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Modelling vital success factors in adopting personalized medicine system in healthcare technology and management

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ABSTRACT

Biomedical engineering has grown as a vast field of research that includes many areas of engineering and technology also. Personalized Medicine is an emerging approach in today's medicare system. It bears a very strong potential to consolidate modern e-health systems fundamentally. Scientists have already discovered some of the personalized drugs that can shift the whole medicare system into a new dimension. However, bringing the change in the whole medicare system is not an easy task. There are several factors that can affect the successful adoption of Personalized Medicine systems in the healthcare management sector. This paper aims at identifying the critical factors with the help of an empirical study. A questionnaire was distributed amongst some clinicians, clinical researchers, practitioners in pharmaceutical industries, regulatory board members, and a larger section of patients. The response data collected thereby were analyzed by using appropriate statistical methods. Based on the statistical analysis, an attempt is made to prepare a list of critical success factors in the adoption of personalized medicine in healthcare management. The study indicates that eight of the thirteen hypothesized factors have statistical relationship with "Success". The important success factors detected are: data management, team work and composition, privacy and confidentiality, mind-set, return on investment, sufficient time, R&D and alignment. To the best of our knowledge, this is the first academic paper in which an attempt has been made to model the vital critical factors for the successful implementation of Personalized Medicine in healthcare management. The study bears the promise of important applications in healthcare engineering and technology.

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1. Introduction

Personalized Medicine (also sometimes referred to as Precision Medicine), an important enabler in modern e-health systems, is a new medicare approach that can shift the entire healthcare system towards a new paradigm: from reaction to prevention [7,15,27]. Other synonyms used for Personalized Medicine (PM) are: Stratified medicine, targeted medicine, and pharmacogenomics. In the present context, stratification means categorization of patients having a specific ailment into different subgroups, such that patients belonging to a particular subgroup respond to a given drug.

In the personalized medicare system, care is taken to see that the side effects of a particular drug for a specific for a subgroup are minimum. Investigations related to changes in DNA and RNA characteristics due to the administration of a particular medicine come under the purview of pharmacogenomics. Both stratification and pharmacogenomics are important constituents of 'Personalized Medicine'. In this novel medicare system, therapeutic measures are also taken with an aim to improve the health of a patient. In the personalized approach, adequate care is taken to include information on the anatomy, physiology and environment of the patient. Physiological information about patients should cover condition of the cardiovascular and nervous systems, as well as metabolic activities, while information regarding environment refers to whether the patient is in the ICU (Intensive Care Unit) or in general bed or in the house. Of late, physiological sensors are also being used in good hospitals, with an aim to observe the medicare responses of different organs of each patient.

Variation in the type of people takes place due to the difference in climatic conditions of different places, where they live and also due to the change in food habits of people. These variations are

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significant determinants of health pathology. It is known that there are some specific drugs, which do not suit all individuals. This fact has been taken care of in the Personalized Medicare system, because in the new system, it is possible to treat the patient by taking account of the individual's requirement and variation of the conditions of climate and space. There are several advantages of the Personalized Medicare system. In this system, there is opportunity to screen the medicines. This system also enables the clinician to intervene at an early stage and to immediately start the treatment procedure. There is no room here for the trial and error method used in the traditional medicare system. One can expect safe and effective treatment for different subgroups of people made using genetic variations [31]. Cases in which variation in a single gene alters, the phenotype may be considered as a subgroup of single gene variation; but cases in which there occurs variation in multiple genes constitute another subgroup of complex variations. Interaction of genes with different factors may lead to single/complex gene variations. However, complex variation usually involves small gene-mutation effects. Personalized Medicare system consists of identifying nature and contribution of genes as well as different environmental factors and preparation of personalized drugs based upon the information derived. DNA tests may be classified into somatic and germ cell genomic tests. Personalized Medicine system can then facilitate disease prediction and treatment, by determining whether an individual runs the risk of developing a disease. Thus this novel medicare system facilitates early prevention strategies for different diseases. In this system, it is possible to diagnose different diseases faster and therefore, treatment can be started early. Because of these advantages, it becomes possible to minimize side effects that are resulted from medicines given to a patient by trial and error method using the traditional system of treatment. In India, activities in the realm of personalized healthcare have started recently, but these activities are progressing very fast. Advances in researches on genomics technology are expected to revolutionize personal genomics, leading to significant improvement in preventive healthcare in India. The Medicity (a joint venture between Positive Bioscience and Medanta) has been a pioneering clinic for personal genomics in India [41]. Some other Indian projects related to personalized medicare include Nutragen's genetic testing for type 2 diabetes on a commercial scale, efforts made by the company Xcode Lifesciences to take care of some lifestyle-related health problems, like obesity and diabetes using non-invasive techniques of high-throughput genotyping, AVESTAENOME project for developing pharmacogenomics-based therapies and for treatment of age-related health disorders, etc. [41].

Since India is a diverse country having huge population and since a large number of Indians suffer from genetic diseases (mainly owing to marriages among blood relations), the need for personalized medicine is quite high [16]. Once this novel medicare system is adopted in a larger scale, it will earn popularity in no time, because this system of treatment takes care of genetic variation, as well as the difference in lifestyle and environment of early diagnosis, but also more accurate treatment and better clinical management. In India, as per the assertion of Gunashekar [16], this novel medicare system is already in place, more particularly in several specialized areas, such as diabetology, oncology, psychiatry and cardiology. For cancer treatment in India, it has been reasonably popular amongst medical practitioners. Chatterjee and Pancholi [8] remarked that the concept of personalized medicine was prevalent in the Indian mode of medical treatment, Ayurveda which takes into account the lifestyle, diet and medication. They made an observation that this mode of treatment existed in ancient India, whereas in the present century – personalized medicine is based on analysing DNA, RNA an genomes of different people. Jauhari and Rizvi [18] while discussing personalized medicine

in the Indian context, stressed upon the need for proper sequencing of human genomes, while Nair [25] asserted that in the personalized medicine system, different therapies are prescribed for different patients on the basis of the patients' pharmacogenetics and pharmacogenomics investigations. Further discussions on the prospects and impact of personalized medicine in India were made by Patel [29], Yadav [44] and Ramprasad [34].

All the discussions made above indicate that there are distinct advantages in the Personalized Medicare system, which can be summarized as follows:

- i) In this novel system, it is possible for the medical practitioners to prevent onset of different diseases more effectively.
- ii) It is more time and cost effective.
- iii) This treatment procedure bears the potential to reduce the possibility of adverse reaction of drugs.

However, it is to be borne in mind that for successful adoption of the Personalized Medicare system, it is highly necessary to first identify the 'critical success factors'. This act of identification will significantly add to the success of the personalized healthcare system management.

As indicated above, the novelty of personalized healthcare lies in the fact that it treats people by taking cognizance of their genomic type makes use of information regarding their environment.

At this juncture, it may be pointed out that although scientists and technologists have dwelt on the importance and advantages of Personalized Medicine system, none of them made any attempt to develop a model and to analyse it scientifically with an aim to explore the success factors in the adoption of personalized medicine. If the success factors are identified and adequate attention is paid to them, we can expect success in adopting personalized medicine. Otherwise, adoption of PM may turn out to be a failure. The specific question that we want to address here is as follows:

What are the main factors that must be paid special attention in order that the adoption of Personalized Medicine System in healthcare management is successful?

In view of this, we have made an endeavour in this paper to identify the critical success factors by employing an empirical method. The highlights of the study are given below:

- i) An appropriate questionnaire was designed. It was distributed to a variety of people, consisting of clinicians, researchers, pharmacists, regulatory board members and patients.
- ii) The feedback was collected and the data were processed.
- iii) The processed data were analysed by using appropriate statistical techniques, *t*-test and correlation/regression analysis.
- iv) Based on the statistical analysis, eight critical factors have been identified, which contribute to the success of adoption of personalized medicine.
- v) The list of critical success factors includes – (a) Data management, (b) Team work and composition of the team, (c) Privacy and confidentiality, (d) Min-set of people, (e) Return on investment, (f) Time, (g) Research and development (R&D) and (h) Alignment.

To the best of authors' knowledge, this is the first article in which an attempt is made to identify the critical factors that can affect implementation of Personalized Medicine.

2. Background and motivation

While considerable amount of research has been done on conventional medicine system and its implementation, literature on

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