СОЦІАЛЬНА МЕДИЦИНА І ФАРМАЦІЯ: ІСТОРІЯ, СУЧАСНІСТЬ ТА ПЕРСПЕКТИВИ РОЗВИТКУ

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The paradigm of the professional education program "Clinical Research Management"

Aim. To substantiate the need to develop professional management knowledge essential to conduct clinical research in Ukraine, as well as develop the paradigm of the professional education program "Clinical Research Management".

Materials and methods. Scientific and statistical publications, as well as the results of a questionnaire survey designed to interview specialists working for medical and scientific institutions were used as research materials; the methods of systematization of theoretical and practical materials, content analysis, generalization of the survey results were applied.

Results. The relevance of the professional education program "Clinical Research Management" has been substantiated based on scientific literature and recommendations of professional organizations for conducting clinical studies in healthcare. The questionnaire survey of specialists working for medical and scientific institutions has shown their participation in planning, organizing, and controlling the clinical studies. The results of the survey have demonstrated that a significant part of the specialists is involved directly in the clinical studies at different phases; it actualizes the need for professional knowledge on modern management. The study has revealed that all categories of specialists interviewed create the demand for an advanced training or additional education in the field of management. However, medical specialists and researchers are the most interested in gaining new knowledge. Based on the peculiarities of phases of clinical research the paper develops the main learning outcomes that convey the knowledge, skills, and competencies required to conduct clinical research and assure enhanced quality.

Conclusions. Taking into account the urgent need for training the specialists who should be able to carry out clinical research in Ukraine the program for training professional clinical research managers has been offered. After completion, the specialist should be able to organize the clinical trials of new drugs, ensure effective allocation of limited resources, develop and implement the quality management system according to the requirements of current standards, carry out audits and manage risks to assure the appropriate quality of clinical research.

Key words: professional education program; clinical studies; educational content; program learning outcomes.

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Парадигма освітньо-професійної програми «Менеджмент клінічних досліджень»

Мета: обґрунтувати необхідність формування професійних знань з менеджменту у фахівців, які здійснюють клінічні дослідження в Україні, а також надати ґрунтовний опис парадигми освітньо-професійної програми «Менеджмент клінічних досліджень».

Матеріали та методи: наукові й статистичні публікації, а також результати анкетного опитування фахівців медичних і наукових закладів; методи: систематизація теоретичного і практичного матеріалу, контент-аналіз, узагальнення результатів опитування.

Результати досліджень. Спираючись на наукову літературу та рекомендації щодо проведення клінічних досліджень, підготовлених професійними організаціями у сфері охорони здоров'я, обґрунтовано актуальність освітньо-професійної програми «Менеджмент клінічних досліджень». Здійснено анкетне опитування фахівців медичних і наукових закладів щодо їхньої участі в плануванні, організації та процесі контролю клінічних досліджень. Результати опитування продемонстрували, що значна частина фахівців залучається безпосередньо до проведення клінічних досліджень на різних фазах, що актуалізувало потребу в отриманні професійних знань з основ сучасного менеджменту.

У ході дослідження встановлено, що попит на додаткову освіту з менеджменту чи підвищення кваліфікації створюють фахівці всіх опитаних категорій. Проте найбільш зацікавленими виявились лікарі-спеціалісти та науковці. Враховуючи особливості фаз клінічних досліджень, у роботі сформульовано основні результати навчання, які розкривають знання, уміння, навички та компетентності, необхідні тим фахівцям, які працюють у сфері клінічних досліджень.

Висновки. Враховуючи існуючу потребу в підготовці сучасних фахівців, які здійснюють клінічні дослідження в Україні, запропоновано парадигму програми підготовки професійних менеджерів клінічних досліджень, які мають організовувати проведення клінічної апробації нових лікарських засобів, забезпечувати ефективне використання наявних ресурсів, розробляти й упроваджувати систему управління якістю процесу клінічного дослідження згідно з вимогами чинних стандартів, здійснювати аудит якості та управління ризиками з метою формування належного рівня якості клінічних досліджень.

Ключові слова: освітньо-професійна програма; клінічні дослідження; навчальний контент; програмні результати навчання.

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Парадигма образовательно-профессиональной программы «Менеджмент клинических исследований»

Цель: обосновать необходимость формирования профессиональных знаний по менеджменту для специалистов, которые осуществляют клинические исследования в Украине, а также детально описать парадигму образовательно-профессиональной программы «Менеджмент клинических исследований».

Материалы и методы: научные и популярные публикации, а также результаты анкетного опроса специалистов медицинских и научных учреждений; методы: систематизация теоретического и экспериментального материала, контент-анализ, обобщение результатов опроса.

Результаты исследований. Основываясь на научной литературе и рекомендациях касательно проведения клинических исследований, подготовленных профессиональными организациями в сфере здравоохранения, обоснована актуальность образовательно-профессиональной программы «Менеджмент клинических исследований». Выполнен анкетный опрос специалистов медицинских и научных учреждений касательно их участия в планировании, организации и процессе контроля клинических исследований. Результаты опроса продемонстрировали, что значительная часть специалистов привлекается непосредственно к проведению клинических исследований на различных фазах, что актуализирует потребность в получении профессиональных знаний по основам современного менеджмента. В ходе исследований установлено, что спрос на дополнительное образование по менеджменту или повышение квалификации создают специалисты всех категорий, которые были подвержены опросу. Однако наиболее заинтересованными являются врачи-специалисты и ученые-исследователи. Учитывая особенности фаз клинических исследований, в работе сформулированы основные результаты обучения, которые раскрывают знания, умения, навыки и компетентности, необходимые тем специалистам, которые работают в сфере клинических исследований.

Выводы. Учитывая существующую потребность в подготовке современных специалистов, осуществляющих клинические исследования в Украине, предложена программа подготовки профессиональных менеджеров клинических исследований, которые должны организовывать проведение клинической апробации новых лекарственных средств, обеспечивать эффективное использование существующих ресурсов, разрабатывать и реализовывать систему управления качеством во всех фазах процесса клинического исследования в соответствии с требованиями существующих стандартов, осуществлять аудит качества и управления рисками с целью формирования необходимого уровня качества клинических исследований.

***Ключевые слова*:** образовательно-профессиональная программа; клинические исследования; учебный контент; программные результаты обучения.

Statement of the problem. Currently, the pharmaceutical industry in Ukraine is in a leading position. However, international competition continues to penetrate the national pharmaceutical market. According to experts, about one third of medicines registered at the domestic market is of Ukrainian production, while the rest is foreign. Therefore, strengthening the competitive position of Ukrainian pharmaceutical companies at the market is a very important issue. And it is clear that competing in this sector of the economy can only be due to production of quality medicines.

Clinical research is an integral part of the drug development process, which determines the quality of drugs and their further control. Taking this into account it is necessary to note that the quality of medicines depends on the soundness of clinical trials. The latter, in turn, largely depends on the proper level of planning and organizing clinical research.

Analysis of recent research and publications. Currently, randomized and controlled clinic-based studies are the most common planning tool, in which participants are randomly divided into groups, i.e. one group is exposed

to the intervention under research and the other implements the standard methods [1]. Such "large" clinical studies, which assure successful clinical practice, have been comprehensively analyzed in scientific literature [1]. Special attention is drawn to the issue how to manage this important process since many clinical studies have not been completed due to the lack of expertise [2]. Taking into account that clinical studies consume significant financial and human resources, which should be effectively distributed and utilized, to conduct a randomized research requires professional management inherent to any business.

The analysis of 114 clinical multi-center studies funded by the National Institute for Health Research (NIHR) [3] showed that 45% of them failed to achieve 80% of the pre-defined outcomes. Less than one third of the research was implemented over the planned span of time and reached the goals, and more than one third increased in time and resources. However, the crucial factor in ensuring the effectiveness of studies was the recruitment of clinical research managers who managed all processes and organized an efficient allocation of resources at various phases of clinical research [3].

Francis et. al [4] analyzed clinical studies from the project management (business) perspective and concluded that successful research was based on the "marketing", "sales" and "client-management" strategy. They noted that the most difficult aspect of conducting randomized controlled trial was the introduction of effective management methods and tools used to run a business successfully. Based on the experience of noncommercial academic trials Farrell and Kenyon [5] in their guide on effective test management indicated that managing all stages of clinical trials was of paramount importance.

Considering the widespread scientific literature and practical cases on clinical research [6-10], nevertheless, there is no answer to the following question: "Do the clinical research participants create the demand for knowledge of management?". As a result, there is still no professional education program tailor-made for clinical research specialists to get new knowledge of management.

Objective statement of the article. The aim of the article is to substantiate the need to develop professional management knowledge essential to conduct clinical research in Ukraine, as well as develop the paradigm of the professional education program "Clinical Research Management".

Presentation of the main material of the research. In March, 2019, an anonymous survey was conducted among the participants of the seminar "Good clinical practices" (ICHGCPE6 (R2)) organized by the State Expert Center of the Ministry of Health of Ukraine and the National University of Pharmacy (Kharkiv). The questionnaire contained eight questions about the respondents' position, the company they worked for, whether they needed to improve their professional basic knowledge of management, whether they performed functions of management in their professional activities, as well as possible forms of obtaining additional education.

In total, 110 out of 440 seminar participants from different institutions and organizations involved in scientific and practical activities in medicine and pharmacy took part in the survey. 54 % of them were representatives of higher education institutions and research institutions, 40 % were employees of communal non-profit enterprises (CNP), and almost 7 % were specialists from medical centers represented mostly by private organizations (Fig. 1). In addition, the research covered various professional groups of specialists in the given sector, namely medical specialists (35 people), researchers (31 people), heads of different departments (17 people) and others (20 people).

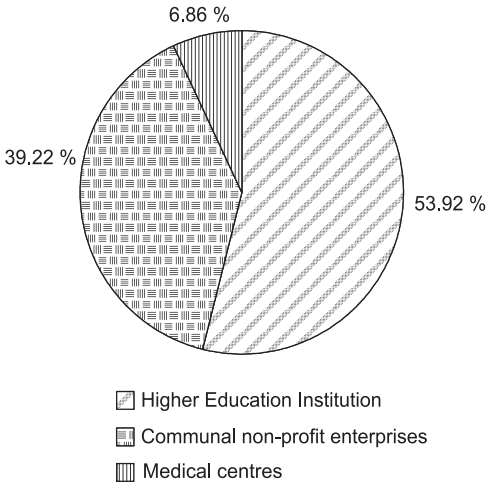

Fig. 1. Distribution of institutions and organizations participated in the survey

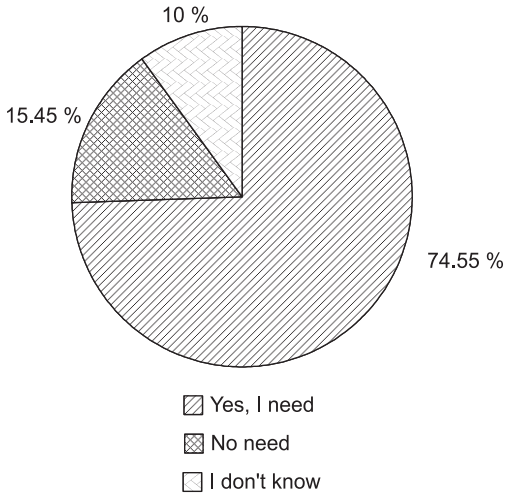

Fig. 2. Distribution of respondents based on their need to obtain additional knowledge of management

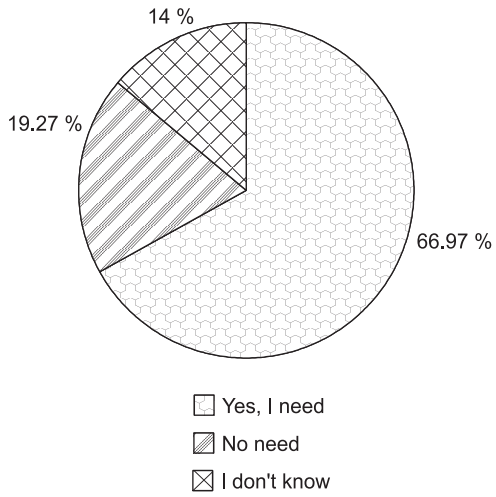

Fig. 3. Distribution of respondents according to their answer to the following question "Is there a need for training specialists in the field of "Clinical Research Management"?

According to the survey, approximately 58 % of respondents during their professional activities were involved in planning and organizing clinical research to some extent, and 23.6 % performed the assessment and regulatory control of the results. Thus, the majority of respondents had the experience in conducting clinical studies and created the need for professional management knowledge and skills in planning, organizing and coordinating such research. Therefore, almost 75 % of the interviewed experts indicated the need for additional knowledge of the basic management, which would provide an opportunity to enhance the quality of clinical research, as well as increase the number of successful research projects (Fig. 2).

A need for knowledge and managerial skills cannot be explained only by a managerial position of the respondents. On the contrary, medical specialists and researchers were among those respondents who took more interest in developing their own professional managerial competencies. These specialists also showed an interest in additional education or training to improve their knowledge of management (Table).

The results of the survey also show a high interest of different specialists in obtaining additional knowledge of clinical research management (Fig. 3).

With regard to the results of the research, the National University of Pharmacy introduces a new professional education program "Clinical

Table

DISTRIBUTION OF RESPONDENTS BASED ON THEIR NEED FOR ADDITIONAL EDUCATION (AND/OR ADVANCED TRAINING) IN THE FIELD OF "MANAGEMENT"

Do you have the need to receive an additional education in the field of "Management"?		
Options	The total amount of respondents, who gave the answer	75% of respondents who expressed the need for developing their knowledge of management and gave the answer
Yes	47	46
No	42	21
Don't know	21	15
Do you have the need for advanced training in the field of "Management"?		
Yes	45	44
No	43	21
Don't know	22	17

Research Management" in the field of "Management" (branch of knowledge – 07 "Management and Administration"), which is currently the unique one in Ukraine. Applicants who meet all the requirements of the program are supposed to receive the following qualifications: an educational one "Master of Management", and a professional one – "Public Health Manager".

The focus of the program is training specialists for organizational, managerial and analytical activities in the field of clinical research.

The goal of the professional education program is to train highly qualified professionals capable of planning, organizing, monitoring clinical research according to ethical standards, efficiently and effectively managing the financial, material and information resources, as well as project team in healthcare institutions, contracting research organizations and pharmaceutical companies.

The competitive advantages of the program are the uniqueness and originality of its educational component containing management-oriented disciplines providing fundamental knowledge for organizing, planning, monitoring the clinical research. The curriculum is enriched with the practical part (internship and fieldwork), which is supposed to be organized at the sites of the research, including contract research organizations, clinical research departments, analytical laboratories, pharmaceutical enterprises, faculties of education institutions. Students can have additional credits under the supervision of mentors from two departments: the Department of Clinical Pharmacology and Clinical Pharmacy and the Department of Management and Administration.

Through a flexible curriculum that balances management and clinical studies professionals are supposed to develop social communication skills, analytical skills. They should be able to work with large databases, conduct statistical and quantitative analysis, manage clinical research, providing systematic exchange of the practical experience. After completion of the program graduates should be able to assess the crucial role of randomized controlled trials and understand the life cycle of clinical research. The latter includes the development of detailed project plans, their approval, statistical analysis, data management, and risk-based monitoring, as well as implementation of the action plan.

In addition, graduates should be able to provide appropriate resources, as well as organize and perform clinical testing of new drugs, make conclusions and interpret accurately results of the studies and implement them in practice. Graduates are also supposed to be able to develop and implement the quality management system in accordance with the requirements of current standards, carry out audits and manage risks to assure the appropriate quality of clinical research, monitor the effectiveness and safety of the drug use by the population according to their clinical and pharmaceutical characteristics, etc.

Conclusions and prospects for further research. Based on scientific literature, survey results, and recommendations for conducting clinical research the paper substantiates the relevance of training professional clinical research managers who should be able to organize the clinical trials of new drugs, ensure effective allocation of limited resources, develop and implement the quality management system according to the requirements of current standards, carry out audits and manage risks to assure the appropriate quality of clinical research, etc.

The professional education program "Clinical Research Management" takes into account the most progressive concepts of education, best practices of leading countries in providing educational services, recommendations of employers and potential students.

Conflict of interests: authors have no conflict of interests to declare.

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