Level of Technological Maturity of Telemonitoring Systems Focused on Patients with Chronic Kidney Disease Undergoing Peritoneal Dialysis Treatment: A Systematic Literature Review

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Abstract: In the field of eHealth, several works have proposed telemonitoring systems focused on patients with chronic kidney disease (CKD) undergoing peritoneal dialysis (PD) treatment. Nevertheless, no secondary study presents a comparative analysis of these works regarding the technology readiness level (TRL) framework. The TRL scale goes from 1 to 9, with 1 being the lowest level of readiness and 9 being the highest. This paper analyzes works that propose telemonitoring systems focused on patients with CKD undergoing PD treatment to determine their TRL. We also analyzed the requirements and parameters that the systems of the selected works provide to the users to perform telemonitoring of the patient’s treatment undergoing PD. Fourteen works were relevant to the present study. Of these works, eight were classified within TRL 9, two were categorized within TRL 7, three were identified within TRL 6, and one within TRL 4. The works reported with the highest TRL partially cover the requirements for appropriate telemonitoring of patients based on the specialized literature; in addition, those works are focused on the treatment of patients in the automated peritoneal dialysis (APD) modality, which limits the care of patients undergoing the continuous ambulatory peritoneal dialysis (CAPD) modality.

Keywords: chronic kidney disease; peritoneal dialysis; technology readiness level; telemonitoring system

1. Introduction

EHealth is the term coined as the set of information and communication technologies (ICT) used as a tool in the health field [1]. For the World Health Organization (WHO), this concept of eHealth is related to the safe and cost-effective use of ICT in different settings [1]. In the eHealth context, the telemedicine paradigm has emerged [2] and is defined as the remote assistance of medical services. Its implementation requires information and communication technologies, as well as human resources specialized in implementing such systems [2]. There are several concepts associated with telemedicine [3]:

- Remote patient monitoring or control allows patients with chronic and degenerative diseases to be monitored from their homes, work environments, etc.
- Storage or forwarding technology stores clinical data and information to be forwarded to another clinical facility for interpretation, e.g., examination or X-ray imaging.
Interactive telemedicine allows doctors and patients to be connected in real time through video conferencing [4]. Telemedicine consists of health professionals using ICT to diagnose, treat, and prevent diseases.

The telemonitoring or remote monitoring of biomedical parameters seeks the patient’s participation in managing their disease, promoting prevention and self-care.

In the telemonitoring field, several works [5–20] have proposed systems focused on telemonitoring patients with chronic and degenerative diseases, such as diabetes mellitus, heart failure, chronic obstructive pulmonary disease, and chronic kidney disease (CKD). CKD is a condition in which the kidneys are damaged and cannot filter blood as well as they should. Because of this, excess fluid and waste from blood remain in the body and may cause other health problems. When the loss of the kidney’s ability to filter blood in chronic kidney disease is severe, kidney function must be replaced either by hemodialysis, peritoneal dialysis, or kidney transplantation. This refers to a chronic renal disease stage 5 (CRDS5). CRDS5 generates multiple health complications to patients, such as hypertension, anemia, cardiovascular complications, chronic kidney-disease-related mineral bone disorder, salt and water retention, metabolic acidosis, and electrolyte disorders, as well as uremic symptoms. Therefore, CKD is considered catastrophic because of high morbidity and mortality rates and poor quality of life [21,22]. Compared to hemodialysis treatment, peritoneal dialysis (PD) treatment has several potential advantages, such as the fact that it is a technique that is easy to learn and apply, it has greater feasibility of use in remote communities and lower costs, and fewer specialized health personnel are required. In addition, PD treatment allows greater survival in the first years, permission to patients to travel, fewer dietary restrictions, and better preservation of residual renal function. Moreover, it is reported that patients have greater satisfaction with PD treatment and better quality of life, and the treatment can be performed by patients themselves at home, among others [23]. In this context, some works [24,25] have reviewed the specialized literature on different aspects of telemonitoring systems oriented to patients with CKD on PD. However, no work has been undertaken that presents a systematic review regarding the level of technological maturity of such telemonitoring systems from the perspective of the technology readiness level (TRL) [26]. TRL measures how far a technology has progressed along its development path from basic research (TRL 1) to mature technologies ready for commercialization (TRL 9). The TRL [26] is a method developed by the National Aeronautics and Space Administration (NASA) in the 1970s as a tool that measures the degree of maturity of a technology. Among the main advantages of using technology maturity levels in ICT projects related to telemonitoring systems are the following: they generate a standardized analysis of the project’s status, they allow the identification and management of risks in projects, and they help to classify the proposed work in terms of research, development, and innovation, which contributes to decision-making in terms of funding and project transition between technology maturity levels [26–28]. Therefore, this paper analyzes works that propose telemonitoring systems focused on patients with CKD undergoing PD treatment to determine their level of technological maturity based on the NASA TRL framework. The results of our work show the main contributions, gaps, and opportunities of the proposed work concerning the TRL framework, which motivated the discussion of important future research directions.

2. Materials and Methods

The approach used in our systematic literature review (SLR) embraced the strategies and rules depicted by Kitchenham et al. [29] and Ali et al. [30]. In the first instance, the research questions were defined to identify the purpose of the review and the interest under study.

- Q1: What kinds of services and parameters are used in telemonitoring systems focused on patients with CKD on PD proposed in the specialized literature? This question is motivated by identifying the functional requirements and desirable parameters to monitor in a system-oriented telemonitoring of CKD on PD.
Q2: Is it possible to identify the level of technological maturity of telemonitoring systems for patients with CKD on PD proposed in the specialized literature? This question aims to analyze the level of technological development achieved in these types of solutions by adopting a measurement framework used worldwide.

Q3: How has the publication rate of studies related to telemonitoring systems for patients with CKD on PD proposed in the literature changed over time? This question aims to examine the period and frequency of publication of such works.

Q4: Can we identify opportunity areas and challenges still pending in the telemonitoring systems for patients with CKD on PD implemented to date? This question aims to identify gaps in care that remain open in this treatment area to contribute to its solution.

2.1. Search Strategy

As a comprehensive search strategy, each research question was formulated as individual search terms, highlighting:

- Peritoneal dialysis;
- Telemonitoring system;
- Telehealth;
- Telemedicine;
- CKD;
- Telenephrology.

In the same way, some synonyms, abbreviations, and alternative spellings of the terms described were used. The search strategy was developed using these terms in combination with the logical operators AND and OR to generate more specific search sequences to query in the search engines. As can be seen in Table 1, the scope of the search query was defined based on three topics:

1. Telemonitoring via a device or service;
2. Applications or the scope of the software of such applications;
3. Type of disability or chronic illness targeted by the applications.

Table 1. Context and example search query.

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<thead>
<tr>
<th>Context</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Telemorning</td>
<td>(telemonitoring OR “telemonitoring system” OR tele-monitoring OR “tele monitoring”) AND</td>
</tr>
<tr>
<td>Application</td>
<td>(apps or software or device(s) or application(s) or service(s)) AND</td>
</tr>
<tr>
<td>Disease</td>
<td>(CKD OR “chronic kidney disease” OR “peritoneal dialysis”)</td>
</tr>
</tbody>
</table>

The electronic database sources used in this SLR included those relevant to our research’s aim. Thus, the SLR was based on the following digital databases: Springer, Elsevier, EBSCO, SCOPUS, Cochrane Library, MEDLINE via PubMed, IEEE Xplore, and Google Scholar. The selection of studies is described in Section 2.4.

2.2. Inclusion Criteria

The purpose of the selection criteria is to identify primary studies that directly respond to the research questions [29]. In our case, each study found was evaluated using the following inclusion criteria (Cr_In):

- Cr_In1: Systems focused on telemonitoring of CKD patients on PD treatment were considered for the study.
- Cr_In2: The study includes evaluations of the described systems considering end users in clearly identified scenarios (real or simulated).
- Cr_In3: The article was published in an indexed, refereed, peer-reviewed journal or conference proceedings in the specialty.
- **Cr_In4**: We considered studies with experimental or research-oriented designs, i.e., randomized control trials (RCTs), non-RCTs, and pre- and post-experimental studies.
- **Cr_In5**: Studies include eHealth interventions with digital information or any communication technology component using any type of device.

2.3. **Exclusion Criteria**

The exclusion criteria (Cr_Ex) used in our SLR were as follows:
- **Cr_Ex1**: The study is not written in English or Spanish.
- **Cr_Ex2**: The article was published before 2014.
- **Cr_Ex3**: The study considers systems focused on the telemonitoring of patients with CKD but treated exclusively by hemodialysis.

2.4. **Selection of Studies**

We obtained 91 articles from PubMed, 36 articles from IEEE Xplore, 31 from Cochrane Library, 100 from Google Scholar, and 40 from EBSCO. The sum of these results produced 298 articles. After removing duplicate articles and those written in languages other than English and Spanish, 223 articles remained. Later, the title, keywords, and abstracts of these 223 articles were reviewed and 20 articles were selected. Those articles were read and checked in detail, and only 14 articles were included in the review because 6 articles did not meet the Cr_In2, Cr_In4, and Cr_In5 criteria. Figure 1 shows this process using the guidelines defined by Kitchenham et al. [29] and Ali et al. [30].

**Figure 1.** Paper selection process of our literature review.

Studies from different publication sources focused on implementing various types of systems aimed at patients with CKD on PD. From 10 different publication sources (journals), 14 articles relevant to the present study were found [7–20]. Based on the research scopes covered by those journals, the studies were divided into three main categories: computer science, health, and technology. Twelve studies were published in journals with a health focus [8,9,11–20], one in a journal with an informatics focus [10], and one in a journal with a technology focus [7], as shown in Table 2. According to the type of study in question, these publications provided the most relevant and necessary information for the analysis of each telemonitoring system, demonstrating that relevant research efforts are being made in this area.
Table 2. Publication sources of selected studies.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Name of the Conference/Journal</th>
<th>Research Domain</th>
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</thead>
<tbody>
<tr>
<td>[8]</td>
<td>American Journal of Nephrology</td>
<td>Health</td>
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<tr>
<td>[9]</td>
<td>BMC Nephrology</td>
<td>Health</td>
</tr>
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<tr>
<td>[20]</td>
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<td>Health</td>
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</tbody>
</table>

2.5. Risk of Bias Control

We considered various digital databases to ensure a comprehensive search, achieve higher sensitivity levels, and reduce publication bias of sources [31]. The inclusion of papers published only in indexed, refereed, and peer-reviewed journals or conferences ensures a certain degree of conceptual and methodological rigor at the scientific level [32]. In our case, we did not include papers published before 2014 because the technologies used in the proposed systems before this year are obsolete today. The inclusion of two pairs of evaluators during the selection process of relevant works, and of a third evaluator in case of disagreement, substantially reduced the bias of the evaluators that could have arisen from the subjective nature of applying the inclusion and exclusion criteria. In our work, the inclusion criteria Cr_In2, Cr_In4, and Cr_In5 were defined because we were interested in determining the actual levels of implementation, use, acceptance, and effectiveness of technologies used in the remote monitoring of people with CKD.

2.6. Requirements and Parameters to Be Monitored in PD Treatment

We also assessed selected works in terms of requirements and parameters to be monitored in PD treatment based on the study proposed by Nayat et al. [33]. This study states that a telemonitoring system focused on peritoneal dialysis must meet the following requirements:

- Allow the user flexibility in movements and activities. Some of the systems analyzed provide total flexibility at any time to patients in terms of movements and activities, while other systems provide such flexibility only “out of treatment time”, i.e., while the treatment is being developed, it restricts the patient movements and activities.
- Allow bidirectional communications through image capture or high-definition video. Some systems fully complied with this item, allowing bidirectional communication in “real-time” between the patient and medical staff; however, others only allowed an “asynchronous” communication between actors or some kind of restricted communication, such as audio transmissions.
- Provide intuitive and straightforward alarm systems. The systems that met this criterion have implemented various alarm systems.
- Incorporate modifiable and customizable mechanisms. Flexibility is analyzed in terms of modification, adaptation, and customization of various functional aspects (“customizable concerning treatment”).
• Generate useful reports. The systems that complied with this feature have incorporated several mechanisms to generate reports or treatment reports.

• Are nonintrusive and portable. In general, in the analyzed studies, some systems complied with both aspects, being nonintrusive and having portability in their operation. Only a couple of systems complied only with being “nonintrusive” in their operation but omitted portability.

On the other hand, the parameters of PD exchanges to be monitored must be the following [33]: filling and draining volumes, filling and draining times, blood pressure, pulse, oxygen saturation, weight or bioimpedance, time/duration of treatment stay, number of exchanges, dialysis prescription, symptoms during therapy, alarms and patient response to alarms, and activity during the day.

These characteristics allow a system to provide a required level of virtual assistance, leading to greater patient satisfaction, improved comfort, and eventually, higher acceptance levels of peritoneal dialysis as a preferred form of renal replacement therapy [33].

3. Results

Our SLR aimed to find as many primary studies as possible that respond to the research questions. The results obtained for each question are as follows:

RQ1. Telemonitoring requirements and parameters used in telemonitoring systems focused on patients with CKD on PD.

For each of the 14 selected studies, Tables 3 and 4 present the analysis result considering the characteristics previously described and supported by Nayak et al. [33]. In Table 3, the first column (from left to right) lists each of the studies analyzed, the following six columns describe the requirements for PD telemonitoring in each system, and the last column shows the peritoneal dialysis modality to which each system is oriented (continuous ambulatory peritoneal dialysis—CAPD, automated peritoneal dialysis—APD, or both modalities). In Table 4, the first column (from left to right) lists each of the works analyzed; the following 12 columns describe the consideration or not of each parameter to be monitored in PD.

Table 3. Requirements for telemonitoring of PD [33].

<table>
<thead>
<tr>
<th>Studies Included</th>
<th>R1</th>
<th>R2</th>
<th>R3</th>
<th>R4</th>
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Where R1: Allows user flexibility in movement and activities, R2: Two-way communications with high-definition video or image capture, R3: Simple and intuitive alarm systems with a high degree of specificity, R4: Modifiable and customizable, R5: Generate useful reports, R6: Nonintrusive and portable, and PSZ: Patient sample size.

Table 4. Parameters of PD exchanges to be monitored [33].

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Table 4. Cont.

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</table>


The results in Tables 3 and 4 show that the requirements and parameters described by Nayak et al. [33] are partially considered in all the selected studies. Regarding the requirements for telemonitoring of people with CKD on PD, only three studies [7,11,14] cover entirely all the requirements proposed by Nayak et al. [33]. Concerning the parameters to be monitored in peritoneal dialysis treatments, seven studies [7,15–20] considered 11 of the 12 parameters proposed by Nayak et al. [33] (see Table 4). The results also show that several of the studies privilege the implementation of requirements, such as ensuring flexibility in patient movements and activities [7–20], allowing bidirectional communication among patients and medical teams [7–20], and granting portability and nonintrusiveness to the systems [7–20], rather than the consideration of other requirements also described by Nayak et al. [33] (see Table 3). In the selected studies, we found implementations using proprietary systems from Baxter Healthcare Corporation [15–20]. These implementations mostly consider the characteristics defined by Nayak et al. [33]; however, they are oriented only to peritoneal dialysis treatment under the APD modality, excluding patients in the CAPD modality (see Table 3).

RQ2. Degree of technological development of telemonitoring systems for patients with CKD on PD proposed in the specialized literature

Given the detailed analysis executed for each paper, it was also possible to identify the distinctive characteristics of the levels of technology maturity described by Ibáñez de Aldecoa [34]. In addition, as a complement to the process of identifying the levels of technological development in which the analyzed projects are located, the Guide for the Diagnosis of the Level of Technological Maturity implemented by the National Council of Humanities, Science, and Technology (CONACyT) of Mexico in various calls for proposals were used to systemically present the process of technological development and innovation [35]. The results of the ranking process were as follows (see Table 5):  

- Eight telemonitoring systems described within the selected studies [8,10,15–20] were identified within level 9 of implemented technology maturity;
- Two selected telemonitoring systems [7,14] were identified within the maturity level 7 of the implemented technology;
- Three selected telemonitoring systems [9,12,13] were identified within the maturity level 6 of the implemented technology;
- One selected system [11] was identified within the maturity level 4 of the implemented technology.
### Table 5. Classification of selected studies.

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RQ3. Changes over time in the publication rate of studies related to telemonitoring systems for patients with CKD on PD.

Concerning the publication date, the frequency of publication has changed over time. In 2014, three articles were published [12–14]. One study was published in 2015 [11] and one in 2019 [18]. In 2017, two studies were registered [9,10]. Four articles were published in 2018 [7,8,19,20]. Finally in 2020, three studies were published [15–17]. Twelve studies were published in journals with a health research scope [8,9,11–20], one in a journal with an informatics research scope [10], and one in a journal with a technology research scope [7]. Approximately 30% of the studies published in health research journals were published in *Peritoneal Dialysis International*. On the other hand, it is noted that there is limited research on telemonitoring systems focused on patients in peritoneal dialysis treatment from a technological perspective.

RQ4. Areas of opportunity and pending challenges of telemonitoring systems focused on patients with CKD on PD proposed in the specialized literature.

After the analysis, it was also possible to identify some opportunity areas, such as:

1. Most studies limit their treatment approach to peritoneal dialysis care modalities, either APD or CAPD, which restrict patient care and treatment options (see Table 3).
2. It is important to consider the advantages of certification in the early stages of development. This concept provides compliance with regulations applicable to telemonitoring systems oriented to health care. Thus, some of the selected systems declare such registration neither from the beginning of the process nor any description during the system design, which limits the possibility of obtaining a greater assessment of their degree of technological development.
3. The telemonitoring systems proposed are still in the process of evaluating and validating their usefulness from the patient perspective with CKD on PD.

In general, it is also possible to observe the need to promote the development of new implementations of telemonitoring systems, both software and hardware, specifically oriented to the treatment of patients with CKD on PD. Within the studies analyzed, four of them [7,9,11,14] refer to implementations of software systems, two studies [8,10] refer to implementations of hardware devices for monitoring, six studies [15–20] deal with implementations of systems that work together, both software and hardware, and two studies [12,13] refer to implementations of support systems via telephone, through a scheme of periodic interviews with patients.

4. Discussion

The telemonitoring systems focused on patients with CKD ongoing PD must have the ability to have bidirectional, fast, and real-time communication to help solve treatment problems, according to the study presented by Nayak et al. [33]. Nevertheless, it is observed that in many of the systems analyzed (7 of the 14), the communication between
the patient and the medical staff is asynchronous and not necessarily in real time, which
could hinder the rapid detection and attention of incidents present in PD treatment. In
addition, the telemonitoring systems must obtain and analyze the treatment information
in an automatized form. However, the review shows that many analyzed systems require
the manual recording of biometric data or additional compatible devices to capture this
information. Another point to highlight is that many analyzed systems do not consider
the main parameters that need to be monitored in a system focused on peritoneal dialysis
treatment. For example, the parameter that is generally not considered in the selected
studies is related to monitoring patient activity during the day (a parameter considered
only in the description of the system referred to by Juan Li et al. [12]). It was also observed
that it is necessary to consider, within the selected systems, the nutritional intake of the
patients, since accurate monitoring of the nutritional parameters can help to prevent and/or
treat early the deterioration of the nutritional status, body composition, and functional
capacity of the patients [36,37].

On the other hand, we have identified that all the systems with the highest
level [8,10,15–20] (8 of the 14 studies), according to the TRL framework, correspond to imple-
mentations made with the use of proprietary systems of international companies specialized
in telemedicine treatment of CKD such as Baxter (www.baxter.com, accessed on 1 July 2023),
eQOL (https://eqol.ca, accessed on 1 July 2023), and GlobalMed (www.globalmed.com,
accessed on 1 July 2023). It is important to note that despite the advantages of the propri-
etary systems described, there are also limitations in their use, derived from their status as
proprietary systems, such as incompatibility with other devices or systems developed by
different companies, difficulty in the migration of patient information between systems,
and user dependency in general regarding cost, information, and functionalities. In addi-
tion, it was observed that all the implementations that make use of proprietary systems of
the company Baxter [15–20] are focused on the care of patients with chronic CKD treated
by peritoneal dialysis under the APD modality, which limits the care of patients who
are under the CAPD modality. Regarding the two selected telemonitoring systems [7,14],
which were identified within the maturity level 7 of the implemented technology, it was
observed that they do not declare the beginning of the process related to the registration
of the certifications required in these types of systems for their commercialization, which
limits their classification in a higher level; however, the effort shown in the development
of these systems is remarkable because of their level of development through a process of
independent research and open architecture.

Finally, and based on the results obtained, we identify the following findings of the
telemonitoring systems for patients with CKD on PD:

• The telemonitoring systems proposed are still in the process of validating their efficacy
  and effectiveness in the patient’s treatment with CKD on PD.
• There is an orientation to discuss usability, functionality, and cost–benefit.
• There is an evident need to provide telemonitoring treatment options for both APD
  and CAPD peritoneal dialysis patients.
• The requirements and parameters that a PD system must monitor have already been
  defined and accepted as a reference in the literature, but many of the implementations
  analyzed do not consider them or comply with them in a limited way.
• Aspects such as the use, management, and ownership of personal data become relevant
  concerning telemonitoring systems for patients since these systems imply having the
  ability to capture treatment information and can even integrate clinical records of
each patient. In the case of Mexico, there are various regulations in this regard whose
  observance must be met, such as the Mexican Official Standard NOM-004-SSA3-2012,
  which confirms the criteria of ownership and confidentiality (among others) for the
  management of information and the clinical record itself.
• The telemonitoring systems proposed must comply with specific standards and re-
  quirements that vary from country to country, which increases the complexity of the
  technological development of this type of system.
5. Conclusions

This paper presented a systematic literature review of telemonitoring systems focused on patients with CKD undergoing PD based on the TRL framework. The results of this SLR describe the main contributions and limitations of selected works concerning the TRL framework. The implementations of telemonitoring systems that reached the highest level of technological maturity correspond to studies developed with the use of proprietary devices and services of international companies specialized in telemedicine treatment of CKD with some limitations regarding their status as proprietary systems incompatible with other devices or systems. Their main limitation is that they are oriented only to treating patients in the APD modality, which limits the care of patients undergoing the CAPD modality. The level of technological maturity is highly relevant for telemonitoring systems. Therefore, this work can serve as a reference point for researchers and technologists focused on developing telemonitoring systems for patients with CKD undergoing PD. Future work will extend to analyzing the level of technological maturity of cyber–physical systems aimed at telemonitoring CKD patients undergoing PD.


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Conflicts of Interest: The authors declare no conflict of interest.

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