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Research Article

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Expectations of Healthcare Providers in MENA region towards the Roles and Responsibilities of Clinical Research Coordinators (CRC)

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Abstract Background: The role of CRC is crucial for the success of clinical trials. However, a lot of health care providers are not fully aware of the roles and responsibilities of CRC.
Purpose: To explore the awareness of health care providers in MENA region about roles and responsibilities of CRC.
Method: *A qualitative study was conducted* using survey monkey software between17th of February 2015, and 18th of January 2018, where 103 health care providers from different regions and specialties completed the survey.
Results: 80.81 % of respondents claimed that they were aware of GCP Guidelines. GCP certified respondents represented 50.51 % of study population. Respondents were asked about 28 tasks if they belong to responsibilities of clinical research coordinator in conducting clinical research, and they indicated their level of agreement or disagreement on a Likert scale. The mean percentage of the right answers of nurses was 50.89 %, followed by clinical research specialties "CRAs and CRCs" (47.62 %), pharmacists (41.67 %), and MD/PhD (37.14 %). However, the results were not statistically significant (p= 0.19).
Conclusion: A higher level of awareness about GCP guidelines and CRC job description is required.

Keywords Clinical Research Coordinator, Healthcare provider, Clinical research, Good Clinical Practice guidelines

Introduction

Research is a systematic analysis that adopts disciplined scientific methodologies trying to answer questions or solve problems [1]. The main components of clinical trials are a proposed methodology, a study of a certain interference, and a comparison to a control group that does not undergo that interference [2].

The decade between 1987-1997 saw an intense increase in the number of clinical trials registered with the Food and Drug Administration (FDA) [3]. The scope of clinical research has widened encompassing academic organizations, pharmaceutical enterprises, contract research organizations (CROs), and clinical researchers in community settings [4]. This widened scope has raised concerns regarding the ethical conduct of studies [5]. Procedural issues e.g. including Institutional Review Board (IRB) review, data monitoring, and informed consent forms have been given much of these concerns. Nevertheless, human subjects cannot be protected by merely depending on procedural safety measures [6].

Clinical trials involving human subjects require multidisciplinary teams including principal investigators, sub-investigators, clinical monitors (clinical research associates "CRAs"), data management teams, statisticians, and clinical research coordinators (CRCs) [7]. Role of a CRC is crucial for processing a clinical trial successfully [6, 8]. According to the results of the study conducted by Kang et al. [9], a CRC is the one responsible for coordinating and performing duties among investigators, participants, and sponsors as stated in the Good Clinical Practice (GCP) at organizations carrying out clinical trials. CRCs are at the heart of clinical research; working with principal investigators (PIs) on developing protocols, writing consent forms, helping in selecting subjects and explaining the study to them, coordinating with relevant healthcare institutions, collecting and maintaining clinical data, and serving as the main contact person for subjects during a study [4]. In 1996, Papke has identified 128 different activities carried out by study coordinators [10]. Integrating a coordinator to a study team has been proved to remarkably improve subject enrollment rate [11], increase subject retention rate [12], and raise overall study efficiency [13]. However, clinical research is not a formalized specialty that requires a formal training except for GCP [14, 15]. The position of CRC does not necessitate a certain educational level, but usually a medical field Bachelor's degree along with clinical studies experience or closely related research experience is recommended [2].

The rapid population growth, need for medication, and widespread life-style related and rare genetic diseases in the Middle East and North Africa (MENA) region should have been met with large numbers of clinical studies. However, MENA countries sponsor only less than one percent of global clinical studies [16]. Accordingly, healthcare providers in MENA region are not fully aware of GCP guidelines and roles of CRC. Very few studies were conducted to explore the awareness of healthcare professionals in MENA region about GCP guidelines and responsibilities of CRC, e.g. a study carried out in Kingdom of Saudi Arabia [17]. Therefore, this study was conducted trying to cover this gap through investigating the awareness of health care providers in MENA region regarding GCP guidelines, and explore their expectations of the roles and responsibilities of CRC.

Methods

Study Design

A qualitative study was carried out where semi-structured survey was conducted using Survey Monkey software. The study was conducted between 17th of February 2015, and 18th of January 2018, where 103 healthcare providers were enrolled. Questions of the first part were dedicated to collecting the contact information and demographics of respondents. Questions of the second part were designed to collect data about respondents' awareness of GCP guidelines, their GCP certification status, number of studies in which the they have participated, their expectations of the roles and responsibilities of CRC, and their opinions regarding the number of active patients that a CRC can handle on a clinical trial.

Results

Part 1. Demographic Data

Table 1 shows demographics of respondents. Males and females represented 61.62 % and 38.38 % respectively.

The majority of respondents (65.35 %) came from Kingdom of Saudi Arabia, followed by 17.82 % from Egypt, 6.93 % from Jordan, 5.94 % from United Arab Emirates. Each of Sudan, Lebanon, Yemen, and Palestine was represented by 0.99 %. Most of respondents (43.43 %) worked at governmental hospitals, followed by 16.16 % at pharmaceutical companies, 10.10 % at academic hospitals, 6.06 % at private hospitals, and 7.07 % at universities. Other areas of work were represented by 17.17 %. Specialties of respondents were as follows: 29.29 % pharmacists, 21.21 % MD/PhD, 13.13 % registered nurses, 8.08% CRCs, 5.05% CRAs, 2.02 % data entry, and 2.02 % research committee (member/reviewer). Other specialties were represented by 19.19 %.

Table 1: Demographic Data of Respondents

Variable	Count	Percent
Gender*		
Female	38	38.38%

Male	61	61.62%
Residence/ Countries**		
KSA	66	65.35 %
Egypt	18	17.82%
Jordan	7	6.93%
UAE	6	5.94%
Sudan	1	0.99%
Lebanon	1	0.99%
Palestine	1	0.99%
Yemen	1	0.99%
Area of Work/ Affiliation*		
Governmental Hospital	43	43.43%
Private Hospital	6	6.06%
Pharmaceutical Company	16	16.16%
Academic Hospital	10	10.10%
University	7	7.07%
Other	17	17.17%
Specialty*		
MD / PHD	21	21.21%
Pharmacist	29	29.29%
Registered Nurse	13	13.13%
Clinical Research Associate	5	5.05%
Clinical Research Coordinator	8	8.08%
Data Entry	2	2.02%
Research Committee (member/ reviewer)	2	2.02%
Other	19	19.19%

* 4 participants with missing data ** 2 participants with missing data

Part 2. Professional Data

Table 2 shows that the majority of respondents (80.81 %) claimed that they were aware of GCP guidelines. GCP certified respondents represented 50.51 % of the study population. Participation in clinical studies was as follows: 33.33 % (1-5 studies), 17.17 % (11-20 studies), 14.14 % (6-10 studies), and 7.07 % (≥ 21studies), while 28.28 % of respondents did not participate in any study. Regarding the number of active patients a CRC can handle on a clinical trial, 90.24 % of respondents provided numbers ranging between 1 and 100, while 4.88 % of respondents provided numbers ranging between 101 and 200. Each of the answers "500" and "≥1000" was provided by 2.44 % of respondents.

Table 2: Answers of Professional Questions (1-4)

Variable	**Count**	**Percent**
Are You Aware of GCP Guidelines?*		
Yes	80	80.81%
No	19	19.19%
Are You GCP Certified?*		
Yes	50	50.51%
No	49	49.49%
Number of Studies in Which You Participated*		
Zero	28	28.28%
1-5	33	33.33%

6-10	14	14.14%
11-20	17	17.17%
≥ 21	7	7.07%
In Your Opinion, How Many Active Patients a clinical research coordinator can handle on a clinical trial? **		
1-100	37	90.24 %
101-200	2	4.88 %
500	1	2.44%
≥1000	1	2.44 %

* 4 participants with missing data ** 62 participants with missing data

Table 3 summarizes the 28 responsibilities listed for CRC; seven of which were out of scope and were added to explore awareness of the study population about CRC job responsibilities. The percentages of the right answers ranged from 15.22 % to 82.22 % with a median 60.94%, and the percentages of wrong answers ranged from 17.78 % to 84.78 % with a median 39.06 %.

Table 3: Answers of Professional Question (5)

Please check all that apply about the Clinical Research Coordinator (CRC) responsibilities in conducting clinical research					
Task	**Correct Answers**		**Wrong Answers**		**Total**
	Count	**Percent**	**Count**	**Percent**	
Writing the study protocol*	10	20.83 %	38	79.17 %	48
Ensuring the informed consent form is translated and back-translated into the local language**	32	69.57 %	14	30.43 %	46
Helping PI in assessing the feasibility of conducting study at the site***	29	64.44 %	16	35.56 %	45
Ensuring that the enrolled study subjects are informed about their schedule of visits well in advance and they do not miss their visits***	37	82.22 %	8	17.78 %	45
Meeting with study sponsor to find out about availability of space, equipment, trained manpower to handle a particular study***	34	75.56 %	11	24.44 %	45
Obtaining consent form process in term of signing and explaining the study with the patients****	15	34.09 %	29	65.91 %	44
Evaluating the site's access to the subject population–whether the required number of subjects can be enrolled within the required time****	26	59.09 %	18	40.91 %	44
Collecting and organizing subjects data and disseminate the information to the study sponsor on time***	29	64.44 %	16	35.56 %	45
Ensuring that all the requirements are in place for the site initiation visit****	34	77.27 %	10	22.73 %	44
Managing the storage of the study drug - account for study drug received from sponsor, distributed to the patient, returned from the patient and finally back to the sponsor****	9	20.45 %	35	79.55 %	44
Coordinating with the IRB for their required study submission package****	25	56.82 %	19	43.18 %	44
Ensuring that all laboratory specimens such as blood, urine, tissue etc. are properly labeled, packaged and stored before shipment to the lab****	29	65.90 %	15	34.09 %	44
Following up with the IRB for a faster approval of the trial****	28	63.64 %	16	36.36 %	44

Following up with the sponsor for any study documents amendments and ensure that are implemented at the site only after the written approval by the IRB*****	27	62.79 %	16	37.21 %	43
Responding to IRB OR Audits study findings****	26	59.09 %	18	40.91 %	44
Helping PI in regular physical examination assessment****	17	38.64 %	27	61.36 %	44
Negotiating the trial budgets at the site (investigator fees, IRB fees, site administration fees, laboratory costs, study subject travel and other reimbursements) ****	11	25 %	33	75 %	44
Assuring the availability of all required study data, files to be audited or inspected from the sponsor, the auditor, and the trial inspector during the trial****	34	70.59 %	10	29.41 %	44
Screening the patients using the clinic list for any potential candidate****	19	43.18 %	25	56.82 %	44
Reviewing and assessing the AE / SAE relation during study***	12	26.67 %	33	73.33 %	45
Assessment of Inclusion / Exclusion criteria before subject enrollment****	11	25 %	33	75 %	44
Maintaining and updating the Trial Master File (TMF) in organized and secured place****	31	70.45 %	13	29.55 %	44
Reading / Assessing / Reporting any findings from investigational examination (ex. CT, MRI, ECHO, Lab. etc.) ****	13	29.55 %	31	70.45 %	44
Doing regular check of the case report forms (CRFs), maintain an archival inventory of records and CRFs in a secure place and coordinate the close out visits***	33	73.33 %	12	26.67 %	45
Timely submission of all the safety reports to the IRB***	32	71.11 %	13	28.89 %	45
Solving Data Queries raised from data management team**	30	65.22 %	16	34.78 %	46
Helping PI in source documents entry**	7	15.22 %	39	84.78 %	46
Following patients after withdrawing from the trial******	22	44.90 %	27	55.10 %	49
	Median	60.94%	Median	39.06%	

* 55participants with missing data ** 57 participants with missing data

*** 58 participants with missing data **** 59 participants with missing data

***** 60 participants with missing data ****** 54 participants with missing data

Table 4 summarizes the correlation between specialties and awareness of CRC responsibilities; the mean percentage of the right answers of nurses was 50.89 %, followed by clinical research specialties "CRAs and CRCs" (47.62 %), pharmacists (41.67 %), and MD/PhD (37.14 %). However, the results were not statistically significant (p= 0.19).

Table 4: Correlation between Specialties and awareness of CRC responsibilities

Specialty	**Count**	**Total Right Answers**	
		Count	**Mean Percentage**
Registered Nurse*	8	114	50.89 %
Clinical Research specialties (CRA & CRC)**	9	120	47.62 %
Pharmacists***	18	210	41.67 %
MD/PhD***	10	104	37.14 %
Total	45	P=0.19	

* 5 participants with missing data ** 4 participants with missing data

*** 11 participants with missing data

Discussion

Most of respondents (43.43 %) worked at Governmental hospitals. Respondents who worked at pharmaceutical companies, academic hospitals, private hospitals, and universities represented 16.16 %, 10.10 %, 6.06 %, and 7.07 % respectively. Other areas of work were represented by 17.17 % of respondents. These results differ slightly from those obtained by a study conducted online by CenterWatch between August and September 2012, where 50 % of respondents worked for academic medical centers or government-funded hospitals, while the other 50 % belonged to profit investigative sites [18]. The majority of respondents (29.29 %) were pharmacists, whereas CRCs represented only 8.08 %. These results differ from those obtained by Rico-Villademoros et al. [7] regarding the majority of respondents who were data managers, and correlate with it regarding CRCs who represented 8.6 % of study population.

Percentages of GCP certified respondents and non GCP certified respondents were 50.51 % and 49.49 % respectively. Higher results were published in a study conducted in Kingdom of Saudi Arabia in 2014 where 85 % of respondents received GCP training. On the other hand, Rico-Villademoros et al. [7] found that 40.5 % of respondents in their study in Spain received GCP training.

Respondents who participated in 1-5 studies, 6-10 studies, 11-20 studies, and more than 21 studies represented 33.33 %, 14.14 %, 17.17 %, and 7.07 % respectively, whereas 28.28 % of respondents did not participate in clinical studies. This reflects that the study population needs an extensive training to widen their experience.

The answers of questions 1 and 5 reflect the gap between respondents' claims and reality where 80.81% of respondents thought that they were aware of GCP guidelines, while the median of right answers was 60.94 %. This points to underdeveloped awareness of GCP guidelines, and inaccurate expectations of roles of CRC.

It is worth noting that the task "ensuring that the enrolled study subjects are informed about their schedule of visits well in advance and they do not miss their visits" got the highest percentage of right answers (82.22 %) which reflects the awareness of the majority of respondents about this task. Not only do CRCs contact their patients to confirm the trial schedule, but also to assess adverse events, and provide psychosocial support as needed [19]. On the other hand, the task "Helping PI in source documents entry" -does not belong to CRC responsibilities- received the highest percentage of wrong answers where 84.78 % of participants did not recognize that this task does not belong to CRC responsibilities. This reflects the confusion of participants about the tasks that CRC should be helping PI with. It is true that CRC is a must for any institute to master clinical trials [6]. CRC is usually hired by the PI, and is often responsible for helping with the coordination management and conduct of clinical trial [20]. A CRC should possess skills required for looking at the broader context, paying attention and planning for small details, assigning times, and effectively managing time [21]. However, a CRC is not responsible for helping PI in source documents entry.

The highest mean percentages of right answers were achieved by nurses (50.89 %). Upon mentioning nurses, it is important to state that despite the significant role of nurses in clinical research, their status as research professionals is underestimated [22]. Owing to the rapid growth of clinical research industry, with its requirement of securing evidence-based treatment, the number of nurses shifting to CRC role is increasing significantly [23]. In clinical research, nurses are given a variety of titles including "research nurse", "research coordinator", "CRC", "research clinician", or "clinical trial coordinator". Nurses involved in clinical studies perform various tasks concerned with gathering, organizing, and documenting clinical research data [2]. As the majority of research coordinators do not receive official training, incorporating GCP guidelines and research management communication skills into syllabi of undergraduate and graduate nursing programs would be an important step towards ensuring all potential CRCs receive an adequate basic training [22].

Our study has an obvious limitation: a low response rate which is a common disadvantageous consequence of mailing questionnaires [24], and it led in turn to a small sample size.

Conclusion

The awareness level of participants about GCP guidelines and CRC responsibilities is not satisfactory. A higher level of awareness about GCP guidelines is required, in addition to promoting GCP training and certification.

Recommendation

Clinical research should be incorporated in the curricula of various undergraduate medical degrees. Establishing centers to provide and promote clinical research training and certification would be helpful. Even in times when healthcare providers have no chance to enroll in trials, joining training programs or volunteering in hospitals having ongoing clinical research projects would help to widen their experience in clinical research.

References

1. Polit, D.F. and C.T. Beck, Nursing Research: Principles and Methods. 2004: Lippincott Williams & Wilkins.
2. Fowler, S.B. and K. Stack, Research and the clinical trials coordinator. Journal of Neuroscience Nursing, 2007. 39(2): p. 120-123.
3. Hovde, M. and R. Seskin, Selecting US clinical investigators. Applied Clinical Trials, 1997. 6: p. 34-45.
4. Davis, A.M., et al., The invisible hand in clinical research: The study coordinator's critical role in human subjects protection. The Journal of Law, Medicine & Ethics, 2002. 30(3): p. 411-419.
5. Department of Health and Human Services, O.o.I.G., The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects. 2001.
6. Jha, S., The nurturing of the clinical research coordinator. Academic radiology, 2010. 17(11): p. 1325.
7. Rico-Villademoros, F., et al., The role of the clinical research coordinator – data manager – in oncology clinical trials. BMC Medical Research Methodology, 2004. 4(1): p. 6.
8. Pawlik, T.M. and J.A. Sosa, Success in Academic Surgery: Clinical Trials. 2013: Springer London.
9. Kang, H.S., et al., Job analysis of clinical research coordinators using the DACUM process. J Korean Acad Nurs, 2012. 42(7): p. 1027-38.
10. Papke, A., The ACRP national job analysis of the clinical research coordinator. The Monitor, 1996: p. 45-53.
11. Cooper, J. and J. Lomax, The role of the research nurse in clinical trials. British Journal of Clinical Practice, 1989. 43(5): p. 167-168.
12. Good, M. and L. Schuler, Subject retention in a controlled clinical trial. Journal of advanced nursing, 1997. 26(2): p. 351-355.
13. McKinney, J. and W. Vermeulen. Research nurses play a vital role in clinical trials. in Oncology nursing forum. 2000.
14. Burgess, L.J. and N.U. Sulzer, GCP accreditation-a worthwhile investment. 2006.
15. Getz, K., Rising clinical trial complexity continues to vex drug developers. ACRP Wire, 2010. 13.
16. Nair, S.C., H. Ibrahim, and D.D. Celentano, Clinical trials in the Middle East and North Africa (MENA) Region: Grandstanding or Grandeur? Contemporary Clinical Trials. 36(2): p. 704-710.
17. Al-Nomay, N.S., Knowledge, perception, and attitude of health care professionals towards ICH-GCP guidelines in Saudi Arabia. Avicenna, 2016. 2016(1): p. 1.
18. Getz, K., Are CRCs reaching their tipping point. Applied Clinical Trials: Applied Clinical Trials, 2012.
19. Fujiwara, N., et al., Qualitative analysis of clinical research coordinators' role in phase I cancer clinical trials. Contemporary Clinical Trials Communications, 2017. 8: p. 156-161.
20. Woodin, K.E., T.C. Inc, and T.A.H. Consultants, The CRC's Guide to Coordinating Clinical Research. 2004: Thomson CenterWatch.
21. Shields, A.-M. and E.M. LaRue, Transitioning from clinician to clinical research coordinator. AJN The American Journal of Nursing, 2010. 110(1): p. 26-27.
22. Merry, L., A.J. Gagnon, and J. Thomas, The Research Program Coordinator: An Example of Effective Management. Journal of Professional Nursing, 2010. 26(4): p. 223-231.
23. Yin, C., Improving the quality of clinical research: Recognizing issues in training. Research Practitioner, 2008. 9(1): p. 20.

24. Nicholls, K., et al., Enhancing response rates in physician surveys: the limited utility of electronic options. Health Serv Res, 2011. 46(5): p. 1675-82.