Internal Medicine and Medical Investigation Journal
E-ISSN: 2474-7750
Homepage: www.imminv.com

SYSTEMATIC REVIEW PROTOCOL

Personal Electronic Health Record for Patients with Diabetes; Health Technology Assessment Protocol

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ARTICLE INFO

Article history
Received: Aug 17, 2017
Accepted: Sep 03, 2017
Published: Oct 05, 2017
Volume: 2
Issue: 4

Conflicts of interest: None
Funding: None

Key words
Diabetes,
Personal Electronic Health Record,
Health Technology Assessment,
Effectiveness,
Systematic Review,
Meta-Analysis

ABSTRACT PROTOCOL

Introduction: In recent decades, diabetes has contributed significantly to the burden of disease in developed and developing countries, due to the considerable prevalence and involvement of various age groups in the communities. Today, a variety of ways to manage and control the disease are used, one of which is the use of personal electronic health records. Recently there has been a remarkable upsurge in activity surrounding the adoption of personal electronic health records systems for patients and consumers. personal electronic health records systems are more than just static repositories for patient data; they combine data, knowledge, and software tools, which help patients to become active participants in their own care. The present study was conducted with the goal of Health Technology Assessment the impact of personal electronic health records in Patients with Diabetes. **Methods and Analysis:** Writing is based on PRISMA standards. This was a Health Technology Assessment study. It aimed to evaluate the technology of personal electronic health record. The scoping review was conducted to evaluate 8 dimensions (Health Problem and Current Use of the Technology, Description and technical characteristics of technology, Safety, Costs and economic evaluation, Ethical analysis, Organizational aspects, Patients and Social aspects, Legal aspects) of Personal electronic health record. This study was based on answering questions which were developed based on Health Diagnostics Technology Assessment Documents Framework and Health Technology Assessment (HTA) Core Model 3.0. A systematic review was conducted to evaluate the Clinical Effectiveness dimension of personal electronic health record in controlling diabetes. In order to gather evidences, Ovid databases, Cochrane Library, PubMed, CRD, Trip database and EMBASE, and Randomized Controlled Trial Registries, such as the Clinical Trial and Trial Registry, were searched using specific keywords and strategies. Articles are evaluated on the basis of the quality criteria of JADAD. The data is analyzed by the STATA software. **Dissemination:** The results of the study will be published in a peer-reviewed journal and presented at relevant conferences. Policy makers and healthcare decision-makers can use these results.

INTRODUCTION

Diabetes is a metabolic disorder that leads to absent the ability of the body to produce insulin or make the body to resistance against insulin; so, the produced insulin may not do its normal function, and finally, the blood glucose will increase. In long-term, the excessive amounts of blood glucose level may damage various parts of the body such as cardiovascular system, eyes, kidneys, genital system, and nervous system (1-3). In recent years, the incidence of diabetes has increased in worldwide (4). According to latest statistics, the

Published by Mehrabani Publishing LLC.

http://dx.doi.org/10.24200/imminv.v2i4.100

global prevalence of diabetes reached to 382 million people in 2013. It is predicted that in 2035, it will reach about 592 million people (5). In Iran, the number of individuals who were infected with this disease was 9.9% in 2013; according to predictions, it will reach to 10.1% in 2035 (6). Nowadays, diabetes is epidemic in the world; the world's prevalence of diabetes increases by about 6% annually. Considering the increased prevalence of diabetes in the world, the treatment, control, and acute complications of diabetes require considerable expenditure by both patients and community health system. In a report which was published in 2001 by World Health Organization (WHO), in which the global burden of diseases was calculated, diabetes ranked 20th in years lived with disability; in other words, 1.4% Years lost due to disability (YLD) was associated with this disease (7).

The economic and physical consequences of diabetes are significant; it increases mortality and causes a lot of economic burdens (8). However, the negative consequences of diabetes may be prevented (9). The effective care and disease management are the only available solutions. The management of diabetes is complex and requires basic healthcare, coordinated care, nutritionist and endocrine experts' cooperation, etc. The patient education including proper lifestyle, healthy nutrition, having physical activity, and appropriate use of medications therapy is necessary to facilitate controlling blood glucose levels (10). However, the increased number of people with diabetes, low numbers of primary care providers, and increasing healthcare costs have made it harder to take care of diabetic patients. In 2001, the National Academy of Medicine presented a solution to this problem which was known as improving communication between patients with chronic disease and self-care (11).

The improved knowledge and performance of patients with diabetes mean improved metabolic situation control and performing proper self-care behaviors (12). Therefore, the patients with diabetes will take care of him/herself well if he/she will be aware of his/her illness and treatment, tests, drugs, medical recommendations, follow-up visits, and blood glucose monitoring blood glucose levels. Indeed, the patients need conditions through which they may participate more in making decisions about their health status.To achieve this, the electronic personal health record (ePHR) is one of the appropriate tools which also empowers patients (13, 14). The concept of ePHR has existed from the past and is not new. In the past, the patients hold their health information in paper form. Archer *et al.* (2011) reported that among 47% of patients who keep their health records, 87% stated that they keep them in paper form.Nowadays, the ePHR maintains the health and medical information of people in electronic form and they are available at anytime (15). The ePHR is an electronic software in which people access and manage their medical information. Hence, people may access to this confidential information in a secure medium (16).

This study aims to evaluate the technology of ePHR in patients with diabetes compared with those who only received routine services and have not used ePHR. It can helped policy-makers in entry, design, and how to use it.

In dictionary of International Bureau of Health Technology Assessment (HTAi), this field is defined as HTA is a systematic evaluation of clinical effectiveness, cost-effectiveness, or social and ethical effects of health technology on patient's life and healthcare system. This process specifies that whether the desired health technology should be used (17). If so, how should it be used and which patients will benefit most from it? The evaluations are different, but it mostly focuses on cost and impact of technology on population or society.

According to this definition, the HTA studies address various dimensions of health technologies impacts; these dimensions may be divided into nine general domains including (health problem and current use of the technology, description and technical characteristics of technology, safety, clinical effectiveness, costs and economic evaluation, ethical analysis, organizational aspects, patients and social aspects, and legal aspects) The examination of these technology dimensions effects and their related results may influence policy-maker and decision-making.The HTA Core Model is a methodological framework for collaborative production and sharing of HTA information. The HTA Core Model is a registered trademark. According to HTA Core Model 3.0, the technology dimensions study in HTA includes some elements; questions should be answered in each element (18).

METHODOLOGY

This was a HTA study. It aimed to evaluate the technology of ePHR. The scoping review was conducted to evaluate 8 dimensions (health problem and current use of the technology, description and technical characteristics of technology, safety, clinical effectiveness, costs and economic analysis, ethical issue, organizational aspects, patients and social aspects, and legal aspects) of ePHR. This study was based on answering questions which were developed based on Health Diagnostics Technology Assessment Documents Framework and HTA Core Model 3.0 (18). A systematic review was conducted to evaluate the clinical effectiveness dimension of ePHRin controlling diabetes.

Questions

Databases including Cochrane library, PubMed, Center for Review and Dissemination(CRD), Trip database, and EMBASE, randomized controlled trial (RCT) studies register databases (such as Clinical Trial and Trial Registry) were searched bykeywords as follow: personal health record, personal medical records, ePHR, diabetes mellitus, and records. The search was performed without any time and language limitation.The final articles were collected for systematic review based on the process of selecting specific resources; their quality was evaluated based on Critical Appraisal Skills Program (CASP) critical evaluation checklist which is designed for RCT studies. The structured questioning components (PICOD) at population, intervention, comparison, outcome, and design levels are as follows Table 1 and 2 both here .

Examined dimension	Questions	Answers
1-Health problems and current technology use	What disease or major health problem is the target of intervention? Define diabetes disease and categorize it? What are the symptoms of diabetes? What are the risk factors for diabetes? What are the outcomes and consequences of disease? How many people are in the group of patients with diabetes? What is the burden of diabetes? What is the rate of applying ePHR technology? How the application of ePHR technology varies in different countries, regions, and programs? How developed is the ePHR technology (study, emerging, stabilized, declining phases)? Does ePHRtechnology fall into the basic services package of different countries? What is the coverage of technology in other countries? Who produces PHR technology?	Scoping review
2- Technology features	What is ePHR? How is the scientific foundation and mechanism of its effect? Why is ePHRused? For whom the ePHR technology is applicable? Is public information about technology necessary? What information is needed to inform people? What are capital factors required to use ePHR technology? What kind of specific platform is required to use ePHR technology? What type of equipment is required to use ePHR technology? What types of data are required to monitor the application of ePHR technology? What type of training or information on PHR technology is required to be provided to patients, their families, and the general public? What are the proven and potential applications of ePHR technology?	Scoping review
3-safety	What are the potential risks and possible damages of PHR technology? What is the range of risks which are associated with ePHR technology; incidence, severity, duration? How is the prevalence of technology-related damages? When damage occurs (immediately or delayed)? Which of the damages which are associated with ePHR technology are more important considering their prevalence and severity? Does the prevalence of ePHR-related damage changes over time? How ePHR technology is safe compared to alternative technologies? What are the ways to reduce user-related safety risks? Is there any evidence of environmental damages? What kind of environmental protection is needed?	Scoping review
4- Effectiveness	What is the effect of ePHR technology on overall mortality? What is the effect of ePHR technology on the mortality rate of target disease? What is the effect of ePHR technology on mortality which is caused by other reasons? What is the effect of ePHR technology on severity and frequency of disease symptoms and findings? What is the effect of ePHR technology on the progression of disease? What is the effect of ePHR technology on recurrence of disease symptoms? What is the impact of ePHR technology on health-related life quality? What is the impact of ePHR technology on quality of life which is associated with target disease? What is the effect of ePHR technology on patient's return to work and previous life situation? What is the impact of ePHR technology on patient's daily activities? Is ePHR technology valuable to the patient?	Systematic review
5- Costs and economic assessment	What types of resources are used to provide evaluated technology and comparing it (identification of used resources)? How many resources are used in providing evaluated technology or competing technologies (costs which are specifically related to technology)? What is the unit price of consumed resources at the time of providing evaluated technology and its comparators? What is the effect of PHR technology on indirect costs? What are the incremental effects of technology relative to comparators? What is the incremental cost-effectiveness ratio?	Scoping review

(*Contd...*)

Examined dimension	Questions	Answers
6-Ethical	Is ePHR technology a new and innovative technology which adds to standard care or replaces a standard? Does ePHR technology challenge the religious, cultural, or spiritual principles and beliefs of some groups or change the current social principles of society? What are the unanticipated and unwanted results and implications of ePHR technology? Does the use of ePHR technology affect the patient's ability? Does PHR technology have any risks or challenges that the patient needs to know it? Does the institutionalization and use of ePHR technology affect human status? Does institutionalization and use of ePHR technology affect human dignity? What are the benefits and dangers for the patients, and how will there be a balance between the benefits and risks when the technology is institutionalized and when it is not institutionalized? Who creates a balance between risks and benefits? And how? Can ePHR technology harm other stakeholders? What are the effects of institutionalizing and not institutionalizing of technology on justice in health care? Are the principles of equality, justice, and integrity respected?	Scoping review
7-Organizational	What kind of workflow and disease flow will be required? What kind of partnership of patients and relatives is needed to be developed in the process of treatment and care? What type of staff training and other human resources is needed? What will be the results of the centralized and decentralized expansion of implementing new technology? What investment (material and immaterial) should be undertaken to set up and expand technology? What effect will the technology implementation have on government spending and budgets? What are the challenges and management opportunities which are associated with technology? Who decides about whether the patient uses ePHR technology? How will the new ePHR technology be accepted?	Scoping review
8-Social	What social domains are affected by ePHR technology? In addition to the patient, what is the effect of technology on other important people? What kind of support and resources are needed when PHR technology is used? How will technology affect the position, role, and functions and important life issues of the patient in society? How the use of ePHR technology changes the physical and psychological functioning of patients in main living areas? How do patients and other important people react to ePHR technology? How is the understanding and knowledge of patients and other important people about ePHR technology? How are the information on using ePHR technology analyzed and exchanged?	Scoping review
9-Legal	Whether the use of technology by patient needs an informed consent from the patient? Whether in the case of using alternative technologies of evaluated technology, the patients should be informed? Considering patient's conditions, whether they have enough time to decide on technology? Is it possible to obtain the informed consent of the patient before using technology? Does the use of technology require access to personal and private information of patient? Do all people need (or will have) same access to evaluated technology? Does the technology require a specific registration mechanism? Does the technology need a specific assessment and monitoring mechanism? Are there enough rules for technology use? Are certain rules and regulations required for using technology? What areas are considered in using these rules?	Coping review

Table 1. Structured questioning components (PICOD)

Population	Patients with diabetes
Intervention	ePHR
Comparison	received regular care
Outcome	Health problems and current use of the technology, description and technical characteristics of technology, safety, clinical effectiveness, costs and economic evaluation, ethical issue, organisational aspects, patients and social aspects, legal aspects
Design	HTA, systematic review, RCT, non Clinical -trial studies, economic evaluation, guidelines

Table 2. Applied search strategy in electronic databases CRD York

Result	Searches
(Personal Health Record OR Personal Health Records OR Personal Medical Records) AND (Diabetes Mellitus, Type 1 OR Diabetes Mellitus, Type 2 OR Glucose Intolerance OR Diabetic Ketoacidosis OR Diabetes Insipidus): TI IN DARE, NHSEED, HTA	0

Search Name Cochran: library

Search	Query	Items found
1#	((((“”Personal Health Record “”[Title/Abstract]) OR “”Personal Health Records “”[Title/Abstract]) OR “”Personal Medical Records””) OR “”Personal Electronic Health Records “”) OR “”Personal Electronic Health Records “”[Title/Abstract]”,	844
2#	(((((“”Diabetes Mellitus””[Title/Abstract]) OR “”Diabetes Mellitus, Type 1 “”[Title/Abstract]) OR “”Diabetes Mellitus, Type 2 “”[Title/Abstract]) OR “”Glucose Intolerance “”[Title/Abstract]) OR “”Diabetic Ketoacidosis “”[Title/Abstract]) OR “”Diabetes Insipidus””[Title/Abstract]”,	177851
3#	((((((“”Personal Health Record “”[Title/Abstract]) OR “”Personal Health Records “”[Title/Abstract]) OR “”Personal Medical Records””) OR “”Personal Electronic Health Records “”) OR “”Personal Electronic Health Records “”[Title/Abstract])) AND ((((((“”Diabetes Mellitus””[Title/Abstract]) OR “”Diabetes Mellitus, Type 1 “”[Title/Abstract]) OR “”Diabetes Mellitus, Type 2 “”[Title/Abstract]) OR “”Glucose Intolerance “”[Title/Abstract]) OR “”Diabetic Ketoacidosis “”[Title/Abstract]) OR “”Diabetes Insipidus””[Title/Abstract])”,	21
4#	((((((“”Personal Health Record “”[Title/Abstract]) OR “”Personal Health Records “”[Title/Abstract]) OR “”Personal Medical Records””) OR “”Personal Electronic Health Records “”) OR “”Personal Electronic Health Records “”[Title/Abstract])) AND ((((((“”Diabetes Mellitus””[Title/Abstract]) OR “”Diabetes Mellitus, Type 1 “”[Title/Abstract]) OR “”Diabetes Mellitus, Type 2 “”[Title/Abstract]) OR “”Glucose Intolerance “”[Title/Abstract]) OR “”Diabetic Ketoacidosis “”[Title/Abstract]) OR “”Diabetes Insipidus””[Title/Abstract]) Filters: Randomized Controlled Trial”	2

ID	Search hits	Items found
#1	Personal health record: ti, ab, kw (Word variations have been searched)	374
#2	Personal health records	1682
#3	Personal medical records/	1531
#4	Computerized patient records/	612
#5	ePHR s/	1426
#6	patient-held record	51
#7	personally controlled health record	103
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7	2404
#9	Diabetes Mellitus, Type 1	18472
#10	Diabetes Mellitus, Type 2	21837
#11	Glucose Intolerance	1356
#12	Diabetic Ketoacidosis	375
#13	Diabetes Insipidus	139
#14	#10 or #11 or #12 or #13 or #14	24447
#15	#9 and #15	366
#16	#9 and #15 Publication Year from 2000 to 2016, in Trials	27

Selection of studies

The phase of searching and reviewing quality of articles will be done by two individuals independently. In the case of disagreement, the judgment was made by the third person. After completing the search, all found articles were entered into EndNote software, and the duplicates items will be deleted.Then, the titles and abstracts of articles will be reviewed by two people based on inclusion and exclusion criteria. In the case of unclear title and abstract, the full text was extracted. Also, articles’ references will be reviewed and the related studies will be searched.The inclusion and exclusion criteria in the first (based on title and abstract) and second (based on full text) stages are as follows:

Inclusion and exclusion criteria of study

- Population:

The studies that have survey the other diseases more than diabetes will be excluted.

- Intervention:
  The studies which have examined PHR will be excluded from.
- Comparison:
  The studies which have not studied target comparison group will be excluded.
- Outcome:
  The studies which have considered unrelated impact will be excluded from the study.
- Design:
  Other types of studies other than related studies will be excluded.

Data Extraction

The data extraction checklist will be designed based on articles data. To ensure all authors who participate in study will obtain comparable data, the data of some articles will be entered in the pilot checklist. After modifying it, the final checklist will be designed and articles data will be extracted according to designed checklist.The checklist includes several parts as follow: the first part consist of main data of article such as title, corresponding author name, year of study, year of publication, place where the study was conducted, date on which the study began and ended, age of patients, and conflict of interests; the next parts includes items that are related to population and outcome of study. The selected studies will be divided into two groups, and each of them will be assigned to two colleagues for data extraction; each of them will independently extract the data from articles. After completing data extraction checklist, each of colleagues examine other colleague's data extraction checklist.

Evaluation of Bias Risk in Articles which are Entered into Meta-Analysis

If all studies will be RCT, the Cochrane Collaboration's Risk Bias (RoB) tool will be used. The bias risk in studies may be assessed using Cochrane Collaboration tool. We will use GRADE template making software to facilitate the presentation of findings of this evaluation. This assessment includes selection bias, relationship bias, performance bias, and biases in the identification, the report, and other bias sources including intervention compatibility, validity, and reliability of studies.

Analysis and Aggregation of Data

After a systematic search, if meta-analysis is possible, the selected studies will be entered into Rev Man and Stata software and based on a fixed or randomized model (the fixation model will be used in this study), the mean difference and confidence interval will be calculated.

Heterogeneity Assessment

The I2 and Chi-squared tests will be used to examine the heterogeneity of studies. In this method, according to values of I2 index, the heterogeneity level is presented as follows: low heterogeneity (25%- 50%), medium heterogeneity (50%-75%), and high heterogeneity (more than 75%). If the numerical value of this index will be zero, it indicate that the results are homogeneous and if the score will be higher, it suggest that the results are heterogeneous. If the heterogeneity in results of various studies will be confirmed, the analysis will be conducted in subgroup analysis. Indded, the studies will be grouped based on probabilistic factors causing heterogeneity, and separate statistical analysis will be performed in each group. In the case of meta-analysis, the Forest Plot and Funnel Plot will be drawn.

Missing Items

Some articles will be excluded due to various reasons such as inaccessibility of full text. The data of missing items will not be considered (for primary or secondary outcomes) and will not affect results of this study.

Sensitivity Analysis

If necessary, the sensitivity analysis will be performed by re-running analyses without using studies that have high bias risk.

Evaluation of Quality of Studies

The JADAD criterion will be used to evaluate the quality of clinical trials studies. This checklist includes three main items including randomization, blindness, and description of results; the standard score for first and second items is 2 and for the third item is 1. Also, the expert views will be used to check the quality of articles. Among the factors which are considered for the evaluation of the quality of articles are validity of results, method of assigning participants to intervention and control groups, checking that the results are achievable, the external validity of results, etc.

ACKNOWLEDGMENT

The corresponding author appreciates all authors of this article.

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