

Quality Care in Outpatient Chemotherapy. Design and Validation of the Novel Care Quality Ambulatory Instrument

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Theme: Healthcare technologies

Contribution to the theme: The present study allowed expanding the theoretical conception of quality care and evidencing aspects such as the importance of companions for patients and the effects of providing care. It also provided a novel, valid, and reliable instrument that promotes the measurement of quality care in especially sensitive services due to the experiences of the people receiving care there, such as chemotherapy services. This study can provide a reference for research in other practice scenarios, as it is the first instrument in Spanish that evaluates quality care.

Abstract

Introduction: Neither validated scales nor scales translated into Spanish currently exist to evaluate the perception of quality care in people receiving outpatient chemotherapy, despite their usefulness in evaluating the care provided by nurses and in promoting changes in the delivery of these services. **Objective:** To design and validate the novel Care Quality Ambulatory-I (CQAMB-I) instrument in outpatient chemotherapy services. **Materials and methods:** This is an instrument validation study carried out in three stages: literature review, design, and validation of the instrument. Content validation was performed with 14 specialists with at least a master's degree and experience in chemotherapy or quality services; face validation was carried out through a pilot test with 31 participants diagnosed with cancer who received curative chemotherapy, and construct validation was carried out through an exploratory factor analysis with 436 users who received outpatient chemotherapy with curative intent. **Results:** A total of 15 items were removed in the content validation stage; none were removed in face validation. In construct validation, participants had a median age of 56 years, a median treatment time of 5 months, and breast cancer was the most commonly diagnosed form of cancer. Eighteen models were run, 30 items were removed, 6 factors emerged, and a KMO of 0.80 and a Cronbach's alpha of 0.82 were obtained. **Conclusion:** The CQAMB-I proved to be valid and reliable for the evaluation of quality care in outpatient chemotherapy services. Additionally, it enabled expanding the conception of such care beyond the attributes of structure, process, and outcome.

Keywords (Fonte: DeCS)

Total quality management; nursing; drug therapy; validation study; neoplasms.

4 Cuidado con calidad en quimioterapia ambulatoria. Diseño y validación del nuevo instrumento Care Quality Ambulatory

Resumen

Introducción: no existen escalas validadas, ni traducidas al español para evaluar la percepción del cuidado con calidad en personas que reciben quimioterapia ambulatoria, a pesar de su utilidad para evaluar la prestación de servicios enfermeros y generar cambios en la entrega de estos. **Objetivo:** diseñar y validar el nuevo instrumento Care Quality Ambulatory-I (CQAMB-I) en servicios de quimioterapia ambulatoria. **Materiales y métodos:** estudio de validación de instrumentos en tres fases: revisión de la literatura, diseño y validación del instrumento. Se realizó validación de contenido con 14 expertos con formación mínima de maestría y experiencia en servicios de quimioterapia o calidad; validación facial a través de prueba piloto con 31 participantes con diagnóstico de cáncer que recibían quimioterapia curativa; y validación de constructo por medio de un análisis factorial exploratorio con 436 usuarios que recibían quimioterapia ambulatoria con intención curativa. **Resultados:** en la validación de contenido se eliminaron 15 ítems; en la validación facial no se eliminó ninguno; y en la validación de constructo los participantes tuvieron una mediana de edad de 56 años, mediana de tiempo de tratamiento de 5 meses y cáncer de mama como el más diagnosticado. Se ejecutaron 18 modelos, se eliminaron 30 ítems, emergieron 6 factores y se obtuvo un KMO de 0.80 y un alpha de Cronbach de 0.82. **Conclusión:** el instrumento CQAMB-I demostró ser válido y confiable para evaluar el cuidado con calidad en servicios de quimioterapia ambulatoria y, adicionalmente, permitió ampliar la concepción de este más allá de los atributos de estructura, proceso y resultado.

Palabras clave (Fuente: DeCS)

Gestión de la calidad total; enfermería; quimioterapia; estudio de validación; neoplasias.

Cuidado com qualidade em quimioterapia ambulatoria. Desenho e validação do novo instrumento Care Quality Ambulatory

Resumo

Introdução: não existem escalas validadas nem traduzidas ao espanhol para avaliar a percepção do cuidado com qualidade em pessoas que recebem quimioterapia ambulatoria, apesar de sua utilidade para avaliar a prestação de serviços de enfermagem e gerar mudanças na entrega destes. **Objetivo:** desenhar e validar o novo instrumento Care Quality Ambulatory-I (CQAMB-I) em serviços de quimioterapia ambulatoria. **Materiais e método:** estudo de validação de instrumentos em três fases: revisão da literatura, desenho e validação do instrumento. Foi realizada validação de conteúdo com 14 especialistas com formação mínima de mestrado e experiência em serviços de quimioterapia ou qualidade; validação facial por meio de teste-piloto com 31 participantes com diagnóstico de câncer que recebiam quimioterapia curativa e validação de constructo por meio de uma análise fatorial exploratória com 436 usuários que recebiam quimioterapia ambulatoria com intenção curativa. **Resultados:** na validação de conteúdo, foram eliminados 15 itens; na validação facial, não foi eliminado nenhum; na validação de constructo, os participantes tiveram uma média de idade de 56 anos, média de tempo de tratamento de 5 meses e câncer de mama como o mais diagnosticado. Foram executados 18 modelos, foram eliminados 30 itens, emergidos 6 fatores e obtido um KMO de 0,80 e um alpha de Cronbach de 0,82. **Conclusões:** o instrumento CQAMB-I demonstrou ser válido e confiável para avaliar o cuidado com qualidade em serviços de quimioterapia ambulatoria e, além disso, permitiu ampliar a concepção deste mais além dos atributos de estrutura, processo e resultado.

Palavras-chave (Fonte DeCS)

Gestão da qualidade total; enfermagem; tratamento farmacológico; estudo de validação; neoplasias.

Introduction

The quality of healthcare is a construct that has become more prominent with the proposal of Avedis Donabedian and his triad of process, structure, and results. Bautista states that quality is a multidimensional construct, which can be understood as being integral and total, it is perceived when needs are met or satisfied, and it is subjective. The author also states that quality in healthcare services can be technical, depending on the institution, and subjective, depending on the service users (1). In their analysis of the concept of quality in healthcare services, Allen and colleagues have identified four attributes: effectiveness, safety, excellence culture, and desired health outcomes (2).

As one of the most relevant aspects of healthcare for users, quality must become objective to be measured and reflect the reality experienced by users. For this purpose, the literature indicates that the most widely used instrument has been the Servqual, based on its five dimensions: reliability, responsiveness, safety, empathy, and tangible elements (3, 4).

Therefore, nursing is an essential component in the provision of services and, consequently, in the establishment of the perception of quality by the users. The quality of care has been associated mostly with patient safety, but it is not limited to this, and involves aspects related to technical, personal, and interpersonal skills and to the results that can be achieved through nursing interventions (5).

Varied and alternate definitions of quality of care can be found, and it can be understood at several levels. According to Ebnetter (6), quality of care starts at a level of safety considered the minimum level of perceived quality. It is followed by a level of comfort, which expresses a balance between perceived quality and resources. Then, there is the level of perfection, understood as the absence of errors, flaws, or imperfections. Also, from a qualitative perspective, quality care implies holistic care, which is an interpersonal aspect and a matter of leadership and responsibility to provide the best care (7). In light of the importance of nursing care in the context of healthcare services, instruments have also been designed to address this perception and experience (8, 9), with the CUCACE being the most widely used in a variety of nursing settings and services (10).

On the other hand, one of the most devastating health-related experiences can be an oncological disease. The testimonies of people who have experienced cancer recount the suffering resulting from the loss of normality, the disruption of relationships with others, and the emotional impact (11). People who experience this condition require care that goes beyond technical aspects such as safety and the staff's technical skills: they require a different and transcendent sensitivity that allows them to identify, understand, and meet the

real needs stemming from a condition such as this (12). The experience of treatment, specifically chemotherapy, must be added to the diagnosis of an oncological disease. Studies have shown how this experience can be an equal or greater source of suffering in people due to the lack of knowledge regarding the treatment, the changes, and the test of coping strategies that allow them to reach a temporary adaptation (13, 14).

Therefore, quality of care in oncology should be mandatory and its measurement unavoidable. Thus, the literature identifies several instruments to measure the perception of quality in oncology services in general, and within them, some aspects of this construct in the field of oncology nursing specifically focused exclusively on care satisfaction (15, 16, 17, 18, 19, 20). However, no instruments for the evaluation of the quality of nursing care in oncology patients were found in the literature review in Spanish, and there are no instruments that particularly evaluate the quality of care in outpatient chemotherapy services. Hence, the objective of the present study was to design and validate a new instrument to measure the quality of care in patients undergoing outpatient chemotherapy.

Methodology

This is a study for psychometric validation of scales, which was carried out in three stages: a literature review, the design of a new instrument, and the validation of the aforementioned instrument. For the literature review stage, primary articles with a qualitative approach were searched in the SAGE, Scopus, Pubmed, Lilacs, EBSCO, Science Direct, and Springer databases, using the following keywords: quality (*calidad*), nursing care (*cuidado de enfermería*), and qualitative study (*estudio cualitativo*) in Spanish and English, within the limits of the publication year (2009-2019), and which allowed answering the following guiding question: what are the dimensions that comprise the quality of nursing care identified from the perception of the subjects of care?

For the design phase, a reflexive model was used, and the items were defined based on the categories and subcategories identified in the literature review studies. The items were not defined based on other instruments, since no instruments measuring quality care in outpatient chemotherapy services were identified in the literature. This implies clarifying that no existing instrument has been validated, therefore it was not necessary to resort to translation processes or cultural and semantic adaptation. A five-response, Likert-type scale was used to evaluate each item's frequency or intensity.

Subsequently, in the validation stage of the new instrument, content, face, and construct validations were carried out. For the content validation, an informal consensus method was used,

through the Delphi technique, with ten specialists who met the following criteria: they were nurses with a master's degree, with clinical experience providing care to people diagnosed with cancer undergoing chemotherapy or who worked in the quality field as professors or administrators. A link to the executive summary and the instrument drafted in Google Forms were sent by email, for rating the items in three criteria: simplicity, clarity, and relevance, assigning a score ranging from 1 to 5. With the ratings, the Aiken V test was applied and a value of 0.7 and a 95% CI ranging from 0.7 to 1 were defined as the cutoff point for retaining the item.

For face validation, a pilot test was conducted with 10% of the total estimated sample, as long as they were people with a diagnosis of cancer and were undergoing curative chemotherapy, intending to measure the estimated time for its completion, as well as to evaluate item comprehension and the rating scale.

A cross-sectional design was chosen for the construct validation, which included patients aged over 18, with a cancer diagnosis, who were undergoing outpatient chemotherapy in a healthcare institution in the city of Medellin (Colombia), and who wished to participate in the study at least one month before the instrument was applied. Patients aged over 18, who were receiving chemotherapy as palliative management were excluded. Potential participants were approached in the waiting rooms of the healthcare institution after they had left their oncology medical appointments.

The sample was estimated to consist of at least 200 patients, with a moderate condition, consisting of communalities ranging from 0.4 to 0.7 and 3 to 4 items per factor. The sampling was non-probabilistic by convenience. The following variables were defined as participant characterization variables: Sex, age, marital status, occupation, level of education, type of cancer, and months of chemotherapy.

A univariate analysis was conducted using the distribution frequency of the characterization variables, and then an exploratory factor analysis was carried out using the freely available Jamovi 1.6.23 software. The Pearson product-moment correlation matrix was reviewed first, considering there were five response options for each item. Subsequently, the adequacy level of the exploratory factor analysis was calculated through Bartlett's sphericity test and the Kaiser-Meyer-Olkin sample adequacy measurement, for which case a minimum value of 0.7 was adopted to define whether it was appropriate to perform an exploratory factor analysis.

For the estimation of factors, the maximum probability option was selected, considering that the matrix to be analyzed was Pearson's product-momentum matrix and the item categories were a minimum of five, combining this with a parallel analysis to determine the number of factors to be retained, and considering the retention of larger factors, that is, with a minimum of 3 or 4 items, saturations of at

least 0.4 in the items and making theoretical sense. An oblique rotation of the factors was performed through the Promax method, and each factor was named. Finally, the instrument's reliability was reviewed through internal consistency, measured via Cronbach's alpha, although it should be noted that sensitivity to change was not measured.

The study was classified as of minimum risk, according to article 11 of the Resolution 8430 of 1993, with the respect and protection of the privacy of the study participants prevailing, in addition to the fact that the respective informed consent form for participation in the study was provided, and each survey was labeled with its respective code for tabulation. This project was approved in the first instance by the Research Ethics Committee of the School of Health Sciences of the Universidad Pontificia Bolivariana, according to Act 09 of May 20th, 2019, and in the second instance by the independent Research Ethics Committee of the Instituto de Cancerología, as recorded in Act 11-2020 of November 30th, 2020.

Results

In the literature review, 215 articles were retrieved from all the databases, of which 141 were excluded based on their title or abstract, and 58 were excluded for not being qualitative studies or for not addressing the perception of the quality of nursing care, which resulted in a total of 16 articles included. From the review of these 16 articles related to the perception of the quality of nursing care in a variety of services and with different subjects of care, some preliminary dimensions or attributes comprising the construct of quality care were identified.

Based on these dimensions, the items that would compose version I of the new instrument to be validated were designed, consisting of 94 items, and then a review was performed by the researchers, which eliminated 23 items, resulting in version II with 71 items, which was submitted to content validation by 14 specialists who performed a scoring round. After validation by the specialists, 15 items were removed as they failed to meet Aiken's V 95% CI lower limit criterion of 0.7, and the format of 4 more items was changed, resulting in a total of 56 items in version III.

A pilot test was then carried out with 31 participants undergoing outpatient chemotherapy with curative purposes, in which the average time used to respond to the instrument was 9 minutes. Based on this, the necessary adjustments were made, according to the feedback to develop the instrument's final version IV.

The median age of the study participants was 56 years (IQR=17), and the median time undergoing chemotherapy was 5 months (IQR= 6). All sociodemographic characteristics can be found in Table 1.

Table 1. Participants' Sociodemographic Characteristics

Sociodemographic Characteristics	n	%
Sex		
Female	349	80
Male	87	20
Marital Status		
Married	214	49.1
Single	100	22.9
Separated	51	11.7
Free union	38	8.7
Divorced	19	4.4
Widowed	14	3.2
Level of Education		
Incomplete high school	103	23.6
Complete elementary school	92	21.1
Incomplete elementary school	75	17.3
Complete high school	54	12.4
Technical	33	7.6
Undergraduate	33	7.6
Technological	23	5.3
Specialization	18	4.1
Master's Degree	4	0.9
PhD	1	0.2
Occupation		
Housekeeper	172	39.4
Employed	176	40.3
Unemployed	44	21.9
Independent	54	12.4
Retired	31	7.1
Student	3	0.7
Type of Cancer		
Breast	196	44.8
Colo-rectal	53	12.1
Ovary	31	7.1
Cervix	29	6.7
Lung	25	5.7

Note: Prepared by the authors.

For the final version of the instrument, 18 models were run, out of which 30 items were removed. The final model led to an instrument consisting of 6 dimensions and 26 items; the complete data from the analysis are presented only for this final model. The sample adequacy tests demonstrated the correlation matrix does not correspond to an identity matrix (Bartlett's sphericity test: 5523 degrees of freedom = 325; $p < 0.001$), also presenting excellent data adequacy, with a KMO (0.80) that indicated the relevance of the EFA data, in addition to demonstrating an explained variance of 55.7% (Table 2).

Table 2. Explained Variance of the Instrument Factors

Factor	Load	Variance %	Cumulative %
1	2.96	11.40	11.4
2	2.98	11.46	22.9
3	2.76	10.62	33.5
4	2.25	8.65	42.1
5	1.88	7.22	49.3
6	1.65	6.35	55.7

Note: Prepared by the authors.

When the rotated factor structure matrix was analyzed, all correlations were found to be above 0.4 (Table 3). The final model led to 6 factors, named as follows: factor 1 – person-centered care (6 items); factor 2 – interpersonal competencies (6 items); factor 3 – care effects (4 items); factor 4 – companion visibility (4 items); factor 5 – suffering relief (3 items), and factor 6 – care satisfaction (3 items). In the reliability assessment, an overall score of 0.82 was obtained for the instrument.

Table 3. Rotated Factor Matrix with Item Loadings

	1	2	3	4	5	6	Uniqueness
Item_17		0.560					0.6362
Item_18		0.739					0.4084
Item_21		0.647					0.5580
Item_22		0.802					0.3761
Item_23		0.662					0.5354
Item_24		0.458					0.7664
Item_25			0.680				0.4337
Item_27			0.463				0.5349
Item_33			0.478				0.7373
Item_34			0.849				0.2650
Item_35			0.823				0.2364
Item_36						0.544	0.6365
Item_37						0.808	0.2387
Item_38						0.564	0.5075
Item_39				0.600			0.5569
Item_40			0.591				0.4990
Item_41					0.776		0.4295
Item_42					0.789		0.3299
Item_43					0.592		0.5311
Item_46				0.501			0.6453
Item_48	0.921						0.1516
Item_49	0.664						0.3780
Item_50	0.980						0.0717
Item_51	0.771						0.2715
Item_53				0.900			0.1870
Item_54				0.630			0.5980

Note: Prepared by the authors.

Discussion

This study aimed to validate the CQAMB-I instrument in people undergoing outpatient chemotherapy. This name, corresponding to the designation of Care Quality Ambulatory, was defined strategically to favor the internationalization of the instrument, its use, and validation in American and European contexts. This instrument allowed the recognition of the multidimensionality of quality care by including dimensions that involve the professionals, the users, the companions, and the disease conditions.

The first dimension, entitled “Person-Centered Care”, contains items related to people’s needs, the information provided, and the proximity of the nursing staff. Person-Centered Care involves changes in the model of care, multidisciplinary teams, reconceptualizing the use of resources, new care roles, and infrastructure changes (21). From a nursing perspective, Person-Centered Care implies individualizing care, reaching care agreements, and considering and intervening in each user’s specific needs, with the resulting improvement in quality (22).

The dimension entitled “Interpersonal Competencies” covers items related to respect, commitment, responsibility, and personal presentation. In nursing, Interpersonal Competencies entail, among other aspects, effective interpersonal relationships, considered to be the most relevant factor for the growth of care at a holistic level. Interpersonal relationships also entail affection as an emotional commitment to others and recognition of others, in an authentic exchange that favors interaction, with implicit therapeutic properties and positive effects for both parties (23).

The third dimension, entitled “Care Effects”, covers the intermediate nursing outcomes perceived by the users, such as teaching, management of side effects, improvement of the disease condition, and the reduction of complications. According to Gao et al. (24), care interventions can have effects on users in several components, namely: they can improve self-care skills, reduce the occurrence of complications, and contribute to the improvement of quality of life and adherence to medical treatment.

The dimension “Companion Visibility” consists of items on information, comfort, respect, and the companion’s involvement in the care of users. Providing companionship to people receiving healthcare is vital, as this practice builds trust and security, in addition to the emotional and social support provided to patients. On the other hand, the companion can contribute to the care of those people and improve their stay in the healthcare institution (25), especially considering that one of the main concerns of people who experience a form of cancer is the impact on their family members or partners (26).

Another dimension of the instrument is entitled “Suffering Relief,” which consists of items that mention the relief of pain, physical and

emotional suffering, and distress. Although suffering is probably intertwined with diagnosis and later with treatment, it is clear that users expect nurses to be able to contribute to alleviating the experience of suffering, especially because of what they consider to be the sources of suffering, such as the loss of health and, with it, the chain of losses that can involve work, among other aspects, to which the assessment and control of threats and the management of social contexts are added (27).

Finally, the dimension “Care Satisfaction” presents items related to the evaluation of satisfaction, expectations of care, and feelings of satisfaction. In general terms, people may feel satisfied with nursing care, and such satisfaction may be determined by the assignment of nurses for individualized care, previous contact with nursing care, and the admission process by these professionals (28).

As limitations of this study, we found that the distribution of cancer etiology was centered on the female gender and breast cancer, thus the sample of male patients was smaller; furthermore, the study was carried out in a single institution.

Conclusions

It can be concluded that the new CQAMB-I instrument that was designed and validated complied with the content, face, and construct validation tests, through the results of the statistical tests applied. Likewise, its reliability is acceptable, as it does not present low consistency or redundancy of its items. This novel instrument can be used to evaluate the perception of quality care in Colombian oncology centers where outpatient chemotherapy services are provided. It highlights the importance of patient companions in the care provided to users undergoing chemotherapy, as well as the perception of the effects of care on the suffering stemming from the disease and treatment. It is recommended to validate it in other institutions, both nationally and in Latin American, North American, and European contexts, where it is possible to obtain a sample with a larger number of male participants.

Conflict of interest: None declared

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