnaire	Correct responses N (%)
1. Your participation in research study related to your child is voluntarily	1745 (87.3)
2. Declining to participate in a research would adversely affect health care provided to your child	1181 (59.1)
3. You can skip any questions (e.g. shameful or private question) in the research	1281 (64.1)
4. You cannot withdraw from the research if you agreed to participate	1043 (52.2)
5. Your child has the right to make a decision about his/her research enrollment	1459 (73)
6. You have to be informed about the purpose of study before you decide to participate	1321 (66.1)
7. You cannot contact any person for any questions about the research if you agreed to participate	1397 (69.9)
8. You should not be informed about the privacy and confidentiality of participants' data	1403 (70.2)
9. You should be informed about any benefits that is expected from the research	1524 (76.2)
10. You should not be informed about any risks or discomforts to the subject	1535 (76.8)
11. You can ask any question before you decide to participate in the study	1567 (78.4)

Factors affecting research participation

The majority of parents agreed on that all listed factors could affect their children's participation in medical research (Figure 1). Almost 80% agreed on that permission of the partner (Factor # 4) and involvement of healthcare professionals (Factor # 5) affect their child participation. Importantly, third of parents were undecided (with 'neural responses') whether incentives could affect their research participation.

Attitudes of parents towards research participation for the benefit of others

Three quarters of parents (76.3%) were willing to let their children participate in research to help others. On the other hand, third of parents (34%) were not willing to support children involvement in research to help others if blood sample would be required. In addition, half of parents (46%) were not willing to support their children involvement in research to help others if X-rays would be done. It is noteworthy mentioning that only 18 parents had previously permitted their children to participate in medical research.

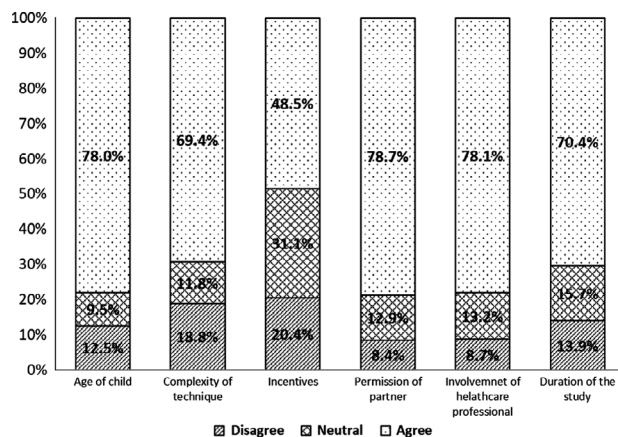
Discussion

Medical research in paediatrics is essentially important and necessary to support and improve their health outcomes. An appropriate ethical framework should be considered when research involves this specific group of populations.

Table 3 Univariate and Multivariate analysis of factors predicting the level of parents' knowledge

Variable [†]	Univariate analysis			Multivariate analysis	
	Not knowledgeable N = 552	Knowledgeable N = 1448	P value	OR (95% CI)	P value
Gender					
Male	259 (46.9)	618 (42.7)	0.088	ND	ND
Female	293 (53.1)	830 (57.3)		ND	ND
Age (years) [‡]	37 [30–45]	37 [29.75–45]	0.591	ND	ND
Number of children [‡]	3 [2–4]	3 [2–4]	0.850	ND	ND
Parents with comorbidity					
No	469 (85)	1313 (90.7)	<0.001	Ref	0.001
Yes	83 (15)	135 (9.3)		0.60 (0.44–0.82)	
Having child with comorbidity					
No	532 (96.4)	1414 (97.7)	0.116	ND	ND
Yes	20 (3.6)	34 (2.3)		ND	ND
Level of parents' education					
School education	251 (45.5)	494 (34.1)	<0.001	Ref	0.016
Bachelor degree	301 (54.5)	954 (65.9)		1.33 (1.05–1.68)	
Monthly family income					
<500 JD	256 (46.4)	512 (35.4)	<0.001	Ref	0.070
500–1000 JD	230 (41.7)	632 (43.6)		1.25 (0.82–1.58)	
>1000 JD	66 (12)	304 (21)		2.12 (1.50–2.98)	

CI, confidence interval; ND, no data, OR, odds ratio.

Bold values indicate statistical significant $P < 0.05$.[†]All data expressed as n (%) of parents unless otherwise indicated.[‡]Data described as median [interquartile range].**Figure 1** Factors affecting participation in medical research.

Therefore, it is important to highlight parental knowledge and views towards ethical aspects of research. Assessing knowledge is considered as the first step in the decision-making process for voluntarily participation in research.

The present study indicated that most of participated parents in Jordan were knowledgeable about ethical issues of children's participation in medical research. Consistent with this, a previous focus group ($n = 2$) interview study in Jordan showed that parents have good perspectives regarding the information that should be provided during the informed consent/assent process.^[15] In fact, all items in the knowledge section of the current study questionnaire are basic

components of an informed consent. Two reasons can explain the familiarity of parents in Jordan with the ethical aspects; first, these elements may be recognized as the basic truths or axioms (i.e. common sense). Second, two quarters of participated parents are educated (as detailed later that it is one of the main factors affecting a better knowledge) and are exposed to technology, and thus understand better about medical research. In 2003, Tait *et al.*^[17] reported that characteristic of the study and the consenting document in addition to parental understanding were predictors of parental decision to participate in anaesthesia and surgery research.

In the current study, the results of LR indicated that Bachelor's degree and monthly income >1000 JD were significantly associated with positive parental knowledge regarding appropriate participation of their children in medical research. This is not surprising as family income and the level of parental education act as driving forces in acquisition for knowledge and can provide the parents with more opportunities to actively pursue research-related reading abilities and learning experiences.^[21] It has been reported that both parameters of socioeconomic status were good predictors of knowledge level in different health-related issues.^[22–24] On the other hand, parents with comorbidity were more likely to be less knowledgeable about ethical aspects of research participation. We have conducted a subanalysis to evaluate the associations between reported comorbidity and both their level of education and income. Significant associations were identified. Participants with Bachelor's degree and with high monthly income had less comorbidity.

Despite the high proportion of knowledgeable parents in Jordan, they appeared to be more concerned about a number

of factors that could affect their actual participation in research. The permission of the other partner was an important issue in Arab society highlighting the challenging process to obtain the informed consent from both parents. In addition, most study participants agreed on that the involvement of healthcare professional affects their children participation in medical research. This finding underlines the vital role of healthcare professionals in the process of the informed consent. Significantly, in this study third of participants have stated that healthcare professionals acted as a source for their knowledge information. Healthcare policy in Jordan should encourage children to be involved in their health-related decision-making process. Due to the lack of experience and perspective of children, both physicians and parents have the full responsibility to encourage children to communicate openly regarding their participation in the active process of assent.

In this study, incentives were the factor that had the lowest rate of agreement among parents. Approximately, third of them were even undecided (had neutral responses) regarding this factor. This finding raised an ethical issue on the role of incentives in research participation. Wiener *et al.*^[14] investigated the views of parents on the role of financial compensation in accepting the possible research risk. They found that compensation had significant influence on healthy volunteers compared to parents who had children with comorbidity. Offering incentives is a form of power, particularly large ones, and it can also be used as coercive offer or undue influence. This is considerably sensitive especially in conducting human research that involves invasive procedures such as in obtaining organ for transplantation and blood transfusion.^[25,26] Incentives can work against the principle of beneficence in human research if they are used inappropriately in terms of its type and amount. To justify using incentives in research and protect against any harm, both researchers and institutional review board committees have a major responsibility to eliminate unnecessary risks and preserve human dignity.

Most respondents in the present study were willing to support their children's involvement in some research from which the study participant will not benefit as this would make an important contribution to help others. This finding is in agreement with other studies.^[11-14] However, parents in our study sample appeared to be more cautious regarding some research procedures that pose some risk to their children such as drawing blood samples and performing X-rays. These attitudes suggest that individuals' willingness to participate in non-beneficial research may be decreased by citing specific chances of harm, and this is not surprising as 'nonmaleficence – do no harm' is one of the main principles of research ethics.

Limitation

Although closed-ended questions used in the current questionnaire are quicker and easier to answer, they can lead respondents in certain directions and can limit their expression of what they think. However, this method was chosen to enhance parental participation in this research study.

Conclusion

The current study demonstrated that parents in Jordan were knowledgeable about ethical issues of their children's participation in research. Parental educational level, monthly income and a documented parental comorbidity were good predictors of the knowledge. Parents in the present study agreed that different factors could affect their decision in research participation. In addition, they supported the involvement of their children to some research risk for the benefits of others with some precautions/ reservations. Decision-making process in paediatric research is challenging for physicians, children themselves and parents. Future research that shed the light on understanding of the paediatrics knowledge, views and preferences to be involved in decision-making is highly recommended. This will underline the agreement/ disagreement between parents and children views. In addition, exploring paediatricians' perspectives on ethical issues of research participation is important for the successful establishment of paediatric research in Jordan.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Author contributions

Basima Almomani and Sayer Al-Azzam contributed to conception and design; Basima Almomani contributed to data collection and processing; Basima Almomani, Sayer Al-Azzam and Samah Al-Shatnawi contributed to analysis and/or interpretation; Basima Almomani drafted the manuscript; Sayer Al-Azzam and Samah Al-Shatnawi revised the manuscript. The submitted version was approved by all authors. All Authors state that they had complete access to the study data that support the publication.

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