

## AD HOC STUDY OF THE ROLE OF HOSPITAL PHARMACISTS IN CLINICAL TRIALS IN BULGARIA

Liliya Bogdanova<sup>1</sup>, Evgeni Grigorov<sup>2</sup>, Valentina Belcheva<sup>3</sup>, Ilko Getov<sup>4</sup>

<sup>1</sup>*Faculty of Pharmacy, Medical University of Sofia*

<sup>2</sup>*Medical College, Medical University of Pleven*

<sup>3</sup>*Faculty of Public Health, Medical University of Sofia*

<sup>4</sup>*Faculty of Pharmacy, Medical University of Sofia*

### ABSTRACT

**PURPOSE:** The aim of our research is to study the role and responsibilities of the hospital pharmacists in conducting clinical trials in Bulgaria.

**MATERIAL AND METHODS:** A special questionnaire was developed in the Faculty of Pharmacy, MU-Sofia. A total number of 30 hospital pharmacies were contacted and included in the study. Three of them refused to take part in the survey. The interview was via phone and included 4 questions (3 closed and 1 open). Mainly the head hospital pharmacy manager of the participating health institutions was interviewed.

**RESULTS:** Analysis of the results shows that current practice in Bulgaria allowed hospital pharmacists to be involved in clinical trials but this case is not prevalent. The majority of the trials, conducted in our country that includes hospital pharmacies were with narcotic investigational products, which according to the specific local legislation can only be located at the site of the hospital pharmacy in a special metal shelf box. However there are lots of trials conducted without participation of hospital pharmacist/research pharmacist.

**CONCLUSION:** The participation of the hospital pharmacist can be extended – to help manage adverse events, monitor the effect of the drugs under the study and awareness for the drug-to-drug interactions. There are protocols where apart from the investigational product – there are non-drugs under the study, i.e. placed on the market which should be dispensed at the beginning of the trials during the washout period and again here is the place for the research pharmacist to control these non-investigational products.

**Keywords:** *Bulgaria, hospital, pharmacist, role, clinical, trial*

### INTRODUCTION

#### *Clinical trials in Europe*

The evolution of clinical trials passed through a very long and strewn with many difficulties times. From the first study, performed on a bean in biblical times, to the first randomized trial. For all that time the history of clinical trials goes through a series of challenges - scientific, ethical and mostly regulatory (8).

Pharmacists are traditionally involved in clinical trial research in a variety of ways, through different activities: from providing medicine and keeping

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**Address for correspondence:**

Liliya Bogdanova

Faculty of Pharmacy

Medical University of Sofia

2 Dunav Str., 1000 Sofia, Bulgaria

e-mail: [lilly.bogdanova@gmail.com](mailto:lilly.bogdanova@gmail.com)

**Received:** February 27, 2014

**Accepted:** April 3, 2014

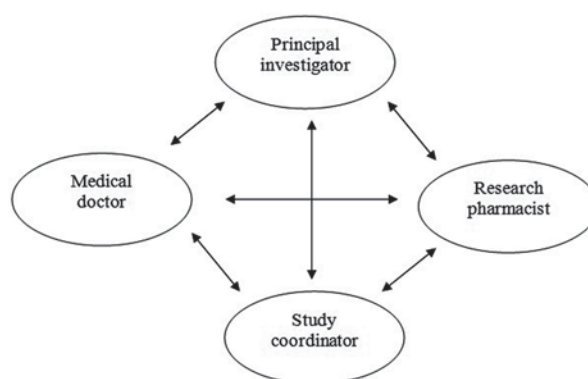
record for drug accountability to taking part as coordinators or principal investigators (11). Today, hospital pharmacists are on the forefront of patient care (14). They have a significant impact on the patients' health status, directly with value-added pharmacy services (12) and indirectly by connecting patients to pharmaceutical treatments (10) through the practice of Evidence Based Medicine (2) with existing treatment or with participation in clinical trials (6). The work of clinical and hospital pharmacists includes philosophy of care, combined with a specific orientation towards the patients to ensure optimal results from the ongoing pharmacotherapy (5).

The difference in responsibilities of the participants in the agreements about the clinical trials is due to the fact that usually the party elaborating the agreement focuses its attention on the obligations of the other party – in this case the emphasis lays on the obligations of the principal investigator and the trial site (4).

Currently the largest and the most commonly used international clinical trial register is the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (15). This is an easily accessible database of ongoing clinical trials found on the Internet. The database provides information about both patients and healthcare professionals on clinical trials for a wide range of diseases and conditions (9). According to it, the results from the search about clinical trials conducted in Europe – up to 28 December 2013 are 43379 clinical studies and 11486 of these studies are still opened and recruiting patients.

### *The research pharmacist concept*

Pharmacists can improve the quality of drug therapy by improving the organizational structures through which drug therapy is provided, specifically by creating medications use systems and by regularly evaluating their performance (7). The clinical trial team includes doctors, pharmacist (often called research pharmacist), nurses, injectors, as well as other healthcare professionals (1). The research pharmacist is an appropriate, qualified individual (i.e. licensed/registered) designed by the protocol to perform the day-to-day pharmacy activities and study product management including, but not limited to – the procurement, storage, preparation, dispensing and final disposition of study products (3).



*Fig. 1. Relationship in the research team*

### *Advantages of having a hospital pharmacist involvement while conducting a clinical trial*

- ❖ Better conditions for drug storage;
- ❖ The research pharmacist is responsible for proper drug dispensing and allocation;
- ❖ The research pharmacist is responsible for maintaining the logs related to the Investigational Product (IP).

## **MATERIAL AND METHODS**

Using pseudo-randomization we selected a sample of 30 hospital pharmacies and the pharmacy managers were interviewed with a standardized questionnaire. Hospital pharmacists' role and participation in clinical trials were examined.

The aim of our research is to study the role and responsibilities of the hospital pharmacists in clinical trials in Bulgaria. We contacted 30 hospital pharmacies. Three of the pharmacy managers refused to participate and the rest (n=27) were contacted directly. The interview was via phone call and all of them were asked 4 questions – 3 of them closed-ended and 1 open-ended.

## **RESULTS**

Among the 30 hospital pharmacy managers included in our telephone research study, 27 responded, with an overall response rate of 90%.

The first question we asked the contacted pharmacy managers at the hospital was:

- ❖ *How many pharmacists work at the hospital pharmacy?*

From the interviewed 27 managers of hospital pharmacies, two of them refused to answer the ques-

tion, insisting that this information is confidential (Fig. 2).

How many masters of pharmacy work in the hospital pharmacy?

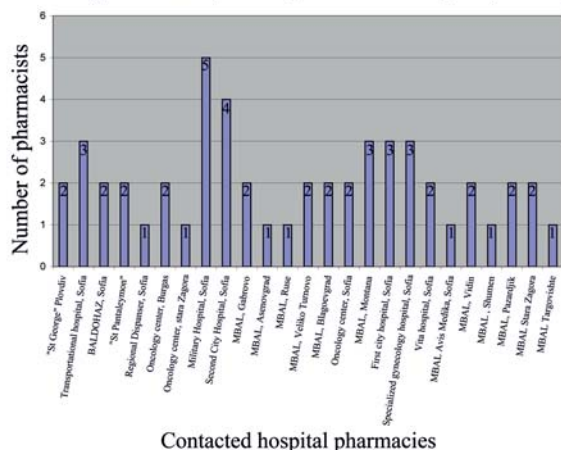


Fig. 2. Number of pharmacists working in the hospital pharmacies we contacted.

The second question we asked was:

- ❖ **Do you know if there are ongoing clinical trials in the hospital?**

Sixteen out of 25 managers of hospital pharmacies confessed, that they knew that there were ongoing clinical trials in their hospital (Fig. 3).

Do you know if there are any ongoing clinical trials in the hospital?

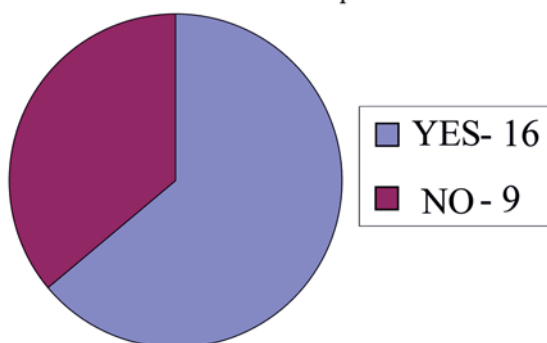


Fig. 3. Number of hospital pharmacies managers aware that there are ongoing clinical trials in the hospital at the moment

The third question we asked was:

- ❖ **Are the hospital pharmacists/the hospital pharmacy involved in the Clinical Trial?**

Unfortunately, only 6 of those 16 who admitted that there are ongoing clinical trials in the hospitals they work– were involved in those same trials, or at least in one of them (Fig. 4).

Are the hospital pharmacists/the hospital pharmacy involved in the Clinical Trial?

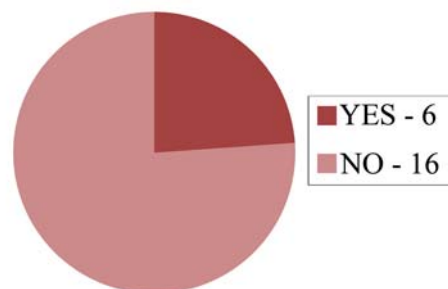


Fig. 4. Involvement of hospital pharmacist/hospital pharmacies in the clinical trial

The fourth question we asked the interviewed pharmacists was asked only to those six, who answered positively to question №3:

- ❖ **What were the tasks and competences you have?**

## DISCUSSION

### Clinical trials in Bulgaria

Nowadays the funding for the public hospitals in Bulgaria is insufficient (13) so taking part in clinical trials could help the hospital to fill at least few of its financial gaps and improve the financial results. In spite of this, not every hospital has the opportunity to take part in a clinical trial. According to [www.clinicaltrials.gov](http://www.clinicaltrials.gov), there are 959 ongoing clinical studies in Bulgaria as of December 2013. 233 studies from these (approximately one thousand) are still open for recruiting patients.

According to the Bulgarian Law – involvement of a hospital pharmacy and a research pharmacist is obligatory only when the investigated product is a narcotic or consists a narcotic substance. In the contract between the hospital and the clinical research organization (CRO) is clearly stated that one of the obligations is the enrolment of the hospital pharmacy. Another point is when the protocol has blinded and unblinded team – usually a pharmacist is needed for the unblinded team, but in this case the role of the research pharmacist could also be taken by a doctor. Such a possibility leads to the

*Table 1. Answers to the open-ended question № 4*

Answers to the open-ended question № 4	Number
- Storage of the IP under appropriate conditions	1
- Drug accountability	1
- In some cases the research pharmacist is responsible for receiving the drug and dispensing it	1
- The hospital pharmacist follows the function and operation of the IP	1
- Monitors the overall condition of the patient, following drug interactions	1
- In some cases – the pharmacist is unblinded and his/her task is to sustain the blindness of the study	1

abovementioned results for the participation of hospital pharmacists in clinical trials in Bulgaria.

In hospital settings it is extremely important that proper medication is allocated to any patient in need at any time under appropriate form. On the other hand, drug use monitoring during clinical trials is important to be done not only by physicians but also by a hospital and/or clinical pharmacist. Clinical research in humans is conducted in phases. Phase 1 trials are the first studies to involve human subjects. These are small studies using healthy volunteers in order to evaluate the safe doses, the route of administration, pharmacokinetics and establish some side effects. Phase 2 studies are related to safety and efficacy of a drug and evaluate how the drug affects the body of patients with the targeted disease. After the drug shows promise in early life – phase 3 trials are conducted. These are very large studies whose patients may be national or international, depending on the trial. Phase 3 usually compares the new drug with the current standard of therapy in patients with the targeted disease. All these phases are suitable for involving pharmacists to ensure IP quality, study results (efficacy) and participants' safety.

### CONCLUSIONS

The majority of the clinical trials conducted in Bulgaria that involved hospital pharmacies were with IP – narcotic. This special requirement according to the Bulgarian law can be the only one reason to include the hospital pharmacy staff in clinical trials. Analysis of the results shows that current legislation and practice in Bulgaria allowed the hospital pharmacist to be involved in clinical trials but this practice is not prevalent. There is no definitive requirement to include a pharmacist in the study team which

has to be followed from the regulatory agency during clinical trial assessment and authorization. However there are lots of trials conducted without the participation of hospital pharmacist/research pharmacist.

The participation of the hospital pharmacist can be extended – by helping for monitoring AE, monitor the effect of the drugs under the study, monitor the drug-to-drug interactions, etc. There are many protocols where apart from the IP – there are medicinal products placed on the market, which should be dispensed at the beginning of the trials during the washout period and again here is the place for the research pharmacist to control these non-investigational products.

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