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Chemotherapy administration checklist for patients receiving chemotherapy: Development and validation

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Abstract:

BACKGROUND: With the increase in the number of new cancer cases, the number of patients receiving chemotherapy increases. The administration of chemotherapy is a very significant task. Unfortunately, the availability of a chemotherapy administration checklist still lags behind. The aim is to develop a chemotherapy administration checklist for patients receiving chemotherapy.

MATERIALS AND METHODS: This study was conducted at the oncology day care and in-patient department (IPD) wards of the All India Institute of Medical Sciences, Jodhpur, Rajasthan. Methodological research design was used in this study. It took place in five phases: preliminary phase includes literature review, focussed group discussion, assessment of current practices, generation of item pool, and preparation of preliminary draft; then its validation by modified Delphi technique, pilot testing; final try out, and evaluation phase. A total of 260 patients were enrolled.

RESULTS: The content validity index was 0.97. To perform factor analysis and principal component analysis KMO and Bartlett's test of sphericity was used, which allows the data for factor analysis to yield eight components. A total of 26 items were formulated. The scoring was done dichotomously; a score of 1 is for done and 0 for not done and not applicable. Cronbach's alpha was used to find out the internal consistency of the checklist was found to be 0.72. For interrater reliability, the Cohen kappa's value was found to be 0.91.

CONCLUSIONS: Chemotherapy administration checklist was a valid and reliable checklist. This checklist is feasible and easy to incorporate into clinical practices.

Keywords:

Cancer, checklist, chemotherapy, construct validity, modified Delphi technique

Introduction

Chemotherapy is usually given to patients suffering from cancer to kill the dangerous malignant cells.^[1] Administration of chemotherapy is a very significant task. The procedure of chemotherapy administration requires great competency as it has a tendency to cause harm.^[2] According to Global Cancer Observatory (Globocan) 2020, an international agency for research on cancer; a total number of 1,324,413 new cases were reported in India.^[1] More than 1 million cancer patients each day

receives intravenous chemotherapy for various types of malignancy. There was still a 0.1% to 6% risk for occurrence of chemotherapy-related extravasation if administered via the peripherally inserted intravenous catheter and around 0.26% to 4.7% if administered via a centrally inserted intravenous catheter.^[2] All the healthcare professionals must be keen observers while chemotherapy was going on and trained enough to closely monitor and notice the side effects as early as possible.^[3] Literature was focused on the symptom assessment of patients with cancer and self-management scales for cancer patients. Therefore, a checklist is essential to strictly surveil the

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administration of chemotherapy with the purpose of promoting and improvement in the health status of cancer patients. The checklist ensures uniformity in providing care to the patients. So, this study aims to design the chemotherapy administration checklist.

Ethical consideration

Ethical clearance was obtained from the Institutional Ethical Committee of All India Institute of Medical Sciences, Jodhpur. Reference No. AIIMS/IEC/2021/3470, Date: 30/04/2021.

Materials and Methods

A methodological research design was used to conduct the study. Study duration was 1 year (January 2021–2022). The chemotherapy administration checklist was developed in five phases. Figure 1 shows the schematic representation of the research.

Phase I preliminary phase

This phase was completed in five steps.

- i. Review of literature: In-depth literature review was done related to chemotherapy, its administration, various protocols, and guidelines were referred through different books and journals related to oncology and chemotherapy administration, electronic databases like PubMed, CINAHL, Google Scholar, etc.
- ii. Assessment of current practices: Results of assessment show that there were admission forms, various regimen forms, and discharge forms for patients all together they were attached and used throughout the process.
- iii. Focused group discussion (FGD): A descriptive focused group discussion was done at the medical oncology ward and day care. It includes eight members from the multidisciplinary team like nursing officers, junior residents, and senior residents. FGD concludes that there was no protocol available regarding the administration of chemotherapeutic medications for patients receiving chemotherapy.
- iv. Generation of item pool: The item pool was generated from a review of literature, assessment of current

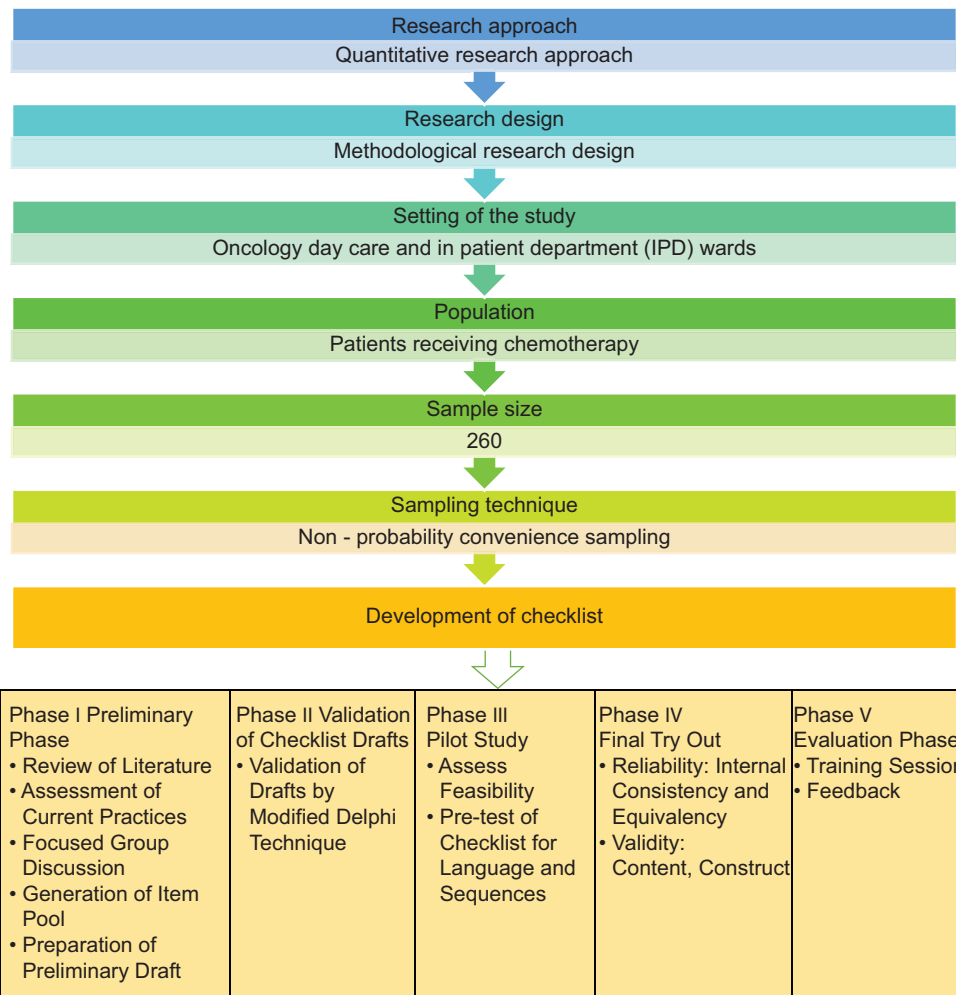


Figure 1: Schematic representation of research methodology

practices, and focused group discussion. These items were then categorized under three parts and eight domains: patient and family information, patient assessment, equipment preparation, chemotherapy treatment plan, following standards, monitoring during chemotherapy, immediate interventions after chemotherapy completion, and record keeping under all these domains, items were distributed. These eight domains consist of 39 items.

- v. Preparation of preliminary draft: Preliminary draft of the chemotherapy administration checklist was formed after completing these four steps. The scoring was done dichotomously; a score of 1 was given for done and 0 was given for not done and not applicable.

Phase II validation of checklist drafts

Validation of drafts was done by modified Delphi technique. Three rounds of modified Delphi were completed.

First round of modified Delphi: Preliminary draft consists of eight domains and 39 items
↓
Second round of modified Delphi: Second draft consists of three domains with 28 items
↓
Third round of modified Delphi: Final draft of chemotherapy administration consists of three domains and 26 items.

Final draft of chemotherapy administration: The chemotherapy administration checklist for patients consists of three domains. These three domains consist of 26 items. The three domains were prechemotherapy administration, chemotherapy administration, and post chemotherapy administration. The item-level content validity index (ICVI) ranges from 0.89 to 1; the scale-level CVI/average (S-CVI/Avg.) was 0.97. This shows good content validity.

Phase III pilot study

Pilot study was done to assess the feasibility, practicability, the availability of the study subjects, to test the arrangement and completeness of items in the checklist, to examine the checklist for its lucidity, and to estimate the actual time required to fill the checklist. Pilot study was conducted on 26 patients receiving chemotherapy at day care. The result shows that the checklist was feasible and there was adequacy in the availability of subjects. Items were found complete and arranged in sequence as per the course of the chemotherapy administration process. The checklist was lucid in terms of its language and understanding. As the checklist started with the prescription of chemotherapy administration and ends up with the patient's discharge time requires to fill this checklist was conditional.

Results

Phase IV final try out

The final tryout was conducted on 260 patients receiving chemotherapy at day care and IPD ward. The data was collected in the month of October 2021. Nonprobability convenient sampling technique was used.

Validity of chemotherapy administration checklist

Exploratory factor analysis was done to find out construct validity. Principal component matrix was used to normalize the sets of data. The appropriateness of chemotherapy administration checklist was checked by Kaiser–Meyer–Olkin (KMO) test and the Bartlett test of sphericity by using Statistical Package for the Social Sciences (SPSS, version 20). The KMO value of the chemotherapy administration checklist was 0.78 and Bartlett's test of sphericity shows P value of 0.000 with a χ^2 value of 5009.36, which was significant. These values show the adequacy of the sample for factor analysis.

Extraction communality of items

For extraction communality of each item of the checklist, the extraction method of principal component analysis was used. The initial communality of each item was 1 (100%). The range for extraction communality of items was from 0.32 to 0.95. Average communality was found as 0.76. Hence, this data was appropriate for factor analysis.

Rotated component matrix

To analyze the rotated component matrix for the checklist, the method of principal component analysis along with varimax rotation with Kaiser normalization was used. Eight components were generated listed as 1, 2, 3, 4, 5, 6, 7, and 8 depicted in Table 1.

Factor extraction

Items on the checklist were extracted and grouped into interrelated items with the use of a correlation matrix. Eight factors were extracted. All the items have loaded more than 0.30 on the eight extracted factors except item 13 but due to its significant importance in practice, it was also retained with others. Hence, all the items were retained in the chemotherapy administration checklist as shown in Table 1.

Scree plot

Scree plot was the graphical representation of the factors extracted through the principal component analysis. Figure 2 shows that there was a continuous deflection of the curve after the 8th component, which shows that the eigenvalue of less than 1. Eigenvalues of eight components were 8.57, 2.69, 1.87, 1.63, 1.47, 1.32, 1.07, and 1.02.

Table 1: Rotated component matrix

ITEM	Component							
	1	2	3	4	5	6	7	8
Prechemotherapy administration								
Confirm the chemotherapy admission form/prescription form.	0.72							
Explain to the patient and his family about the procedure [goals, duration, and side-effects] of chemotherapy administration.	0.84							
Review the patient's history of any known allergy/fluid restriction/nutritional deficit.	0.81							
Ensure patient's baseline laboratory reports like Hb, WBC, platelet count, LFT, RFT, etc.	0.86							
Obtain written informed consent from patient/family member.	0.73							
Monitor the vital signs: baseline/continuous			0.87					
Check the written order [regimen, date, time, duration, sequence, route, and dose and special instructions for chemotherapy administration.		0.63						
Select the chemotherapy drug administration site (IV/PICC line/Chemo-port/oral/feeding tube) and assess for its patency/signs of infection.	0.83							
Confirm and administer the prescribed premedication as ordered.	0.83							
Chemotherapy Administration								
Arrange the items for chemotherapy drug preparation: PPE, medications, IV fluids, syringes, needles, and IV set/Codon set.		0.54						
Perform hand hygiene and follow aseptic technique							0.93	
Donning of personal protective equipment including inner gloves, cap, gown, shoe cover, face mask, face shield/goggles, and outer gloves.						0.89		
Preparation of medication in biosafety cabinet.			0.20					
Priming of IV set/Codon set with normal saline.		0.69						
Reconfirm the patient's identity and reassure the patient about the procedure.				0.79				
Follow the rights of drug administration and start the chemotherapy drug administration.				0.85				
Use a new IV set and flush the line for each chemotherapy drug.							0.93	
Monitor vital signs and side effects like hypersensitivity, vomiting, extravasation, infiltration, etc.			0.94					
Discard the cytotoxic drugs in appropriate bins and follow the institute protocol if left or reusable.		0.56						
Postchemotherapy Administration								
Flushing the line with compatible fluid as prescribed.		0.49						
Monitor and record the vital signs and observe the patient for immediate side effects of chemotherapy			0.94					
Withdraw the IV line, apply dressing at the respective site and observe for bleeding.				0.59				
Doffing of the personal protective equipment, remove shoe cover, outer gloves, face shield/goggles, gown, cap, inner gloves, and face mask.					0.96			
Record the entire procedure with date, time, and side effects, if any with signature.		0.54						
Educate the patient about the use of postchemotherapy medication and precautions to be taken								0.80
Ensure the enclosure of discharge summary plan including date of next chemotherapy cycle and laboratory tests required. (Keep a copy for records).								0.85

Reliability of chemotherapy administration checklist

Cronbach's alpha was used to find out the internal consistency of the checklist and was found to be 0.72. Interrater reliability was measured to find its equivalence. The kappa's value was found to be 0.91, which showed almost perfect agreement and the chemotherapy administration checklist.

On the application of the corrected item to the total correlation on all the items on the checklist, 17 items had a score between 0.2 and 0.6 and nine items had a score less than 0.2. All the nine items, which show the less corrected item to total correlation, had a significant role in the checklist as they measure different phenomena. Hence, all were retained as shown in Table 2.

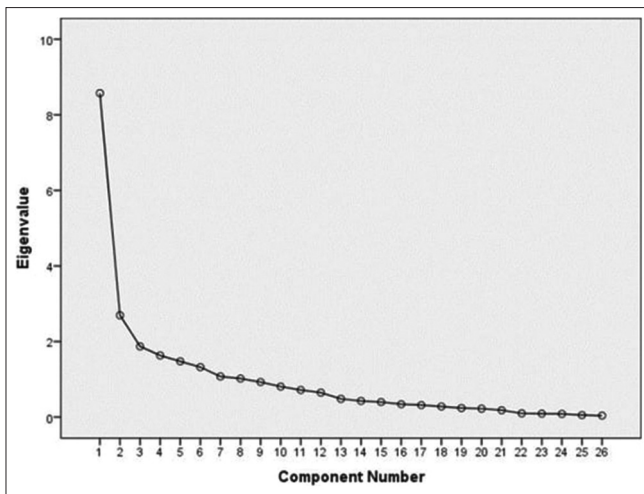
To find the contribution of each item individually to the checklist, all the items were removed one by one from the checklist. This results in either decrease or the same value of Cronbach's alpha for 19 items, which shows that these items were contributing to the checklist. Seven items show a mild increase in the Cronbach's alpha value if deleted. These seven items had their significant contribution to the checklist, the reason behind that might be their less use in daily practices. Hence, all the 26 items were retained in the checklist as shown in Table 2.

Phase V evaluation phase

The training session was arranged for the healthcare workers to discuss regarding the use of the checklist, its scoring, and its interpretation. Feedback was also taken from the nursing officer and senior nursing officer working

Table 2: Reliability analysis of checklist by Cronbach's alpha

Item	Mean if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
1	19.13	0.58	0.70
2	19.14	0.64	0.69
3	19.16	0.61	0.69
4	19.15	0.63	0.69
5	19.17	0.57	0.69
6	19.61	0.21	0.72
7	19.11	0.43	0.71
8	19.13	0.54	0.70
9	19.14	0.58	0.69
10	19.12	0.49	0.70
11	19.17	0.03	0.72
12	19.95	-0.14	0.74
13	19.85	-0.13	0.75
14	19.13	0.36	0.71
15	19.12	0.40	0.71
16	19.12	0.37	0.71
17	19.17	-0.00	0.73
18	19.75	0.13	0.73
19	19.11	0.49	0.70
20	19.29	0.10	0.73
21	19.73	0.15	0.73
22	19.12	0.35	0.71
23	19.97	0.08	0.73
24	19.10	0.33	0.71
25	19.13	0.28	0.71
26	19.26	0.14	0.72

**Figure 2:** Scree plot of chemotherapy administration checklist

in day care unit and oncology wards. Feedback states that the checklist was complete, well organized, easy to use, and applicable to all patients receiving chemotherapy.

There was a total of 26 items on the chemotherapy administration checklist. Content validity index (CVI) is calculated for the checklist. The scale-level CVI/average (S-CVI/Avg.) based on the expert's rating

was found to be 0.97 and scale-level CVI/universal agreement (S-CVI/UA) was 0.77. These values show good content validity. Construct validity of the checklist was calculated by the use of principal component factor analysis, which yielded eight factors. Thus, all the items were having loading value >0.30 on factors except item 13 but due to its significant importance in practice, it was also retained with others. Hence, all 26 items were retained in the checklist. The scoring was done dichotomously; a score of 1 was given for done and 0 was given for not done and not applicable. Cronbach's alpha was used to find out the internal consistency of the chemotherapy administration checklist. Cronbach's alpha of the checklist was 0.72 and was found to be acceptable. Interrater reliability was measured to find its equivalence. The kappa's value was found to be 0.91, which showed almost perfect agreement.

Discussion

Cancer is one of the leading causes of death in our country. This study was conducted to develop the chemotherapy administration checklist for patients receiving chemotherapy. In this study, on the basis of literature review and expert suggestions, 26 items were formulated. Chemotherapy administration checklist was developed under three domains, which consist of events taking place in a sequential manner from patient's admission to discharge and follow-up. The three domains are named prechemotherapy administration, chemotherapy administration, and postchemotherapy administration. Similarly, Peng and Wu developed the oral chemotherapy self-management scale, which consists of the following domains: daily life management, symptom management, medication management, emotional cognitive management, and social support.^[4] S-CVI/Avg and S-CVI/UA were 0.97 and 0.77, respectively. Construct validity of the checklist was calculated by the use of principal component factor analysis, which yielded eight factors. Item to total correlation for 17 items had a score that lies between 0.2 and 0.6 and nine items had a score less than 0.2. All the nine items which show the less-corrected item to total correlation had a significant role in the checklist as they measure different phenomena. Hence, all were retained.

Likewise, Grunigen *et al.*^[5] conducted a study to build Cyto-SAT a self-assessment tool for the safe handling of cytotoxic drugs, which consists of 137 items with 10 domains and 28 subdomains checklist. Similarly, Tofthagen *et al.*^[6] conducted a study with the objective of development and psychometric evaluation of the chemotherapy-induced peripheral neuropathy assessment tool, the item to total correlation of this tool ranges from 0.38 to 0.70, and content validity was found to be 0.95.

Cronbach's coefficient alpha and interrater reliability by using Cohen's kappa measure were 0.72 and 0.91, respectively. Similarly, Kim, Sung, and Jae conducted a study with the objective to develop and validate a tool for evaluating the core competencies of nurses for cancer patients on chemotherapy, the Cronbach alpha was 0.97.^[7] Similarly, Kano *et al.*^[8] develops an instrument to assess the specific symptoms of chemotherapy-induced alterations, Cronbach alpha was 0.9. Likewise, Jeyram, Subathra *et al.*^[9] develop the symbolic assessment of fatigue extent in cancer patients with Cronbach alpha 0.86. Maguire *et al.*^[10] develop the daily assessment of chemotherapy toxicity with good internal consistency. Kanda develops the comprehensive assessment scale for chemotherapy-induced peripheral neuropathy with a reliability of 0.82.^[11] Peng *et al.*^[4] developed the oral chemotherapy self-management scale with a reliability of 0.929.

Findings suggested that the chemotherapy administration checklist is a valid and reliable checklist for chemotherapy administration. Therefore, this checklist can strictly surveil the administration of chemotherapy with the purpose of promoting and improving the health status of cancer patients. Its development can highly contribute to the hospital practices and also assure the completeness of chemotherapy administration.

Study limitations

This study was conducted only at the All India Institute of Medical Sciences, Jodhpur, Rajasthan, India. More research is needed to assess the impact and effectiveness of checklists in different settings. The study can be repeated on a large population and at multifarious centers to validate the findings of the study.

Conclusion

The chemotherapy administration checklist has good validity and reliability. This checklist was designed in such a way as to administer chemotherapy in a comprehensive manner. This checklist is feasible and easy to incorporate into clinical practices. This checklist is highly relevant and has a significant role in healthcare.

Acknowledgment

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Conflicts of interest

There are no conflicts of interest.

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