American Journal of Pharmacology and Pharmacotherapeutics

Editorial

Clinical Pharmacist Active Role in Registrative Clinical Trials

Luisetto M*

Applied Pharmacologist, Hospital Pharmacist Manager, Italy, PC 29122

*Corresponding author e-mail: M.Luisetto@ausl.pc.it

ABSTRACT

The gold standard for a registrative trial is to obtain the best results in clinical outcomes under research to be sure that the drugs can give the best results. But are we sure that the actual registrative procedure are really the best?

Keywords: Pharmaceutical care, Pharmacological therapy, Pharmacodynamics.

INTRODUCTION

We start this work observing recent scientific works published in 2016 that reported:

"A last question: Is request clinical pharmacist presence in clinical trial for drug registrative use? If the pharmacist presence in medical team gives improving in some clinical outcomes why is not request by regulatory clinical pharmacist presence in registrative trial?" Luisetto[1], J Pharma Care Health Sys 2016, 3:2

A 2015 research article[2] by M. Luisetto, F. Carini, G. Bologna and Behzad Nili A Pharmacist cognitive service and pharmaceutical care today and tomorrow outlook. UKJPB 3: 67-72. We have seen that a general improvement of clinical outcomes can be achieved with a stabile presence of clinical pharmacist in many medical team[2].

The same in example a reducing in mortality rate can be observed when clinical pharmacist is part of ICU Multi-professional healthcare equipe.[3].

The same we observed that in oncology field for example: "We submit to the scientific community "Clinical pharmaceutical care as a new discipline". Discipline intended to improve clinical and economic endpoint in pharmacological therapy reducing therapy errors and with a more rational application

of resource in medical team (clinical pharmacist). This new approach takes advantages using the Management and ICT principles. We ask also to international organization involved in hospitals accreditation and University to recognize this new health care professional activity. We think that core training must include principles of Management, ICT Professional social media, psychological behavior skills for team working added to be added to the classic clinical pharmacy programs.

THEORY AND PRACTICAL APPLICATIONS

"Every drug is registered for specifically indication, at the same time every drug to be a rational therapy need a rational decision making system that require a multidisciplinary team that can cover all aspect of pharmaceutical molecular metabolism kinetics and pharmacodynamics[4] this create great possibility for clinical pharmacist but it must increase expertise in field of diagnostic (lab medicine and imaging) for the high relationship whit drug therapy. The old algorithm was "physicians - patients - classic pharmacist" Luisetto editorial and useful instrument in today healthcare j. ph. care and health omics 2016[1].

CLINICAL RESEARCH AND DRUG DEVELOPMENT

"Both these things are related to clinical trials. There are countless clinical research organizations present in the country. Clinical research coordinator, clinical research associate (CRAs), research statisticians and higher positions (with optimum experience) are suitable posts for CPs in clinical research organizations. CPs can even work as principal investigators and patient educators in clinical trials. Pharmacists can play a role in enhancing patient participation in clinical trial research. Skills needed to work clinical research organization include knowledge of statistical, medical and pharmacologic terms[5], pharmacovigilance, sincerity in documentation, ability to travel extensively (especially for CRAs)[6]."

DISCUSSION AND CONCLUSION

According APha "Clinical trials: Pharmacists play an important role in the clinical trial process. Abdelghany is often involved with the design of the protocol and determining how a drug will be dispensed, stored, and even manufactured. "You feel like you are part of a group that enhances patient care and moves science forward," said Abdelghany. "Trying to find a cure for a disease, improve what we know, or enhance the knowledge we have in disease states is very rewarding."

In addition to the daily activities that include dispensing research drugs, randomization, record keeping, and inventory management, Abdelghany regularly meets with investigators, site coordinators, study monitors, and sponsors' representatives to coordinate study logistics. Clinical trial sponsors include drug manufacturers, federal entities such as the National Institutes of Health (NIH), foundations, or cooperative groups[7].

The introduction of clinical pharmacist in medical equip involved in registrative trial can give general positive results helping the clinicians to complete in more rational way

their works as well as we have seen in clinical outcomes in medical team[2].

The clinical pharmacist are considered the expert for excellence of drugs and their knowledge in medicinal chemistry, pharmacology, toxicology, metabolism, molecular biology, kinetics, and dynamics, structure activity relationship, pharmaco-economy can be useful instrument also in clinical trial activity.

For example, what are the global results in clinical trial is many patient go out of the study by incorrectly undetected toxicity or not optimal solution chooser? The same for other ADR, interaction or since the patient's pathological status.

In these cases the results of clinical trial can be incorrect.

The same way also pharmaceutical industries can have damage if not correctly managed the drugs under study.

Under the light of these papers we can observe that with stabile presence of clinical pharmacist in many medical teams we can see improving in clinical outcomes that the decision-making system in drug therapy is often multi-professional including the clinical pharmacist.

And this 2 factor drives to this consideration:

Why also in drugs registrative trials is not required in officially way the clinical pharmacist presence with active role?

For this kind of results and in order to have improving in clinical results starting from the registrative trial we ask to the public institution involved to introduce this requirement in every new clinical trial.

We think also that the same pharmaceutical industries, institutions, insurances and patients can have advantages to a more efficiently procedure.

REFERENCES

1. Luisetto J. Editorial an useful instrument in future health care systems. Pharma Care Health Sys. 2016;3:2.
2. Luisetto M., Carini F., Bologna G., et al. Pharmacist cognitive service and pharmaceutical care today and tomorrow outlook. UKJPB. 2015;3:67-72.
3. Nili-Ahmadabadi B., Luisetto M., Nili-Ahmadabadi H., et al. Clinical impact of pharmacist presence in ICU medical team on mortality rate. Clinicians Teamwork. 2016;1:15-33.
4. Luisetto M. Editorial efficacy of oncologic drug therapy: Some to rethink in the management of the system? Journal of Business Management and Economics. 2016;4:07.
5. Luisetto M., Pharmaceutical care and toxicology, a synergy in high risk situation. J App Pharm. 2016;8:4.
6. Prasanna RD., Raghuram V., Chaitanya Lakshmi CH., et al. Clinical pharmacists: The major support to Indian healthcare system in near future. J Pharm Bioallied Sci. 2015;7:3:161-74.
7. Amy KE. Tomorrow's drugs: Improving lives through clinical trials. APhA. 2013;19:4:2-4.