ORIGINAL ARTICLE

Validation of a graphic protocol for evaluating patient safety in teletherapy

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ABSTRACT

Objective: To construct and validate in content and appearance a graphic protocol and checklist to evaluate safe care in teletherapy.

Method: Methodological study, carried out between March and May 2022, in three stages: construction, validation and application of the graphic protocol and checklist to evaluate safe care in teletherapy. The construction was based on national and international guidelines and data from a scoping review, being elaborated from the structure, process and outcome components of Donabedian and the reference of Pasquali. Content and appearance validation was performed using the Delphi technique (Content Validation Coefficient >80%). After validation, the constructs were applied in a teletherapy service in Minas Gerais by two evaluators. These results were analyzed using the care classification proposed by the graphic protocol. The interobserver reliability was given by the Kappa coefficient.

Results: The graphic protocol and checklist were considered valid in content and appearance (>90%) after two rounds of Delphi. During the application of the graphic protocol and checklist in the teletherapy service, it was observed that the structure and result elements are safe, and the process element is partially safe. Still in this process, the evaluators observed that the constructs are suitable for use, with no need for adjustments at the time of application.

Conclusion: The graphic protocol and checklist for evaluating safe care in teletherapy were considered valid. Its use will enable the recognition of structural and procedural elements in the service, encouraging actions to improve patient safety according to the local reality.

Keywords: Patient safety, Teletherapy, Radiotherapy, Protocols, Validation study.

INTRODUCTION

Malignant neoplasms represent one of the main public health problems. The world estimates for 2020 were 19.3 million new cases of cancer. In addition, by 2040, there may be a 47% increase in the number of new cases mentioned above, which will represent a quantity of about 28 million new cases[1].

In this context, specialized and organized multidisciplinary care is important to improve the outcomes of cancer patients, as well as greater financial investments in this area[1,2].

Among the necessary improvements, the improvement of patient safety (PS) stands out, leading to the reduction of avoidable damages and errors that can

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happen during the therapeutic process[3]. In response to this, in 2019, the 72nd World Health Assembly supported the creation of a document that encouraged the adoption of measures aimed at users of health systems with the objective of eliminating negative outcomes resulting from the care process[4]. These recommendations can be applied in the treatment of cancer patients, especially in teletherapy, which is considered as one of the high-risk areas for PS.

Among the possible measures to improve PS in teletherapy, it is recommended to implement risk management programs, perform process risk analysis and report incidents, as well as promote a safe workflow[5]. Thus, each service needs to strategically organize its resources to improve PS at all stages of the therapeutic process according to its assistance reality[4].

Risk management, an important step in the promotion of PS in teletherapy, concerns the creation of indicators that evaluate the security conditions of the site. Moreover, there is a need for systematic and constant evaluation of the quality of teletherapy services to certify the technical quality of equipment and care staff, as well as to improve oncological PS[6,7].

In this scenario, the Donabedian Triad stands out, an exercise to evaluate the structure, process and outcome of health services, developed by Avedis Donabedian. In the scope of teletherapy PS, this evaluation model consists of a way to measure the conditions involved in the provision of health care for the oncological patient[6,8].

Thus, in addition to controlling and determining the quality of health care provided, this process is able to provide a contribution to improving the management of these teletherapy services and for PS, because it enables the recognition of structural and procedural elements in the service, promoting strategic actions according to local reality[6-8].

In this context, this study was guided by the following research question: what is the validity of content and the appearance of a graphic protocol and checklist for the evaluation of safe patient care in cancer treatment by teletherapy? To answer this question, the objective was to build and validate in content and appearance a graphic protocol and checklist to evaluate safe care in teletherapy.

METHOD

This is a methodological study with quantitative approach, developed in the period from March to May 2022 according to the methodological framework of psychometrics of Pasquali[9], based on three procedures: 1) theoretical, 2) empirical and 3) analytical.

The construction of the graphic protocol and checklist was based on national, international guidelines and data from a scoping review entitled "Patient safety in teletherapy: scoping review"[10], published by the journal Research, Society and Development in 2022. In addition to the components structure, process and result of Donabedian[8] and psychometrics of Pasquali[9,11]. The design of the appearance of the graphic protocol was carried out from the reference of Pimenta et al.[12], which establishes graphical forms of meaning to the construct.

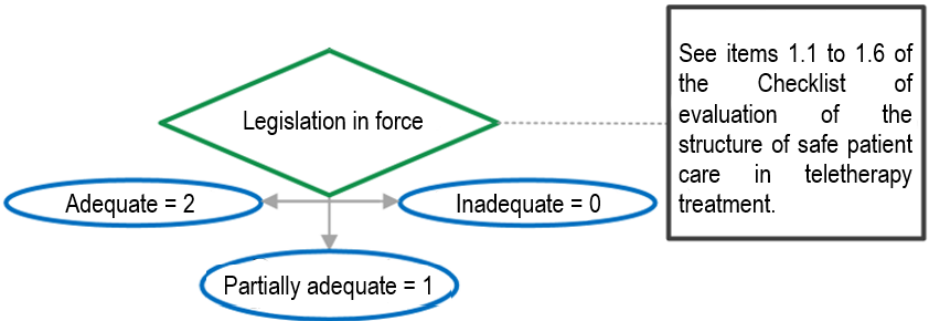
Therefore, the graphic protocol was based on a checklist composed of 21 items/ dimensions that has specific items that correspond to the requirements for obtaining compliance for the safe service, regarding the elements structure, process and result.

The objective of such organization is to allow, through observation of the service, the evaluators to fill out the checklist scoring the presence (S = yes, "one point") or absence (N = no, "zero point") of the 21 checked items. At the end, the sum of items is performed and a classification by dimension is assigned according to the percentage of compliance found, which may

be: adequate if, during observation, 100% of the descriptions of each item are covered by the teletherapy service; partially adequate if more than 50% of the topics analyzed are present; and inadequate if less than 50% of the listed items are discrimined[11].

The dimensions evaluated in the checklist were inserted into the graphic protocol as a diamond[12], which indicates decision making with three response possibilities (adequate, partially adequate and inadequate). Next to each diamond is a dashed line that connects it to an explanatory box[12], which indicates which items of the checklist should be checked, as shown in figure 1.

Figure 1: Organization of the graphic protocol to evaluate safe patient care in teletherapy treatment



Therefore, each dimension receives a score regarding the adequacy of the items evaluated. This score can vary from zero to two, according to the judgment of each dimension. The sum of all dimensions of the score allows the evaluation of whether the care offered in the teletherapy service is safe, partially safe or unsafe for the patient, according to the evaluated element, as represented by chart 1.

Chart 1: Sum of the scores of the dimensions of the Graphic Protocol by evaluated element

Sum of the final score		Care Classification
Structure	0 - 3 points	Unsafe structure
	4 - 6 points	Partially safe structure
	7 - 10 points	Safe structure
Process	0 - 10 points	Unsafe process
	11 - 21 points	Partially safe process
	22 - 30 points	Safe process
Outcome	0 - 4 points	Unsafe outcome
	5 - 9 points	Partially safe outcome
	10 - 12 points	Safe outcome

In order to support the use of the constructs, a "Guide for the use of the graphic protocol and checklist for the evaluation of safe patient care in teletherapy treatment" was developed. The checklist contains all observation items in a structured way about the teletherapy service and should be consulted to facilitate the analysis of the requirements listed in the graphic protocol.

The validation of content and appearance of the constructs occurred in the months of March to May 2022. Data collection used the Delphi technique; the selection of judges took place by advanced research in the Lattes platform, of the National Council for Scientific and Technological Development – CNPq (http://lattes.cnpq.br/), in order to identify Brazilian health professionals able to act in the validation.

The validation process of the graphic protocol and checklist took place in two rounds of Delphi (Delphi I and Delphi II)[12,13]. The population of Delphi I was composed by 245 judges registered in the Lattes platform; the judges who did not answer or did not accept to participate in the survey were automatically excluded from the study. With this, the final sample of Delphi I consisted of 30 judges and in Delphi II all the contacted judges answered again, corresponding to 30 judges in the second round of validation.

The operationalization of the Delphi technique occurred by Google Forms. The evaluation of the agreement of the judges used the Likert scale, where: "1 - inadequate (I)" classified as degree of disagreement; items "2 - partially adequate (PA)" and "3 - adequate (A)" as agreement.

The content validation was made through the theoretical analysis of the items that make up the graphic protocol and checklist, based on the twelve validation criteria established by Pasquali et al.[9]: behavior, objectivity, simplicity, clarity, relevance, precision, variety, modality, typicity, credibility, amplitude and balance. For the validation of appearance, the instrument "Suitability Assessment of Materials" (SAM) was used, with the following criteria: content, language, illustrations, layout and culture[14].

In the two rounds of Delphi, a free field was provided to be answered optionally for the judges to write their suggestions on the graphic protocol and checklist. The answers of the open questions were analyzed according to the similarity of the subjects addressed and their relevance, comparing with the literature.

In the summary and analysis step, the data were grouped in the Microsoft Excel® program, with subsequent calculation of the degree of agreement of the responses, by means of the Content Validity Coefficient (CVC), thus the items that presented more than 80% of agreement were considered valid among the judges and the items with percentages below 80% were reformulated, from the suggestions and the evidences available in the literature, as well as those that, despite having reached a level of agreement greater than or equal to 80%, were relevant to better adapt the graphic protocol and checklist[9]. For descriptive and inferential analysis (binomial test), the ρ-value 0.05 was adopted for statistical significance.

After the first and second rounds of Delphi (I and II), all the modifications suggested by the judges about the graphic protocol and checklist were analyzed and carried out, thus at the end of this process of content and appearance validation, the graphic protocol and checklist has gone through three versions since its initial construction. Items that needed to be reviewed regarding their form of presentation, inclusion, exclusion, relocation or division were duly modified, meeting the request of the judges. Table 2 presents a summary of the modifications suggested by the judges.

Chart 2: Summary of modifications suggested by judges for the graphic protocol and checklist in Delphi I and II.

Round	Evaluation items	Suggestions/ considerations made by the judges
***Delphi* I**	*Structure*	List items according to the standard;
		Offices for the entire team (for common use or not);
		Combine subitems 5.1, 5.2 and 5.3, as well as 5.8 and 5.9;
		Reallocate items and reduce them according to the legislation, since the service has already been approved by the Health Surveillance Agency and CNEN;
		Change the wording: Patient care area / Human Resources;
		If possible, add a subitem referring to Financial Resources, since they are directly related to the process elements and subsequently results;
		Add some specific information about the Radiological Protection Plan, proposed by NR32;
	Process	Item not only for checking the wristband, but also for verbal checking with the patient or family member, the wristband and the medical record regarding the patient's identification;
		Would replace the terms in items 9, 12, 13, and 16 for clinical evaluation, clinical and technical reviews, termination of treatment, and fair culture, respectively;
		Item that assesses communication with the patient during the effective application of radiotherapy;
		Include an assessment of professional satisfaction;
		Avoid using acronyms or writing them out in full or with captions;
		Change: it is not the responsibility of the dosimetrist to perform this monitoring/testing. And it is common for radiotherapy services not to have a certified dosimetrist.
		Item 11: This is not a list; what is required is a computerized system for managing patient information with registration and presentation of the patient's photograph in all documents related to the treatment, as well as on the control panel of radiation sources during treatment.
	Outcome	Do patient/client safety indicators 18 to 25 intend to provide quantitative answers? Review the wording;
		Item 18: 1,000 patients/day is not the reality for most services (I suggest 100);
		Review items 21, 23 and 25;
		Include an indicator related to the number of appointments per day;
	Graphic protocol	I suggest separating the graphs into "three pages" (structure for care, safe care and results), since all of them on just one page have a small image to view;
		Some texts have a small font which makes it difficult to read, and there are also diamonds that are on top of the text and make it difficult to read.
***Delphi* II**	*Structure*	Add daily testing of teletherapy equipment (execution and recording of tests).
	Process	Add: whether the software for treatment planning is periodically updated/corrected according to patient flow;
		Change items: 9.8, 10.5 and 18.6 (errors due to incidents);
	Outcome	Change item 17.2 (review wording): “were there any incidents related to identification failure?”;
		Change items: 18.1, 18.2, 18.3: describe mild, moderate and severe severity in parentheses;
		Change items (review wording so as not to impact results after analysis of the service, some items may have a positive answer (yes), and still be unsafe if they occur during patient care): 17.2; 18.1-18.8; 19; 20; 21.

At the end of the validation process of the constructs, the application of the graphic protocol and checklist in a teletherapy service was also performed by two evaluators trained, in a face-to-face and observational way, in the perspective of understanding the applicability and effectiveness of constructs on site.

During the application of the graphic protocol and checklist, the two evaluators were together at the same place and time to observe the teletherapy service routine, and to perform the systematic recording of the reality found without communication between them. This procedure is essential so that there is no interference and exchange of information during the collection.

To determine the level of interobserver agreement, the Kappa coefficient was used (Statistical Package for Social Sciences (SPSS) 29.0 software).

RESULTS

The graphic protocol and checklist to evaluate safe patient care in teletherapy treatment were built based on national, international guidelines and scientific evidence recovered by the scoping review.

The organization of the graphic protocol and the checklist obeyed the assumptions of the Donabedian triad, from the elements "structure", "process" and "outcome" and the psychometry of Pasquali et al.[9], which resulted in a set of items grouped into dimensions.

The dimensions structure, process and outcome that compose the checklist were arranged in a frame form, with spaces for marking with "x" the answer possibilities "yes" in the requirements that give the safe care in the teletherapy service, or "no" for those dimensions that do not meet these requirements, as shown in chart 3.

Chart 3: Organization of the checklist to evaluate safe patient care in teletherapy treatment

CHECKLIST TO EVALUATE THE SAFE PATIENT CARE IN TELETHERAPY TREATMENT				
Place (as letter): _____	Evaluator 1 ( ) Evaluator 2 ( )	Date of evaluation: ____ /____/____	Beginning: ____h___' End: ___h___'	
ITEMS TO EVALUATE THE STRUCTURE			**YES**	**NO**
1. Legislation in force	1.1 Is there an operating license issued by the competent health authority?			
	1.2 Is there a Radiological Protection Plan approved by CNEN?			
	1.3 Are periodic audits carried out to verify compliance with the standards established by the Technical Regulation?			
	1.4 Is there an Occupational Health Medical Control Program?			
	1.5 Is there a preventive maintenance program for teletherapy equipment provided by the manufacturer or by the equipment maintenance team?			
	1.6 Is there an undifferentiated office for the entire health team?			
2. Infrastructure in the area of patient/client service	2.1 Does the teletherapy room have air conditioning?			
	2.2 Does the teletherapy room have doors with interlocks that prevent unauthorized access during treatment?			
	2.3 Does the teletherapy room have light indicators in a visible position to enable checking the operation of equipment?			
	2.4 Does the teletherapy room have an oxygen point with a demand of 60 liters/minute, on the wall and/or available cylinders?			
	2.5 Are the fire extinguishers within their expiration date?			
	2.6 Are there signs on the walls and floors of the exits to the fire areas and areas?			
	2.7 Are there alcohol-based preparation dispensers?			
	2.8 If there are elevators: is there monthly preventive maintenance, as well as emergency and corrective maintenance when necessary?			
	2.9 Are there labels posted in visible places with the dates of the last and next air conditioning maintenance?			
	2.10 Is there pest and vector control?			
	2.11 Is there an active waste segregation system (chemical, physical, biological) and Healthcare Waste Management Program?			
	2.12 Is there an emergency vehicle with a heart monitor, electrocardiograph, defibrillator; bag-valve-mask device (ambulance with reservoir); expired emergency medications and materials; wall-mounted or portable aspirator; complete intubation material (endotracheal tubes, cannulas, guides and laryngoscopes with a full set of blades)?			
	2.13 Is the emergency vehicle checked on a pre-established date and after each use, with the seal number and date of inspection recorded on a specific form?			
	2.14 Is the cardioverter's operation tested and recorded daily?			
	2.15 Is the emergency vehicle subject to an annual preventive inspection?			
3. Use of routines and protocols	3.1 Are there written standards and routines, reviewed annually or according to the institution, for therapeutic conduct and procedures by doctors, physicists and nurses?			
	3.2 Are there written standards and routines, reviewed annually, for biosafety, radiological protection and use of Personal Protective Equipment?			
	3.3 Are there standards and routines for performing daily tests of teletherapy equipment (execution and recording thereof)?			
	3.4 Are there educational manuals for patients/clients and family members on teletherapy treatment, adapting them to their social reality?			
	3.5 Are there standard operating procedures for Healthcare Waste (HSW) regarding generation, segregation, packaging, identification, collection, storage, transportation, treatment and environmentally appropriate final disposal?			
4. Human and financial resources	4.1 Is there a radiotherapist who is the technical manager and a substitute, who is responsible for the teletherapy service before the local Health Surveillance Agency?			
	4.2 Is there a Radiation Protection Supervisor and a substitute?			
	4.3 Is there one radiotherapist for every 600 new patients/clients per year in the Teletherapy Service?			
	4.4 Is there a specialist in radiotherapy medical physics for every 600 new patients/clients per year in the Teletherapy Service?			
	4.5 Are there at least two radiotherapy technicians per shift, per piece of equipment?			
	4.6 Is there a radiotherapist present for at least 2/3 (two thirds) of the entire daily operating period, with the remaining third being covered by another medical professional?			
	4.7 Is there a technically responsible nurse who is responsible for the teletherapy service before the local Health Surveillance Agency?			
	4.8 Is there an adequate number of nursing professionals to meet the demand for care at the location?			
	4.9 Are there radiological and cleaning support staff during the service operation?			
	4.10 Does the service receive funding from the public sector?			

5. Permanent education		5.1 Is annual training provided to occupationally exposed individuals for both normal work situations and incident or accident situations?		
		5.2 Is there at least two technical and scientific updates with an emphasis on advanced life support for the entire healthcare team during the year?		
		5.3 Is there at least one annual course that addresses patient/client safety?		
		5.4 Is periodic training on care protocols and standard operating procedures provided?		
		5.5 Is appropriate training provided to new professionals admitted to the team?		
		5.6 When implementing new equipment or process changes, does the team receive sufficient training to ensure competence before implementation in practice?		
		5.7 Are records of attendance at training activities kept and archived?		
ITEMS TO EVALUATE THE PROCESS			**YES**	**NO**
6. Patient/client identification		6.1 Is there a computerized system for managing patient/client information, with registration and presentation of photographs on all documents related to treatment?		
		6.2 Is the patient/client's identification checked and verbally verified: white wristband, in legible letters and with at least two indicators (full name of the patient/client; full name of the patient/client's mother; date of birth of the patient/client; and/or medical record number)?		
		6.3 Is the family member/companion involved in identifying the patient/client?		
TREATMENT PHASES	7. Clinical evaluation	7.1 Is the patient/client's identification checked and verbally verified: white bracelet, in legible letters and with at least two indicators?		
		7.2 Is there a medical evaluation to indicate treatment and define the best modality?		
		7.3 Is there a consultation with other professionals from the multidisciplinary team?		
		7.4 Are patients/clients with the potential to become pregnant assessed for pregnancy?		
		7.5 Are patients/clients with implanted medical devices that are sensitive to radiation identified?		
		7.6 Is an intravenous contrast test performed before the treatment simulation, if its use is necessary?		
		7.7 Are patients/clients and/or their family members instructed to carefully read and sign the informed consent form before starting teletherapy treatment or any procedure during medical monitoring?		
		7.8 Are patients/clients verbally instructed and given written instructions (manual, folder) about teletherapy care?		
	8. Simulation, design and planning	8.1 Is the patient/client's identification checked and verbally verified: white wristband, in legible letters and with at least two indicators?		
		8.2 Is the computerized tomography exam (or other complementary images) for planning performed following protocols defined by the physician (positioning, making or adapting immobilizers for the patient/client and, finally, acquisition of planning images)?		
		8.3 Is the delimitation of the area to be treated marked on the skin with ink? Or are individual molds and masks used?		
		8.4 Is double checking performed in the simulation, delineation and planning processes?		
		8.5 Is the electronic transfer of patient/client information from the simulation to the planning system verified for each patient/client?		
		8.6 Is any software used to prevent errors in the simulation, delineation and planning processes?		
		8.7 If used, is the treatment planning software periodically updated/corrected according to the flow of patients/clients?		
	9. Application of treatment dose	9.1 Is the patient/client identification checked and verbally verified: white wristband, in legible letters and with at least two indicators?		
		9.2 Does only trained and authorized personnel operate and handle radiation sources?		
		9.3 Are imaging exams performed in the treatment room itself to ensure proper positioning?		
		9.4 Are lead shields used on healthy tissues and organs when necessary?		
		9.5 Is the computerized patient/client information management system used in the process of applying the treatment dose?		
		9.6 Is double checking performed in the processes of positioning and applying the treatment dose?		
		9.7 Is there a system for monitoring and audiovisual communication of patients/clients?		
		9.8 Are technical treatment plans and identified incidents notified, discussed and reviewed through regular team meetings?		
	10. Clinical and technical review	10.1 Is the patient/client's identification checked and verbally verified: white wristband, in legible letters and with at least two indicators?		
		10.2 Is there a medical evaluation to assess acute toxicity and response to treatment?		
		10.3 Is there a consultation with other professionals on the multidisciplinary team for guidance and toxicity monitoring?		

		10.4 Is a standardized or validated instrument used to monitor systemic toxicities related to teletherapy?		
		10.5 Are possible incidents prior to the review reported in the incident reporting system?		
		10.6 Are regular monitoring of mechanical, dosimetric, electronic parameters and safety systems performed by the medical physicist?		
	11. End of treatment	11.1 Do patients/clients receive discharge instructions at the end of treatment?		
		11.2 Do patients/clients receive a follow-up plan at the end of treatment?		
		11.3 Does a physician complete a document that contains a summary of treatment?		
		11.4 Is there a means of communication for monitoring the patient/client post-treatment (in their home, such as telenursing)?		
12. Risk prevention and management		12.1 Is there a teletherapy quality management program in the institution?		
		12.2 Is a flow map (flowchart) used to solve problems in teletherapy processes?		
		12.3 Is a method used to prevent failures and analyze process risks?		
		12.4 Does the team have autonomy to make decisions in the Teletherapy Service?		
13. Incident notification		13.1 Is there an institutional system for voluntary incident reporting?		
		13.2 Is the team encouraged to voluntarily report incidents?		
		13.3 Are recorded incidents reported, discussed and reviewed through monthly team meetings?		
		13.4 Are risk events and situations classified (taxonomy) according to the institutional reality?		
14. Fair culture		14.1 Is there an institutional system for learning from incidents?		
		14.2 After incidents are recorded, are they investigated to determine the root cause?		
		14.3 After determining the root cause, are strategies developed to correct process deficiencies?		
15. Adherence to the National Humanization Policy		15.1 Is assistance offered based on humanization, ethics and respect for all professionals in the service?		
ITEMS TO EVALUATE THE OUTCOMES			**YES**	**NO**
PATIENT/CLIENT SAFETY INDICATORS	16. Hand hygiene adherence	16.1 Is the consumption of alcoholic preparation at least 100 patients/clients/day?		
		16.2 Is the consumption of liquid soap at least 100 patients/clients/day?		
	17. Patient/client identification	17.1 Do all patients/clients have identification bracelets standardized by the institution?		
		17.2 Are incidents related to failure to identify the patient/client reported and analyzed monthly?		
	18. Process and risk management	18.1 Are incidents of mild severity (minimal short-term damage or functional loss) reported and analyzed monthly?		
		18.2 Are incidents of moderate severity (long-term or permanent damage or functional loss) reported and analyzed monthly?		
		18.3 Are severe incidents (major long-term or permanent damage or functional loss) reported and analyzed monthly?		
		18.4 Are the occurrence of grade I and II radiation-induced lesions (erythema and dry desquamation) reported and analyzed monthly?		
		18.5 Are the occurrence of grade III radiation-induced lesions (wet desquamation) reported and analyzed monthly?		
		18.6 Are the occurrence of grade IV radiation-induced lesions (wet, confluent desquamation, severe crusting) reported and analyzed monthly?		
		18.7 Are incidents associated with the prescription of irradiation doses reported and analyzed monthly?		
		18.8 Does the service monitor the occurrence of equipment unavailability (due to planned or unplanned failures) monthly?		
		18.9 Are indicators monitored regarding the number of appointments per month?		
		18.10 Are patient/client, family and professional satisfaction surveys conducted, and the results compiled and analyzed?		
Trigger Tool (HEALTHCARE MODULE)	19. Abrupt treatment interruption	19.1 Does the service monitor the occurrence of abrupt interruptions in the application of the treatment dose on a monthly basis?		
		19.2 Does the service monitor the occurrence of reactions or other reasons that may have led to the abrupt interruption of treatment on a monthly basis?		
	20. Complications associated with treatment	20.1 Does the service monitor the occurrence of complications associated with the application of the treatment dose on a monthly basis?		
		20.2 Does the service record the etiology of complications associated with the application of the treatment dose (if any)?		
		20.3 Does the service monitor the occurrence of cardiorespiratory arrest (CPA) and its etiology during or shortly after the application of teletherapy treatment on a monthly basis?		
		20.4 Does the service monitor the occurrence of transfers to hospital admission or emergency care that occurred during or shortly after the application of teletherapy treatment on a monthly basis?		

	21. Patient/client fall	21.1 Does the service monitor the occurrence of falls (frequency of unplanned events that caused the patient to fall to the ground, with injury) during or immediately after the application of teletherapy treatment on a monthly basis?		

The dimensions of the graphic protocol were inserted in a diamond, connected to a dashed line that contains an explanatory box that refers to the checklist, and three other lines connected to the answer possibilities and scoring: "adequate = 02 points", "partially adequate = 01 point" and “inadequate = 0 point" by evaluating the teletherapy service. At the end of the application in teletherapy services, according to the final sum per evaluated element (structure, process and result), it is possible to verify whether the care offered on site is safe, partially safe or unsafe for the patient. Figures 2, 3 and 4 show the final arrangement of validated protocols for evaluating the safety of the teletherapy service structure, process and outcome.

Figure 2: Organization of the graphic protocol and checklist to evaluate the structure for safe care

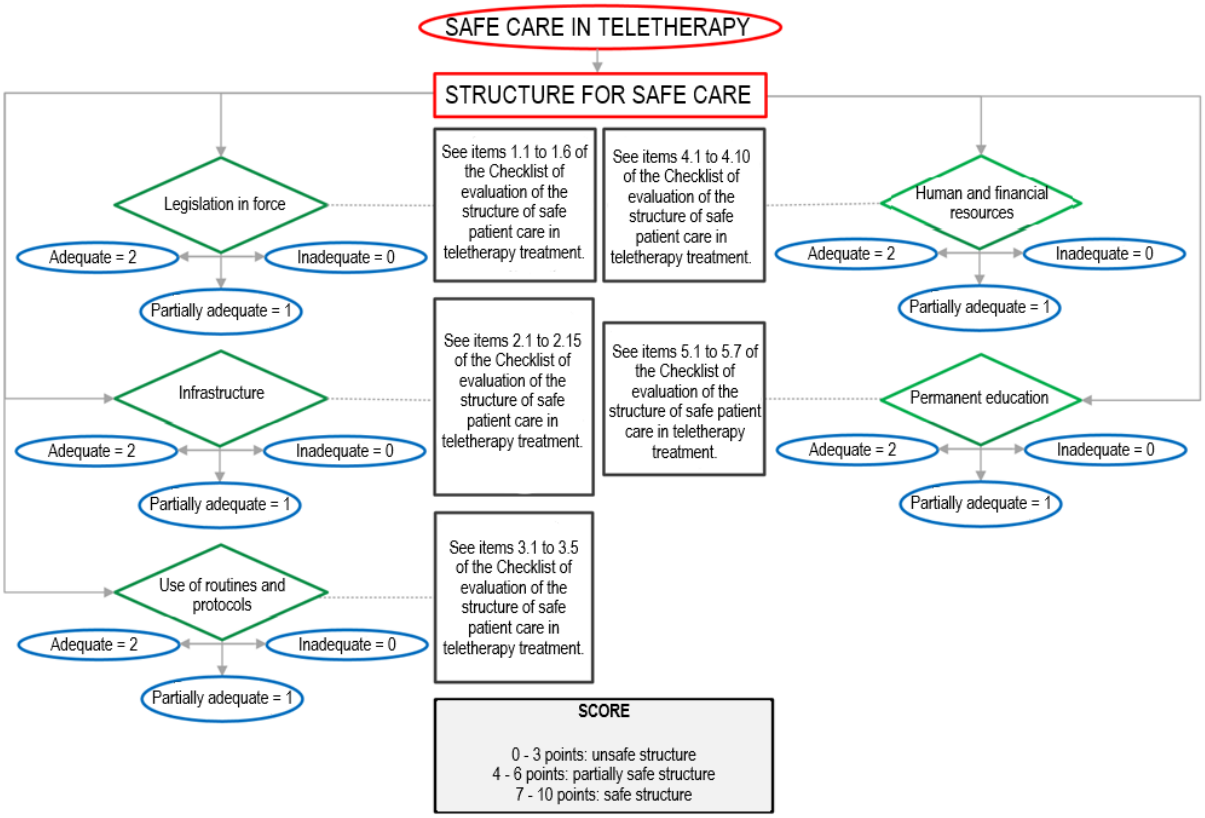
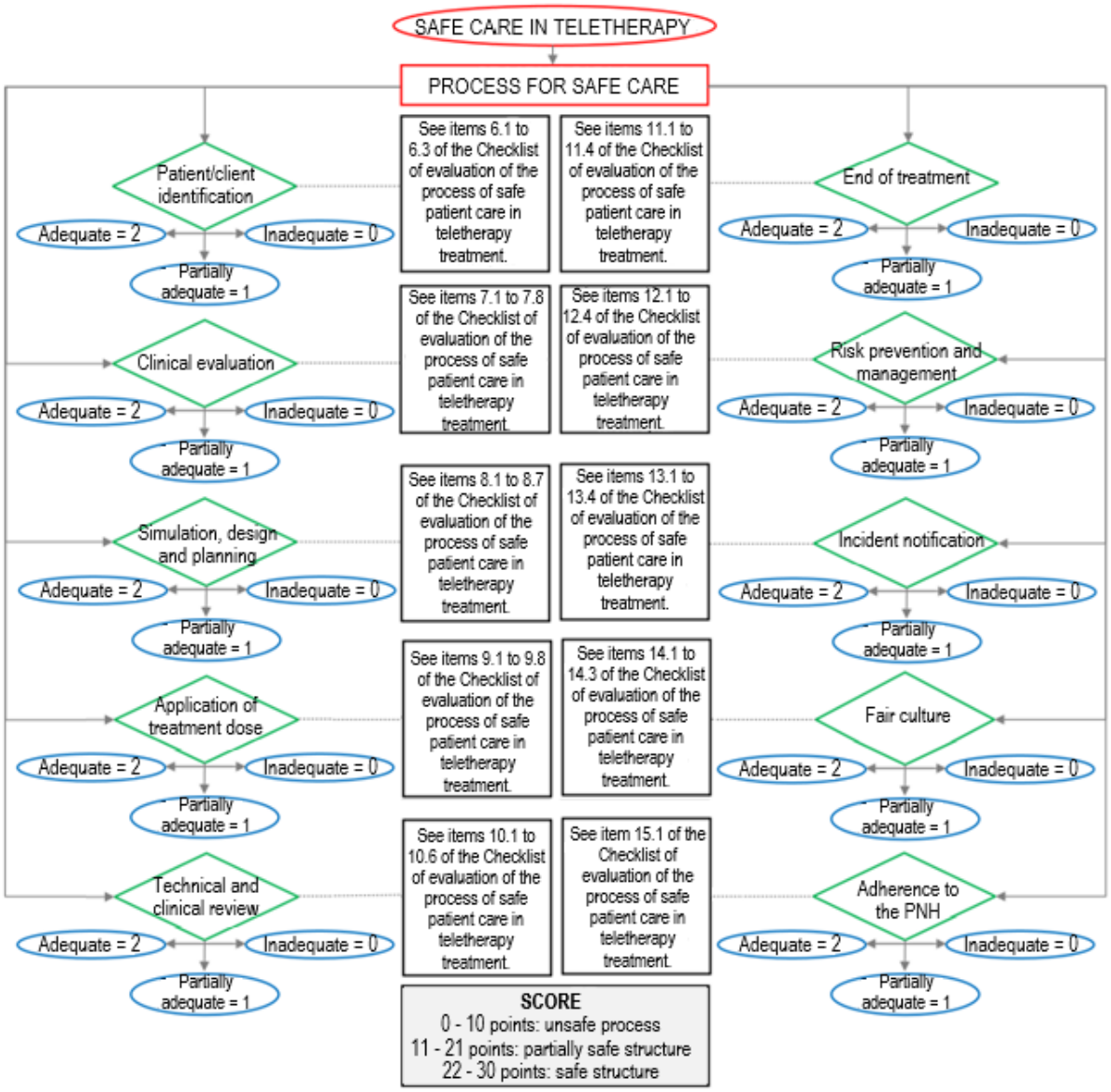


Figure 3: Organization of the graphic protocol and checklist to evaluate the process for safe care



The graphic protocol and the checklist for evaluating safe care in teletherapy, after the two rounds of Delphi, were considered valid in content (CVC>90%) and appearance (CVC>90%), as established by the methodological reference[9].

For the validation process of content and appearance, a total of 30 judges participated in the first and second rounds of Delphi, most of them female (60% - 18/30), with age range between 27 and 64 years. Regarding the training time, 53.3% (16/30) of the professionals had more than ten years of training.

Most judges (43.3%) had a degree in nursing, 33.3% were physicists/ dosimetrists and 23.3% were doctors. Regarding degree, 36.7% had PhD and in relation to the area of practice, most worked in the area of RT with 66.7%, followed by work in the area of PS with 23.3%, in oncology and radiodiagnosis with 10%.

The final consensus among the judges regarding the items analyzed for content validation[9,15] and aparences[14] of the graphic protocol and checklist that obtained agreement ("adequate"), according to the criteria of Pasquali et al.[9,15] for Delphi I and II are described in Table 1.

Table 1: Consensus among judges for content and appearance evaluation (Delphi I and II), Divinópolis, MG, Brazil, 2022.

Evaluation criteria		Structure, process and outcome			
		Delphi I (n=30) n (%)	ρ-valor	*Delphi II* (n=30) n (%)	ρ-valor
Content evaluation	Usefulness/ relevance	25 (83.3%)	0.004**	30 (100.0%)	0.00**
	Consistency/ breadth	27 (90.0%)	0.002**	30 (100.0%)	0.00**
	Clarity	20 (66.6%)	0.038**	27 (90.0%)	0.002**
	Objectivity	23 (76.6%)	0.16**	30 (100.0%)	0.00**
	Simplicity	21 (70.0%)	0.21**	27 (90.0%)	0.002**
	Feasible	24 (80.0%)	0.005**	27 (90.0%)	0.002**
	Modality	22 (73.3%)	0.046**	30 (100.0%)	0.00**
	Precision	20 (66.6%)	0.038**	30 (100.0%)	0.00**
	Credibility	27 (90.0%)	0.002**	30 (100.0%)	0.00**
	Variety	25 (83.3%)	0.004**	30 (100.0%)	0.00**
	Typicality	26 (86.6%)	0.003**	30 (100.0%)	0.00**
	Balance	28 (98.3%)	0.001**	30 (100.0%)	0.00**
Appearance evaluation	Content	26 (86.66%)	0.003**	30 (100.0%)	0.00**
	Language	21 (70%)	0.21**	30 (100.0%)	0.00**
	Illustrations	26 (86.66%)	0.003**	27 (90.0%)	0.002**
	Layout	22 (73.33%)	0.046**	27 (90.0%)	0.002**
	Culture	26 (86.66%)	0.003**	30 (100.0%)	0.00**

**ρ-value - ≤ 0.05.

Table 1 shows that, in the first round of Delphi (I), only the requirements clarity (66.6%), objectivity (76.6%), simplicity (70.0%), modality (73.3%) and precision (66.6%) were below the recommended for the protocol to be considered valid. In Delphi II, all requirements obtained agreement above 80.0%, including some previously validated, which reflects high approval rate of the graphic protocol and the checklist by the judges.

In the Delphi I round, 96.7% of the judges agreed that the protocol meets the objectives for which it was proposed and 90.0% recommended its use/application in teletherapy services. After the suggested changes and in the second evaluation round (Delphi II), all judges recommend the use of the construct in teletherapy services.

Finally, the graphic protocol and checklist validated on July 27, 2022, by two independent evaluators in a reference teletherapy service in Western Minas Gerais was applied. The total time spent was one hour and 29 minutes (starting at seven hours and 43 minutes and ending at nine hours and 12 minutes).

There were no complications in the teletherapy service during the application of the graphic protocol and checklist. According to the observed by the evaluators, the constructs were suitable for use, are objective, easy to read and interpret. No adjustments are required at the time of application.

The graphic protocol and the checklist show that this teletherapy service presented in the final evaluation in the structure element the total of nine points (safe structure); in the process element, the total of 15 points (partially safe process); and in the outcome element, the total of ten points (safe outcome). The results of the evaluation are presented in table 2.

Table 2: Application of the graphic protocol and checklist for evaluating teletherapy care, Divinópolis, MG, Brazil, 2022.

Evaluation elements/ items	Evaluation result			
	Yes / Safe	No/ unsafe	Care evaluation	*k*/* LA**
Structure				
Legislation in force	06 (100.0%)	-	Safe structure	1.0 / Excelent/ <0.001***
Infrastructure in the area of patient/client care	14 (93.33%)	01 (6.66%)		
Use of routines and protocols	05 (100.0%)	-		
Human and financial resources	09 (90.0%)	01 (10.0%)		
Permanent education	07 (100.0%)	-		
Process				
Patient/client identification	03 (100.0%)	-	Partially safe process	1.0 / Excelent/ <0.001***
Clinical assessment	06 (75.0%)	02 (25.0%)		
Simulation, design and planning	06 (85.7%)	01 (14.2%)		
Application of treatment dose	08 (100.0%)	-		
Clinical and technical review	05 (83.33%)	01 (16.6%)		
End of treatment	03 (75.0%)	01 (25.0%)		
Risk prevention and management	04 (100.0%)	-		
Incident notification	04 (100.0%)	-		
Fair culture	03 (100.0%)	-		
Adherence to the National Humanization Policy	01 (100.0%)	-		
Outcome				
Hand hygiene adherence	02 (100.0%)	-	Safe outcome	1.0 / Excelent/ <0.001***
Patient/client identification	-	02 (100.0%)		
Process and risk management	02 (100.0%)	-		
Abrupt interruption of treatment	02 (100.0%)	-		
Complications associated with treatment	02 (100.0%)	-		
Patient/client fall	02 (100.0%)	-		

k* - Kappa Coefficient; LA** - Level of agreement interobservers; ρ-value*** - ≤ 0.05

The process element presented a higher percentage of inadequacies, indicating the need to review work processes with a view to improving the quality of care. A report with these considerations was delivered to the evaluated location.

DISCUSSION

Safe teletherapy assistance involves not only the management of neoplastic treatment, but also the risks inherent in the procedure. In this context, it is important to build and validate the graphic protocol and checklist developed in this study. Due to its strategic potential in monitoring the performance and quality of service through the structure, process and outcome, its use is expected to help in management decision making for transformation of care practice.

The process of validating the information that makes up a construct in content and appearance is fundamental for its validity and reliability, since it makes it safe for application in the services to which it is intended (LEITE et al, 2018).

The graphic protocol and the checklist for evaluating safe care in teletherapy after

the two rounds of Delphi was considered valid in its content regarding the evaluation of behavior, objectivity, simplicity, clarity, relevance, precision, variety, modality, typicality, credibility, breadth and balance[9]; and, regarding appearance as to language appreciation, illustrations, layout and culture[14].

In this study, the process of content and appearance validation occurred from multiple points of view, in a juxtaposition of knowledge by the judges. The selection proposal adopted[16] allowed a robust group of judges to be formed, highly experienced in different areas (nursing, medicine, medical physics and dosimetry), giving reliability to the process[9].

Still on the group of judges who participated in the validation of this study, regarding the degree, more than half of them had MSc/ PhD, and a remarkable time acting in the areas of patient safety, oncology and radiotherapy. Therefore, it is understood that the participation of these professionals with expertise in research and healthcare[3] is relevant for the validation of constructs as in this study, since they have applicability to the practice of teletherapy care.

The final consensus among the judges for the validation of content and appearance of the constructs was calculated by means of the CVC, with this study adopting the minimum value for validation of 80%[9]. The CVC evaluates the agreement between the judges from the assessment of constructs and their items. Thus, in this study, the consensus among the judges was reached, attested by the validity of content and appearance of the graphic protocol and checklist, as well as what it proposes to measure when evaluating the patient safety in teletherapy.

Studies on the construction and use of graphic protocols for PS developed based on solid evidence, clear and concise language and symbology have grown in Brazil.[11,17-19] The use of these tools standardizes the evaluation of health services quality, enabling the identification of frailties and eliciting solutions.

The American Association of Physicists in Medicine (AAPM) developed an online tool for self-assessment of RT services in the United States of America in 2015. Driven by the large number of guidelines and standards on how to improve quality and safety, the tool entitled Safety Profile Assessment (SPA) aims to condense the main recommendations based on local reality, in a compact set of indicators[20], as performed in this study.

Careful observation of the specificities of the health service structure, the workflow of health professionals and the assistance indicators should be carried out prior to the preparation of a graphic protocol for evaluating the health service[11,21].

The evaluation of the structural element aims to verify organizational indicators based on physical, human, material and financial resources of the health service for the provision of care[8]. In this study, the items that composed the graphic protocol and the checklist analyze the teletherapy service regarding compliance with current legislation for its operation, based on the recommendations of the National Health Surveillance Agency (ANVISA)[22], National Nuclear Energy Commission (CNEN)[23] and American Society for Radiation Oncology (ASTRO)[6].

The main considerations made by the judges in the structure element were to summarize some items on compliance with legislation, since the service is operating previously approved by ANVISA and CNEN. Therefore, the item could be more objective. There was a suggestion to include the following subitems: financial resources; Radiological Protection Plan; and daily testing of teletherapy equipment.

In a health service as complex as teletherapy, it is essential to promote the organization of safe work flow. Some strategies such as adapting the number of professionals according to service demand, conducting continuous training and

improving communication between professionals have a positive impact on the safety of health professionals and patients[6,24,25].

The evaluation of the process element involves the observation of the performance of the care team in relation to the patients[8]. In this element, the changes suggested by the judges were the rewriting of the items: patient identification, emphasizing the importance of verbal and visual check while checking the patient identification; and if the teletherapy service uses some computerized system for managing patient information during treatment.

The provision of safe and quality care in teletherapy requires firm and problem-solving practice by all the care team, thus, from the beginning to the end of treatment, actions directed at reducing risks and incidents are fundamental. Furthermore, the commitment of the professional team and managers of the RT service contributes to the consolidation of the PS culture[5,6].

The evaluation of the outcome element involves the investigation of the response to the assistance offered, based on the state of health of patients and their satisfaction with the service received[8]. In this study, the evaluation items were categorized into two groups, patient/client safety indicators and trigger tool, with the perspective of reflecting on the incidents that may occur in the teletherapy unit. This division was carried out in accordance with the international and national goals of PS, enabling the teletherapy service and the PS Center to recognize and analyze the local care indicators.

The judges recommended the following changes in the outcome element: under the subitem alcohol consumption, review the suggested number for patients/day; describe the concept of mild, moderate and severe severity in the subitems of incidents; and, review the writing of some items that could confuse the assessment of this element in the checklist.

In Brazil, six basic protocols were developed to assist the process of PS implantation in health services, namely: correct patient identification; effective communication; improvement of the safety in the use of medicines; safe surgery; hand hygiene; reduction of the risk of falls or pressure injury[11,26].

In this study, the indicator related to patient/client identification analyzes if all patients/clients have standardized identification bracelets during their stay in teletherapy service and if there was a notification of incidents that occurred due to failure in the identification.

The correct identification of the patient is the first goal to improve the PS recommended by the WHO. This process aims to ensure that care is provided to the intended person, all patients should be properly identified.

It is also noteworthy that, through the application of the graphic protocol and checklist, the recommendation of the judges regarding its use was confirmed. The evaluators observed that the constructs have clear language and are easy to apply, not being necessary to change them at the moment. Moreover, it is understood that the high Kappa coefficient suggests the high reliability of the evaluation.

The findings found after applying the graphic protocol and the checklist in the teletherapy service revealed that the process element is partially safe on site. There was emphasis on four of the ten items that make up the evaluation of this element: clinical assessment; simulation, design and planning; clinical and technical review; end of treatment.

In the analysis of the clinical evaluation item, in this teletherapy service, the identification of the patient/client is not made as recommended by the first goal of PS of the WHO, which recommends the use of white bracelet, in legible letters and with at least two identification indicators[26]. In addition, there is no differentiated

identification for patients/clients using radiation sensitive implanted medical devices.

In the items simulation, design and planning, and clinical and technical review, it was also observed during the evaluation of the teletherapy service that the identification of the patient/client does not comply with the recommendation.

According to the WHO, all patients must be identified correctly, and their identity must be verified verbally before any service in health services, especially for those patients that are in specific clinical situations, predisposing the increase of risks for occurrence of incidents[26].

During the evaluation of the end of treatment item, it was pointed out the absence of means of communication for monitoring the patient/client post-treatment (in their home, such as telenursing) in this teletherapy service.

Telemonitoring uses forms of communication or information technologies to provide remote health care to patients, which allows the interpretation and analysis of early undesirable symptoms harmful to patients. The use of telemonitoring is an effective approach to oncological treatment[27,28].

The subjectivity of the options to evaluate the content and appearance of the constructs and the evaluation of care in a single service is recognized as a limiting aspect of the study.

The application of the graphic protocol and checklist validated in this study allowed the identification of improvements for PS in a reliable way in the teletherapy service. Furthermore, this study will serve as a reference for researchers and teletherapy services at national and international level to evaluate the care provided to cancer patients.

CONCLUSION

It was possible to build and validate in content and appearance a graphic protocol and checklist for the evaluation of safe care to patients in cancer treatment by teletherapy.

These constructs can be applied in other localities/ realities that offer teletherapy treatment, and their use may contribute to the improvement of PS in this context.

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Authors' contribution

DFF - Substantial contribution to the design of the study or interpretation of the data.
- Participation in the drafting of the preliminary version.
- Participation in the review and approval of the final version.
- Agreement to be responsible for the accuracy or integrity of any part of the study.
PPO - Substantial contribution to the design of the study or interpretation of the data.
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