


## Content validation and development of a software for hemodialysis

Validação de conteúdo e desenvolvimento de um *software* para hemodiáliseValidación de contenido y desarrollo de un *software* para hemodiálisisSimone Soares da Silva<sup>1</sup>  <https://orcid.org/0000-0001-9293-2048>Walckiria Garcia Romero Sipolatti<sup>1</sup>  <https://orcid.org/0000-0002-1365-4797>Bruno Henrique Fiorin<sup>1</sup>  <https://orcid.org/0000-0002-1629-9233>Leila Massaroni<sup>1</sup>  <https://orcid.org/0000-0001-7327-887X>Andressa Bolsoni Lopes<sup>1</sup>  <https://orcid.org/0000-0003-1244-5667>Mirian Fioresi<sup>1</sup>  <https://orcid.org/0000-0002-8560-4385>Lorena Barros Furiere<sup>1</sup>  <https://orcid.org/0000-0003-3859-2227>**How to cite:**

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**Abstract**

**Objective:** To describe the development of a software for the management of clinical and quality indicators in patient care under hemodialysis.

**Methods:** This is a methodological study, which involved three stages: 1) survey of the theoretical framework for structuring content about clinical and quality indicators, relevant for registry in hemodialysis service and assessment of hemodialysis effectiveness; 2) content validation by judges; 3) software development. The methodology proposed by Pressman was used for its creation, which consists of five steps: communication, planning, modeling, construction, and implementation.

**Results:** The software produced consists of 112 validated items, with the functionality of the system for registering and searching patients at the service, updating clinical and laboratory data as well as generating reports related to infections, vascular access implantation, adverse events, hospitalization and quality indicators.

**Conclusion:** This study enabled the development of a software as a tool for compiling and organizing patient data on hemodialysis, with a view to generating information and knowledge that supports assessment and clinical decision making of nursing supported by critical judgment.

**Resumo**

**Objetivo:** Descrever o desenvolvimento de um software para o gerenciamento de indicadores clínicos e de qualidade no cuidado de enfermagem de pacientes em hemodiálise.

**Métodos:** Trata-se de um estudo metodológico, envolvendo três etapas: 1) levantamento do referencial teórico para estruturação de conteúdo acerca de indicadores clínicos e de qualidade, relevantes para registro no serviço de hemodiálise e avaliação da efetividade dialítica; 2) validação de conteúdo por juízes e 3) desenvolvimento do software. Utilizou-se para sua criação a metodologia proposta por Pressman, que consiste em cinco passos: comunicação, planejamento, modelagem, construção e implantação.

**Resultados:** O software produzido compõe-se de 112 itens validados, tendo como funcionalidades o sistema de cadastramento e busca de pacientes do serviço, a atualização de dados clínicos e laboratoriais, bem como a geração de relatórios relacionados às infecções, ao implante de acesso vascular, aos eventos adversos, à hospitalização e aos indicadores de qualidade.

**Conclusão:** Este estudo possibilitou a elaboração de um software como ferramenta para compilação e organização de dados de paciente em terapia hemodialítica, com vista à geração de informações e conhecimentos que subsidie a avaliação e tomada de decisão clínica de enfermagem apoiada em julgamento crítico.

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Conflicts of interest: nothing to declare.

## Resumen

**Objetivo:** Describir el desarrollo de un software para la gestión de indicadores clínicos y de calidad para los cuidados de enfermería de pacientes en hemodiálisis.

**Métodos:** Se trata de un estudio metodológico, que incluye tres etapas: 1) análisis del marco referencial teórico para la estructuración del contenido sobre indicadores clínicos y de calidad relevantes para el registro en el servicio de hemodiálisis y evaluación de la efectividad didáctica; 2) validación del contenido por jueces, y 3) desarrollo del software. Para su creación, se utilizó la metodología propuesta por Pressman, que consiste en cinco pasos: comunicación, planificación, modelado, construcción y despliegue.

**Resultados:** El software producido se compone de 112 ítems validados y tiene como funcionalidades el sistema de registro y búsqueda de pacientes del servicio, la actualización de datos clínicos y de laboratorio, así como la generación de informes relacionados con las infecciones, el acceso vascular, los eventos adversos, la hospitalización y los indicadores de calidad.

**Conclusión:** El estudio permitió la elaboración de un software como herramienta para compilar y organizar datos de pacientes en terapia de hemodiálisis, con el fin de producir información y conocimientos que respalden la evaluación y toma de decisiones clínicas de enfermería basadas en apreciaciones críticas.

## Introduction

Health has been strongly influenced by technological advances in the daily life of health institutions, permeating the work processes in the production and incorporation of a body of knowledge necessary for health care, education, and management.<sup>(1,2)</sup> In nursing, health technologies are applied to the organization of service, care, and management of people in different spaces of professional practice.<sup>(3)</sup>

The work of nurses is based on making clinical and management decisions based on scientific evidence that, when combined with Information Technology (IT) resources, make professional care safer and more effective. It also makes it possible to record patient data more securely, improves communication between team professionals and facilitates access to information.<sup>(4)</sup>

With regard to health services that provide assistance to people with chronic kidney disease (CKD), it is required by Ordinance 389 Minister's Office (MO)/Ministry of Health (MoH) of March 13, 2014 to produce information to meet the defined quality indicators and compliance goals to ensure comprehensive care to patients' health needs.<sup>(5)</sup> CKD has high incidence, being present in 10% of the world population; and, in Brazil, more than 120 thousand people are CKD patients undergoing hemodialysis; 93.1% use hemodialysis as renal replacement therapy.<sup>(6)</sup>

IT tools qualify the work processes of health professionals, allowing for a wide visibility of service, agility in access and transfer of information.<sup>(7)</sup> Using nursing assistant software in care planning

makes it possible to record and strictly store data and, consequently, obtain more reliable results, decreasing the chances of errors and corroborating the support for clinical decision and patient safety.<sup>(8)</sup>

In this sense, nursing actions must be monitored in order to assess their results, identifying the weaknesses and key points that will guide the planning of improving the quality of care. Assessment is a continuous process of collecting relevant data on the responses of the health-disease process and interventions through indicators, which are management tools to support decision-making regarding care quality and safety.<sup>(9)</sup>

Thus, this study aims to describe the development of a software for the management of clinical and quality indicators in patient care under hemodialysis.

## Methods

This is a methodological study approved by the Research Ethics Committee (REC) of the study hospital under CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 61987216.3.0000.5071, with technological development divided into three stages, namely: 1) survey of the theoretical framework; 2) content validation by judges; 3) software development.

In the first stage, a survey of the theoretical framework for structuring content about clinical and quality indicators was performed, relevant for registry at hemodialysis service and for assessment

of hemodialysis effectiveness. Data governed by Ordinance 389 MO/MoH of March 13, 2014, which establishes the quality indicators that should be monitored by health establishments providing assistance to people with CKD<sup>(5)</sup> and additional data were added, which are registered at the hemodialysis service of a study hospital to identify and monitor complications resulting from hemodialysis treatment.

In the second stage, the content built by judges was validated. Nurses who have been working at the nephrology service of the study hospital for at least two years have been selected, including hemodialysis of chronic and acute patients, peritoneal hemodialysis and specialists in nephrology or studying specialization.

Contact with the selected judges took place via letter sent by electronic means, followed by the Informed Consent Form (ICF) and the instrument in the online format of the Google Forms, with the following information: “Characterization of nurses/judges” and the “Instrument for content validation to compose software for a hemodialysis service”. Nurses whose characteristics met the inclusion criteria, who duly filled out the forms and who sent the ICF signed, were considered eligible.

To validate the instrument, which took place in February 2018, nine nurses from the nephrology service were selected as judges and who worked at hemodialysis. The judge graded the relevance of the content as: 1. not relevant, 2. little relevant, 3. indifferent, 4. very relevant and 5. extremely relevant.

Content Validation Index (CVI) was used to quantify the degree of agreement among experts, which measured the percentage of judges who judged the constructed content as very and extremely relevant.<sup>(10)</sup> Items with a CVI greater than or equal to 0.80 were considered fully applicable.<sup>(11)</sup> Items that received CVI  $\geq 0.70$  and  $< 0.80$  were revised according to the judges’ suggestions. After returning the instrument, data were tabulated using Microsoft Excel<sup>®</sup> 2013.

The third stage consisted in the elaboration of the software using the Cascade Model or Classic Life Cycle proposed by Winston Royce in 1970. This model aims to establish order in the devel-

opment of great software products, and suggests a sequential and systematic approach in which software requirements are well understood by both the proposer and the development team. To this end, communication, planning, modeling, construction, and implementation, steps proposed by Pressman 2016, were followed.<sup>(12)</sup>

In the communication stage, the project started with requirements gathering, definition of objectives, functionalities and scope and development of the system development schedule.

The scope was then planned with the developer team to estimate costs and details to be observed in the subsequent phases.

In modeling, the software prototype was created by applying the design steps defined during planning. With the list of requirements, an agile project development methodology, called SCRUM, was applied, which, by dividing the stages of the project into continuous weekly periods, presented constant feedback, making it possible to monitor the development in all its stages.<sup>(13)</sup>

For the development of software, coding and tests were performed. The programming language used was C++; and the graphical interface platform was Qt Creator.<sup>(14)</sup> MySQL was used as a database management system, which uses the language SQL as an interface,<sup>(15)</sup> being hosted on the Hostinger company cloud server.<sup>(16)</sup>

## Results

### Characterization of judges

Nine nurses met the inclusion criteria and agreed to participate in the study. All were female; more than half were between 31 and 35 years old (56%) and had been working in nephrology for 4 years; 33% worked in the care of patients on peritoneal hemodialysis; and five nurses (67%) provided assistance to patients on the chronic and acute hemodialysis program.

Most judges (89%) had completed nephrology specialization or residency. A judge, a specialist in nephrology, has a master’s degree in progress, and only one judge (11%) is completing the specialization course.

## Content validation

Of the 112 items and subitems built, 63 (56.2%) reached the CVI score = 0.89 and 38 (33.9%) reached the score of 1.0, i.e., 90.2%

obtained CVI  $\geq 0.80$  and were relevant to the theme. Only 11 (9.8%) reached a score of 0.78 and were reviewed according to the judges' suggestions (Table 1).

**Table 1.** Content analysis of items for dialysis service registry

Items for dialysis service registry	CVI
1. Number of patients undergoing conservative treatment during the month	1.00
2. Hemoglobin value of patients under conservative treatment	1.00
3. Phosphorus value of a patient under conservative treatment	1.00
4. Patients under conservative treatment referred for dialysis and with matured AVF	0.89
5. Patients under conservative treatment who abandoned treatment	0.89
6. Hospitalization of patients under conservative treatment due to clinical complications	1.00
7. Monthly number of patients on peritoneal dialysis	0.89
8. Tenckhoff catheter implantation	0.89
9. Changing the peritoneal dialysis catheter extension	0.89
10. Infection of tenckhoff catheter (signs/symptoms)	0.89
10.1. Infection of tenckhoff catheter (access removed)	0.89
10.2. Infection of tenckhoff catheter (laboratory tests collected)	0.89
10.3. Infection of tenckhoff catheter (used antibiotic)	0.89
10.4. Infection of tenckhoff catheter (result of peritoneal fluid culture/swab)	0.89
11. Peritonitis in patients with APD and CAPD	0.89
12. Hospitalization of patients on peritoneal dialysis due to clinical complications	0.89
13. Hemoglobin value in patients on peritoneal dialysis	0.89
14. Value of albumin in patients on peritoneal dialysis	0.89
15. Phosphorus value in patients on peritoneal dialysis	0.89
16. PTH value of patients on peritoneal dialysis	0.89
17. Death in patients on peritoneal dialysis	0.89
18. Patients eligible for transplant and older than 6 months on peritoneal dialysis, enrolled in the CNPDO	0.89
19. Number of patients with chronic kidney disease on dialysis	1.00
20. Number of patients with acute kidney disease on dialysis	1.00
21. Short-term central venous catheter implantation (local)	1.00
21.1. Short-term central venous catheter implantation (reason)	1.00
21.2. Short-term central venous catheter implantation (withdrawal date)	1.00
21.3. Short-term central venous catheter implantation (length of use)	0.89
22. Long-term central venous catheter implantation (site, reason, date of withdrawal, length of use)	1.00
22.1. Long-term central venous catheter implantation (reason)	1.00
22.2. Long-term central venous catheter implantation (withdrawal date)	0.89
22.3. Long-term central venous catheter implantation (length of use)	0.89
23. Preparation of AVF (site: brachy basic; brachiocephalic; femoral; radiocephalic; ulnar-basilic;). Manufacture of polytetrafluoroethylene (PTFE) prosthesis.	0.89
24. Short-term catheter infection/double lumen-CDL catheter (signs/symptoms)	1.00
24.1. Short-term central venous catheter infection/double lumen-CDL catheter (access removed)	1.00
24.2. Short-term central venous catheter infection/double lumen-CDL catheter (laboratory tests taken)	1.00
24.3. Short-term central venous catheter infection/double lumen-CDL catheter (antibiotic used)	1.00
24.4. Short-term central venous catheter infection/double lumen-CDL catheter (duration of antibiotic use)	1.00
24.5. Short-term central venous catheter infection/double lumen-CDL catheter (culture result/swab)	1.00
25. Long-term central venous catheter infection/Permicath® (signs/symptoms)	1.00
25.1. Long-term central venous catheter infection/Permicath® (access removed)	1.00
25.2. Long-term central venous catheter infection/Permicath® (laboratory tests taken)	1.00
25.3. Long-term central venous catheter infection/Permicath® (antibiotic used)	1.00
25.4. Long-term central venous catheter infection/Permicath® (length of antibiotic use)	1.00
25.5. Long-term central venous catheter/Permicath® infection (culture result/swab)	1.00
26. AVF infection and prosthesis (signs/symptoms, laboratory tests taken, antibiotic used, culture result/swab)	0.89
26.1. AVF infection and prosthesis (laboratory tests taken)	0.89
26.2. AVF infection and prosthesis (used antibiotic)	0.89
26.3. AVF infection and prosthesis (result of culture/swab)	0.89
27. AVF thrombosis	0.89
28. PTFE prosthetic thrombosis	0.89
29. Loss of AVF	1.00

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Items for dialysis service registry	CVI
30. Other types of infection during the period (urinary tract infection)	1.00
30.1. Other types of infection during the period (intestinal infection or abdominal focus)	0.89
30.2. Other types of infection during the period (surgical site)	0.89
30.3. Other types of infection during the period (skin infection: parasitic infestation or infectious cellulitis)	0.89
30.4. Other types of infection during the period (respiratory infection/pneumonia)	0.89
31. Number of dialysis patients using a short-term central venous catheter on the last day of dialysis of the month	1.00
32. Number of dialysis patients using a long-term central venous catheter on the last day of dialysis of the month	1.00
33. Number of dialysis patients using AVF duration on the last dialysis day of the month	1.00
34. Number of dialysis patients using PTFE prosthesis duration on the last day of dialysis of the month	1.00
35. Hospitalization of dialysis patients due to clinical complications	0.89
36. Death of patients under dialysis	0.89
37. Seroconversion for positive Hepatitis C in patients undergoing Dialysis	0.89
38. Seroconversion for positive Hepatitis B in patients undergoing Dialysis	0.89
39. Hemoglobin value of dialysis patients	1.00
40. Albumin value in dialysis patients	1.00
41. Phosphorus value of dialysis patients	1.00
42. PTH value of dialysis patients	1.00
43. Ktv value of dialysis patients	1.00
44. Patients eligible for transplant and older than 6 months on dialysis, enrolled in the CNPDO	0.89
45. Matured AVF	0.78
46. Adverse events (infection and signs of infection (shaking/fever/chills)	0.78
46.1. Adverse events (rupture of dialyzer fibers)	0.89
46.2. Adverse events (coagulation of the extracorporeal system)	0.89
46.3. Adverse events (breakdown of the extracorporeal system)	0.78
46.4. Adverse events (material defect)	0.89
46.5. Adverse events (use of inappropriate material)	0.89
46.6. Adverse events (capillary exchange between patients)	0.89
46.7. Adverse events (AVF puncture error)	0.78
46.8. Adverse events (hematoma)	0.89
46.9. Adverse events (AVF rupture)	0.89
46.10. Adverse events (accidental disconnection of the central venous catheter with the blood line)	0.89
46.11. Adverse events (accidental disconnection of the fistula needle)	0.89
46.12. Adverse events (reaction to sterilizer)	0.89
46.13. Adverse events (reaction to transfusion of blood products)	0.89
46.14. Adverse events (reaction to medication)	0.89
46.15. Adverse events (reaction to dressings)	0.89
46.16. Adverse events (skin injury)	0.78
46.17. Adverse events (related to water treatment/distribution failure)	0.89
46.18. Adverse events (related to the dialysis machine)	0.89
46.19. Adverse events (patient fall)	0.89
46.20. Adverse events (loss of access during dialysis)	0.78
46.21. Adverse events (non-functioning central venous catheter)	0.89
46.22. Adverse events (inadequate access blood flow)	1.00
46.23. Adverse events (inadequate central venous catheter implantation)	0.78
46.24. Adverse events (bleeding from venous access)	0.78
46.25. Adverse events (dialysis prescription error)	0.89
46.26. Adverse events (omission of care)	0.78
47. Reason for entry (hypertensive nephrosclerosis; diabetic nephropathy; glomerulopathies; urological disease; chronic graft disease; cardiorenal; hepatorenal; patient in transit for parathyroidectomy surgery or for hospitalization for other reasons; systemic lupus erythema; other causes; exchange of therapy nephrotic syndrome; sepsis; polycystic disease or obstructive causes (myeloma).	1.00
48. Patient withdrawal (change of therapy)	0.89
48.1 Patient withdrawal (renal function recovery)	0.89
48.2 Patient withdrawal (clinic transfer)	0.89
48.3 Patient withdrawal (return to the clinic of origin),	0.89
48.4 Patient withdrawal (patient in transit)	0.78
48.5 Patient withdrawal (kidney transplant)	0.89
48.6 Patient withdrawal (abandonment of treatment)	0.89
49. Blood transfusion (red blood cells, platelets, plasma)	1.00
50. Use of ferric hydroxide sucrate	0.89
51. Use of EPO	0.89

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Continuação.

Items for dialysis service registry	CVI
52. Clinical complications (hypotension, hypertension, nausea/vomiting, cramps, hypoglycaemia/hyperglycaemia)	1.00
53. Monthly, semi-annual and annual blood collection	0.78

CVI - Content Validation Index; APD - Automated Peritoneal hemodialysis; CAPD - Continuous Ambulatory Peritoneal hemodialysis; PTH - parathormone; PTFE - polytetrafluoroethylene prosthesis; CNPDO - Central for Notification, Procurement and Distribution of Organs and Tissues; Ktv - Formula to measure the quality of hemodialysis; AVF - arteriovenous fistula; EPO - erythropoietin.

## Software development

The technology developed was called staff-assisted home hemodialysis (SAHD). It is considered a management technology, as it is used in the management of assistance as a mediator of quality improvement.<sup>(17)</sup> For proper operation, computers must have an internet connection to access the server.

The set of functionalities required for the performance of the software was listing patients registered in the hemodialysis program, adding a new patient, viewing and searching for patients, and updating patient data, such as vascular access, reuse of their dialyzer and clinical indicators and quality.

The functions are presented to users through an initial menu, with two options: new patient and list of registered patient names. In the “register patient” option, a screen opens that allows registry of information, creating a database for organization and accessibility of information about patients registered in the hemodialysis program.

SAHD starts with a login screen as shown in Figure 1-A. Once logged in, professionals can consult, register a patient and update data (Figure 2-B and C).

By clicking on the “access infection” button, a tab opens where it is possible to choose the type of infected access, signs and symptoms of infection, which laboratory tests were collected, if the result was positive (which microorganisms were found), antibiotic used and if there was infection elsewhere. In the tab referring to adverse events, there is an option to choose about 33 adverse events during hemodialysis, being able to select up to four different types. In the “patient movement” button, it is possible to select the patient’s current situation: start of treatment; change in renal replacement therapy; death; evasion; or other situation not mentioned. It is possible to select the current vascular access, facilitating the monitoring of implantation of new accesses, so that it identifies which type implanted, the most used insertion site and the fre-



Figure 1. Initial access screen to software (A)

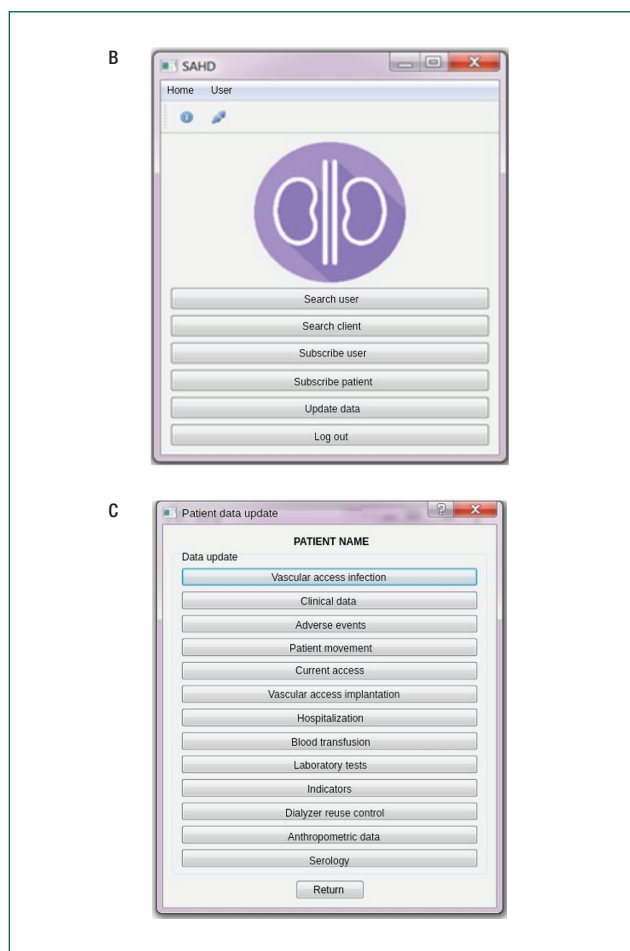


Figure 2. Navigation menu screen for software (B) and screen for updating registered patient data (C)

quency of exchange. Hospitalizations, blood transfusion control, anthropometric data and serology can also be recorded and detailed. The program allows the generation of graphs and tables related to infection and implantation of vascular access, adverse events, hospitalization, and quality indicators. The software was registered at the Brazilian National Institute of Industrial Property (NIIP) via the Institute of Technological Innovation (ITIN) of *Universidade Federal do Espírito Santo*, under number BR512019000264-4.

## Discussion

A very applicable solution for the health field is the construction of software and applications, as they are capable of providing resolution, speed and security, both in the storage of data and in the appreciation of the client.<sup>(18)</sup> The development of technologies requires that health systems improve quality and that costs are minimized. Furthermore, information technologies come into play that are capable of integrating information so that professionals collaborate in achieving goals and improving the quality of care.<sup>(19)</sup>

Quick and easy access to data on patients with CKD allows service organization and assessment, with provision of safe and quality care. Since, in many hemodialysis services, clinical data and some quality indicators defined in ordinances are collected, however, they are little accessed and discussed.

The challenge was to develop a software that corresponds to the specific needs of the hemodialysis sector and meets the expectation of reducing the time spent searching for information through a manual record, minimizing the mistakes made. SAHD is an imperative tool for monitoring patients undergoing hemodialysis, helping collection, storage and rapid search for information. It allows dynamism in the adoption of intervention measures appropriate to complications and adverse events, very common during renal replacement therapy.<sup>(3)</sup>

Content construction through literature review and subsequent validation by nurses were essential steps for the development of software, since it was

built based on scientific and practical evidence, involving nurses, who are the target audience for using technology. In other words, it sets the potential of participatory and collaborative interface in methodological research on producing technologies in nursing.<sup>(20)</sup> Therefore, it can contribute to reduce the resistance of health professionals to use technologies, whether due to lack of intimacy with information technology or to reluctance to adhere to new work methodologies.<sup>(21)</sup>

The software was developed with the intention of being incorporated into the work routine of health professionals working at hemodialysis service of the study hospital as a tool to face the challenges of those who assist patients with CKD. The program will bring work organization as an advantage and allow grouping of data that will serve as subsidies for the Nursing Process care.<sup>(18)</sup> It is a private activity of nurses in which the needs of patients are identified and the goals and care are determined.<sup>(22)</sup>

Some limitations need to be pointed out, mainly because software does not work interconnected to the electronic medical records system of the study hospital. As a goal, it is intended to establish an operating interface between the software developed and the hospital's medical record system, in addition to assessing the impact of using SAHD on quality indicators and clinical indicators in the sector studied.

## Conclusion

It is expected that this management technology will contribute to the optimization of nursing work processes by compiling data, generating information and knowledge for service organization, enabling the identification of the needs of patients and software implementation before, during, and after hemodialysis, always based on clinical judgment. The information available in the system can assist nurses in the definition, performance and registry of the Nursing Process. By systematizing care, nurses can optimize their time with management activities, making time available for care activities.

## Collaborations

Silva SS, Sipolatti WGR, Fiorin BH, Massaroni L, Lopes AB, Fioresi M and Furieri LB declare that they contributed to the study design, data analysis and interpretation, article writing, relevant critical review of intellectual content and version approval final to be published.

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