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ABSTRACT Ethical and regulatory oversight of research may be suboptimal in low- and middle-income countries. To determine patients' attitudes and perceptions toward research participation and perceptions of their rights, we recruited 202 participants from hospitals in Egypt, Lebanon, Saudi Arabia and Sudan and asked them to complete a questionnaire assessing attitudes and perceptions. Around 20% believed that doctors sometimes perform research on patients without their knowledge and 35% believed that if participants withdrew from the research they would not receive good medical care. Over 85% believed that they should have rights regarding confidentiality of data, free medical care if injured during the research and asking questions. Almost half believed they have a right to withdraw without penalty and around 75% believed they could make complaints without fear of harm. Those who were illiterate or unemployed were less likely to appreciate their rights compared with their counterparts.

Attitudes et perceptions des patients à l'égard de la recherche et de leurs droits : étude pilote au Moyen-Orient

RESUME La surveillance éthique et réglementaire de la recherche peut ne pas être optimale dans les pays à revenu faible et intermédiaire. Afin de déterminer les attitudes et les perceptions des patients à l'égard de la participation à la recherche et des perceptions de leurs droits, nous avons recruté 202 participants dans des hôpitaux en Arabie saoudite, en Égypte, au Liban et au Soudan, et leur avons demandé de compléter un questionnaire évaluant leurs attitudes et perceptions à ce sujet. Environ 20 % croyaient qu'il arrivait que des médecins mènent des recherches sur des patients sans leur consentement, et 35 % pensaient que si les participants se retiraient du processus de recherche, ils ne bénéficieraient pas de soins médicaux de qualité. Plus de 85 % pensaient qu'ils devaient avoir droit à la confidentialité de leurs données, à des soins médicaux gratuits en cas d'incident durant la recherche et qu'ils devaient pouvoir poser des questions. Près de la moitié étaient d'avis qu'ils avaient le droit de se retirer de la recherche sans être pénalisés, et environ 75 % pensaient qu'ils pouvaient adresser des plaintes sans craindre de subir des préjudices. Les participants illettrés ou sans emploi étaient moins susceptibles d'évaluer leurs droits que les autres participants.

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Introduction

The number of clinical trials conducted in low- and middle-income countries has increased worldwide (1), including the Middle East (2). Despite growing political volatility, the Middle East is poised for an escalation in the numbers of clinical trials as pharmaceutical companies continue their search for regions with large, treatment naïve populations (3). Since medical research involves human subjects, knowledge regarding their attitudes and perceptions vis-à-vis research would help with understanding and addressing their concerns, which would enhance

the overall trust between the public and the scientific community. Studies eliciting the views of patients on medical research have been performed in the United States, Denmark, Australia, and Japan (4–7), however these results might not be generalizable to low- and middle-income countries that may have different cultures, religions and economic backgrounds. Currently, there is limited empirical research involving the perspectives of patients from the Middle East (8–13). Additional studies would help with clarifying further the underlying assumptions of patients regarding their participation in research.

Another issue that warrants further investigation is the extent to which potential research participants are aware of and understand their rights in the research process. Although adherence to research ethics principles and guidelines help protect the welfare and the rights of research participants and their communities (14–16), commentators have expressed concerns regarding the regulatory framework (17), the functionality of research ethics committees (18), and the training of the research team regarding responsible research conduct (19) in low- and middle-income countries, including the Middle East. Such concerns make clear that research participants' realization of their rights provides them with a mechanism to protect their interests and prevent potential exploitation.

The concept of rights in research first developed after World War II in response to the practices of Nazi physicians who had experimented on unwilling subjects. The first international instrument on the ethics of medical research, the Nuremberg Code of 1947, was a direct outcome of these unethical practices, and it emphasized that the voluntary consent is "absolutely essential" and that "the human subject should be at liberty to bring the experiment to an end", i.e. a right to withdraw (20, 21). Since the Nuremberg Code, other international instruments have emphasized either directly or indirectly the existence of human rights in biomedical research, e.g. the Declaration of Helsinki in 1964, which has since undergone multiple revisions (17), the United Nations' International Covenant on Civil and Political Rights (1966) (22) the Council of Europe's "The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine" (1997) (23) and in 2005, the "Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research" (24). These documents make clear that the rights in research ethics are linked to ethics guidelines and governmental regulations, and emanate from fundamental ethical principles.

The use of "rights" language can help apply the general ethical principles in research. For example, to secure autonomy investigators need to disclose adequate information to potential research participants and ensure their understanding (i.e. the doctrine of informed consent). Other rights include the right to privacy and confidentiality and the right to medical treatment for any trial-related injury. The corresponding obligations on investigators and sponsors that help secure these rights include mechanisms to respect privacy, measures to enhance confidentiality

protections, and the requirement to obtain indemnity insurance for research-related injuries.

Several studies have investigated the awareness of patients regarding their rights in clinical care in non-Western countries (25–34), but there are limited data regarding the perceptions of research participants regarding their rights (13). Accordingly, this study aimed to identify attitudes and perceptions towards research participation and awareness and understanding of the rights of potential participants from several countries in the Middle East: Egypt, Lebanon, Saudi Arabia and Sudan.

Methods

Survey tool

We developed a survey which contained the following sections: demographic information that included age, sex, education level, employment type and hospital type; attitudes and perceptions toward aspects of research participation; the extent of agreement to receive certain types of information necessary to decide upon participation in research; and the extent of agreement with certain rights in research. Questions required either a single/multiple response or were in the form of a 5-point Likert scale (strongly agree, agree, uncertain, disagree, strongly disagree).

Participants were also asked to respond to the following case study:

Rebekah comes to the clinic to have her blood drawn for routine laboratory examination. The investigator withdraws a little more than usual for research purposes. Which of the following are true?

The investigator does not have to tell Rebekah the purpose of taking more blood.

The investigator does not have to tell Rebekah whether the blood will be used in research.

The investigator should have asked for permission and informed consent from Rebekah

It is expected that patients participate in research without patients' knowledge

If Rebekah suspects that the blood will be used in research, she can do which of the following:

Ask the investigator to withdraw this sample

Complain to the hospital director

Submit a complaint to the medical syndicate or the organization giving the license

Call the police

Go to court

Tell her family members, colleagues and friends not to go to this doctor

Tell the media in order to warn the public from dealing with this doctor and this clinic

Do nothing as nothing will be done about it

The survey was developed in English and then translated into Arabic followed by a back-translation into English to ensure accuracy of the Arabic translation. We pilot tested the survey among several lay persons to assess readability and understanding. Several changes were made in response to this assessment. Reliability of the questionnaire was calculated using the Cronbach α test for internal consistency. Reliability of the questionnaire was judged by the internal consistency coefficient (Cronbach α) of the 29 items using a 5 point Likert scale; this

was 0.901, indicative of a good degree of internal consistency.

Participants

Trained coordinators recruited participants from several sites at university and private-affiliated hospital outpatient clinics at the following locations: Beni Suef, Egypt; Beirut, Lebanon; Medina, Saudi Arabia; and Khartoum, Sudan. We used a convenience sampling technique with a target recruitment of 50 participants per site. The only inclusion criterion was age above 18 years. Participants were recruited during January and June 2014. The questionnaire was self-administered, however, for those who could not read or write, a study team member helped these individuals by reading and explaining each questions and the possible answers.

Statistical analysis

We entered the data into a Microsoft Excel coded file and transformed the data to SPSS, version 22. We used descriptive analysis and chi-squared analysis to determine the strength of the association of each of the independent variables (sex, education levels, and employment type) with each of the responses. Statistical differences within the sex, education and employment subgroups were determined using the Fisher's exact test. We set the significance level at P-value

To enhance our analyses, we collapsed the independent variables into the following subgroups.

Education: illiterate, high school or less, greater than high school

Employment status: unemployed, manual worker/merchant, professional.

To improve the power, we collapsed the Likert scale responses of "strongly agree" and "agree" into one category; and the combination of "uncertain", "disagree" and "strongly disagree" into another category.

Ethics review

We received ethics approval from the research ethics committees at: University of Maryland School of Medicine, Baltimore (United States); College of Dentistry, Taibah University (Saudi Arabia); Faculty of Medicine, Beni Suef University (Egypt); Makassed General Hospital

(Lebanon); and the University of Medical Sciences and Technology (Sudan).

Results

We enrolled 202 participants, 51 each from Egypt and Sudan and 50 each from Saudi Arabia and Lebanon. Results were not significantly different between these countries and therefore, we aggregated the data into a single group. The mean age of the participants was 42.1 [standard deviation (SD) 15.6] years. Twenty-eight respondents (13.9%) had participated in medical research, of whom 17 were currently enrolled in research. Responses from those with and those without experience in research were not significantly different and hence we only present the results of the entire study sample.

Table 1 shows the respondents' demographic data. There were an almost equal number of men and women participants (46.5% and 54.5% respectively). Sixty-four (31.7%) participants had an education level above high school. Approximately one-third were unemployed. The ratio of patients attending private and university hospital outpatient clinics was 1:3.

Table 2 shows respondents' attitudes toward medical research. Overall, 92.6% believed that medical research was necessary to improve health within a society. Respondents held decreasing preferences for participation in the following types of research: questionnaire studies, blood sampling studies and drug trials (87.1%, 64.4%, and 44.6%; respectively). The top 3 reasons for enrolling in research were: to help other patients (50.0%), the belief that patients in research get better treatment (41.6%) and the chance to get better care (41.1%).

Around 20% of respondents believed that doctors sometimes perform research on patients without their knowledge; individuals who were illiterate were more likely to hold this opinion compared with those in the 2 other education groups (42.1% vs. 22.7% and 10.9%, respectively; P Table 2). A little over a third of the respondents (35.0%) believed that if research participants withdrew from the research they would not receive good medical care from their doctors.

Actions that respondents would take if they had have a complaint about the research included: complain to the investigators (41.0%) and complain to the hospital director (28.8%) (Table 2).

In response to the case study regarding a clinic patient from whom a physician withdraws

additional blood for research purposes, 80.5% believed that the investigator should have asked for the patient's informed consent for the additional blood (Table 2). Those who were unemployed were significantly less likely to believe that physicians should ask for consent from the patient compared with manual workers/merchants and professionals (68.2% vs 85.24% and 89.1%, respectively; P

When asked what the patient could do about the additional sample of blood that was withdrawn, the top choices included: ask the physician to withdraw the sample (51.0%); complain to the hospital director (25.7%); and one should do nothing as nothing would be done (22.3%) (Table 2). Those who were illiterate were more likely to believe that "one should do nothing as nothing would be done" compared with those at a higher educational levels; (36.8% vs. 25.2% and 12.5%, respectively; $P < 0.05$). Similarly, those who were unemployed were more likely to believe this compared with manual workers/merchants and professionals (31.3% vs. 20.5% and 12.8%, respectively; $P < 0.05$). Those who were unemployed were significantly less likely to ask the physician to withdraw the sample compared with those who were manual workers/merchants and professionals (37.3% vs. 53.4% and 66.0%, respectively; $P < 0.01$). However, those who were unemployed or were manual workers/merchants were more likely to complain to the hospital director compared with professionals (32.8% and 28.4% vs. 10.6%, respectively, P