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## Original research article

## The role of the research nurse in clinical trials

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## ABSTRACT

Clinical trials are one of the important tools leading to progress in health care and a part of clinical practice. Indispensable support to research teams is provided by research nurses responsible for managing the care for subjects enrolled in clinical trials. The objective was to assess the actual job duties of general nurses participating in clinical trials and to identify the main obstacles and expectations from their point of view. A method of questionnaire survey administered to a selected group of respondents was used. Eight teaching hospitals and two specialized centres in the Czech Republic were approached that are currently carrying out clinical trials. Eight health care providers participated in the survey. Of the total of 10,603 general nurses working at the eight facilities involved in the study, 203 nurses working in research participated in the survey. The data analysis revealed insufficient education in research being the main shortage and limitation for research nurses (74.4%). The majority of nurses were expected to develop professionally when being involved in clinical trials (69.0%). No difference was established in expectations as far as the socio-demographic characteristics of respondents were concerned ( $p \geq 0.05$ ). Nurses having attended GCP (Good Clinical Practice) courses perceived their work as more time consuming ( $p = 0.022$ ). The results of the survey have shown that the framework job description of research nurses in clinical trials is insufficiently prepared. The key practical outcome of the study will be educational recommendations and the initiation of a professional discussion on the governmental level on the legislative definition of the position of research nurses in Central Europe and the Czech Republic.

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## Introduction

The term “clinical trials” denotes research or clinical studies, i.e. clinical research projects in different fields. Clinical trials most frequently involve trials on medicinal products for human use or investigations on medical devices [1].

After their inclusion in a study, patients participating in clinical trials are called “subjects”. A clinical trial is to be conducted on any new drug before it can be registered and used. No field of medicine would be conceivable without research. Research, or more specifically phase III prospective randomized trials, represents the foundations of Evidence Based Medicine [2].

Every patient entering a health care facility can be a potential candidate for participation in a clinical trial. As part of this process, the patient meets with a general nurse working in research (a position called “research nurse”) who performs many independent tasks in cooperation with a physician. Since the “research nurse” knows the protocol and criteria for the inclusion of a patient in a clinical trial in detail, the nurse helps with subject selection and assignment. To a certain extent, a patient who has been included in a study receives special care [3]. In accordance with the strict protocol criteria, he/she is, for instance, subject to more frequent examinations and check-ups. In the diagnostic part of the study, the “research nurse” plays a key role. She should attend to a patient from the start, when the patient is included in the research study group until the end of the treatment and the subsequent observation, as provided for in the protocol.

The “research nurse” has an irreplaceable position, which is gradually developing in Central Europe as well [3]. Currently, there is no legislation defining the “research nurse” position in the Czech Republic. As a result, the position is not sufficiently anchored in the current system of non-medical professions as it is relatively new. We can therefore encounter certain problems in practice.

The “research nurse” role in clinical trials has several levels contributing to the quality of the evaluation. It involves the processing of all the important data, and good and open cooperation with principal investigators and co-investigators, which provides study results that can be easily evaluated [4]. What is of equal importance is the above-mentioned cooperation with subjects, i.e. providing them with sufficient information proportional to their competences, ensuring their satisfaction and also their willingness to participate in studies and research [5]. All current activities performed by “research nurses” within clinical trials should be in accordance with the valid legislation [3]. In most foreign institutions, the position of a general nurse in research is clearly defined. However, in the Czech health care system there is no clear definition of the position on the national level, and it is not included in the valid catalogue of works either.

## Materials and methods

The main goal of the questionnaire survey was to assess the actual job duties of general nurses participating in clinical

trials and research in the Czech Republic, and to identify the main obstacles and expectations from their point of view.

For the purposes of the survey, a questionnaire was created (a non-standardized questionnaire form) for general nurses participating in clinical trials. The questionnaire survey was administered to a selected group of respondents (intentional selection). Eight teaching hospitals and two specialized inpatient centres in the Czech Republic were approached currently carrying out clinical trials. To ensure adequate operationalization and confirm that respondents understand the research tool, a pilot study was conducted on a group of ten respondents in a specialized research centre with a long-established team of research nurses.

For the purposes of the survey, general nurses participating in clinical trials were selected as the target group, this being the main criterion for inclusion and participation in the survey, and they were selected as described below. All general nurses were approached that participate in research and work both in outpatient and inpatient departments regardless of their age, sex, highest level of education, occupational title and experience with research and clinical trials.

The reason for including general nurses participating in clinical trials and research regardless of their occupational title was the fact that in the Czech Republic, there is no official catalogue position of a research nurse as yet, and therefore different categories of health care workers can work in this position in accordance with the Act No. 96/2004 Coll., as amended [6]. Health care providers (hereinafter referred to as HCPs) that have a catalogue position of a research nurse have been granted an exception by the Ministry of Health of the Czech Republic (hereinafter referred to as the MHCR) on a contractual basis.

Statistical processing of data was carried out using Microsoft Office Excel 2010 and IBM SPSS Statistics for Windows (version 22.0.0.1). Testing was performed at a significance level of  $\alpha = 0.05$  (Pearson chi-square test).

### *Characteristics of the target population*

Of the total of 10,603 general nurses working in the eight facilities involved in the study, 203 nurses working in research participated in the survey. As the questionnaire forms were distributed electronically, the response rate cannot be determined. All 203 respondents were women (100%). The majority of respondents (42.9%) completed secondary education and 26.6% stated that they had completed a vocational college of health care and nursing. 62 respondents completed higher education (19.7% of respondents had a bachelor's degree and only 6.9% of them a master's degree). 8 respondents were currently PhD students (3.9%). The shortest practical experience of respondents was 2 years, and the longest experience was 18 years (average practical experience was 7 years). In categorizing the length of practical experience it was found that the majority of respondents selected the “less than 8 years of experience” option. 36.0% of respondents stated that they had experience of 2–5 years, while 36.9% indicated their experience was 6–8 years. 55 respondents (27.1%) stated that their experience was longer than 9 years. The occupational titles of respondents were varied as well. The majority of respondents (59.6%) stated the occupational title provided for

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