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An Unrecognized Problem? Health Science Students' Awareness of and Attitudes towards Clinical Research and Biothics - An Experience from Jordan

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ABSTRACT

Background: This study is the first of its kind in Jordan to survey knowledge, attitude and participation of health sciences students at The University of Jordan (UJ) towards clinical research.

Aim. To investigate UJ undergraduate Health Sciences final year students' knowledge, attitudes towards and participation of students in clinical research.

Methods: A self-administered structured questionnaire, composed of 28 questions with pre-formulated answers was used. The questionnaire contained questions that examined the knowledge, attitudes towards and participation of students in clinical research. Target sample was 250 students of the 5 health sciences faculties (Medicine, Pharmacy, Dentistry, Nursing and Rehabilitation sciences). Data was coded and entered into SPSS database for Windows-version 17 for analysis.

Results: out of 250 questionnaires distributed, 240 were completed (response rate= 96.0%). The majority of respondents (84.5%) reported that they had heard of the term 'clinical research studies' (CRS) before. However, only 59.6% correctly identified the definition of CRS, and only 38.2% knew that this type of research is conducted in Jordan. Only 3.4% identified the term 'IRB', and only 6.4% identified 'declaration of Helsinki'. The most common source of knowledge of this information was university courses and seminars (62.2%).

Conclusion: This study concludes that the training in the clinical research and bioethics area among health sciences students at UJ is still unsatisfactory. We hope that the data of this preliminary study inspires further development and refinement of educational approaches.

Keywords: Attitude, Bioethics, Clinical research, Health sciences, Jordan, Knowledge.

INTRODUCTION

Being an indispensable part of the drug development sequence, clinical research forms the cornerstone in assuring the safety and effectiveness of any drug, technique or device (Slater, 1962; Berkowitz, 2007; US Food and Drug Administration, 2011). However, despite the concentrated efforts to protect human rights through the introduction of influential codes of regulations that guide ethical clinical research such as the Nuremberg Code of 1947, the Belmont Report of 1979, and the Declaration of Helsinki of 2000, the field still suffers from intermittent concerns over the safety of such studies (Ho and Cummins, 2006; Scudellari, 2008). Moreover, misconceptions and lack of awareness may greatly reduce recruitment for clinical trials and thus delay provision of valuable treatments for certain diseases like cancer (Yates, 2003; Wright et al., 2004).

Clinical research has recently come into appearance in a developing country as Jordan. With the establishment of the Jordan Food and Drug Administration (JFDA) in 2003 and the foundation of the Clinical Research Law in

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2001 clinical research is now known to be conducted in a safest environment possible in Jordan (Jordan Food and Drug Administration, 2001). In the past, international pharmaceutical companies sought to do clinical research in third world countries for economical reasons because it's cheaper or the availability of participants in need of money. In addition the location for this type of research is influenced by the widespread pool of diseases targeted in CRS like diabetes mellitus and hypertension. While the situation is still the same in some countries, which lack the judicial system that protects participants, Jordan appears to be a pioneer in this area. It is the first Arab country of the region where participants have been protected by law since 2001 (Jordan Food and Drug Administration, 2001). This has formed the basis for international pharmaceutical companies to perform their studies in Jordan. Currently, neighboring countries like Syria and Lebanon have recently started to have a law to protect participants in CRS (Abou-Mrad, 2010; Syrian Arab News Agency, 2011)

Moreover, this domain witnessed advancement since its birth in Jordan, where the number of contract research organizations (CROs) currently conducting CRS (both therapeutic and non-therapeutic) is 7. The number of clinical study protocols submitted for approval by JFDA has increased over the years as shown in Table 1.

Table 1: Number of protocols of clinical research studies (CRS), both therapeutic and non-therapeutic (bioequivalence studies) submitted to the Jordan Food and Drug Administration (JFDA) for approval over the years (Al-Khateeb, 2011)

Year	No. of therapeutic CRS protocols submitted	No. of therapeutic CRS protocol approved	No. of Bioequavalenec studies protocols submitted	No. of Bioequavalenec studies protocols approved
2005	2	2	131	131
2006	3	2	168	168
2007	10	9	178	178
2008	13	12	180	179
2009	18	18	161	161
2010	28	28	175	175

As much as the picture might seem bright, the main obstacle that stands in way of the popularity of this type of research is the lack of public knowledge including the medical sciences' students and professional personnel who are responsible for both conducting the clinical research and for maintaining the safety of the volunteer or patient. Furthermore, the negative role played by the media in depicting the nature of the research as using humans as lab rats and playing on the tunes of its ethical basis helped in creating a form of strong aversion towards participating.

The goal of fostering balanced, informed, and thoughtful perspectives among future clinical researchers regarding the complex issues arising from clinical research participation by human volunteers is recognized as an important aim of medical education (Miller & Rosenstein, 2003; Miller et al., 1998; Weijer&Miller, 2003)., The role of the medical sciences' students in improving the awareness and correct misconceptions about CRS can be significant once they enter the professional world either in practice or research. Therefore, it is important to assess how much they know about the subject to guide educational initiatives and teaching strategies.

To the best of our knowledge, there have not been any studies in Jordan that tackled this area. Therefore, the aim of this research paper is to explore the knowledge and attitudes of the Medical Sciences students at the

University of Jordan towards clinical research. The results of this paper would hopefully serve as ground-floor for improvement in health care education.

METHODS

Data analyzed in this paper were collected via a self-administered structured questionnaire, composed of 28 questions with pre-formulated answers. The questionnaire contained questions that examined the knowledge, attitudes towards of students, and their participation in clinical research in general and in Jordan in particular. The research instrument was phrased in English which is the language of instruction in the medical sciences' faculties at UJ. The questionnaire was constructed by conduction of extensive literature review to ensure content validity (Ellis, 2000, Bj€orkstr€om *et al.,* 2003; Rees *et al.,* 2004; Robert *et al.,* 2007). Moreover, face validity was also ensured by consulting with experts in the field at UJ and JFDA. The questionnaire was sent to 3 different experts with different specialties (Clinical Pharmacy, Medicine) who had experience in research ethics. Changes to the questionnaire were made according to their recommendations.

The target sample was 250 final-year students, 50 from each of the five medical sciences' faculties; medicine, dentistry, pharmacy, nursing and rehabilitation sciences, at the University of Jordan, the main state university. The questionnaire was piloted first (n=10; two students from each faculty) and minor changes were introduced to improve readability of the instrument. This data was not included in the final analysis.

The data collection spanned a period of around one month in November 2008, where students were given the questionnaires either after their lecture classes or in their break times. The classes were randomly selected from the final year timetable in each faculty. Some students completed the questionnaire directly and some preferred to complete it at home and return it at a later time. The questionnaire took around 20 minutes to fill thoroughly.

After collection, the answers were assigned numeric values and were introduced for statistical analysis into the Scientific Package for Social Science (SPSS) program for Windows, version 17.

Chi-square and Fisher exact tests were used to test for significant differences between groups ($P < 0.05$). In a few cases, participants failed to answer every question, resulting in missing data. Missing data were not estimated or used in analyses.

Approval to conduct this research was granted by the Department of Biopharmaceutics and Clinical Pharmacy at the Faculty of Pharmacy at The University of Jordan (UJ), The Scientific Research Committee at the same faculty and the head of the Jordan University Hospital (JUH).

RESULTS

Out of 250 questionnaires distributed, two hundred and forty questionnaires were completed (response rate=96%), divided as 50 Pharmacy, 50 Nursing, 48 Medicine, 47 Rehabilitation sciences and 45 Dentistry. The reasons for refusal to participate were either lack of time or just not being interested in this kind of research. The majority of respondents were female (n=164, 68.3%), Jordanians (n= 198, 82.8%) and in the age range of 21 to 23 years (n=221, 92.1%).

KNOWLEDGE

Around 84.5% (n=201) of participants have heard of the term 'clinical research study' (CRS) before, whereas only 59.6% (n=143) identified the correct definition of CRS. Pharmacy students were the most to identify the term 'JFDA' while surprisingly none of nursing students did ($p<0.05$). However, only 91 (38.2%) knew that this type of research is conducted in Jordan, and pharmacy and nursing students were significantly the most to be aware of the conductance of CRS in Jordan ($p<0.05$), whereas the rest of the faculties scored almost the same in this question. Tables 2 and 3 summarize this data.

Table 2: Knowledge of medical sciences' faculties of issues related to clinical research studies (CRS) in Jordan (N=240)

Faculty	CRS (%)	JFDA (%)	Conductance of CRS in Jordan (%)
Medicine (n=48)	38 (18.9)	18 (23.1)	15 (16.5)
Dentistry (n=45)	40 (19.9)	11 (14.1)	13 (14.3)
Pharmacy (n=50)	43 (21.4)	41 (52.6)	26 (28.6)
Nursing (n=50)	40 (19.9)	0 (0.0)	27(29.7)
Rehabilitation Sciences (n=47)	40 (19.9)	8 (10.3)	10 (11.0)
p-value	***0.815***	***0.002***	***0.000***

*CRS= clinical research studies, JFDA= Jordan Food and Drug Administration

Table 3: Clinical Research Studies (CRS) definition by medical sciences' students

Definition	Frequency (%)
Studies carried on animal models to ensure that a drug or device is effective and safe to use.	44 (18.3)
Chemical studies carried out in a lab to ensure that a drug or device is effective and safe to use	18 (7.5)
Studies carried out on human subjects to ensure that a drug or device is effective and safe to use	143 (59.6)
Don't know	35 (14.6)
Total	240 (100)

More than half of the participants (n=133, 55.4%) were aware that CRS are of two types; therapeutic and non-therapeutic. Sources of knowledge consisted of radio, television or internet, university courses or seminars, newspapers, and community physicians, pharmacists or nurses (Figure 1). Luckily, the source with the greatest share was university courses or seminars (n=138, 62.2%).

Table 4: Knowledge of medical sciences students regarding the rights of volunteers participating in clinical research studies (CRS)

Right of volunteer in CRS	No. (%)
Being told honestly and clearly of the benefits and risks of participating.	198 (82.5%)
Understanding the research procedure, duration and purpose.	194 (80.8%)
Withdrawing at anytime from the study	104 (43.3%)
Receiving monetary compensation	96 (40.0%)
Knowing if there is any special interest or benefit for the investigator to conduct the study.	118 (49.2%)
Giving approval at every single step of the study	130 (54.3%)

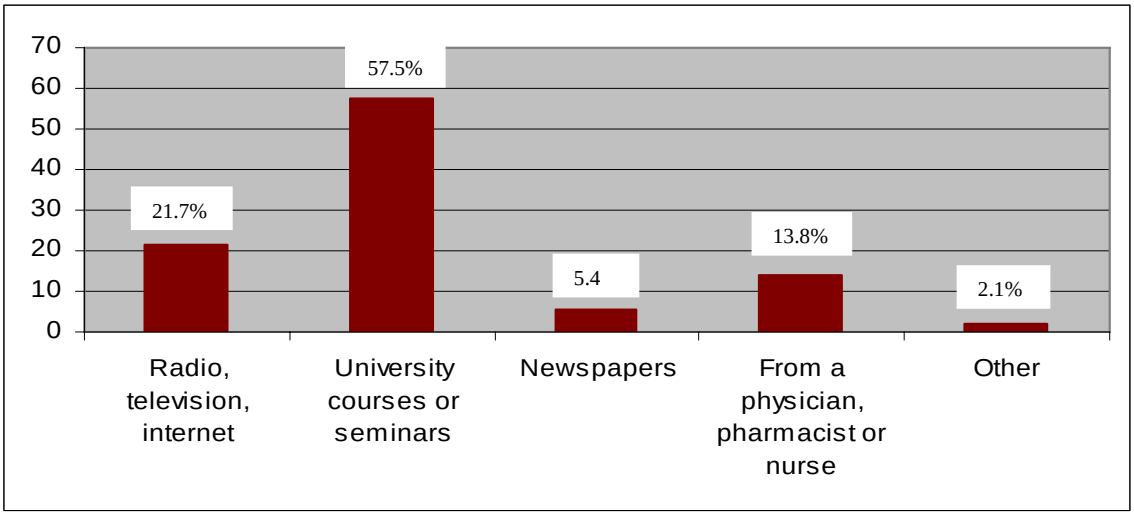

Figure1: Sources' of participating students knowledge regarding clinical research (n=240)

Of those who were familiar with the term 'CRS' (n=201), more than two-thirds (n=136, 67.6%) thought that medical studies on human subjects in general are regulated by law and almost one in every 4 students (n=47, 20.3%) thought that the ones conducted in Jordan are regulated by law. Concerning the familiarity of the students with terms such as Institutional Review Board (IRB), Contract Research Organization (CRO) or the declaration of Helsinki only a very humble number were acquainted as follows: IRB (n=8, 3.4%); CRO (n=7, 3.0%) and declaration of Helsinki (n=15, 6.4%).

Unfortunately, more than half of participating medical sciences students (52.5%) did not know what is "informed consent form", while 35.8% identified the correct definition as illustrated in Figure 2.

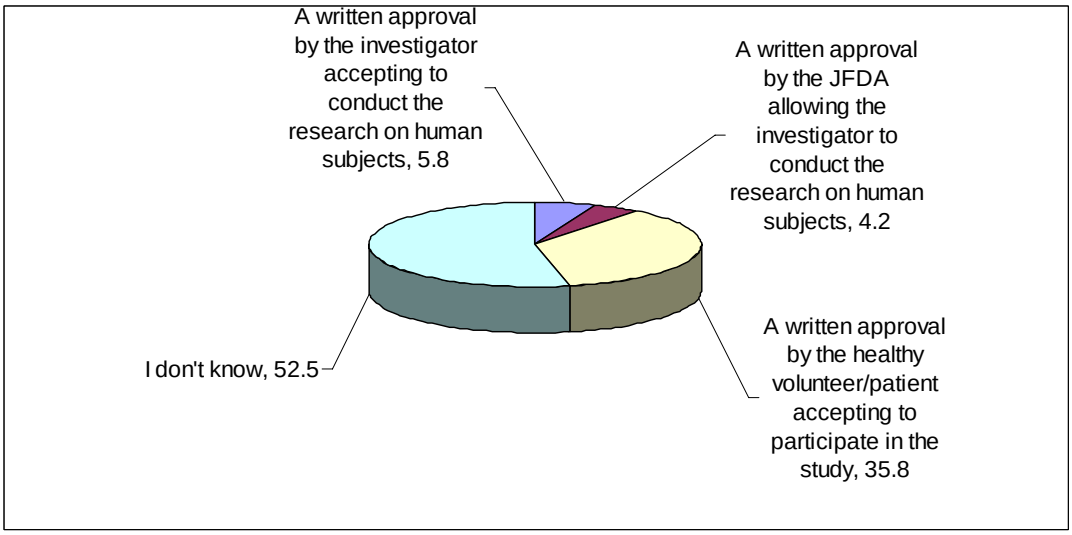

Figure 2: Medical students' answers to the question "what is the informed consent form?"

Regarding the rights of CRS volunteers (Table 4), which is a major area of concern for all people, the majority of students were aware that the volunteer is told honestly and clearly of the benefits and risks of participating (n=198, 83.5%) and second that the research procedure, duration, and purpose are thoroughly understood by the volunteers (n=194, 81.9%). Only 55.3% (n=130) knew that volunteers' approval should be taken at every single step of the study. Moreover, only 90 students (38.6%) agreed that CRS are monitored by an independent ethical committee.

Attitude

The significant contribution of CRS in building a new face for medicine over the years was not recognized satisfactorily by the students; since only 44.4% agreed of this statement.

Seventy six students (32.7%) felt that conduction of CRS is ethical whereas 85 (36.7%) thought them to be conditionally unethical, for instance when conducted on pregnant women, children, or prisoners. For the rest, it was completely unethical (n=72, 30.6%).

Fortunately, 40.8% (n=98) reported that they would feel comfortable to participate in a CRS conducted in Jordan. The remainders either totally refused (n=63, 26.3%) or were hesitant (n=79, 32.9%). The two major conditions for participating were complete knowledge of all the risks the study comprised (74.2%) and if the study would benefit the involved person or someone else (54.2%). Moreover, the type of the study affected the tendency to participate. These findings are summarized in Figure 3 and Table 5.

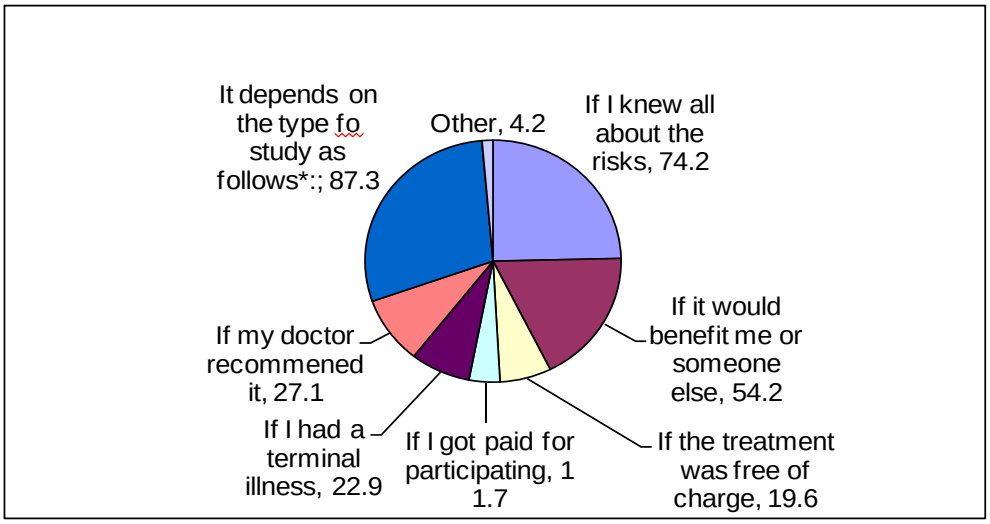

Figure 3: Conditions under which students would consider participating in medical research conducted on human subjects. (Note: multiple responses were allowed)

*: as follows in Table 5

Around 2 of every 5 students agreed that the risks and benefits of CRS vary significantly case to case. Unfortunately, the main reason why students thought that International Pharmaceutical Companies would seek to do CRS in Jordan was the economic factor (n=107, 46.1%). Only 20.3% were aware that Jordan has this type of research regulated by law thereby making any CRS conducted here credible and internationally acceptable.

Only 8 students reported that they had participated previously in CRS, out of which 7 were in Jordan. Of those who reported participation, 6 mentioned that they were given appropriate information before participation.

Table 5: Types of CRS that participating students may consider participating in (n=194, 87.3%)

The Study involves:	**YES**	**MAYBE**	**NEVER**
Blood/urine samples	154 (79.4)	30 (15.5)	10 (5.2)
biopsy	137 (70.6)	33 (17.0)	24 (12.4)
New intervention (device, technique..)	43 (22.8)	55 (29.1)	91 (48.1)
New investigational drug	27 (14.5)	51 (27.6)	107 (57.8)

DISCUSSION

To our knowledge, this is the first study in Jordan to examine health sciences students' knowledge and attitudes towards clinical research studies and ethics. This study revealed some inadequacy in awareness of these future researchers regarding clinical research studies as a concept in general and their conduct in Jordan in particular.

The majority of participants in this study have heard of the term "clinical research study. CRS" which is good news until we learn that only 59.6% of health sciences students in our sample identified the correct definition of CRS of being "Studies carried out on human subjects to ensure that a drug or device is effective and safe to use". On the other hand, in a big survey conducted in the USA on 5,822 members of the public, 79.0% understood the meaning of CRS and the main sources reported of knowledge was the media (e.g. TV, radio, newspapers, and magazines; Anonymous, 2004). There is a vital role that the media has to play worldwide in increasing awareness and shaping the attitudes of the general public towards clinical research studies. Such role of the media might not be satisfactory or sometimes in a negative direction in some countries (Glasser, 2008; Johnson, 2010).

Of the findings that are worthy of attention in this study are only 3.4% of health sciences students recognized the term "IRB", 6.4% identified the Declaration of Helsinki, and 35.8% correctly defined "informed consent form". In a survey of all staff (n=154; clinicians, research students, and researchers) within the largest clinical research group of a non-governmental research institute in Australia only 62.0% of the total sample and 54% of participating students claimed to understand the term good clinical research principles (GCRP). In this group 47.0% of the total (41.0% of participating students) had read the Declaration of Helsinki, and 73.0% of the total sample (69.0% of participating students) claimed to understand "informed consent. Reasons given for the lack of GCRP training included insufficient resources, no planned training provided, and no time. It was also shown that 79.0% of staff felt that research auditing was important and 74.0% would like more education in GCRP" (Babl and Sharood, 2008).

The effects of research ethics training on health sciences students' attitudes about clinical research are invaluable especially since the university courses and seminars were the major sources where students learned about CRS. A preliminary randomized controlled trial conducted in Wisconsin in 2007 evaluated 2 didactic approaches to ethics training compared to a no-intervention control. Those in the participant- oriented intervention group exhibited greater attunement to research participants' attitudes related to altruism, trust, quality of relationships with researchers, desire for information, hopes about participation, possible therapeutic misconception, importance of consent forms, and deciding quickly about participation (Roberts et al., 2007). There are some reports about the incorporation of bioethics modules in the pre-graduate curriculum of some medical schools worldwide (Bj€orkstr€om et al., 2003; Schammel et al., 2008; Kennel et al., 2009; Akan, 2010). In Turkey for example, a pre-graduate education about Good Clinical Practice (GCP) is incorporated in the medical school curriculum in Anakara University in addition to on-demand post-graduate programs provided by Ministry of Health (MoH) and Industry (Akan, 2007; Gokhan, 2010). In one attempt in Florida by Kennel et al (2009) hospital nurses involved in research projects mentored students in the clinical environment. They were

asked to do literature reviews, collect and analyses data and help with other tasks. Students' evaluation at the end of the program were positive and analysis of pretest and posttest scores indicated that students' interest in nursing research increased significantly (p=0.00).

Our respondents' top three reasons to possibly consider participating in future CRS were the type of study, followed by the complete awareness of the potential risks of the study, and finally the direct benefit of participation to them or other patients. In a survey conducted in the USA in 2004 on 656 members of the public who had previously participated in CRS the top 3 reasons to participate were to help to advance medicine/ science (56.0%), to earn extra money (50.0%) and then to help others with similar condition (45.0%; Anonymous, 2004). Perhaps the reason for such differences could be cultural in addition to the settings of conduction of the two studies. Reasons why a person actually DID participate as in the first study might be different from potential reasons that one might possibly consider to participate as in the current study.

This study warrants future more detailed research regarding the value of bioethics teaching in shaping attitudes and improving knowledge of health sciences students about CRS. Our results are limited, however, by the small sample size, single site context, and built-in defects in the type of methodology used such as recall and social desirability bias. In addition, this study did not collect detailed information about student's previous participation and experiences in clinical research. Moreover, although anecdotal information suggests that most health sciences faculties in Jordan share similar teaching and training standards, our results may not be entirely applicable to other faculties in Jordan.

The main recommendations that follow this study can be summarized by:

- The integration of a formal mandatory training program on Biomedical ethics (concerning both medical practice and clinical research ethics) in all health sciences faculties on the national and regional level. It is recommended in this regard that various teaching methods be used in shaping students' attitudes (e.g. case-based, small group and experiential learning) towards ethical issues in clinical research (Kelly, et al, 1987; Rees et al, 2004; Roff & Preece, 2004). It is recommended that such training should be incorporated into the first years of university education in order to form a base to build on other modules in different specialties.
- Involve students more in clinical research environment in order to minimize the dryness of ethics modules, similar to what has been described in the literature by Kennel et al., (2009). Such program was proven successful in improving students' awareness and attitudes towards clinical research.
- Use Health Sciences students as key-informants to their society as various required learning activities. It is hoped that the incorporation of biomedical ethics teaching to health sciences students would help in delivering the correct information to the society and minimizes misconceptions.

CONCLUSION

This study concludes that there is inadequate knowledge and training in the clinical research and bioethics area among health sciences students at UJ. More in-depth research is needed to provide additional insight to guide educational initiatives and strategies. We hope that the data of this preliminary study inspires further development and refinement of educational approaches that target knowledge, attitudes, and values related to ethical dimensions of clinical research among medical sciences, research students, and professionals.

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تقييم مدى وعي ومواقف طلاب الكليات الصحية في الجامعة الاردنية من الدراسات الدوائية واخلاقيات البحث العلمي

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ملخص

مقدمة: تعد هذه الدراسة الاولى من نوعها في الأردن؛ إذ تقيّم مدى معرفة ومشاركة طلاب الكليات الصحية في الجامعة الأردنية ومواقفهم من الدراسات الدوائية.
أهداف الدراسة: تهدف هذه الدراسة إلى استطلاع آراء طلبة السنة الأخيرة بالكليات الصحية في الجامعة الأردنية ومواقفهم ومشاركاتهم في الدراسات الدوائية بصورة عامة وفي الأردن بخاصة.
منهجية الدراسة: اتخذت الدراسة اسلوب الاستبيان المنظم ذاتي التعبئة. تم توزيع الاستبيان المكون من 28 سؤالا، تم توزيعها على 250 طالباً من خمس كليات صحية هي: الطب، طب الاسنان، الصيدلة، التمريض، وعلوم التأهيل.
النتائج: تم ارجاع 240 استبانة من أصل 250، تم توزيعها مما يعطي معدل استجابة مقداره 96%. أظهرت النتائج أن 59.6% فقط من المشاركين تمكنوا من تعريف مصطلح الدراسات الدوائية وأن 38.2% عرف أن هذا النوع من الأبحاث تجري في الأردن.
تعرف 3.4% فقط من المشاركين إلى معنى مصطلح IRB (لجنة الاخلاقيات المستقلة)، بينما تعرف 6.4% فقط إلى (اعلان هلسنكي).
الاستنتاج: أظهرت هذه الدراسة أن مستوى المعرفة والتدريب الذي يتلقاه طلاب الكليات الصحية بالجامعة الأردنية بالنسبة لموضوع الدراسات الدوائية وأخلاقيات البحث العلمي لا يزال غير مرض.

الكلمات الدالة: السلوك، اخلاقيات البحث العلمي،، الدراسات الدوائية.

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