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Exploring the Effect of Clinical Trial Capacity-Building Activities on Nurses' Knowledge at A New Specialized Cancer Center in Oman

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Abstract

Introduction*:** Clinical trials are essential in the advancement of global scientific knowledge. The role of nurses at SQCCCRC-UMC has become more significant because of their direct role in caring for clinical trial participants. This necessitated building their capacity through training to care for trial participants as per the International Council of Harmonization- Good Clinical Practice (ICH- GCP). ***Objectives*:** This study aims to investigate the effect of a capacity-building initiative that includes conducting Clinical Trial Workshops (CTW) and getting nurses certified in online ICH-GCP. ***Method: 21 CTW were conducted. Pretest and posttest scores to check knowledge were collected from 2022 to 2024 and analyzed using paired t-tests to compare averages. Nurses were also asked to submit ICH-GCP certification to the clinical trials department (CTD) for record keeping. ***Results*:** CTW had a total of 171 participants composing of 96% of nurses (n=165). Those nurses accounted for 50.6% of the total nursing workforce (n=326). 88.5% (n=146) of those nurses completed both the pretest and posttest. The mean posttest score (87.2%) was compared with the mean pretest score (68.5%) showing an average increase of 19 %, which indicated statistical significance. (CI=95%, t=0.05). 86 nurses have completed ICH-GCP certification during the same period. (26.4 % of all nurses, n=326). ***Conclusion*:** The capacity building approach significantly improved nurses' knowledge about clinical trials which can potentially aid in caring for patients in clinical trials. Additional research is needed to assess the long-term impact of this approach on nurses' attitude in caring for those patients.

Keywords: Clinical Trials as Topic, Capacity-building, Nurses, Clinical Trials Workshop, Good Clinical Practice, Oman.

INTRODUCTION

Clinical trials are essential in the advancement of medical knowledge. The outcomes of clinical trials are vital in determining whether new treatments or procedures provide their intended benefits. The field of clinical research is continuously evolving, and it is increasingly recognized that the context in which clinical trials are conducted affects and interacts with the implementation of the intervention resulting in a variety of outcomes (Piantadosi, 2024). Therefore, despite being the cornerstone to assessing the safety and efficacy of new medical treatments, it requires resources for conducting and monitoring clinical trials to ensure its accuracy and reliability to make scientific conclusions (Klimaszewski *et al.*, 2016).

Wong *et al.*, (2019) emphasized that nurses play a major role in the implementation and the monitoring of clinical trial protocols to ensure their accuracy and reliability. Research nurses carry out clinical trial interventions as well as monitoring of the research process and documenting the study outcomes. Therefore, working with patients under clinical trials necessitates nurses to acquire the knowledge and skills of a research nurse to ensure compliance to protection of human subjects (Eckardt *et al.*, 2017).

The National Institute of Health (NIH) has defined four domains that research nurses work under while caring for patients on clinical trials, which are: care coordination and continuity, clinical practice, human subject protection, study management and contribution to science (CRN 2010, 2009).

There are clinical trials done in different specialties including cancer care. Oncology nurses play a pivotal role in the success of clinical trials conducted in

cancer care settings. The role of an oncology nurse has become more significant because of the advances in molecular science and precision medicine which resulted in more clinical trials being developed (Wujcik, 2016).

There is a growing body of literature that addresses the attitude of nurses towards supporting patients on clinical trials. In most of those studies, nurses believe that they play an essential role in working with clinical trials patients. They also believed that they provide compassionate care and act as patients' advocates. Despite their important role in clinical trials, nurses believed they lack knowledge and information about most trials they work with (Saunder *et al*., 2020).

Participants in a qualitative study conducted on oncology nurses in different countries in 2022 reported that the nurses participated in the study have learnt about clinical trials mostly from exposure in the clinical setting. They had never been exposed to patients on clinical trials during their nursing studies (Flocke *et al.*, 2017). Therefore, since clinical trial studies are not taught extensively in the nursing schools, institutions housing clinical trials need to have a defined process to prepare the nursing workforce in keeping them up to date in the fast-paced discoveries of clinical research. (Wong *et al.*, 2012) On the same note, nurses working in cancer care settings require training and adequate knowledge to support patients who would like to participate in clinical trials or who are enrolled in trials and need further support in deciding their participation in trials as well as their retention in those trials (Jones *et al*., 2022).

On another hand, Zawada and Gągała (2021) suggested that to enhance knowledge about clinical trials, professionals involved in clinical trials require knowledge that translates into skills on various regulations and guidelines. One way to acquire this is by obtaining the International Council of Harmonization-Good Clinical Practice (ICH-GCP) certification. ICH-GCP is an international standard for the design and conduct of clinical trials to ensure ethical and scientific integrity. The certification provides an element of competence management through the building of clinical trials knowledge that can translate into skills.

The GCP certification follows a training that is taken online through accessing a free link on the NIH website. It covers topics on the ethical and regulatory procedures to be followed in the conduct of clinical trials to protect human participants (Arango *et al.*, 2016). Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC) is a new specialized Centre in the treatment of solid tumors in Muscat, Sultanate of Oman. The Vision and mission of SQCCCRC support research and thus the establishment of a specialized clinical trials department (CTD). SQCCCRC has an increasing number of clinical trials that are currently either open for accrual or undergoing the IRB review process.

Currently, 15 clinical trials have been opened at the center in 2022 to 2024 (Fig 1) with more in the review processes necessitating the nurses' involvement in supporting patients who are considering enrolling in clinical trials. Clinical trials were either investigator-initiated trials, pharmaceutical trials, academic trials or trials from corporate groups.

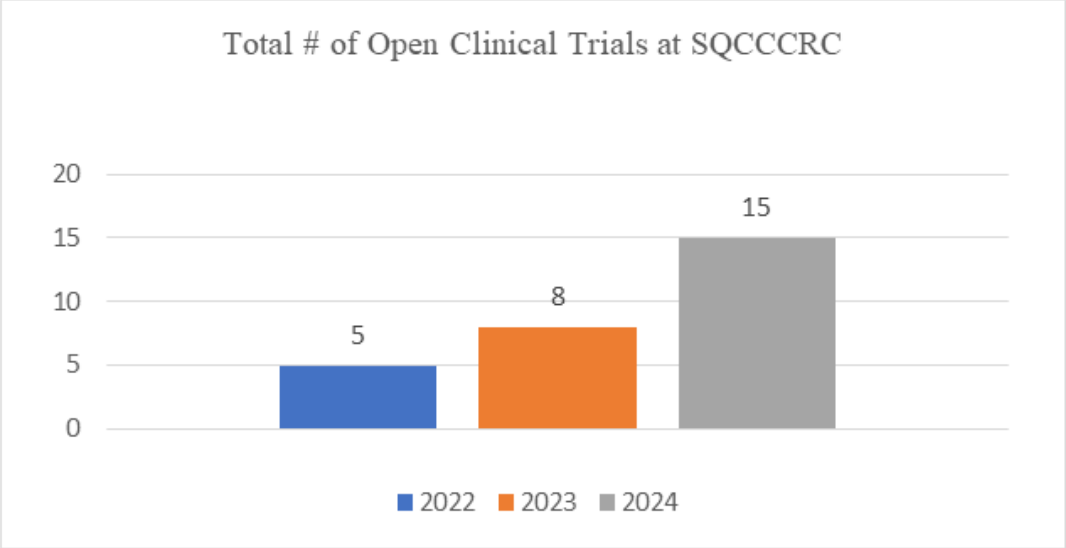

Fig 1: Total Number of Clinical Trials at SQCCCRC in 2022 to 2024

Moving in concordance with the strategic direction of SQCCCRC in opening more clinical trials and the importance of orienting nurses who joined the center from a variety of clinical backgrounds, and who are the front-line professionals in caring for patients on clinical trials, a specialized CTW was developed and offered to nurses.

The CTD is the only one of its kind in Oman. There is no much data about the perception of the medical community and the public about the conduction and participation in clinical trials in Oman as an Arab and Muslim country. Yet, there were studies conducted in other countries that identified some challenges and barriers. A study conducted in the UAE in 2022 exploring the barriers and facilitators of conducting oncology clinical trials found that there is a lack of clinical trial culture in the medical community. The author explained that the negative culture in healthcare providers (including nurses) was attributed to heavy workloads, lack of motivation, lack of research experience, knowledge and mentorship, lack of financial incentives and protected time, and lack of understanding of the importance of research.

Those healthcare professionals who have clinical trial experience migrated to the West for better opportunities, which resulted in a lack of expertise (Al-Shamsi, 2022). Hammad 2020 reported on additional barriers in assessing the knowledge, attitudes, and perception of healthcare professionals in pharmaceutical-initiated clinical research in UAE, Qatar, Bahrain, and Jordan found that the major barrier to participation of medical doctors and nurses in clinical trial activities was because of lack of time and resources, limited awareness about the legal protection associated with such studies and lack of necessary training and education. This highly reflects on the patients' culture in accepting clinical trials, coupled with some pre-existing wrong beliefs of fear, lack of trust, and becoming experimental subjects who may receive sub-optimal healthcare (Al-Shamsi, 2022).

In Oman, a study showed that the barriers to patients' participation was mainly the lack of knowledge of clinical trials despite patients' moderate level of interest, thus, it was recommended that patients should be educated and informed about clinical trials (Al-Lawati *et al.*, 2018).

Another study highlighted on challenges faced in Oman in accessing desirable clinical trials, (Mehdi *et al.*, 2022). The CTD department is composed of a team that works collaboratively in building the infrastructure of the clinical trials including the development of standard operating procedures, standardizing clinical trials practices, and educating staff. CTD started reviewing the feasibility of clinical trials and started working on activating trials in February 2022. The first clinical trials started in the out-patient department with selected experienced nurses played a major role in identifying potential trial participants and referring them to the research nurse who in turn ensured the process of patient recruitment into the clinical trials.

Then, trials started in the day care unit with oncology nurses in the unit setting started to support those patients in terms of providing them with information about clinical trials and referring them to the research team. New clinical trials were activated where patients required hospitalization and efforts were made to provide in-service education to bedside nurses in all nursing units of the center. To date, 636 clinical trials participants have been enrolled in the center with the majority being looked after by the clinical nurses (Fig 2).

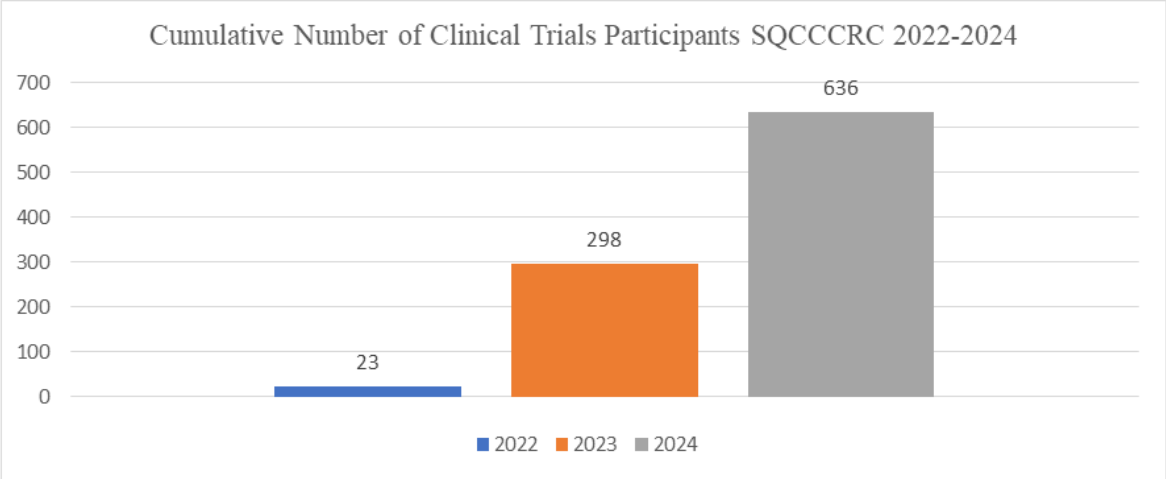

Fig 2: Total number of clinical trials participants from 2022-2024

All the nurses at the center are considered new not only to the Centre but the majority are new to the concept of clinical trials. Nurses are hired from different countries and come from a variety of educational backgrounds and experiences including new local graduate nurses. All nurses working at the Centre have a minimum qualification of bachelor's degree in nursing.

Since the Center vision and mission is to conduct and support clinical trials at the center, the clinical trial team had designed and implemented a clinical trial workshop (CTW) to improve nurses' knowledge about research ethics and clinical trials. To further enhance the nurses' knowledge about clinical trials, all nurses were encouraged to get GCP training

online. There is no expectation that the bedside nurses who attended the workshop and completed their GCP training will function as specialized research nurses, but expectations are set as to prepare them to function collaboratively in a setting that admits patients on clinical trials.

This study aims to examine the effect of nurses' knowledge before and after the CTW as well as to explore nurses' initiative to complete and attain the ICH-GCP certification from 2022 to 2024.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board (IRB) at the Center. The CTD focused on two approaches to increase the nurses' knowledge about clinical trials, conducting the CTW and encouraging nurses to complete GCP certification. The CTW was developed by the author and reviewed by the co-author. The main objective of the workshop is to provide the nurses with adequate information to build up their knowledge about clinical trials such as levels of evidence, the importance of clinical trials, phases of clinical trials, the history behind them, the infrastructure of clinical trials at the center and general training on Good Clinical Practice standards. Registration for CTW was interest-based and emails were sent out to all nurses notifying them of open dates for the workshop. The workshop was nursing-directed, however, participants from other healthcare disciplines who were interested in learning about clinical trials were allowed to attend. On the workshop day, a knowledge test was administered to the participants pre and post the workshop. The tests assessed the participants based on their baseline knowledge about clinical trials. Test results were compiled from a total of 21 sessions. The average score of the entire group of pretests was compared with the posttest.

As for the GCP training, education about the importance of GCP certification was communicated to the nurses starting from the nursing leaders. The nursing leaders included the head of departments; head nurses and units team leaders (shift in-charges) encouraged their teams to complete the training during their unit meetings and hurdles. The author sent emails to the nurse leaders and shared with the nursing staff an email on how to create an account on the National Institute on Drug Abuse (NIDA GCP) website. All nurses who took part in research studies or clinical trials had to have a valid GCP certification. Nurses were instructed to share the certificate with CTD team who kept a record of all completed certifications. The total number of certificates obtained by nurses at SQCCCRC was recorded. Statistical analysis was done for the CTW part using paired t-tests to compare 2 pretest and posttests. Each participant acted as their control. CI was set at 95% with Alpha value of 0.05. As for the GCP certification part, the number of nurses who completed the certification was calculated in percentage of the total number of nurses hired.

RESULTS AND DISCUSSION

Twenty-three (23) workshops were scheduled out of which 2 were cancelled due to low registration within the span of 3 years from 2022 to 2024. A total of 171 participants attended the CTW distributed over 21 sessions. About 96 %(n=165) of the participants were nurses and the remaining (n=6) were from other healthcare disciplines such as a physician (n=1), cardiology technician, (n=1) audiometry technician (n=1), a physiotherapist (n=1), a pharmacist (n=1) and a respiratory therapist (n=1). Healthcare workers other than nurses were excluded from this study analysis. The nurses who attended represented 50.6 % of the total nursing staff (n=326) at the center. Out of the 165 nurses' data analyzed, 11.5% (n=19) were also excluded because either the pretest or the posttests were not completed. This was due to coming late to the workshop or leaving early due to different reasons. The total pretest/posttest responses analyzed were from 146 nurses (88.5% of the participants) (Fig 3).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	posttest	87.1918	146	12.54856	1.03853
	pretest	68.5274	146	18.68401	1.54630

Paired Samples Correlations

		N	Correlation	Significance One-Sided p	Significance Two-Sided p
Pair 1	posttest & pretest	146	.372	<.001	<.001

Paired Samples Test

		Paired Differences					t	df	Significance One-Sided p	Significance Two-Sided p
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper				
Pair 1	posttest - pretest	18.66438	18.22627	1.50842	15.68306	21.64571	12.373	145	<.001	<.001

Paired Samples Effect Sizes

			Standardizer[a]	Point Estimate	95% Confidence Interval Lower	Upper
Pair 1	posttest - pretest	Cohen's d	18.22627	1.024	.822	1.223
		Hedges' correction	18.27358	1.021	.820	1.220

a. The denominator used in estimating the effect sizes.
Cohen's d uses the sample standard deviation of the mean difference.
Hedges' correction uses the sample standard deviation of the mean difference, plus a correction factor.

Fig 3: Paired t-test Analysis of pretest and posttest scores

Before the CTW intervention, participants had a mean score of 68.5% in their pretest (SD=18.68). After completing the workshop, posttest with the same questions was administered and participants mean score was 87.2 % with a (SD=12.54).

63% of the test takers showed improved scores (n=109) with an average increase of 19 % in the posttest compared to the pretest, while 30 nurses showed no difference (21%) indicating statistical significance. (CI=95%, t=0.05) (Fig 4).

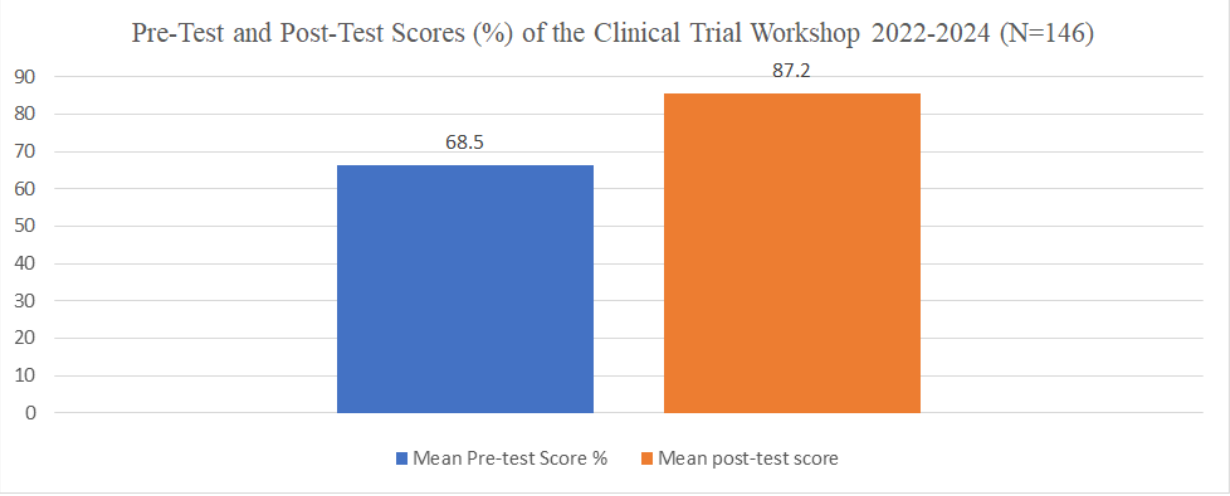

Fig 4: Clinical Trials Workshop- Pretest Versus Posttest Scores

By the end of 2024, 86 nurses out of a total of 326 nurses (26.4%) submitted valid GCP certificates and only nurses who have a GCP certificate were allowed to work with patients assigned to clinical trials. This was ensured during the one-on-one in-service education that nurses receive prior to being assigned to patients on clinical trial protocols delivered by the clinical research nurse coordinators.

When comparing the pretest and the post test scores, there is a significant statistical improvement in knowledge, which shows that the CTW did indeed improve the nurse's knowledge and awareness about clinical trials. Several centers across the globe shared similar initiative in cancer centers and other healthcare settings but did not combine both methods, i.e. A clinical trials workshop and GCP training. In Virginia in 2016, the University of Virginia Cancer Center collaborated

with the University of Virginia School of Nursing to develop an educational program focusing on cancer clinical trials. Oncology nurses who attended the program reported increased satisfaction, comfort, and knowledge about cancer clinical trials (Burnett *et al*., 2016).

A systematic review done in 2018 by Occa and Morgan to assess studies between 1998 and 2016 that covered the communication training programs designed to improve outcomes of clinical trial offered in different healthcare settings, found that 18 out of the 22 of the included peer-reviewed studies had training programs that were designed as workshops and those ranged from few hours to 3 days. The researchers found that the length of the training program indicated its effectiveness and positive outcomes. The systematic review focused on the communication components of those trainings and recommended that training health care professionals in effective communication skills for clinical trials is best done using a workshop and role play educational method. All those studies resulted in improving patients' participation in clinical trials due to improved healthcare professionals' communication skills.

In another study done in India, a training program was conducted around GCP training testing the awareness and perception of the participants of the GCP standards. 8 participants from the interdisciplinary healthcare providers took part in the study. Participants took pretest and posttest. Results suggested that there is significant improvement in the scores which reflected improved knowledge about the participants' knowledge of clinical trials (Sharoo *at al.*, 2019).

In Finland, an in-house GCP training program was developed, nurses and physician scored better in the posttest of GCP attitudes and knowledge comparing to the pretest (Kuusisto *et al.*, 2011).

Scant data was found in the Arab world which was mostly focused on research workshops rather than clinical trial workshops that encouraged evidence-based practice (Alomari *et al.*, 2023). Therefore, this study is important because there are no similar studies in Oman that covers the capacity-building approach in clinical trials that encompasses a CTW and alongside encouraging nurses to complete GCP certification at a cancer center.

Despite conducting 21 workshops between 2022 and 2024, there were many practical limitations including the availability of nurses to attend the workshop due to their busy schedule of nursing duties and responsibilities. Add to that, as mentioned earlier, the application was interest-based and was not done based on needs. Therefore, despite the interest of some nurses in attending the workshop, their applications to attend the workshop were not always granted based on the needs of providing the nursing services.

Regarding the GCP, despite the encouragement to obtain the GCP, it is all self-effort for self-development and was not linked to role benefits or privileges except taking care of patients on clinical trial which sometimes might be more challenging compared to other patients. On another hand, even though this study reported the positive effect of knowledge improvement post training, the reported pretest and the posttest occurred on the same day of the workshop. This is not an indication if long term learning has occurred and there was no follow test of knowledge done for participants. Another limitation is motivation and interest to learn about clinical trials as this study did not assess the reasons for the nurses to participate in CTW.

In this paper, it was not possible to assess the knowledge level of those staff who have completed the GCP training except for the fact that they passed the assessments in each module. The certification is also not a guarantee that the participant reviewed all the contents prior to attempting the quizzes. Add to that, the GCP is designed based on the United States Rules and Regulations and not all the educational materials are relevant to SQCCCRC setting or the country's rules and regulations. This might cause some confusion for novice nurses who have limited nursing experience as well as clinical trial experience.

CONCLUSION AND RECOMMENDATIONS

The growth of clinical trials at SQCCCRC-UMC has required having trained nurses who will follow the clinical trials protocols to the T. Nurses' role are unquestionably vital to the progress of trials as they provide clinical care for the patients as well as implement study specific interventions. Thus, the implementation of this capacity building approach of a structured clinical trials workshop and encouraging nurses to complete the ICH-GCP certification is a positive step towards the direction of improving their knowledge on the requirements of clinical trials. This paper can by no means translate the knowledge gained from attending the CTW and completing the GCP certification into competencies for nurses to provide care to patients on clinical trials protocols. To further assess this point, it is recommended that a follow up study is conducted to assess the nurses' comfort levels in working competently with patients on clinical trial protocols.

Conflict of Interest: The authors have no conflict of interest to declare.

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