PREVENTION OF EVENTS WITH VASCULAR CATHETERS: VALIDATION OF AN INSTRUMENT* PREVENÇÃO DE EVENTOS COM CATETERES VASCULARES: VALIDAÇÃO DE UM INSTRUMENTO* PREVENCIÓN DE EVENTOS CON CATÉTERES VASCULARES: VALIDACIÓN DE UN INSTRUMENTO*

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ABSTRACT

Objective: to develop and validate an audit instrument for vascular catheter insertion and maintenance. Audits can help healthcare institutions in the evaluation of healthcare processes and contribute to the quality of care. Method: a methodological study that involved the construction of the instrument, content validation, pre-testing, and reliability assessment. The committee for content evaluation was composed of five experts. In the pre-testing, 30 patients were considered, as well as 50 patients for the reliability evaluation, selected intentionally. Content validity was assessed by the Content Validity Index, whereas the interobserver reliability was assessed by the Kappa coefficient. Results: The initial version of the instrument, with 16 items, underwent modifications. After two rounds of evaluation, the Content Validity Index was 1.0 for all items. The Kappa coefficient ranged from 0.41 to 1.00. The final version of the instrument had 14 items distributed into four sections (dressing, maintenance, tubes/devices, and catheter management). Conclusion: the “Vascular Catheter Audit” instrument is valid, reliable, and can be used to identify weaknesses, plan staff training activities, review work processes, as well as improve the quality of health care and patient safety.

RESUMO


RESUMEN

Objetivo: desarrollar y validar instrumento de auditoria para la inserción y mantenimiento de catéteres vasculares. Las auditorias pueden ayudar a las instituciones sanitarias a evaluar los procesos de atención de la salud y contribuir a la calidad de la atención. Método: estudio cualitativo, metodológico, que incluyó la construcción del instrumento, validación de contenido, prueba previa, y evaluación de fiabilidad. El comité de evaluación de contenido estuvo compuesto por cinco expertos. En la prueba previa, se consideraron 30 pacientes y 50 pacientes para la evaluación de la fiabilidad, seleccionados intencionalmente. La validez de contenido se evaluó mediante el Índice de Validez de Contenido y la confiabilidad entre evaluadores, mediante el Coeficiente Kappa. Resultados: la versión inicial del instrumento, con 16 ítems, sufrió modificaciones. Tras dos rondas de evaluación, el índice de validez del contenido fue de 1.0 para todos los items. El coeficiente Kappa osciló entre 0,41 y 1,00. La versión final del instrumento contó con 14 ítems distribuidos en cuatro apartados (cobertura, mantenimiento, equipos / dispositivos y manipulación del catéter). Conclusión: el instrumento “Auditoria de Catéteres...
Vasculares” es válido, confiable y puede ser utilizado para identificar fragilidades, planificar actividades de capacitación de los equipos, revisar procesos de trabajo y mejorar la calidad de la asistencia a la salud y la seguridad del paciente.


INTRODUCTION

Concerns related to patient safety affect professionals and institutions all over the world,1 since unwanted complications resulting from events that could have been avoided cause great impact not only on the healthcare system, but also on the areas of social and economic life.2-4

In order to prevent these events, the World Health Organization in partnership with the Joint Commission International have highlighted six priority areas for implementing strategies: proper
identification of patients; improvement of communication processes; improvement of drug
dispensation and administration; safe performance of surgical procedures; reduction in the risk of
injuries from falls and healthcare-associated infections.\textsuperscript{5}

As regards infections, the bloodstream one may be related to the insertion and management of
vascular catheters, being one of the most common infections in health care.\textsuperscript{5} In Brazil, an annual
decrease in the incidence density of Bloodstream Infection (BSI) associated with the use of central
venous catheters has been observed in both adult and pediatric intensive care units.\textsuperscript{6} However, a
study in 43 developing countries found a BSI-related mortality rate of around 17\%,\textsuperscript{7} while in Brazil
this rate was 40\%.\textsuperscript{8}

Moreover, a survey conducted in a public and tertiary care hospital in the state of Goiás, Brazil,
revealed that the average cost per patient with Bloodstream Infection (BSI) was US$ 3,386.00,
while the average cost per patient without BSI was US$ 718.00, which shows the high cost
generated by this event, in addition to the impact of this type of occurrence on the patient’s health
recovery.\textsuperscript{9}

Considering the data presented in which authors highlight the nursing staff’s lack of knowledge
regarding infection prevention measures,\textsuperscript{10} as well as the greater preventive potential of the BSI,\textsuperscript{11}
the development and constant monitoring of the implementation of preventive measures related to
the insertion and maintenance of vascular catheters is of fundamental importance.

The insertion of catheters, in peripheral or central blood vessels, is quite a common practice in
health care; therefore, the recommendation, insertion, and maintenance of these catheters should
be conducted with the appropriate safety measures. An effective way to prevent BSIs is to follow
the suggested recommendations, which include hand hygiene, proper selection of the catheter and
insertion site, skin preparation, stabilization and dressings, as well as the proper maintenance and
removal/change of the catheter.\textsuperscript{11} This requires the development of continuing education
programs, qualification of professionals, surveillance, process evaluation, and feedback of results.\textsuperscript{12}
Process evaluations followed by feedback have been pointed out as strategies that stimulate reflection and change in attitudes,\textsuperscript{13} and can therefore contribute to the improvement of BSI indicators. Audits need to be structured through checklists based on clinical guidelines and applied regularly in order to improve results.\textsuperscript{12}

In order to systematize these assessments and provide feedback on the results, it is necessary to use reliable instruments to guide the processes of insertion and maintenance of vascular catheters. Considering the lack of scientific evidence on instruments used for this purpose, the question that guided this study was: is a checklist elaborated from the literature to guide in the audit process of vascular catheter insertion and maintenance valid and reliable?

**OBJECTIVE**

To develop and validate an audit instrument for vascular catheter insertion and maintenance.

**METHOD**

A methodological study, conducted between February and December 2017, to develop and validate an instrument for auditing processes related to vascular catheters, carried out in four stages:

**Stage 1 - Construction** - the initial version of the instrument was developed after evaluating the manual of work processes (national and international guidelines on good practice recommendations related to vascular catheters\textsuperscript{11,14}) of the institution where the study was developed, being reviewed by an expert in hospital infection control after being formatted.

**Stage 2 - Content validation** - conducted using the Delphi Technique.\textsuperscript{15} According to the literature, the expert group should consist of between five and ten experts.\textsuperscript{16} In face of this recommendation, seven other professionals, selected by convenience, were invited to participate, but only five accepted.

The committee was composed of a Nursing professor, two PhD nurses who work in Hospital Infection Control Commissions, a nurse from the Catheter Management and Infusion Therapy Group,
and a nurse specialized in instrument validation, constituting a team of experienced professionals regarded as reference in the addressed issue. The professionals were selected by convenience, considering their experience in vascular catheter management and validation studies.

These experts evaluated the proposed version, composed of 16 items distributed into four sections: 1) Dressing; 2) Catheter maintenance; 3) Tubes/devices; 4) Catheter management. The instrument’s content was validated by means of a Likert-type scale, with the following options: I) These items do not represent the content; II) These items need a major revision to represent the content; III) These items need a minor revision to represent the content; or IV) These items represent the content. The judges received the versions of the instrument and the instructions for the assessment, which should be done within a maximum period of 15 days, by e-mail.

To analyze this type of validity, the Content Validity Index (CVI) was considered, which reflects the level of agreement among the judges about the assessed content, with values equal to or above 0.8 being considered satisfactory. The CVI was calculated as from the sum of answers III and IV from each judge for each item of the questionnaire, divided by the sum of the total number of answers.

There were two rounds to obtain a consensus on the pre-final version of the instrument.

Stage 3 - Pre-testing - conducted by three nurses in 30 patients, with the objective of testing the understanding of the items and the time needed to apply the instrument. These nurses were selected by convenience, as well as the 30 patients admitted to an adult ward of a tertiary, public university hospital in the countryside of the state of São Paulo. The sample size was established according to the recommendations in the literature, and as inclusion criteria patients aged 18 years or older who had some kind of vascular access were considered.

Stage 4 - Reliability assessment - the final version was applied to 50 patients, selected by two independent evaluators simultaneously and by convenience, in order to check the interobserver reliability (equivalence). Data collection was carried out in the same institution mentioned in the previous stage, with the same inclusion criteria established for the sample composition. The sample
size was established according to the criteria determined for the evaluation of the interobserver reliability.\textsuperscript{17}

The patients were evaluated while in bed, and neither they nor the healthcare team were informed about the survey objectives in order to avoid possible biases. The study, with a waiver of the informed consent, was approved by the University Research Ethics Committee. (CAAE: 69183917.6.0000.5404). The informed consent was not applied considering that vascular access management is part of the institutional routine and no additional intervention was required for data collection.

The data collected were tabulated in the Microsoft Excel for Windows\textsuperscript{®} program, and analyzed by the Statistical Analysis Software\textsuperscript{®} (SAS) program, version 9.4. Absolute and relative frequency tables were devised for categorical variables and measures of position (mean and standard deviation) for continuous variables. To assess reliability, the Kappa coefficient, which can take values between 0 and 1, was calculated, with values between 0.40 and 0.75 considered good, and above 0.75, excellent.\textsuperscript{18}

RESULTS

In stage 1, the 16 items were distributed into four sections: 1) Dressing (three items); 2) Catheter maintenance (seven items); 3) Tubes/devices (three items); and 4) Catheter management (three items). Only two of 16 items were considered descriptive, as they characterize the type of dressing being used and the catheter insertion site. The other 14 were considered assessment items, as they make it possible to assess the process compliance to the stipulated standards.

The answers to the items can be checked among the following options: "yes", which represents compliance to the protocols; "no", which represents non-compliance; and "not applicable" or "not assessed", an option that can be selected when the observation requires the execution of some procedure related to the catheter that may not be going on at the moment of the observation.

In the second stage, in the first round of content assessment by the judges, 15 out of the 16 items underwent changes. Only one item (2.2) obtained a CVI equal to 1.0. Nine items did not
reach the minimum 80% agreement; therefore, according to the suggestions made, seven items were reformulated (1.1, 2.3, 2.4, 2.5, 2.7, 3.2 e 4.2), and two were excluded (2.6 e 3.1) for presenting information that had already been covered in other questions. Still in this round, although six items (1.2, 1.3, 2.1, 3.3, 4.1 e 4.3) had reached CVI equal to 0.8, the authors considered the suggestions made by some of the judges pertinent and opted to modify the items and send them back for assessment. Thus, the instrument, reformulated according to the suggestions, was resubmitted to the committee.

Among the modifications most frequently suggested by the judges were additions of terms to guide the observation. In item 1.1, we added the term “gauze” in the choice of answer for the type of dressing, since the dressing of venous catheters is prescribed in this way in most guides to good practice. Regarding item 1.2, the term “with date” was replaced by “within the validity period”, since the observation of the date on the catheter dressing does not mean that the care with changing the dressing has been taken within the recommended periods. In item 1.3, we added information about the observation of the dressing external appearance, considering that, when performing the audit processes, the dressings are not removed.

In the section regarding the catheter maintenance, item 2.1, the term “peripheral” was added to contemplate the central catheters that are inserted through a peripheral vein. In item 2.3, we included the term “insertion” to inform the observer about the catheter dwell time. The action of infusing physiological saline before and after the administration of medications, in item 2.4, was determined by the term “sorolized” instead of “flush”. Item 2.5 was fully reworded to provide more clarity during the observation of intravenous therapy. Still in this section, the addition of the way in which the catheter should be adequately protected during the shower was made to item 2.7.

In the Tubes/devices section, we added examples of devices that should be observed for compliance to expiration dates and care with the presence of blood and dirt (items 3.2 and 3.3). In item 3.3, “presence” was replaced by “absence” to emphasize good practices in catheter maintenance.
In the Catheter management section, items 4.1 to 4.3 have had some terms replaced to emphasize the recommended time for hand hygiene and the use of appropriate solutions for disinfection.

In the second round, equipped with the description of the changes suggested in the previous round, the judges assessed all items of the instrument again, a consensus among the experts being reached at the end. The CVI of the first and second rounds are shown in Table 1. The pre-final version of the instrument was composed of 14 items, 2 of which were characterization items and 12 were compliance to the established standards, divided into the same previously suggested sections.

Table 1 - Content Validity Index of the instrument items. Campinas (SP), Brazil, 2017.

<table>
<thead>
<tr>
<th>Item</th>
<th>First round</th>
<th>CVI</th>
<th>Second round</th>
<th>CVI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dressing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dressing type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( ) sterile transparent film</td>
<td>40%</td>
<td></td>
<td>( ) sterile transparent film</td>
<td>100%</td>
</tr>
<tr>
<td>( ) microporous tape</td>
<td></td>
<td></td>
<td>( ) microporous tape and gauze</td>
<td></td>
</tr>
<tr>
<td>( ) other ____</td>
<td></td>
<td></td>
<td>( ) other ____</td>
<td></td>
</tr>
<tr>
<td>1.1 Identified and with date</td>
<td>80%</td>
<td></td>
<td>Identified and within the validity period?</td>
<td>100%</td>
</tr>
<tr>
<td>1.2 Clean and dry dressing</td>
<td>80%</td>
<td></td>
<td>Externally clean and dry dressing (no visible blood and no moisture to the touch)?</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Catheter maintenance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertion site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral venous catheter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( ) Upper limbs</td>
<td></td>
<td></td>
<td>( ) Upper limbs</td>
<td></td>
</tr>
<tr>
<td>( ) Lower limbs</td>
<td></td>
<td></td>
<td>( ) Lower limbs</td>
<td></td>
</tr>
<tr>
<td>( ) Other ____</td>
<td></td>
<td></td>
<td>( ) Other ____</td>
<td></td>
</tr>
<tr>
<td>Central venous catheter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( ) jugular</td>
<td>80%</td>
<td></td>
<td>( ) jugular</td>
<td>100%</td>
</tr>
<tr>
<td>( ) subclavian</td>
<td></td>
<td></td>
<td>( ) subclavian</td>
<td></td>
</tr>
<tr>
<td>( ) femoral</td>
<td></td>
<td></td>
<td>( ) femoral</td>
<td></td>
</tr>
<tr>
<td>( ) peripheral</td>
<td></td>
<td></td>
<td>( ) peripheral</td>
<td></td>
</tr>
</tbody>
</table>
The pre-final version, after the changes suggested by the judges, was submitted to pre-testing.

The average time to fill it out was 1.73 minutes, with none of the suggested changes. This version
of the instrument was applied to 50 patients. The Kappa coefficient, used to assess the interobserver reliability, was equal to or higher than 0.41 for all items of the final version (Table 2).

### Table 2 - Interobserver reliability. Campinas (SP), Brazil, 2017.

<table>
<thead>
<tr>
<th>Items</th>
<th>Kappa coefficient (CI* 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1,00</td>
</tr>
<tr>
<td>1.2</td>
<td>0,59 (0,36 to 0,81)</td>
</tr>
<tr>
<td>1.3</td>
<td>0,49 (-0,11 to 1,00)</td>
</tr>
<tr>
<td>2.1</td>
<td>0,41 (0,13 to 0,69)</td>
</tr>
<tr>
<td>2.2</td>
<td>0,67 (0,48 to 0,86)</td>
</tr>
<tr>
<td>2.3</td>
<td>0,48 (-0,14 to 1,00)</td>
</tr>
<tr>
<td>2.4</td>
<td>0,70 (0,39 to 1,00)</td>
</tr>
<tr>
<td>2.5</td>
<td>0,73 (0,37 to 1,00)</td>
</tr>
<tr>
<td>2.7</td>
<td>Not calculated</td>
</tr>
<tr>
<td>3.1</td>
<td>0,80 (0,63 to 0,97)</td>
</tr>
<tr>
<td>3.2</td>
<td>0,72 (0,52 to 0,92)</td>
</tr>
<tr>
<td>3.3</td>
<td>Not calculated</td>
</tr>
<tr>
<td>4.1</td>
<td>Not calculated</td>
</tr>
<tr>
<td>4.2</td>
<td>Not calculated</td>
</tr>
<tr>
<td>43.</td>
<td>Not calculated</td>
</tr>
</tbody>
</table>

*CI - Confidence Interval

The coefficient of items 2.7 (Catheter protected in the shower with plastic and tape?), 4.1 (Hand hygiene immediately before contact with the catheter?), 4.2 (Disinfection of the catheter huber before the procedure with 70% isopropyl alcohol?) and 4.3 (Replacement of the catheter huber caps for new ones after using the lines?) was not calculated, since these activities were not carried out during the period of observation of the patients. For this reason, the observers checked the option "not applicable". The final version of the instrument was named "Vascular Catheter Audit".

### DISCUSSION

The process of constructing and validating an instrument is a complex methodological course that requires teamwork, once the contribution of different professionals allied to the involvement
of those who will use the instrument are fundamental for the provision of valid and reliable tools that are easy to understand and apply.\textsuperscript{16}

In the hospital management process, the development of tools, protocols, and other means has contributed considerably to health care, promoting an improvement in patient safety.\textsuperscript{19-20} Thus, the results of this study contribute, in a unique way, to verify the adherence of the staff to already standardized procedures and work processes.

Non-adherence to good practices can cause adverse events, with bloodstream infection being only one of the many examples. The occurrence of preventable failures during the provision of health care can cause an increase in the average length of stay and mortality rate,\textsuperscript{21} an outcome that goes far beyond the financial impact.

Thus, the importance of auditing in the assessment of healthcare processes is verified, since through its results, feedback can be given among professionals who work at the bedside in order to achieve better outcomes.

In the literature, the use of instruments to assist decision-making in the assessment and safe removal of catheters, as well as to guide audits aiming to verify the adherence of the staff to institutional manuals is observed. However, data on the construction and validation of such tools are not clearly described.\textsuperscript{22-23}

Therefore, the availability of valid and reliable instruments is extremely relevant for professionals who are concerned with producing appropriate measures.\textsuperscript{16} In order to achieve this objective, the authors of this study were concerned about following the recommendations in the literature, with regard to both quantitative and qualitative questions in the selection of the experts who assessed the content of the developed instrument.\textsuperscript{16} The use of the Delphi technique, also adopted and recommended by other authors in content validation studies,\textsuperscript{24} helped in obtaining an instrument that measures exactly what it proposes to measure.\textsuperscript{16}

In the pre-testing stage, also a recommended and adopted phase in another study\textsuperscript{25} which aims to verify whether the items of the instrument are understandable to the target population,\textsuperscript{16} it was
possible to confirm its clarity and ease of understanding, considering that no suggestions were made by the nurses who will use the instrument in the future. Moreover, the short time required to fill it out favors its insertion in clinical practice.

Another extremely important factor is the verification of the measurement properties of an instrument after it has been developed.²⁶ The reliability assessment is also adopted by several researchers,²⁷ and when equivalence is evaluated, as it was in this study, it is possible to demonstrate that the instrument produces similar results when applied by different professionals.

CONCLUSION

The "Vascular Catheter Audit" instrument includes the main recommendations for good practices in the insertion and maintenance of vascular catheters, presenting satisfactory reliability and content validity indexes.

Besides the availability of an instrument such as the one proposed in this study and its use in practice, it is essential to analyze the results obtained, since through them it is possible to identify weaknesses, plan training activities for the teams, review work processes, and thereby improve the quality of health care and patient safety.²⁸

A limitation to this study was the fact that the observers did not witness moments of hand hygiene, huber disinfection and cap replacement by the unit's professionals, or even protection of the access when conducting the patient to the shower, which made it impossible to calculate the coefficient that assessed reliability. An alternative to try to remedy this limitation would be to increase the observers' length of stay in the unit; however, this option was discarded by the researchers since the literature shows that direct observation has a great potential to cause change in the behavior of the professionals observed,²⁹ who, even without being informed about the survey, already noticed and questioned the presence of observers in the unit. Hence, new studies to evaluate accuracy are recommended in order to make the assessment of psychometric properties even more robust.
All authors contributed equally to the study design, data collection, analysis and discussion, as well as in the writing and critical review of the content with intellectual contribution and approval of the final version of the study.

Nothing to declare.

Nothing to declare.

Nothing to declare.


5. Ministério da Saúde (BR). Agência Nacional de Vigilância Sanitária. Implantação do núcleo de segurança do paciente em serviços de saúde. ANVISA [Internet]. 2016 [cited 2020 Jan 30];1-68. Available from: http://portal.anvisa.gov.br/documents/33852/3507912/Caderno+6+-+Implanta%C3%A7%C3%A3o+do+N%C3%BAcleo+de+Seguran%C3%A7a+do+Paciente+em+Servi%C3%A7os+de+Sa%C3%BAde/cb237a40-ffe1-401f-b7fd-7371e495755c

Relacionadas à Assistência à Saúde (IRAS) e resistência microbiana do ano de 2016 (REVISADO).


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Submitted: 06/29/2020
Accepted: 03/10/2021

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