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Indicators for evaluating the vascular access of users in hemodialysis*

INDICADORES PARA AVALIAÇÃO DO ACESSO VASCULAR DE USUÁRIOS EM HEMODIÁLISE

INDICADORES PARA EVALUACIÓN DEL ACCESO VASCULAR DE PACIENTES EN HEMODIÁLISIS

Andressa Garcia Nicole¹, Daisy Maria Rizatto Tronchin²

ABSTRACT

The purpose of this study was to develop reliable assessment instruments to measure hemodialysis vascular access. The design of healthcare indicators involved an in-depth analysis of vascular access practices in hemodialysis and their underlying theoretical rationale, and was grounded on Donabedian's framework. Four indicators were selected: performance of temporary double-lumen catheter, maintenance of temporary double-lumen catheter, monitoring of arteriovenous fistula and complications of arteriovenous fistulas. The first three are process-oriented while the last one relate to outcomes. Data was collected in October and November 2008 using a tree-part questionnaire, thus divided: assessment of the indicators' operations manual, assessment of health attributes of the indicators and assessment of each of the components. The validation of the indicators was carried out by a panel of nine internationally renowned experts in nephrology. All indicators were validated by the panel, with at least a 75% favorable consensus. It is believed that the use of this instrument contributes for evaluation and improvement of quality in hemodialysis services.

KEY WORDS

Renal dialysis.
Nursing care.
Quality of health care.
Health Services Evaluation.

RESUMO

Os objetivos deste estudo foram construir indicadores para avaliar a qualidade das práticas assistenciais relacionadas ao acesso vascular de usuários em hemodiálise (HD) e proceder à validação dos indicadores. As etapas para elaborar os indicadores constituíram-se de seleção das práticas assistenciais relacionadas ao acesso vascular, fundamentação teórica dessas práticas e construção de quatro indicadores, segundo o modelo Donabediano: desempenho de cateter temporário duplo lúmen para HD, manutenção de cateter temporário de duplo lúmen, monitoramento de fístula arteriovenosa e complicações de fístula arteriovenosa. A coleta de dados ocorreu entre outubro e novembro de 2008, por meio de um questionário composto pelo julgamento do manual operacional, dos atributos dos indicadores e de seus componentes. A validação foi realizada por nove juízes, e todos os indicadores foram validados sob o consenso mínimo de 75%. Acredita-se que o emprego dessa ferramenta contribua para a avaliação e gestão da qualidade nos serviços de hemodiálise.

DESCRIPTORIOS

Diálise renal.
Cuidados de enfermagem.
Qualidade da assistência à saúde.
Avaliação de Serviços de Saúde.

RESUMEN

Los objetivos de este estudio fueron construir indicadores para evaluar la calidad de las prácticas asistenciales relacionadas al acceso vascular de pacientes en hemodiálisis (HD) y proceder a la validación de tales indicadores. Las etapas para elaborar los indicadores se constituyeron de selección de las prácticas asistenciales relacionadas al acceso vascular, fundamentación teórica de esas prácticas y construcción de cuatro indicadores, según el modelo Donabediano: desempeño de catéter temporario doble lumen para HD, mantenimiento de catéter temporario de doble lumen, monitoreo de fístula arteriovenosa y complicaciones de fístula arteriovenosa. La recolección de datos se efectuó entre octubre y noviembre de 2008, a través de un cuestionario compuesto por el juicio del manual operacional, de los atributos de los indicadores y de sus componentes. La validación fue realizada por nueve jueces, y todos los indicadores fueron validados bajo un consenso mínimo de 75%. Se cree que el empleo de esa herramienta haya de contribuir en la evaluación y gestión de calidad en los servicios de hemodiálisis.

DESCRIPTORES

Diálisis renal.
Atención de enfermería.
Calidad de la atención de salud.
Evaluación de Servicios de Salud.

* Taken from the thesis "Construção e validação de indicadores de avaliação do acesso vascular de usuários em hemodiálise", University of São Paulo School of Nursing, 2009. ¹ M.Sc. in Nursing, University of São Paulo School of Nursing, Vila Velha, ES, Brazil. andressagnicole@yahoo.com.br ² Ph.D., Professor at Professional Orientation Department, University of São Paulo School of Nursing, São Paulo, SP, Brazil. daisyrt@usp.br

INTRODUCTION

In recent decades, the life expectancy and quality of life of Chronic Kidney Failure (CKF) patients going through Renal Replacement Therapy (RRT) have increased, associated with the development of new biomaterials, new technologies and morbidity control.

Data from the Brazilian Nephrology Society (SBN) demonstrate that, in 2000, 42,695 CKF patients were receiving dialysis, estimated at 87,044 people in 2008. In March 2008, the prevalence rate of dialysis treatment corresponded to 468 patients per million people (pmp), and the incidence rate in 2007 to 141pmp. The large majority of these, 89.4%, are in a hemodialysis program (HD)⁽¹⁾.

A gap is perceived, however, regarding the assessment of HD-related care practices, mainly those whose non-conformity exerts a significant influence on the treatment and quality of life of CKF patients undergoing hemodialysis therapy, such as the presence of intact vascular access (VA), an element or criterion without which this treatment mode cannot be established⁽²⁾.

A study reveals that the main vascular accesses for hemodialysis are arteriovenous fistulas (AVF). The impossibility of their creation is the main indication for the use of double-lumen catheters (DLC). Regarding the functionality time of accesses, four years is observed for direct AVF, two years for prostheses and nine months for catheters. The financial costs to establish vascular access ranged from 0.3% to 1.7% of the total cost spent at a hemodialysis unit⁽³⁾.

Considering that vascular accesses represent an important care practice and are closely related with the quality of care delivery and quality of life of CKF patients, assessment instruments need to be constructed to verify the quality of this treatment modality.

Health care quality can be defined as the achievement of greater benefits to the detriment of smaller risks for the patient/client, benefits which, in turn, are defined in function of what is achievable according to the available resources⁽⁴⁾. This definition implicitly contains the idea that it is not an abstract attribute, but comprises care assessment, covering the analysis of structure, work processes and outcomes. Thus, an assessment model was established based on structure, process and outcomes components⁽⁴⁾.

The structure component refers to available physical, material, human and financial resources. The process component corresponds to the relations established between professionals and users. The outcomes component shows the effects of health care on the users and population and whether these are compatible with the sustainability of the organization⁽⁴⁾.

In general, an indicator is represented by a numerical variable, which can be an absolute figure or a relation between two events. In the construction of an indicator, the following items also need to be established: concept, aim, equation, population/sample, type, information source, collection method, periodicity and criteria for evaluation⁽⁵⁻⁶⁾.

When elaborating an indicator, certain attributes need to be considered to acknowledge its efficacy. According to the dictionary of epidemiology, attributes are specified as qualitative characteristics of a given item, which are: attributable, validity, credibility, sensitivity, specificity, accessible, communicable, effective/precise, feasible and objective⁽⁶⁻⁷⁾.

Later, the indicator needs to be validated to turn into a true evaluation instrument. In summary, various authors indicate opinionated expert validation, also known as content validity, referring to the judgment of an indicator so as to verify whether it actually covers the different aspects of its object, through a given consensus⁽⁸⁻¹⁰⁾.

In view of the above, the goal of this study was to contribute to the assessment of care practice quality, in this case specifically vascular accesses of hemodialysis therapy users, through the construction and validation of indicators.

...vascular accesses represent an important care practice and are closely related with the quality of care delivery and quality of life of Chronic Kidney Failure...

OBJECTIVES

To construct indicators to evaluate the quality of care practices related to the monitoring and prevention of vascular access complication in hemodialysis service users and proceed with the content validation of the elaborated indicators.

METHOD

Approval for this methodological study was obtained from the Institutional Review Board at the University of São Paulo School of Nursing, under protocol No 706/2007.

The first research phase was called construction of indicators, comprising the selection of care practices, theoretical foundations, composition of indicators and elaboration of operating manual.

To select the practices, a literature review was used, in the attempt to identify the main care practices developed in the dialysis process, in view of the following criteria: importance of the condition/problem for analysis, high morbidity and mortality risk, high usage volume, high treatment cost, ability to influence the healthcare outcome and, when measured, permitting changes in outcomes and continuous quality improvement. Other criteria are the possibility to construct indicators in the process and outcome components of Donabedian's assessment model and the application of indicators in most HD services^(5-6,9,11-12).

The theoretical foundations were based on the guidelines by the National Kidney Foundation / Kidney Disease Outcomes Quality Initiative - Clinical Practice Guidelines for Vascular Access, Center for Disease Control and Prevention – Guidelines for prevention of intravascular catheter-related infection and *Guia de acesso vascular en hemodiálisis*⁽¹³⁻¹⁵⁾.

Then, four indicators were composed, three for process and one for outcome, in the Donabedian triad, which are: performance of temporary double-lumen catheter for hemodialysis (PTDLCH); maintenance of temporary double-lumen catheter (MTDLC), monitoring of arteriovenous fistula (MAVF) and complications of arteriovenous fistula (CAVF).

And, finally, the operating manual for each indicator was elaborated, with the following items: title of the indicator, description, theoretical-scientific foundations, indicator type, numerator, denominator, population or sample, information sources, criteria to qualify the collected data and evaluation periodicity. Also, the evaluation worksheet was proposed, comprising the indicator components and an instrument aimed at registering the data during the evaluation processes, followed by the equations to calculate the indicators.

The goal of the second research phase was to select the expert group to put in practice the work technique and establish the consensus method for opinionated validation.

The following criteria were set for inclusion in the expert group: professionals with a Bachelor's degree in nursing or medicine and a minimum experience of five years in nephrology. Thus, 12 professionals were selected and invited to participate, who lived in the state capital or interior of São Paulo State. Literature shows no consensus on the ideal number of experts, but recommends between three and 10 specialists with considerable experience in the theme area involved^(8,16). All participants signed the Informed Consent Term.

It should be highlighted that three experts did not return the data collection instrument. Hence, the expert group comprised nine professionals.

To put in practice the experts' work, the Delphi Technique was chosen, whose essential characteristics are based on opinion exchange among the respondents, the participants' anonymity and the possibility to review individual perspective on the study phenomenon, based on a statistical representation⁽¹⁷⁾.

Regarding the consensus judgment on the indicators, the content validation index (CVI) was set as $\geq 75\%$ for agreement among expert opinions⁽¹¹⁻¹²⁾.

Data were collected in October and November 2008 through a questionnaire, comprising the experts' characteristics and their judgment on the indicators (judgment on operating manual, indicator attributes and components), similar to what various authors have used⁽¹²⁾.

The instruments were mailed to the experts and a deadline was set for their return. After the return, the questionnaires were subject to statistical analysis and readjusted according to the experts' suggestions and comments.

RESULTS AND DISCUSSION

Six participants were nurses (66.7%) and three (33.3%) physicians. The average age was 44.33(sd±8.75) years, the mean time since graduation was 20.78 (sd±8.41) years, six (67%) exclusively worked in clinical care and five (55.6%) worked at a public institution. These findings are in line with the expert selection criteria, in which accumulated experience has been appointed as the main factor⁽¹⁶⁾.

The experts' first judgment was related to the indicators' operating manual, which describes the necessary items of each indicator. This demands a broad bibliographic review, seeking the best scientific evidence to sustain it⁽¹⁵⁻¹⁷⁾.

Table 1 shows the judgment on each indicator's operating manual.

Table 1 - Frequency distribution of judgments on operating manual of indicators for evaluation of vascular access in hemodialysis users, according to experts - São Paulo - 2008

| Manual Items | Indicators | | | | | | | |
|--------------------------------|-------------|-------|-------------|-------|------------|-------|--------------|-------|
| | 1- PTDLCH * | | 2- MTDLC ** | | 3- MAVF*** | | 4- CAVF **** | |
| | N | % | N | % | N | % | N | % |
| Description | | | | | | | | |
| Yes | 8 | 88.9 | 7 | 77.8 | 8 | 88.9 | 8 | 88.9 |
| No | 1 | 11.1 | 2 | 22.2 | 1 | 11.1 | 1 | 11.1 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Theoretical Foundations | | | | | | | | |
| Yes | 8 | 88.9 | 6 | 66.7 | 8 | 88.9 | 8 | 88.9 |
| No | 1 | 11.1 | 3 | 33.3 | 1 | 11.1 | 1 | 11.1 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |

Continues

Continuation

| Manual Items | Indicators | | | | | | | |
|--------------------------------------|-------------|-------|-------------|-------|------------|-------|--------------|-------|
| | 1- PTDLCH * | | 2- MTDLC ** | | 3- MAVF*** | | 4- CAVF **** | |
| | N | % | N | % | N | % | N | % |
| Indicator Type | | | | | | | | |
| Yes | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Numerator | | | | | | | | |
| Yes | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Denominator | | | | | | | | |
| Yes | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| No | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Sample | | | | | | | | |
| Yes | 9 | 100.0 | 8 | 88.9 | 9 | 100.0 | 9 | 100.0 |
| No | 0 | 0 | 1 | 11.1 | 0 | 0 | 0 | 0 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Information collection source | | | | | | | | |
| Yes | 8 | 88.9 | 9 | 100.0 | 8 | 88.9 | 8 | 88.9 |
| No | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 11.1 |
| Did not answer | 1 | 11.1 | - | - | 1 | 11.1 | - | - |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |
| Evaluation criteria | | | | | | | | |
| Yes | 9 | 100.0 | 8 | 88.9 | 9 | 100.0 | 9 | 100.0 |
| No | 0 | 0 | 1 | 11.1 | 0 | 0 | 0 | 0 |
| Did not answer | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 | 9 | 100.0 |

In Table 1, consensus was observed on indicator 2 – MTDLC as to non-conformity (66.7%) for theoretical foundations only. The experts recommended adding other studies to better support the indicator's component items. Hence, the references were incorporated without the need to return for new validation, as conformity was found among the literature the experts proposed.

Although the other indicators obtained a favorable consensus on all items of the operating manual, some specialists also indicated the use of other references to support the indicators, and one suggested reordering the components of indicator 2 – MTDLC. All suggestions were considered to improve the indicators' operating manual, presented below:

Indicator 1 – performance of temporary double-lumen catheter (ptdlch)

1) Description: the TDLC is an option for immediate vascular access to start hemodialysis. It can entail some immediate complications or during its use. TDLC dysfunc-

tions are responsible for 17 to 33% of early catheter removal and thrombosis causes total access loss in 30 to 40% of users. In this sense, adequate monitoring of TDLC performance parameters can identify the dysfunction in due time so as to avoid complications. Literature recommends as adequate performance parameters for central venous catheters in HD: blood flow above 300ml/min, arterial pressure below 250mmHg, venous pressure below 250mmHg, ability to aspirate blood freely and absence of frequent alarms, represented by increased or decreased pre-pump blood pressure, venous pressure or transmembrane pressure, not being responsive to position change or flush.

2) Scientific foundations:

National Kidney Foundation. (NKF-K/DOQI). Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for vascular access: update 2006. Am J Kidney Dis. 2006;48 Suppl 1:S176-276.

Sociedad Española de Nefrología. Guías de acceso vascular en hemodiálisis. Madrid; 2004.

3) Indicator type: process

4) Numerator: number of patient files for TDLC patients with records for all parameters in compliance

5) Denominator: total patient files of TDLC patients assessed

6) Calculation of general indicator or per component:

General Conformity Index of TDLC Performance for HD = (Number of patient files for TDLC patients with records for all parameters in compliance / Total patient files of TDLC patients assessed) x 100

Or:

Component Conformity Index of TDLC Performance for HD = (Number of patient files for TDLC patients with blood flow > 300 ml/min / Total patient files of TDLC patients assessed) x 100

Observation: The above equation can be used with the five monitoring components of TDLC performance.

7) Information evaluation source: analysis of nursing records related to HD sessions through TDLC users' files.

8) Criteria for qualification: patient files will be analyzed for the evaluation. Records of all HD sessions will be analyzed to observe the presence of records and compliance with recommendations. In the worksheet, the following legend will be used: **C**, when the record complies with recommendations, or **NC**, if the record does not comply with reference parameters or if there is no record.

9) Cases for conformity analysis: simple probabilistic sampling can be used, i.e. assessment of all TDLC patients or their files for a given period that responds to the phenomenon's explanatory power. It is highlighted that, per month, all hemodialysis sessions of each TDLC patient will be analyzed.

10) Evaluation periodicity: monthly.**Indicator 2 – maintenance of temporary double-lumen catheter (mtdlc)**

1) Description: TDLCs are important for clinical nephrology because they permit immediate vascular access for emergency HD, while awaiting the confection or maturing of the AVF, in cases of thrombosis of this AVF or impossibility to construct another and implant an indwelling DLC. Its use is associated with the occurrence of complications like infection and thrombosis though. In this sense, adequate measures to maintain this type of access should be strictly observed to prevent unwanted effects. The following maintenance measures are recommended in literature: hand washing before and after handling the catheter; handling the TDLC with a sterile technique; use of mask that covers nose and mouth by professionals and users; inspect and palpate the exit orifice; use of 2% aqueous chlorhexidine to change the TDLC insertion dressing; change the dressing

before the hemodialysis session; use sterile gauze changed each session or transparent film changed every 7 days or earlier, if necessary, to cover the dressing; wash the connectors with 70% alcohol; infuse 10ml of 0.9% saline (0.9% SS) in each TDLC line after the HD sessions and complete with heparin solution after the 0.9% SS infusion.

2) Scientific foundations:

Barros E, Manfro RC, Thomé FS, Gonçalves LF. Nefrologia: rotinas, diagnóstico e tratamento. Porto Alegre: Artmed; 2006.

Boyce JM, Pittet D. Guideline for hand hygiene in health-care settings: recommendations of Healthcare Infection Control Practices Advisory Committee and HICPA/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR Morb Mortal Wkly Rep. 2002;51(1):1-45.

Centers for Disease Control and Prevention. Guidelines for the prevention of intravascular catheter-related infections. MMWR Recomm Rep. 2002;51(RR-10):1-29.

National Kidney Foundation. (NKF-K/DOQI). Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for vascular access: update 2006. Am J Kidney Dis. 2006;48 Suppl 1:S176-276.

Rodríguez-Hernández JA, González-Parra E, Gutiérrez-Julian JM, Segarra-Medrano A, Almirante-Gragera B, Martínez-De Melo MT, et al. Guía de acceso vascular en hemodiálisis. Angiología. 2005;57(2):119-207.

Sociedad Española de Nefrología. Guías de acceso vascular en hemodiálisis. Madrid; 2004.

3) Indicator type: process

4) Numerator: number of TDLC patients with all maintenance items in compliance

5) Denominator: total TDLC patients assessed

6) Calculation of general indicator or per component:

General Conformity Index of TDLC for HD = (Number of TDLC patients with all maintenance items in compliance / Total TDLC patients assessed) x 100

Or

Component Conformity Index of TDLC Maintenance for HD = (Number of TDLC patients handled with sterile glove / Total TDLC patients assessed) x 100

Observation: The above equation can be used with the eight components to assess the indicator.

7) Information evaluation source: direct observation of TDLC handling.

8) Criteria for qualification: direct observation of TDLC handling, considering:

C (Complies):

1. Perform hand washing;
2. Perform TDLC handling with sterile technique;
3. Use of mask covering nose and mouth by professional;
4. Use mask covering nose and mouth by user;
5. Inspect the exit orifice;
6. Palpate the exit orifice;
7. Use 2% aqueous chlorhexidine to change the TDLC insertion dressing;
8. Change the dressing before the hemodialysis session;
9. Cover the dressing with sterile gauze every session or transparent film every 7 days or when necessary;
10. Wash connectors with 70% alcohol;
11. Complete TDLC lines, after the session, with 10ml of 0.9% SS in each line.
12. Complete TDLC lines, after the 0.9% SS infusion, with heparin solution.

NC (Does Not Comply): any non-conformity with the above.

9) Cases for conformity analysis: simple probabilistic sampling can be used for a given period, provided that the phenomenon's explanatory power is guaranteed. To guarantee representativeness, it is important to include all dialysis shifts.

10) Evaluation periodicity: monthly

Indicator 3 – monitoring of arteriovenous fistula (mavf)

1) Description: AVF is the preferred vascular access for HD, but surveillance of this type of access is needed for the early detection of dysfunctions. AVF monitoring or surveillance involves systematic and protocolled procedures, based on physical investigation and imaging, clinical data and hemodynamic parameters, in order to demonstrate the adequate functioning of the AVF or detect any complication. Therefore, literature recommends monitoring the presence of collateral veins, pre-pump blood pressure, blood flow and bleeding time after needle withdrawal.

2) Scientific foundations:

National Kidney Foundation. (NKF-K/DOQI). Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for vascular access: update 2006. Am J Kidney Dis. 2006;48 Suppl 1:S176-276.

Rodríguez-Hernández JA, González-Parra E, Gutiérrez-Julian JM, Segarra-Medrano A, Almirante-Gragera B, Martínez-De Melo MT, et al. Guía de acceso vascular en hemodiálisis. Angiología. 2005;57(2):119-207.

Sociedad Española de Nefrología. Guías de acceso vascular en hemodiálisis. Madrid; 2004.

3) Indicator type: process

4) Numerator: number of patient files for AVF patients with records for all monitoring components in compliance

5) Denominator: total patient files for AVF patients assessed

6) Calculation of general indicator or per component:

General Conformity Index of AVF Monitoring =

(Number of patient files for AVF patients with records for all monitoring components in compliance / total patient files for AVF patients assessed) x 100

Or

Component Conformity Index of AVF Monitoring = (Number of patient files with records on the absence of collateral veins / Total patient files of AVF patients assessed) x 100

Obs.: The above equation can be used with the five components of AVF monitoring.

7) Information evaluation source: analysis of nursing records for HD sessions through patient files of AVF users.

8) Criteria for qualification: records for all HD sessions should be analyzed to observe both the presence of records and whether they comply with recommendations. The following legend will be used in the worksheet: **C**, when the records comply with recommendations or **NC**, if the records do not comply with reference parameters or if there are no records.

9) Cases for conformity analysis: simple probabilistic sampling can be used, i.e. evaluation of all AVF patients for a given period that guarantees the phenomenon's explanatory power. In case of a sample, it is important to include all HD shifts to guarantee representativeness.

10) Evaluation periodicity: monthly

Indicator 4 - complications of arteriovenous fistula (cavf)

1) Description: AVF dysfunctions are known as any complications that alter the normal functioning of vascular access, decreasing usage time or entailing other complications. In literature, different complications are described, but intervention is recommended when adequate blood flow is not achieved, i.e. a reduction by more than 25% in previous blood flow; in case of hemodynamically significant venous stenosis, i.e. decrease in venous diameter by more than 50%, which can lead to thrombosis, detected through Doppler ultrasound or physical examination; aneurism, defined as dilation of an AVF area with intact arterial or venous wall structure, which should be treated when rapidly expanding, with a diameter of more than 12mm and threatened skin feasibility; or hand ischemia, in function of arterial flow inversion, characterized by ischemic pain with AVF limb at rest, which worsens during hemodi-

alysis sessions; presence or not of trophic lesion, characterized by extremely painful ulcer with necrotic background.

2) Scientific foundations:

Besarab A, Raja RM. Acesso vascular para hemodiálise. In: Daugirdas JT, Blake PG, Ing TS. Manual de diálise. 3ª ed. Rio de Janeiro: Medsi; 2003.

National Kidney Foundation. (NKF-K/DOQI). Kidney Disease Outcomes Quality Initiative. Clinical practice guidelines for vascular access: update 2006. Am J Kidney Dis. 2006;48 Suppl 1:S176-276.

Linardi F, Linardi FF, Bevilacqua JL, Morad JFM, Costa JA. Tratamento cirúrgico da “síndrome do roubo” em acesso vascular para hemodiálise com revascularização distal e ligadura arterial. J Vasc Bras. 2006; 5(2):117-22.

Rodríguez-Hernández JA, González-Parra E, Gutiérrez-Julian JM, Segarra-Medrano A, Almirante-Gragera B, Martínez-De Melo MT, et al. Guía de acceso vascular en hemodiálisis. Angiología. 2005;57(2):119-207.

3) Indicator type: outcome

4) Numerator: number of AVF complications

5) Denominator: total number of AVF users

6) Calculation of indicator:

Incidence of complications in AVF users = (Number of AVF complications / Total AVF users) x 100

7) Information evaluation source: analysis of multiprofessional team records through the patient files of AVF patients.

8) Criteria for qualification: the evaluation will be accomplished through patient file analysis. Records of AVF complications by any multiprofessional team member should be taken into account.

9) Cases for conformity analysis: all AVF users undergoing hemodialysis. In this case, the sample is not indicated, as incidence levels are considered and all patients are risk-exposed.

10) Evaluation periodicity: mensal

Vascular access assessment is considered a care quality evaluation measure, represented by the monitoring of AVF use as predominant access and central venous catheter use for more than three months⁽¹³⁾.

The lack of established parameters or indicators is observed though, with a view to assessing care processes and not just the structure or performance of HD services.

In this sense, the validation of the four indicators' operating manual indicates that its content is sufficient and its practical applicability, contributing to the advancement of quality programs in nephrology, as it offers an important tool to monitor practices related to vascular accesses for hemodialysis.

The experts' second judgment referred to the indicators' attributes, i.e. the qualitative characteristics that can make them effective⁽⁷⁾.

The attributes analyzed for the indicators constructed in this study were: **attributable**, the indicator's ability to reflect the quality of the practice it relates to; **validity**, defined as the level or extent to which the indicator reaches its goal, identifies situations in which care and service quality needs improvement; **credibility**, which translates the extent to which the indicator is easy to understand (intelligible), measures and raises hypotheses that make sense for the care practices it relates to and for the users; **sensitivity**, is the level or extent to which the indicator can link all care cases with actual quality problems with the practices it refers to; **specificity**, considered the level or extent to which the indicator can identify only those cases in which actual quality problems exist; **accessible**, i.e. the data needed to calculate the indicator can be accessed rapidly, and at minimum cost; **communicable**, related to the importance of explaining and understanding the measure easily; **effective/precise**, that it measures what it intends to measure; **feasible**, that the measure is applicable and objective, i.e. the measure permits clear verification, without subjective judgment⁽⁶⁻⁷⁾.

For this judgment, the experts used the psychometric scale, considering four degrees of variability: 1 (does not totally comply), 2 (does not comply partially), 3 (complies partially) and 4 (complies totally). The CVI $\geq 75\%$ refers to the sum of degrees 3 and 4 or just 4.

The results obtained on this evaluation appointed that the four indicators scored CVI \geq , so that all indicators were validated.

Regarding the validity attribute, it was mentioned that the use of lower quality materials can interfere in care quality. Material resources, then, refer to the structure dimension of Donabedian's model, which need to be addressed under a specific indicator, as different evaluation types (structure and outcome) need to be measured separately, in accordance with the aims of the service quality evaluation. If necessary, a causal relation can be established⁽³⁾.

As for the objectivity attribute, it is important to clarify that the indicator should be applied at the start and end of the HD session because when handling the AVF during the session, it is not necessary to perform all component practices of the indicator, which would lead to different results, impairing the analysis of the continuous improvement process.

The validation of the indicators elaborated in this study indicates their capacity to describe an existing situation, demonstrate changes or trends during a period and direct health actions that need to be performed in qualitative and quantitative terms.

Thus, it can be affirmed that the four indicators are accurate and precise, i.e. the outcomes of their verification correspond to the true state of the phenomenon that is

measured and permit the achievement of similar scores in sequential measure, permitting statistical analysis to estimate means and test hypotheses⁽¹⁸⁾.

And, finally, the third judgment referred to the assessment of each component for the indicators: PTDLC, MTDLC and MAVF. It is highlighted that the CAVF indicator's description did not include components, as it is an outcome indicator.

The assessed attributes in the indicator components were **simplicity**, i.e. permits one single interpretation; **objectivity**, which indicates that the component permits a punctual response; **clarity**, demonstrated by the use of short phrases, simple and unambiguous expressions; **precision**, i.e. each component differs from the others covering the indicator; **pertinence**, if the component does not suggest a different attribute than what is defined; **variety**, i.e. the terms used specify each component, not permitting confusion with the other components or the idea of repetition and **credibility**, which denotes that the component is described so that it does not seem deprived of the characteristics or nonsensical in relation to the continuum of the indicator that is assessed⁽⁶⁻⁷⁾.

All component attributes reached a favorable consensus for the three indicators constructed, with objectivity, precision, variety and credibility reaching 100% of consensus on all indicators. It was also observed that the MAVF indicator scored 100% on all attributes.

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CONCLUSION

Through this study, four indicators to evaluate vascular access for hemodialysis users were constructed and validated by a group of professionals who were mostly active in care and in public institutions. No favorable consensus (75% or higher) was obtained for the theoretical foundations of the MTDLC indicator only, which was readjusted by incorporating the references the experts suggested.

The accomplishment of the proposed content validation to evaluate vascular access for hemodialysis users, even after the adjustments the experts suggested, does not put an end to inquiries on the quality of vascular access practices as, beyond the range of the discussion on the subject, the indicators need to be tested for internal and external reliability through empirical application.

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