Prerequisites of Personal Health Record for Chronic Kidney Disease: A Scoping Review and Evaluation of the Content Validity

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Abstract. Background: It is obvious that the Personal Health Record (PHR) is a major cornerstone for “improving the self-management of patient”. However, lack of an effective and comprehensive personal health record system prohibits the widespread use of PHRs. The aim of this study was to identify the core data sets and required functionalities for designing a PHR for chronic kidney disease (CKD) management and assess their validity. Methods: It was a study including two phases. In the initial phase, a scoping review was conducted with the aim of determination the core data sets and required functionalities for designing PHRs. Then in the second phase, the validity of data items and functionalities was determined by 25 multidisciplinary experts. Results: 22 studies were eligible after screening 1335 titles and abstracts and reviewing 88 full texts. We determined 20 core data set and 8 required functionalities of PHRs. From the perspective of experts, ‘health maintenance’ and ‘advance directives’ were most often marked as useful but not essential, while ‘test and examination’, ‘medication list’ and ‘diagnosis and comorbid conditions’ were predominantly considered as essential by all experts (n=25, 100%). Conclusion: This research is a step that we have taken to identify prerequisites that could be used for the design, development, and implementation of an effective and comprehensive electronic personal health record.

Keywords. Chronic Kidney Disease, Personal Health Record, PHR, CKD, Core data sets

1. Introduction

Significant social and economic burdens of chronic diseases have led to a shift in the health policy, involving a focus on health promotion, chronic disease prevention, and self-management [1]. Chronic kidney disease (CKD) is a major public health concern [2-
More than 70 million individuals worldwide have CKD, and according to estimates, the prevalence will further increase as will the already enormous impact CKD has on health system resources related to its care [5,6]. Health information technologies (ITs) have the potential to significantly increase the engagement of patients by using personal health records (PHRs) to electronically connect them to their health information and clinical team and continuity of care [7]. PHR is a tool that has the potential to change and possibly to improve patient–provider relationship and enable the healthcare system to evolve a more personalized medical model and promising results to address some of these challenges [8-10]. Unfortunately, designing and developing programs that improve patient care and obtaining complete and high-quality data in nephrology have remained a challenge [11]. The literature does not yet adequately describe the potential functions and prerequisites of PHRs design [12-15]. So, the objectives of these study were to derive core data sets and functionalities specifically for PHRs for patients diagnosed with CKD and determine the validity of these core data sets and functionalities.

2. Method

This review was guided by Arksey and O’Malley’s 6-stage scoping review framework [16]. We searched for relevant articles written in English between 1990 and Jan 2021 using PubMed, Science Direct, Web of Science and Embase databases, and the related websites such as guideline.gov, IEEE, and WHO. A combination of keywords and Medical Subject Headings (MeSH) were used as follows: group A included PHR-related terms and group B included terms related to “kidney failure chronic.” We considered all the full text papers with quantitative, qualitative, or mix method designs and full reports that studied PHRs and determined the data elements and functionalities of chronic kidney disease PHR. However, the papers in the formats of letter to editor, short communication and commentary, and articles in non-English language or those with English abstracts published in languages other than English were excluded. Additionally, if the study was about a personal electronic record but had not the state data items and functionalities, it was excluded from the study. After searching the studies from all databases and eliminating duplicates, the studies were independently reviewed and screened by two members of the research team (FS and RSH) in three phases by title, abstract, and then the full text of the articles. Studies meeting the inclusion criteria were critically reviewed using Arksey and O’Malley’s summative analysis method [16] according to the frequency of the items in the included studies. To validate the core data sets and functionalities, we formed an expert panel. The panel consisted of 25 multidisciplinary experts that were recruited base purposive sampling. In this way, the experts are requested to specify whether the core data sets and functionalities is necessary for designing a PHR for CKD or not via email. To this end, they are requested to score each item from 1 to 3 with a three-degree range of “not necessary, useful but not essential, essential” respectively. The formula of content validity ratio is CVR= (Ne - N/2) / (N/2), in which the Ne is the number of panelists indicating "essential" and N is the total number of panelists. The numeric value of content validity ratio is determined by Lawshe table [17]. Ethical approval was received from the Shiraz University of Medical Sciences by Dr Abbas Rezaeianzadeh, (Ethical number: IR.SUMS.REC.AC.IR.1399.1310).
3. Results

In total, 1335 studies were selected after searching the databases. After removing the duplicates, screening, and applying inclusion and exclusion criteria, 88 studies were eligible for further full-text review. Thereafter, 16 articles, 4 reports, and 2 guidelines were selected for the final analysis.

Most studies were journal article (n=16, 76%), published in the USA (n=10, 45%), and published between 2012 and 2018 (n=15, 71%) (Table1).

Table 1: Description of included study

| First author name & [Ref] | Resource type | Publication Date | Country / Institution |
|---------------------------|---------------|------------------|-----------------------|
| Venuthurupalli [18]       | Article (Cross sectional) | 2017 | Australia            |
| Nakashima [19]           | Article (Cross sectional) | 2017 | Japan                |
| Mendu [6]                 | Article (Prospective study) | 2014 | USA                  |
| Duarte [10]               | Article (Case report) | 2016 | Germany              |
| Khan [23]                 | Article (Cross sectional) | 2013 | USA                  |
| Mendu [21]                | Article (Cross sectional) | 2019 | USA                  |
| Drawz [20]                | Article (Review) | 2012 | USA                  |
| Drawz [22]                | Article (Review) | 2015 | USA                  |
| Kaelber [11]              | Article (Cross sectional) | 2008 | USA                  |
| Dickinson [13]            | Article (Cross sectional) | 2014 | USA                  |
| Do [26]                   | Article (Cross sectional) | 2011 | USA                  |
| Archer [9]                | Article (Review) | 2011 | Canada               |
| Roehrs [31]               | Article (Review) | 2017 | Brazil               |
| Tran [28]                 | Report         | 2012 | USA                  |
| Tang [32]                 | Report         | 2007 | California           |
| Johnston [30]             | Report         | 2008 | Germany              |
| Burke-Bebee [25]          | Report         | 2010 | USA                  |
| Kachar [7]                | Article (Cross sectional) | 2011 | USA                  |
| Bruland [29]              | Report         | 2012 | USA                  |
| Tran [28]                 | Report         | 2012 | USA                  |
| unknown [34]              | Report         | 2012 | European             |

Table 2: Core data sets for designing PHRs for chronic kidney disease based on evidence and expert panel.

| Core Data Sets | Frequency (%) | Expert Panel | CVR* | Interpretation |
|----------------|---------------|--------------|------|----------------|
| Problem list   | 7(31.81%)     | 24(96%)      | 0    | 0.92 Remained  |
| Surgical procedures | 20(90%)   | 23(92%)      | 1(4%)| 0.84 Remained  |
| Diagnostic/comorbid conditions | 9(40.90%) | 25(100%) | 0     | 0.92 Remained  |
| Risk factors & allergies | 8(36.36%)  | 23(92%)      | 0(4%)| 0.84 Remained  |
| Demographics data | 9(40.90%) | 24(96%)      | 0    | 0.92 Remained  |
| Disease characteristic | 9(40.90%) | 24(96%)      | 0    | 0.92 Remained  |
| Advance directives | 20(90%)   | 17(74%)      | 28(12%)| 0.36 Eliminated |
| Physical examination | 20(90%)   | 22(88%)      | 28(12%)| 0.36 Remained  |
| Wellness management | 3(13.62%)  | 22(88%)      | 3(12%)| 0.76 Remained  |
| Care plan      | 20(90%)       | 23(92%)      | 1(4%)| 0.84 Remained  |
| Health summary | 6(27.27%)     | 23(92%)      | 0    | 0.84 Remained  |
| Family record / history | 7(31.81%) | 24(96%)      | 0    | 0.92 Remained  |
| Genetic data   | 20(90%)       | 20(80%)      | 3(12%)| 0.60 Remained  |
| Health patterns | 7(31.81%)    | 20(80%)      | 4(14%)| 0.60 Remained  |
| Test & examination | 17(77.27%) | 27(100%)     | 0    | 1 Remained     |
| Functional status | 20(90%)    | 21(95%)      | 3(12%)| 0.68 Remained  |

Finally, 124 data items were identified from the literature that classified in 20 core data set. “Test and examination” was the most common core data set examined (n = 17) in the included studies. Other common core data item examined included medication list (n=12), “diagnosis and comorbid conditions”, “preventive care & immunization” and “demographic data” (n=9). About data sets, ‘health maintenance’, and ‘advance directives’ were most often marked as useful but not essential or unnecessary, while ‘test
and examination’, ‘medication list’ and ‘diagnosis and comorbid conditions’, were predominantly considered as essential by all experts (n= 25, 100%) (Table2).

### Table 3. Required functionality in designing PHRs for CKD based on evidence and expert panel.

| Required functionality | Sub items | Frequency | Expert plan | CVR* |
|------------------------|-----------|-----------|-------------|------|
| Historical data        | Manage historical clinical data | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage clinical observations | 18 (72%) | 7 (28%) | 0 | 0.44 |
|                        | Manage test results | 25 (100%) | 0 | 0 | 1 |
|                        | Manage provider care plans | 23 (92%) | 1 (4%) | 1 (4%) | 0.84 |
|                        | Manage health calendar | 23 (92%) | 1 (4%) | 1 (4%) | 0.84 |
| Management of decision support | Manage medication | 25 (100%) | 0 | 0 | 1 |
|                        | Manage drug interaction checking | 18 (72%) | 7 (28%) | 0 | 0.44 |
|                        | Manage guidelines and protocols | 23 (92%) | 2 (8%) | 2 (8%) | 0.68 |
|                        | Manage health alerts | 23 (92%) | 2 (8%) | 0 | 0.84 |
|                        | Manage health reminders | 23 (92%) | 2 (8%) | 0 | 0.84 |
| Management of patient support | Manage custom patient education | 23 (92%) | 2 (8%) | 0 | 0.84 |
|                        | Manage family education | 23 (92%) | 2 (8%) | 0 | 0.84 |
|                        | Manage data input errors | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage trading patterns | 21 (84%) | 2 (8%) | 2 (8%) | 0.68 |
|                        | Manage shared patient experience | 15 (60%) | 1 (4%) | 9 (36%) | 0.20 |
|                        | Manage results notification | 23 (92%) | 2 (8%) | 0 | 0.84 |
| Management of security | Manage secure the access to PHR | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage entity authentication | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage entity authorization | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage secure data exchange | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage patient privacy | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage secure messaging | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage consents and authorizations | 23 (92%) | 1 (4%) | 1 (4%) | 0.84 |
|                        | Manage data masking for sensitive | 22 (88%) | 3 (12%) | 0 | 0.76 |
|                        | Manage a registry of actors | 24 (96%) | 1 (4%) | 0 | 0.92 |
| Management of administrative issues | Manage demographics information | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Management scheduling | 24 (96%) | 1 (4%) | 0 | 0.92 |
|                        | Manage advance care directives | 17 (68%) | 2 (8%) | 6 (24%) | 0.36 |
|                        | Manage insurance eligibility | 21 (84%) | 1 (4%) | 3 (12%) | 0.68 |
|                        | Manage clinical trial recruitment | 22 (88%) | 0 | 3 (12%) | 0.76 |
|                        | Manage multiple views of data | 17 (68%) | 3 (13%) | 0 | 0.76 |
|                        | Manage donor information | 16 (64%) | 5 (20%) | 4 (16%) | 0.28 |
|                        | Manage access to public health | 20 (80%) | 4 (16%) | 1 (4%) | 0.60 |
|                        | Manage clinical research | 20 (80%) | 1 | 0 (4%) | 0.92 |
|                        | Manage clinical dashboard | 22 (88%) | 2 (8%) | 1 (4%) | 0.76 |
| Management of electronic communication | Manage team coordination | 23 (92%) | 2 (8%) | 0 | 0.84 |
|                        | Manage of communication | 25 (100%) | 0 | 0 | 1 |
|                        | Manage contact information | 23 (92%) | 2 (8%) | 0 | 0.84 |
|                        | Manage referral authorizations | 16 (64%) | 6 (24%) | 3 (12%) | 0.28 |
|                        | Manage Home monitoring | 23 (92%) | 2 (8%) | 0 | 0.84 |
| Management health monitoring | Manage wellness, preventive, life style | 23 (92%) | 1 (4%) | 1 (4%) | 0.84 |

NOTE: *CVR or Content Validity Ratio = (N e-N/2)/ (N/2) with 25 persons at the expert panel (N=25), the items with the CVR bigger than 0.37 remained at the instrument and the rest eliminated.

In terms of required functionalities, ‘manage of communication’, ‘manage medications’ and ‘manage test and examination’ were considered as essential by all experts (n= 25, 100%). Management of clinical research information and clinical trial recruitment were other functionalities recommended by experts. According to result of expert panel, 2 items out of core data sets items (health maintenance & advance directives) and 4 items out of functionalities (manage shared patient experience, manage advance directives, manage donor information & manage referral authorizations) were eliminated (Table 2&3).
4. Discussion

Based on the results of our study, 20 core data sets were determined. Core data items proposed by this study covered all 11 data components essential for PHRs that were prepared by consensus set of standards of CCD, CCA, CCR, AHIMA, AMIA, DICOM, immunizations, medications, allergies, family history, lab/test results, and procedures/surgeries [28,32]. The corresponding PHRs for CKD, ‘advanced directives’, was checked as unnecessary in most of responses by experts. Considering that advanced directives are not popular in Iran, the number was expected. These findings contrast with other countries which ‘advanced directives’ is very important and, indeed, the legal right of the patient [28,36]. These differ may be due to cultural differences between Iran and other countries might influence the choice of key data sets/functionailities. Essential functionalities that recommended by experts in designing PHRs for CKD were consistent with the results of other on literature [6,10,11,18,19,26,28,29]. An innovative function under strong focused of experts is the “custom patient education”. Health care delivery moves towards a more consumer focused, personalized care, patients and individuals’ roles grow, and many potential advantages of the PHR have been portrayed [37].

5. Conclusions

We propose pre-requisites of personal health record consisting of 20 core data sets and 8 main functionalities for CKD patient. These pre-requisites could be used for designing and implementing effective and comprehensive PHRs for chronic kidney disease management.

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