Clinical Trials: The Educational Need Among Healthcare Professionals in Mauritius

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ABSTRACT

Background: The introduction of the Clinical Trial Act in Mauritius in 2011 has revolutionized the sector of Medicine and Health Sciences in the country leading to a numerous trial being registered and performed in different settings. One of the major challenges face by Clinical Research Agencies is the recruitment of participants which is closely related to the awareness and understanding of clinical trials. Several studies have shown mixed awareness among participants in trials. No study on the awareness of clinical trials has been performed in Mauritius.

Objectives: This study aims to investigate the perceptions and beliefs of participants at a Clinical Trial Workshop. A qualitative survey was organized to analyze perception of participants who were predominantly health care professionals.

Results: The study confirmed the misperceptions and misbeliefs of doctors and pharmacists regarding clinical trials urging campaigns to promote awareness of clinical trials. The main concerns relates to safety and consent procedures of clinical trial participants.

Conclusion: Educational campaigns among the health care professionals and the general population should be set up to increase awareness about clinical trials.

Keywords: clinical trials, Mauritius, health care professionals, perceptions, beliefs

1. INTRODUCTION

Mauritius has seen major developments in the life sciences and research sector for the past few years. Clinical research is one key area which is being promoted by the Government of Mauritius. Clinical trials (CT) are referred to as a prospective study involving humans to assess the effects on health (1). Clinical Research Organizations (CRO) are offered attractive services for example counselling on investment opportunities in Mauritius, assistance with the occupation permits, licenses and clearances and the identification of joint venture partners (2). Organizations such as Centre International de Développement Pharmaceutique (CIDP) and CAP Research, both located in the first regional hub dedicated to biotechnologies in Mauritius have started to develop clinical research in the country.

Clinical research conducted in Mauritius can provide solutions to a wide range of diseases like diabetes, cardiovascular diseases, cancer and hypertension which are prevalent in Mauritius and countries of the region. Prior to the adoption of the CT Act in 2011, projects for conducting clinical research on human beings were banned. The act provides the legal framework for the conduct of CT which are similar to those related legislations in Europe, ensuring the safety of patients and the ethical conduct of CT on human beings in Mauritius.
The Act caters for the setting up of regulatory bodies which oversee and regulate the process from the application for a trial license to the successful completion of the CT in meticulous observance of international norms (3). These institutions are:

1. Clinical Research Regulatory Council (CRRC) responsible for the regulation and control of trial licenses.
2. Ethics Committee (EC) to advise the CRRC regarding welfare, safety, health and protection of human subjects participating in CT.
3. Pharmacovigilance Committee (PC) to monitor all clinical trials being performed and ensure Good Clinical Practice (GCP).

The awareness about the running of clinical trials in Mauritius is limited among the general population and health care professionals (HCPs). In 2017, a clinical trial workshop was set up at the University of Mauritius (4) in collaboration with CIDP, Cap Research and Board of Investment, who are the major drivers of CT in Mauritius. One of the feedbacks received following the workshop is the scarcity of knowledge among general population and HCPs that presents a barrier during the recruitment process of participants.

Perceptions and knowledge of individuals about CT are scant in various developing countries. A cross-sectional study performed in Oman showed that patients were less aware and keen to participate in CT but they could be motivated appropriately (5). Out of 1000 participants only 340 were willing to participate. Fear of adverse effects drove the unwillingness to participate in CT. The findings were mirrored in India where investigators reported good awareness about CT but heightened levels of fear regarding adverse reactions and procedures deterring participation into CT (6).

A study on the perceptions of CT in Saudi Arabia demonstrated good knowledge regarding CT but there were multiple misconceptions and personal barriers towards participation in the research (7). 73.8% agreed to participate in CT following discussion with the family doctor. The role of the family doctor can be pivotal in the participants recruitment (8).

Bhowmick et al furthered the poor awareness theme of professionals in an Ethics Research Committee towards pharmacovigilance in East India (9). They aimed to evaluate the awareness of pharmacovigilance procedures among medical and non-medical committee members. Non-medical professionals had better knowledge compared to medical members. A systematic review in NHS, England in 1998 reported on the limitations of dissemination of research findings due to lack of awareness among healthcare professionals (10). Rahman et al studied the participation of physicians in CT reinforcing the education of doctors about clinical research at an early stage while Bylund et al reported poor knowledge among primary care physicians on CT (11).

Knowledge and attitudes towards research ethics prior to research in the Middle East was studied revealing both a mixture of positive and negative attitudes towards the research ethics committee (12). Lack of training in research ethics was reported in almost half of the participants but the attitudes towards Research Ethics Committee was positive in more than 90% of healthcare professionals.

This study aims at evaluating the Knowledge and Beliefs about CT in Mauritius among a group of individuals attending a clinical trial workshop.

2. METHODOLOGY

A qualitative study with thematic approach was designed. Departmental ethical approval was obtained following screening of proposal. All information regarding the study was provided in written format to participants and implied consent was received if participants returned the filled questionnaire. Out of 98 participants present during the workshop, 21 participants responded to the questionnaire. The audience of the workshop was healthcare professionals, as well as students and academics from various institutions.

The open ended questionnaire comprised of three sections: The first section covered the demographic data of the participants; the second section evaluated the knowledge of the participants and the third section explored the beliefs of the participants on CT.

3. RESULTS

Out of the 21 responders, there were 8 doctors, 2 pharmacists, 2 academics and 7 students. There were 11 female and 10 male respondents. Most respondents (57.1%) were aged between 25 and 35.

Knowledge on clinical trials

Understanding of clinical trials

Overall the participants defined CT as research on humans to test efficacy and safety of medications. One participant stated that clinical trial is “a prospective epidemiological study to primarily access non
inferiority of products and the effect of therapy on end points during hospitalization” while another covered all aspects of CT such as investigation, data collection and protection, intellectual property rights, licensing and financial consideration.

Clinical trials performed in Mauritius
Most of the participants acknowledged that there is a lack of information, knowledge and awareness about the CT performed in Mauritius. One participant commented that “Research in the hands of a few, not properly marketed, research needs to be included in graduate/post graduate studies”. Even though the institutions are well set up and trials are performed according to international standards, the real benefits of the outcomes of these trials are still obscure.

Procedures to set up a clinical trial
Some participants had poor knowledge about the procedures. The participants referred procedures to hospital care set up, trained doctors, trained staff, regulatory authority, data management. The recurrent themes were ethics approval, recruitment, funding, site and consent. There was mention of application for trial license, evaluation by Clinical Research Regulatory Council (CRRC), approval for Ethical Clearance (EC), payment for license fee and application granted by CRRC.

“Selection of trial subjects, stakeholders, regulators, investigators, sponsors, ethical consideration, ethical guidelines, management and funding” were also reported.

Responsibilities of those organizations
Relevant organisation had responsibilities in the area of Ethics, quality assurance, protection of patients and pharmacovigilance. One participant declared that Board of Investment (BOI) is the drive development in CT while others mentioned that the organizations should keep information as confidential but also communicate outcome of research. Insurance coverage, patient compensation, funding of CT, recruitment of volunteers and the MOH a facilitator, were also discussed. Business interest of commercial organizations was also reported.

Pharmacovigilance
There were a variety of comments from different participants but the main focus was on patient safety. It was recognized as an important aspect of CT. Keen participants elaborated on patient safety in terms of drug dosage, withdrawal of drugs for human use and monitoring of drugs and side effects as well as to “regulate use, misuse and abuse of pharmaceutical products”. It can be inferred that pharmacovigilance is understood to be the process regulating the safety of medications in trials and post trials and a body to safeguard standards of procedures during CT. Others reported that:

“There needs to be a follow up of data collection even if pharmacovigilance is not life threatening”
“There is lack of pharmacovigilance in Mauritius and a lot of over the counter prescribing”
“It is the evolution and innovation of drugs used in CT”

Ethical issues concerning clinical trials
Where each participant had their preferred words and phrases to describe ethics, most comments were on the principles of patient safety, rights and confidentiality. Participants described the procedure of consent as flawed leading to ‘coercion into recruitment’. Risks and benefits are important aspects of consenting for a procedure and investigators need to ensure that the potentials risk are clearly explained prior to signing of contracts. Risk management does not end with a good explanation but it entails long term monitoring of side effects and complications among participants.

Knowledgeable participants, in the field of research mentioned the Helsinki’s guidelines, Nuremberg Code and randomization to demonstrate their beliefs.

Terms commonly used by participants were: consent, toxicity, rights, safety, risk, human exposure, training competent staff, data protection, social and clinical value, scientific validity, falsification of data, violation of subject rights, health status, sample population, targets subjects, data collection, morality and religion/culture, universal morality. Beneficence versus maleficience was also discussed.

Other interesting comments included:

“There should be adequate compensation in case of complications”
“The Helsinki's guidelines should be strictly ensured”
“The randomisation should be particularly emphasized”
“The usefulness of the CT for society and patient”

Beliefs on clinical trials

Importance of clinical trials
Participants uniformly believed that CT are important and expressed their beliefs strongly. Terms such as safety benefits, validation of new products, safety of medicinal products prior to marketing, side effects and effectiveness of new drugs, evidence of no harm,
Advantages and disadvantages of clinical trials

The responses received when queried about the pros and cons of CT were wide and varied. Some mentioned the enhanced access and availability of novel treatment with a view to improve outcomes of medical conditions and better quality of life while other advocated refined safety of medications and long term complications. General benefits have also been ascribed to CT such as progress in the field of medicine, economic boost for the countries, societal wellbeing and research innovation.

The disadvantages described by participants overlapped with their feelings on ethics and human rights. Some disadvantages were related to administration difficulties such as time dedication of participant, hospital stay, expensive and recruitment challenges while others were more ethically defined such as beneficence of the outcome and placebo participants being deprived from the treatment implicating restrain on patient’s choice. Other interesting comments included conflict of interest, personal gain and vulnerability of patients.

Challenges for performing clinical trials in developing countries

Some challenges that were pronounced in this study were the audit of the legal framework and the rigor in application of rules and regulations in line with international practices as well as ethical issues such as respect for participants’ rights, good governance and good practice. Technical barriers include lack of qualified dedicated man power, cost factor (cost to start and maintain studies), financial mechanism, subject participation and recruitment due to lack of awareness.

Other concerns presented as lack of appropriate personal injury laws and trend of compensation for personal injuries which raise the risk of unethical behavior.

Ethical challenges include money ethics, exploitation of innocent and vulnerable population, for example illiterate and uneducated participants may not be fully aware of the implications so volunteers can be coerced into participation due to lack of knowledge.

Participant challenges can be lying about their health status and participants not abiding to exclusion and inclusion criteria while some patients are dying due to other health related problems or age confounding the results.

“Personnel needs training, information of outcome of research to participants, absence of legal framework to protect care safety and minimize risk to trial subjects, education and community participation, sustaining the project, minimizing loss to follow up” were some pertinent issues raised by a participant.

Clinical trials on children

Different foci have been identified with this topic, the first being the ethical component of trialing new medications in children. Participants demonstrated awareness of the dilemma of accurate consenting procedures for children based on the convention of right for children under 18 years and in the best interest of the participating child. “The guardian consent” can be questionable. Child age can be another deterring factor when considering trials on children. Safety of children and the responsibilities of guardian can be blurred in the arena of compensation for participating.

Another aspect portrayed was the risk to the child. In low and middle income countries, where all the regulatory or precautionary steps regarding CT are in a pre-term phase researchers may face death of participating child. Safety of children and guarding consent seems to be the prevailing theme in this section. A few participants’ felt against trials on children if there is no need while others encouraged trialing in children with cancer to develop new curative treatment.

Use of biomedical samples for clinical trials

The response to this question was mixed. 6 out the 21 responders did not address this question while a few described the ethics of retaining biomedical samples post trials. The retention of biomedical samples needs to be within set ethical and legal framework as we venture in the field of genomic analysis. The theme that evolved here was a semi agreement of using biomedical samples following clear and vigorous...
consenting procedures for the advancement and progression of research and innovation in medicine contributing holistically to betterment of society through development of drugs. Respect to human life and human right were other enlightening issues that emerged.

4. DISCUSSION

Clinical trial in Mauritius is getting more attention with the clinical trial act of 2011. There are agencies involved in running of trials within an established legal framework. The compound work of these agencies and new legislation in CT warrants the education of general citizen and healthcare professionals about CT. The Workshop on Clinical Trial was open to both general public and healthcare professionals. The strong participation of healthcare professionals and academics might imply the marked lack of knowledge among general population and students. The responses obtained were mixed. According to Dr Edward G. Mansour, one of the factors which can hinder the recruitment of patients is the lack of awareness of CT (13). For some participants, this study provided a platform to display their knowledge and strong feelings. However the proportion of well knowledgeable participants was small, emphasizing the urgent need to promote awareness campaigns to educate the nation. Pertinent issues such as ethics, procedures and consent were primarily discussed. The maturity of development in this field was identified as fundamental concern for responders influencing recruitment of participants. Misconceptions are the laid foundation for minor levels of involvement and the fear of risk and complications are strong barriers to contribute to CT. Burke et al reported misconceptions as a concrete barrier to participation in CT by cancer patients (14).

The recurrent mention of the need to provide a safe and honest environment for the exchange of information between prospective participants and investigators was the essential concern of all participants, which were mostly HCPs. Similar results were reported by Potter et al in their study aiming to assess the knowledge and beliefs on CT on cancer patient (15). This quantitative study demonstrated the unwillingness for people to participate in CT due to the perceptions about the lack of safety. Patients scored low on the knowledge reinforcing the need to further educate patients about CT. Healthcare providers need to portray information underlining the safety of trials. Our study was based on statements from HCPs and like several other studies reinforce the education of healthcare professionals on Clinical Research to boost recruitment rates (11).

Another survey based study on the knowledge of CT (16) demonstrated that knowledge of participants on CT was limited especially on topics such as rationale of study, randomization and placebo and patient protection. Participants were less informed about the agencies conducting CT in Mauritius leading to the belief that CT was performed on a selection of people. A qualitative study performed in Ghana (17) on the perceptions of CT showed reasonably higher levels of knowledge among participants reinforcing the need for education among our population. Participants reported that the quality of care is better in CT than in routine care especially when dealing with children. Our findings however reveal fear of safety and complications when children are involved in trials. Various participants were against children participation in CT. The question that presents here is whether this perception is related to lack of information regarding safety of CT, prior experience of safety issues or just blind opinion. The study performed in Ghana demonstrated the people who had prior participation in CT were more positive and open to CT in children. Children participation in CT has been subject to extensive debate leading to updated policies and guidelines (18) to make this process easier. Consenting in children remains the biggest dilemma faced by all stakeholders of clinical research (11). Joseph et al emphasize the urgent need to promote awareness regarding CT in children for the strengthening of evidence based therapies in children (19).

Poor recruitment has been associated to the inadequate knowledge of participants on CT. Participants in this study acknowledged the challenges of recruitment. Better understanding and knowledge about CT was demonstrated to be statistically significant to participation in trials (20).

5. CONCLUSION

Despite a small sample size, this study reveals a mixed knowledge on CT. The findings concur with international results urging campaigns to promote awareness among healthcare professionals amongst strategies to enhance recruitment in trials. A more systematic research is required to quantify the levels of awareness about CT among the public in Mauritius.

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REFERENCES

2. BOL. BOARD OF INVESTMENT Clinical Research in Mauritius. 2011.
4. BOL. BOARD OF INVESTMENT eNEWSLETTER. Board of Investment. Mauritius; 2017;