Review Article

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A System for Managing Clinical Trial Data for Diabetes

Abstract

The use of novel medications and strategies to forestall, diagnose, treat, and manage polygenic disease needs confirmation of safety and effectively in an exceedingly well-designed study before widespread adoption. Polygenic disease clinical trials square measure the studies that examine these problems. The aim of this study was to develop a web-based system for knowledge management in polygenic disease clinical trials. This analysis was a mixed-methods study conducted in 2019. To spot the specified knowledge parts and functions to develop the system, sixty researchers completed a form. The designed system was evaluated victimization 2 strategies. The usability of the system was at first evaluated by a bunch of researchers (n=6) victimization the think-aloud technique, and once system improvement, the system functions were evaluated by alternative researchers (n=30) employing a form. The most knowledge parts that were needed to develop a case report type enclosed "study knowledge," "participant's personal knowledge," and "clinical knowledge." The purposeful necessities of the system were "managing the study," "creating case report forms," "data management," "data internal control," and "data security and confidentiality." once victimization the system, researchers rated the system functions at a "good" level (6.3±0.73) on a seven-point. Given the quality of the information management processes in polygenic disease clinical trials and therefore the widespread use of data technologies in analysis, the employment of clinical knowledge management systems in polygenic disease clinical trials appears inevitable. The system developed within the current study will facilitate and improve the method of making and managing case report forms similarly as aggregation knowledge in polygenic disease clinical trials.

Keywords: Type 1 diabetes • sleep • Clinical trial protocol • Adolescents • Polygenic disease • Data technologies

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Introduction

Diabetes is one amongst the foremost common chronic diseases within the world. The statistics show that 451 million individuals worldwide were diagnosed with polygenic disease, and this figure is anticipated to rise to 693 million by 2045. The amount of patients with polygenic disease is considerably increasing in several countries. As an example, per the International polygenic disease Federation, the prevalence of polygenic disease in Asian country was to eight.94 in 2017 and this figure is anticipated to achieve thirteen.64 by 2045. Polygenic disease has many complications and will cause disorders in varied body organs, like eyes, kidneys, nerves, heart, and blood vessels. As a result, polygenic disease is among completely different comorbidities [1].

In addition to comorbidities, there square measure psychological damages that patients with polygenic disease and their family's expertise and these will increase health care prices. Given the economic, social, psychological, and health issues that polygenic disease imposes on a patient, family, and society, managing patients with polygenic disease appears to be essential. This might happen by making innovative and simpler strategies for preventing, diagnosing, treating, and managing polygenic disease, as an example, through conducting polygenic disease analysis [2].

Among differing kinds of analysis, clinical trials square measure the foremost vital sort and square measure thought-about as a basis for developing polygenic disease management tips. In fact, no new medication may be offered, and no progress would be seen within the field of polygenic disease, while not clinical trials. Therefore, a big a part of the clinical trials registered in several countries, like the USA (2.7%) and Asian country (3.1%), has been dedicated to polygenic disease over the past ten years (2010 to 2020).

Clinical trials of polygenic disease like alternative clinical trials, square measure complex and varied studies. Every section of those studies needs cautious, applicable, and planned management of clinical knowledge. Clinical knowledge management is that the method of aggregation Associate in Nursing certificatory clinical test knowledge with the aim of conversion into an electronic format for playacting applied math analysis, responsive analysis queries, and ultimately protective for future analysis. In fact, this method permits researchers to create the proper conclusions regarding the effectively, safety, benefits, and potential risks of the merchandise below a study by aggregation and managing knowledge properly, reducing missing knowledge, and increasing knowledge quality. Clinical knowledge management could be a complicated method and a minimum of includes developing case report forms, expansion forms, making databases, coming into knowledge, edificatory knowledge, managing knowledge discrepancies, medical writing, data processing, protection databases, documenting knowledge management processes, and maintaining knowledge security [3].

A clinical knowledge management system is software package that supports management method throughout the clinical test and reduces errors that will happen throughout manual knowledge management. However, the shortage of such a system in analysis centers, particularly in massive and multicenter trials, could end in longer study time, further price for managing knowledge manually, replication, and alternative issues like uncertainty regarding knowledge quality and amount, security threats, and compromising the confidentiality of analysis knowledge.

The results of the previous study disclosed that the method of clinical trials knowledge management isn't performed suitably in Asian country. The analysis centers principally use paper-based forms to gather knowledge. Moreover, the appliance of electronic systems is principally restricted to applied math software package for knowledge analysis. This can be a similar for polygenic disease clinical trials that constitutes an outsized a part of the clinical trials within the country. Therefore, it appears that planning and implementing a knowledge management system supported the scientific principles of clinical analysis will improve the standard of information and facilitate the method of information management. Therefore, the aim of this study was to develop a web-based system for knowledge management in polygenic disease clinical trials [4].

Materials and Methods

The present study was completed in 2019. It had been a mixed-methods study that was conducted in 3 phases. Every section of the study is delineated hereafter. To spot needed knowledge parts and functions for planning the system, knowledge were collected victimization completely different analysis strategies in 3 steps that square measure delineated below.

Initially, the literature associated with the clinical test knowledge management systems and their characteristics was reviewed narratively. Databases enclosed internet of Science, Scopus, Science Direct, ProQuest, Ovid MEDLINE, and PubMed. The search was conducted over a amount of 10 years from 2007 to 2017 by one amongst the researchers (AN), and alternative researchers (HA) and (MSD) contributed to the review method. Additionally to the literature review, studies associated with the polygenic disease clinical trials were reviewed to extract necessary knowledge parts and functions for the system [5].

An explorative qualitative study was conducted in January-February 2019, and clinical test researchers were interviewed by one amongst the researchers (AN). During this study, knowledge was collected through in-depth semi structured interviews with sixteen analysers in 3 medical specialty and metabolism research institutes. Associate

in Nursing interview guide was developed supported the literature review and contained fourteen questions on differing kinds of polygenic disease clinical trials, needed knowledge for polygenic disease clinical trials, knowledge assortment and knowledge entry strategies, knowledge management tools, knowledge quality and security management strategies, knowledge analysis and reportage strategies, and knowledge management standards [6].

To identify the most knowledge parts and purposeful necessities of the system, a form were developed supported the results derived from the literature review and therefore the qualitative study, and a survey study was conducted in July-August 2019. The form enclosed eighty five things and fourteen sections regarding the specified knowledge parts and functions for developing a clinical knowledge management system for polygenic disease clinical trials. parts enclosed the study data (6 items), participants' knowledge (9 items), clinical knowledge (3 items), polygenic disease knowledge (4 items), laboratory tests knowledge (5 items), socioeconomic knowledge (3 items), mode knowledge (3 items), medication knowledge (3 items), and medical record knowledge (2 items), and therefore the needed functions enclosed 5 classes of purposeful necessities for managing the study (15 items), making case report forms (7 items), knowledge management (12 items), knowledge validation and internal control (6 items), and knowledge security and confidentiality (7 items). The face validity and content validity of the form were assessed by 5 researchers World Health Organization were specialists in conducting polygenic disease clinical trials. They were endocrinologists World Health Organization had expertise in planning and conducting a minimum of 5 polygenic disease clinical trials. The responsibility of the form was calculated victimization the Kuder-Richardson coefficient of correlation (KR-20 = 0.88). Once confirming the validity and responsibility, the form was distributed among polygenic disease clinical test researchers across the country by one amongst the researchers (AN) [7].

Discussion

Currently, several national and international scientific organizations and associations get funding and build support for polygenic disease analysis to come up with new data and supply the patients with higher care, diagnosis, and treatment. Polygenic disease clinical trials square measure among the most styles of analysis that square measure primarily conducted to answer questions on the effectively and safety of recent medical merchandise and strategies and develop new data to alter polygenic disease. Finding applicable answers for these queries and applying new data depends on the proper and systematic assortment and management of information. Generally, knowledge management in clinical test analysis could be a complicated method and may be a lot of sophisticated by a rise within the variety of centers concerned in an exceedingly trial, the amount of researchers, and therefore the variety of study participants. Manual management of this level of quality is hardly attainable. This emphasizes the importance of victimization clinical knowledge management systems for facilitating this method, rising knowledge quality, and achieving effective results [8].

In the gift study, a clinical knowledge management system was developed for polygenic disease clinical trials. This technique was developed supported the information parts and functions instructed by the literature review and polygenic disease researchers. It ought to be noted that the majority clinical knowledge management systems have four main parts. The primary element includes a management module for planning clinical test studies, making case report forms, adding analysers and research centers, maintaining security, and dominant user access. The second element consists of the graphical interface for coming into study knowledge, and therefore the third element is that the validation engine for validator and certificatory knowledge entered into the info. The fourth element contains a reportage module to come up with the mandatory reports regarding the information and therefore the study method [9].

In the clinical knowledge management system developed within the gift study, all four major parts were thought-about. The specified knowledge parts were divided into 3 groups: "study knowledge," "participant's personal knowledge," and "clinical knowledge." This knowledge parts

square measure the minimum knowledge parts needed for making polygenic disease case report forms. The functions of the system were divided into 5 main functions, namely, "managing the study," "creating case report forms," "data management," "data internal control," and "data security and confidentiality." The management module of this technique helped the clinical test manager to style a clinical test, add analysers and research centers, outline the role of the users, organize the study teams, disarrange participants, and edit the trial protocols.

As mentioned on top of, another element of a clinical knowledge management system is that the graphical interface for coming into clinical test knowledge. Therefore, a graphical interface was designed for managing, entering, and reportage knowledge. The interface of the system was designed victimization the web-based ASP.NET artificial language that was utilized in the look of comparable systems in alternative studies. though there square measure completely different programming languages that may be accustomed style knowledge management systems, the .NET framework seems to possess comprehensive libraries for developing web-based systems and makes system development easier [10].

Conclusions

In the gift study, a clinical knowledge management system was developed and evaluated to support the information management method in polygenic disease clinical trials. during this system, the knowledge parts enclosed study data, participant's personal knowledge, and clinical knowledge, and therefore the system functions lined managing the study, making case report forms, data management, knowledge internal control, and knowledge security and confidentiality. The results of the analysis study disclosed that the researchers typically evaluated the system functions at an honest level. It appears that the developed system may be economical in follow and facilitates the clinical knowledge management method in medical specialty and metabolism analysis institutes and polygenic disease analysis centers. What is more, it may be helpful for cooperation between the polygenic diseases researches centers set in several geographical areas, because it will support knowledge management processes in multicenter clinical trials. However, any investigations square measure required to deal with the cost-effectiveness of the system and compare the information quality and documentation processes before and once victimization the system in real clinical trials.

Conflict of Interest

None

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References

1. Cho NH, Shaw JE, Karuranga A. IDF Diabetes Atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. *J Diabetes Res*. 138:271-281 (2018).
2. Semenkovich K, Brown ME, Svrakic DM *et al*. Depression in type 2 diabetes mellitus: prevalence, impact, and treatment. *Drugs*. 75:577-587 (2015).
3. Fradkin J. Diabetes clinical trials: what is new at NIDDK? *Clin Diabetes*. 22:109-112 (2004).
4. Lu Z, Su J. Clinical data management: current status, challenges, and future directions from industry perspectives. *Open Access J Clin Trials*. 2:93-105 (2010).
5. Nourani A, Ayatollahi H, Dodaran MS *et al*. Clinical trial data management software: a review of the technical features. *Rev Recent Clin Trials*. 14:160-172 (2019).
6. Krishnankutty B, Naveen Kumar B, Moodahadu L *et al*. Data management in clinical research. *Indian*.33:122-126 (2010).
7. Cavenaugh JS, Snell P, Jeffries D *et al*. A relational database for management of flow cytometry and ELISpot clinical trial data. *Clinical Cytometry*. 72:49-62 (2007).
8. Das S, Zijdenbos AP, HarlapJ *et al*. A web-based data management system for multi-center studies. *Front Neuroinform*. 5:37-11 (2011).
9. Gao QB, Kong Y, Fu Z *et al*. A clinical data management system. *Comput Biol Med*. 38:1042-1044 (2008).
10. Ngari MM, Waithira N, Chilengi R *et al*. Experience of using an open source clinical trials data management software system in Kenya. *BMC Research Notes*. 7:845-853 (2014).