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Potential Roles of Pharmacist in Clinical Research Field in the Developing Countries

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Abstract

Background: There are many challenges for clinical research in the developing countries including shortage of qualified research staff who are interested and able to conduct research project.
Objective: To determine the various potential roles of pharmacist in clinical research field in the developing countries.
Methods: Literature review, personal experience and discussion with experts and pharmacists in the field.
Results: Pharmacists can play vital roles in the research area in the region due to their training, education and qualifications. The pharmacist's knowledge of pharmacology and other drug related issues will be a vital strength to the research operation. Pharmacist can function as scientist in phase 1 unit, clinical research coordinator, clinical research associate, reviewer, research clinical pharmacist in Investigational Drug Service (IDS) pharmacy and principal investigator for various studies.
Although pharmacist in the Arab countries require further training in regulatory and ethical issues, such as human subject protection, but that is not different from all other health care provider, including physician.
Conclusion: Research career track is a viable option for pharmacist in the developing countries with potential major contribution to the advancement of science and patient care.

Introduction

Improving patient care is the ultimate goal of the health care professional. If we are looking to improve this care, we have to think about patient enrollment to clinical trials and the resources available to locate appropriate clinical trials for our patient's population.

During the past 10 years we have seen a remarkable change in biomedical research output.
For instance, the number of published biomedical articles was 480,000 in 2000. By the end of 2009, that tally reached 800,000 representing 67% growth. Who is behind this unprecedented growth? Asian countries – including China, India, Malaysia, Singapore, South Korea, Taiwan, and Thailand – account for 32% in 2009 of the global R&D, up from 24% in 1999 due to the growing of the number of workers engaged in research. Turkey and Iran, two of the five countries that produce more than 1000 papers annually, also show a marked annual growth. Egypt, Saudi Arabia and Jordan have a substantial output but this is not growing at the same rate as the two leading countries. [1]

Research maybe defined as the search for an answer driven by a specific question or idea, directed to solve problems of society rather than publishing data only, for that; it is not just information gathering process or rearranging of facts. Good research has to be based on 4 pillars: vision, strategy, human resource and logistics.

One of the most common challenges of research in Developing countries is the absence of qualified, well trained research staff. To have a successful research project, one has to include health care professionals with different background to enrich your projects, including physicians, pharmacists, nurses, technicians, and so on. [1]

Increasing number of hospitals, pharmaceutical companies, and research centers all over the world is a clear indication of the potential growth of research field for all health care professionals. [2]

Traditionally, being a pharmacist was associated with a lifetime career as a chemist [3], although many think clinical pharmacology is simply the study of pharmacokinetics, pharmacodynamics, and pharmacogenetics, instead the role of clinical pharmacologist cover all aspects of drug discovery, development, formulation, production, quality control, quality assurance, packaging, storage, and marketing drug for clinical use [4].

Why would Pharmacist enhance clinical research?

Pharmacist can coordinate the research and the development process that brings new medication from the laboratory to the familiar corner pharmacy. As the medication expert, this opens the opportunity for the pharmacist to:

- Understand the different drug development process and phases.
- Address medication related problems and improve patient's outcome with their interventions.
- Assist potential participants in understanding and finding an appropriate clinical trial

There are many barriers of pharmacist involvement in the research field including culture and society pressure, lack of confidence to do research, competing care tracks, absence of pharmacist involvement in research projects, lack of proper research skills and knowledge and lack of recognition/ recommendation. [5]

There are seven main areas/roles where the pharmacist can be involved in clinical research field: Phase 1 unit, clinical trial coordinator, clinical research associate, regulatory bodies and investigational drug service, Principal Investigator and community research pharmacist.

This diversity means pharmacist have a broad range of roles and can start in any one of those areas, develop a good career then can move to more advanced role or to a role that maybe will be more interested to the individual .[6]

1. Phase 1 Unit (Development Therapeutics)

A pharmacist working in phase 1 unit will manage all aspects relating to Investigational Product (IP), including not limited to formulation and validation process, knowledge of analytical test methods, handling software for drug development, statistical experimental design, quality control and quality assurance.

2. Clinical Research Coordinator (CRC)

The role of CRC will focus on reviewing the study protocol to be able to discuss it with the patients and physician, involving in patients screening process, knowledge about the available resources, results of previous research, and the type of requested laboratory/radiology tests needed in the study.

CRC can advise patient on the correct usage of the study drug, how study participation will affect their daily life, guide patients for proper management and reporting side effects, and the ability to withdraw from the study at any time and the alternative plan available.

CRC will transfer the data to electronic or paper Case Report Form (CRF), updating the study sponsor and regulatory bodies on the study progress status.

3. Clinical Research Associate (CRA)

Pharmacist can play a CRA role or a "Monitor" [10], most of the time, CRA will work in pharmaceutical company or Clinical Research Organization (CRO) which is an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. CRA will involve in overseeing the regulatory documentation such as clinical trial approvals, permission marketing approval, source documents verification for the collected date, monitoring the conduct of clinical trial in compliance with study protocol following international guideline and national regulatory requirements.

4. Regulatory Bodies

Being a pharmacist in regulatory bodies like Food and Drug Administration or Scientific Review Committee or even Institutional Review Board (IRB), will get the benefit of having experience to evaluate the study design and methodology, assess the study drug and comparator, ethical point on blinding procedures, formulation and administration issue considering possible side effects and interactions. You can work also as Inspector to inspect the quality of data and clinical trial process. It's an opportunity for the pharmacist to work with other professionals in protecting the rights and welfare of human research subjects. [11]

5. Investigational Drug Service (IDS) Pharmacy

A pharmacist who works on IDS, or "research pharmacy", will provide valuable support to clinical trials investigators and sponsors.

They have to cover the following procedures related to Investigational Products (IP)[8]:

* Receipt and recording the delivery of IP.
* Safe handling and storage of IP.
* Proper code breaking (in Randomized Blind Clinical Trials)
* Preparation and dispensing of IP in accordance with study protocol to eligible patients only and institutional SOP.
* Maintaining drug accountability records and ensuring that all IP(s) are labeled with an appropriate pharmacy research label.
* Return and disposal of unused IP(s) in accordance with sponsor/ institution regulations.

* Maintaining a pharmacy study file covering the recruitment/ withdrawal log of all enrolled study patients along with the approved consent forms.
* Training other clinical pharmacy staff about the proper handling of IP(s).
* Archiving the clinical trial documentations and keeping an accurate records with sufficient information to provide a full audit trial from the receipt of the IP(s) to their removal or destruction from the site.

Sometimes, the IDS pharmacy will not be available in the investigator site, in such case, its important to investigator and sponsor to choose a qualified staff to store and dispense the IP as clearly instructed.

6. Principal Investigator

Pharmacist can develop and lead their own research project especially that depends on intervention with medications.

Through an American Association of Collage and Pharmacy database, the number of faculty with a Pharm D. as their terminal degree who received NIH funding increased from 5 in 1998 to 24 in 2007. Most important, clinical pharmacist as principal investigator development is a priority needs to continue making substantial and meaningful contribution in improving public health and meeting the needs of patients. [11, 12]

An increase was noted in the number of publication involving pharmacist as an author in major medical journals in 2003 compared with 1993. Pharmacist must continue to have an active role in clinical research field even with limited training opportunity and funding resource. [13]

7. Community Pharmacist Research Practice

Even the community or retail pharmacist may play a limited role in his/her discussion with the patients about the clinical trial participations when their physicians suggest to be enrolled after the failure of their standard of care regimen.[6]Although community pharmacist provide a potential channel for difficult -to-reach individuals in remote area, as these potential participants visit their pharmacies much more often than city and suburban counterparts. [7]

Pharmacy practice-based research, particularly in community pharmacies, has two significant advantages. First, it uses an existing infrastructure to provide primary care services to patients at the community level and serve as an excellent public health professional approach. Second, the projects have the potential to provide much needed data to demonstrate the values of pharmacist clinical activities. [14]

Recommendation

This expanded diversity roles and the overwhelming mandate of pharmacist in research field is important to start gaining different core skills that can lead them to unique opportunities overseas.

Still we have to change the health care professional's perception about the unique role of pharmacist in research field by following the suggested steps: [9]

- Develop a comprehensive set of Standard Operating Procedure (SOP) to implement the IDS pharmacy, it must fulfill in addition to and not in place of basic local requirements that govern pharmacy practice. Individual practitioners can't work outside their practice as defined by their license. Thus pharmacist can't administer drug as nurse, clinical research coordinator can't dispense and store medication as pharmacist and so on. These SOP will help pharmacist when assessing new studies by identifying the compliance of the study protocol with current local institution practice, and which are not suitable.
- Pharmacist has to gain through knowledge of all worldwide and national guideline such as Good Clinical Practice (GCP), Code of Federal Regulation (CFR), familiarity of these guidelines will help in safe medication dispensing practice and promote high quality research.
- Seeking a master, fellowship or diploma degree in clinical research field, quality control and assurance, there are also international organization where you can be certified in different mentioned roles. As American College of Clinical Pharmacy that work in collaboration with other pharmacy organization to develop strategies for increasing the numbers of clinical pharmacy scientist involvement. [15]
- Looking different in pharmaceutical companies career by working as CRA, clinical trial unit manager, which allow them to travel to investigator sites to train study staff, oversee compliance with study protocol and proper safety reporting.
- Enhance research curriculum in pharmacy schools to increase the awareness and interest of pharmacy students in research.
- Develop a practice-based research network; this network will help in providing descriptive data regarding their practice sites, characteristics of patients served, and clinical services provided as a first step in collaborative research efforts. [16]

Conclusion

Clinical research offers to pharmacist great career opportunities to utilize their strength into advancing the health care and improving patient care.

We have to work on highlighting the importance of their role for the future of research in pharmacy community. [17]

It's clear that clinical pharmacist with appropriate postgraduate training and/or experience are capable of conducting meaningful research. [18]

Clinical research field in Arab countries needs to be addressed

in well-designed strategies and plans in order to overcome the shortage of qualified research staff (both physicians and non-physician's) and resources.

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