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Project Management Office in Clinical Research Projects

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ABSTRACT

Context: Clinical research is an interdisciplinary project which has been given a high priority by health organizations. Because of its complexity and importance, most of health system authorities have supported the using of project management knowledge and skills in performance of health and clinical researches.
Evidence Acquisition: Establishing portfolio management within a project management office can help investigators with the performance of their research projects and increasing efficiency of research projects by centralizing and consolidating.
Results: PMO and its counterparts for instance, clinical trial office and office for good clinical practice can play an important role in the best performance of clinical and health research projects.
Conclusions: In this study we will describe the crucial role of project management and also project management office in clinical research projects.

Keywords: Clinical Protocols; Knowledge; Research

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▸Implication for health policy/practice/research/medical education:
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1. Context

Different types of researches are performed in the field of health and medical sciences worldwide, for instance; behavioral studies, genetic researches, physiological studies, public health, and clinical researches. Nowadays, researchers have formed a second opinion regarding more applied approach and translational investigations. Therefore, translational medicine disciplines are conducted within and across research centers and organizations (1). While it seems that clinical and translational studies have been given a high priority by health authorities. Hence, the role of health and clinical professionals are redefined as clinical research nurses or staff to assure participant safety, integrity of protocol implementation, accuracy of informed consent obtaining procedure and data quality, and follow-up (2). As a project, clinical and health research studies need to manage to deliver on-time, on-budget and of defined quality by using project management knowledge and skills. However, there is little published documentation describing project management use in performing clinical or health research projects (3). In this paper the authors tried to define the functional role of project management and also project management office (PMO) in implementing clinical research, and subsequently considerable improvement in research efficiency, participant safety, and the quality of data.

2. Evidence Acquisitions

2.1. Clinical Research Project

Research is a project that has been defined as a unique and scheduled complex attempt to achieve specific and predefined objectives by using limited budget and resources which is usually no repetitive within an organization. Furthermore, research activity is adjusted to the interests, needs and values of the stakeholders and community, particularly, health and clinical research, adjusted to translational investigations and their applications in health and medicine (4, 5). As a rule, research question should cause a hypothesis and potentially provide innovative results that have an impact on community. Moreover, various health care management and policy decisions are being directed by clinical and health researches (6, 7). Recently, some health research projects have been conducted and followed by considerable impact on public health (5). In this arena, clinical research professionals need not only to learn several clinical and critical thinking skills, but also to spread their knowledge of the administrative, ethical, and scientific scenes of clinical research (2).

2.2. Clinical Research Project Management

The project management body of knowledge (PMBOK) guide has described five processes of project management as initiating, planning, executing, controlling and monitoring, and closing across the life cycle of projects (3). In addition, basic procedures of the management are defined as planning, organizing, directing, and controlling (8). Health and clinical researches are instances of project which take systematic efforts to answer or solve specific health related problems with introduced solutions. Thus, the same principles and methods of management are performed in health research project management (2, 9) since, most of project management features are common to clinical researches and other types of project. These features include; defining and formulating clear objectives and aims with specific outputs (initiation), organizing a team with the requisite knowledge and skills (Planning), setting a timeline and an appropriate methodology (Planning), defining resources to achieve the project objectives (Planning), defining tasks, roles, and activities for all team members which should be completed (Planning), planning for risk management (Planning), conducting the project (executing), operating a quality control system, and finally monitoring progress in accordance with the project program (controlling and monitoring), (9, 10). Accordingly, project management knowledge is used by different systems and disciplines including health and medicine. Usually, several projects include, health organization projects have failed to meet their performance targets on time, within budget, and with the expected quality. While it could be avoided by performing project management (3, 11). There are several clinical studies that used project management skills and knowledge, and showed the usefulness of this part of knowledge in clinical investigation and management (9). It is elucidated that clinical (trial) studies need to establish and implement project management systems, irrespective of the size, scope, costs or duration (10).

2.3. Good Clinical Practice (GCP)

Randomized clinical trial (RCT) as a valuable instance of clinical researches is the gold standard to appraise therapeutic interventions and supply the practice of evidence-based medicine. However, the success of this type of clinical researches relies on the elements of the study design and management (12). GCP is the standard of clinical trial studies which assists scientists to ensure that the appropriate scientific design, rights, safety, informed consent, well-being of research subjects, good performance, and desirable quality of data are being protected in this manner (2, 13). However, many clinical trials are failing in their duties owing to the lack of an organized, practical, administrative approach to clinical trial research management (10). Therefore, most of clinical trial studies intuitively use several methods and knowledge of management principles (10). In recent years, clinical trial office (CTO) has issued within the health and clinical research centers an infrastructure to

unify administrative activities (14), and also to provide a central comprehensive program of financial, legal, and managerial support to the clinical research investigators. Furthermore, the office of good clinical practice (O-GCP) is the focal point within FDA for GCP in human research trials regulated by FDA with the same responsibilities (15). Accordingly, a national instance for PMO is the clinical trial center (CTC) which was established in Tehran University of Medical Sciences (TUMS) as an authorized body to centralize and also to control the management of clinical trial projects.

2.4. Portfolio Management

Portfolio management is defined as "centralized management of one or more portfolios, which includes identifying, prioritizing, authorizing, managing, and controlling projects, programs, and other related works, to achieve specific strategic Objectives " (16) with various fundamental activities include; opportunity recognition, return on investment (ROI) forecasting and value definition, project prioritization, planning, scheduling, project management and execution, and performance monitoring, and measurement (11). In mature organizations, multiple programs or projects may be considered in portfolio frameworks adjusted to greater strategic goals of the organization (16). In healthcare system including health research arrangement many projects fail because of poor portfolio management which most often, is established within a program or project management office (PMO) or project support office (PSO) to allocate and manage several limited resources (11).

2.5. Project Management Office (PMO) in Clinical Researches

Because of the cost and complexity limitations, clinical studies need comprehensive planning, performing, monitoring, and assessment to cover the entire scope of the project (2, 17). As project planning and administration mean more than just a Gantt chart, they can direct the project and promote its growth and success (17). Recently, the value of consolidation or centralization of administrative functions in different projects has been elucidated (14). Indeed, its best performance strongly relies on establishment portfolio management within a PMO. Although, in recent years, CTO and O-GCP have been introduced to increase the capability of clinical trial studies, there are still various challenges with the authorization and governance structure for clinical trial research administration (14, 15). CTO and O-GCP are two counterparts of PMO (in usual project management systems) with the similar responsibilities. In the FDA, O-GCP is a focal point for performing clinical trials and also human Subject Protection (15). These organizational bodies assigned various duties relevant to the centralized and coordinated management of those projects under their arena. A PMO supports project managers in various ways for instance; managing resource allocation across all projects administered by the PMO, designing and developing project methods, coaching, mentoring, training, monitoring compliance with standard policies via audit plans, centralizing and coordinating communication across projects among project managers, sponsors, and other stakeholders (18, 19). The PMO can also be responsible for administering project proposals (20). PMO and its counterparts can improve project management performance and reduce the number of "runaway" projects, run over budget, or become compromisingly delayed (21).

3. Results

Health and clinical research is an interdisciplinary process which is affected by patient care system, public health, health management, and health policy design (7). Moreover, clinical research has some limitations and complexity due to involving human subjects and various stakeholders, including sponsors, scientists, staff, project managers, ethics committees, regulatory authorities, research subjects, and some others (22). Therefore, successful performance of clinical researches crucially depends on implementing well-organized plan and a multidisciplinary approach (23, 24). On the other hand, several health activities such as medical services and researches fall within the project field. This concept suggests that medical and healthcare professionals need to learn project management skills, and adopt them for the field of health and medicine (25). The authors have several experiences about the clinical (trial) projects that were performed by Brain and Spinal Injury Research Center and also Endocrinology and Metabolism Research Institute (affiliated to TUMS) (26-30). Some of the mentioned clinical trials were recognized as national projects which had been supported by the government. For instance, autologous Schwann cell therapy for the treatment of spinal cord injury and fetal stem cell transplantation project were performed as multi centric clinical trials in the country (28, 30). Although, these projects were conducted in a clear framework, according to an accurate timeline, and based on an exact method, a project management concept and framework were needed for centralizing trial management, and performing these types of clinical trials on budget, time, and scope of the designed plan and method. Nowadays, the importance of project management skills and consolidation or centralization of administrative functions are actively supported by scientists in different fields of research such as clinical (trial) studies (14). Indeed, healthcare or health research organizations can use portfolio management within a PMO to ensure the best performance of its programs and projects by using the set aside resources and obtaining favorable outcomes and subsequently impact on health and medicine (11). PMO and its counterparts in medical and health research system (CTO, O-GCP) can help researchers

or research managers to increase the efficiency of clinical studies by centralizing and consolidating of projects. In addition, PMO provides an optimized circumstance of resource allocation, project methods, and processes standardization, monitoring, auditing, data management, and etc.

4. Conclusions

In summary, PMO in health and clinical research is an office or group which defines and maintains the standards and processes related to research project management with the capacity to institute a wide variety of desirable changes within the organization.

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Authors' Contribution

Study concept and Idea: Arjmand B, Babamahmoudi SA, and Larijani B. Drafting of the manuscript: Ajmand B and Goodarzi P. Critical revision of the manuscript: Aghayan HR and Emami-Razavi SH. Literature review: Arjmand B, Goodarzi P, and Norouzi-Javidan A.

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