A Methodological Study to Develop Chemotherapy Spill Kit for Spill Management and Assess Its Acceptability among Nurses in Oncology Wards of a Selected Hospital of New Delhi

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Abstract

Introduction: “Chemotherapy Spill Kit (CSK)” is a kit with various configurations and contents designed for safe and fast clean-up of chemotherapy drug spills in accordance with standard guidelines. Thus, nurses can minimize exposure to hazardous drugs with the use of personal protective equipment and careful technique with the use of this kit. Hence, these spill kits should be available wherever chemotherapy is located.

Objectives: The objectives of the study were to develop a CSK and validate the kit and assess the acceptability of CSK among the nurses in oncology wards of the selected hospital.

Methodology: The conceptual framework of the present study was based on integrating models of diffusion of innovations, which was first proposed by Barbara Wejnert, which consists of characteristics of innovations, characteristics of innovators, and environmental characteristics. Quantitative research approach and methodological research design was used. Tools used for data collection comprised of rating scale criteria to validate the items of CSK by 11 experts from the field of medical-surgical nursing and oncology and to assess the acceptability of CSK among nurses. Non-probability purposive sampling was adopted to select the sample. The study was conducted on 60 nurses working in oncology wards of Safdarjung Hospital, New Delhi.

Result: The data collected was analyzed using descriptive statistics. Content Validity Index (CVI) was used to validate items of CSK. Following validation by the experts, the acceptability of the CSK was assessed. The major findings of the study showed a very positive validation by all the experts with mean CVI score of 0.98, median 1.00, mode of 1.00 and standard deviation of 0.11772. CVI score of more than 0.78 was considered to be valid for this study. From an acceptability perspective, 100% of the subjects found CSK to be highly acceptable.

Conclusion: The conclusion drawn from the study was a positive validation of CSK by 11 experts and an overwhelming acceptability of the CSK. Further all the study subjects opined for the need of CSK in oncology wards.
Introduction

During the 1970s, evidence came to light indicating that healthcare workers may be at risk for harmful effects from antineoplastic drugs as a result of occupational exposure. Since that time, reports from several countries have been documented, drug contamination of the workplace, identified drugs in the urine of the workers and measured genetic responses in the workers.1

In a study done by Falck and colleagues, it was revealed that nurses, who prepared and administered antineoplastic drugs, had higher indicators of mutagenic substances in their urine compared with non-exposed workers.2 Surveys have associated workplace exposure to antineoplastic drugs with acute health effects, primarily in nurses. These include hair loss, headaches, acute irritation and hypersensitivity as well as adverse reproductive outcomes.3

A study was conducted by Clinical Center of Serbia, Institute of Occupational and Radiological Health Dr. Dragomir Karajovic, which showed the results indicating that exposed nurses reported more symptoms than non-exposed nurses, an effect that was not dependent on age, smoking, or night shift. The use of safety precautions was inadequate and reflected the lack of awareness of potential hazards due to occupational exposure to antineoplastic drugs.4

A meta-analysis of 14 studies performed from 1966 to 2004 in the United States and Europe described an association between exposure to antineoplastic drugs and adverse reproductive effects in female healthcare workers.5 The most common reproductive effects found in these studies were increased fetal loss,6,7 congenital malformations,8 low birth weight and infertility.9 A significant association was identified between exposure and spontaneous abortions.

Most studies demonstrated occupational exposure to hazardous drugs can occur when safe handling measures fail or when they are not properly used. Exposure may occur during drug preparation, transport or administration during the disposal process when handling patient excreta, and in the event of spills.10

A study was conducted on self-protective practices of nurses handling antineoplastic drugs. The purpose of this study was to examine the use of precautions used by nurses, as well as explore the reasons for use and non-compliance. It was a cross-sectional study done using a questionnaire filled out by 632 nurses from various facilities and work sites. The study showed use of adequate protection was widely variable. The study also examined why nurses do not use precautions. The reasons cited included lack of available equipment and lack of perceived hazard.11

In India, a study was conducted by Sunita et al.12 about Operationalization of “Chemotherapy Spill Kit” in chemotherapy administration areas. The study revealed that nurses are involved both in the preparation and administration of chemotherapy drugs. While preparing or administering cytotoxic drugs, there are possibilities of spillage which pose exposure not only to the person handling the drugs but also to others in the unit. To prevent this exposure CSK has been recommended by all the leading oncology nursing agencies. Total 43 small cytotoxic spillages were experienced. The satisfaction to the usage of various parts of CSK increased significantly from follow up 1 to follow up 2 (p <.0001). Hence the usage of CSK was recommended while chemotherapy administration.

Aim

- To develop the CSK and validate the kit
- To assess the acceptability of CSK among the nurses in oncology ward

Materials and Methods

The present study was aimed to develop and validate a CSK for spill management and assess its acceptability among nurses in oncology wards of a selected hospital of New Delhi. Quantitative research approach was used for the study and methodological research design was adopted for the study. The study was conducted in oncology wards of Safdarjung Hospital, New Delhi. For this study, the sample comprised of 60 nurses taken by non-probability purposive sampling technique who were working in oncology wards of Safdarjung Hospital, New Delhi.

In the present study, the tools for data collection were divided into the following parts:

Part: I

Rating Scale to Validate the Items of CSK

This scale consisted of 6 sections: Section-1: Items to develop the kit. Section-2: Items required immediately after spill. Section-3: Items on personal protection. Section-4: Items on cleaning and disinfecting. Section-5: Items on documenting the incident.

Part: II

Rating Scale to Assess the Acceptability of Kit

This section consisted of 6 sections: Section-1: Demographic characteristics. Section-2: Items to develop the kit. Section-3: Items required immediately after spill and
personal protection. Section-4: Items on cleaning and disinfecting. Section-5: Items on discarding the waste. Section-6: Items on documenting the incident.

**Procedure**

- Ethical clearance was taken from the Jamia Hamdard Institutional Ethics Committee.
- Formal administrative approval was obtained from the concerned authority of Safdarjung Hospital, New Delhi.
- After establishing the rapport, self-introduction was given to the subjects.
- Purpose of the study was explained to the study subjects.
- Subjects were assured of confidentiality of their data.
- Subjects were screened based on inclusion and exclusion criteria for the study.
- Written informed consent was obtained from the study subjects.
- In the present study, total sample size was 60.

**Results**

- The data coded and entered in a Microsoft Excel sheet and analyzed by using descriptive and inferential statistics.
- Frequency and percentage of nurses working in oncology wards as per their demographic characteristics in (Table 1).
- Content Validity Index of each item of CSK in (Table 2).
- Mean, median, mode and standard deviation of CVI score in (Table 3).
- Acceptability scores of the CSK as evaluated by nurses (Table 4).
- Mean, median, mode and standard deviation of acceptability scores of nurses (Table 5).

### Table 1. Frequency and Percentage of Nurses Working in Oncology Wards as per Their Demographic Characteristics

| S. No. | Sample Characteristics                  | Frequency | Percentage |
|--------|---------------------------------------|-----------|------------|
| 1      | Age (in years)                        |           |            |
|        | 20–29                                 | 3         | 5          |
|        | 30–39                                 | 23        | 38.3       |
|        | 40 and above                          | 34        | 56.7       |
| 2      | Gender                                |           |            |
|        | Male                                  | 5         | 8.3        |
|        | Female                                | 55        | 91.7       |
| 3      | Professional Qualification            |           |            |
|        | DGNM                                  | 44        | 73.4       |
|        | Post Basic Nursing                    | 11        | 18.3       |
|        | B.Sc. Nursing                         | 5         | 8.3        |
| 4      | Experience in Oncology Ward in years  |           |            |
|        | 0–5                                   | 34        | 56.7       |
|        | 6–10                                  | 21        | 35         |
|        | 10 and above                          | 5         | 8.3        |
| 5      | In-service Education                  |           |            |
|        | Yes                                   | 0         | 0          |
|        | No                                    | 60        | 100        |
| 6      | Number of spills encountered          |           |            |
|        | 0–10                                  | 35        | 58.3       |
|        | 10–20                                 | 20        | 33.4       |
|        | 20 and above                          | 5         | 8.3        |

Data presented in Table 1 shows that in the number of spills encountered, more than half 35 (58.3%) nurses had experienced 0–10 spills during their oncology posting, whereas 20 (33.3%) had experienced 10–20 spills and only 5 (8.3%) had experienced 20 spills and above.
Data given in Table 2 indicates that the CVI score of all the items of CSK ranged from 0.81 to 1.00, which means all the items of the CSK were considered to be excellent.

### Table 2. Content Validity Index (CVI) of Each Item of Chemotherapy Spill Kit

| S. No. | Items               | Obtain Score | CVI  |
|--------|---------------------|--------------|------|
| 1      | Size                | 39           | 1.00 |
| 2      | Space               | 39           | 1.00 |
| 3      | Material            | 41           | 1.00 |
| 4      | Absorbent pad       | 40           | 1.00 |
| 5      | Absorbable towel    | 39           | 1.00 |
| 6      | Pillow              | 35           | 0.81 |
| 7      | Warning sign board  | 40           | 1.00 |
| 8      | Non-permanent marker| 38           | 1.00 |
| 9      | Utility gloves      | 40           | 1.00 |
| 10     | Masks               | 41           | 1.00 |
| 11     | Splash goggles     | 42           | 1.00 |
| 12     | Chemotherapy gloves | 42           | 1.00 |
| 13     | Gown                | 42           | 1.00 |
| 14     | Shoe covers         | 35           | 0.90 |
| 15     | Spray bottle        | 39           | 1.00 |
| 16     | Bleaching solution  | 41           | 1.00 |
| 17     | Scoop with scraper  | 36           | 1.00 |
| 18     | Soap in soap dish  | 37           | 0.81 |
| 19     | Forceps             | 39           | 1.00 |
| 20     | 2 Yellow bags       | 42           | 1.00 |
| 21     | Puncture-proof container | 42 | 1.00 |
| 22     | Labels              | 40           | 1.00 |
| 23     | Incident report book| 39           | 1.00 |
| 24     | Check-list          | 42           | 1.00 |

The data presented in Table 3 indicates that the mean, median, mode, and standard deviation of all CVI scores obtained were 0.93, 1.00, 1.00 and 0.11772 respectively.

### Table 3. Mean, Median, Mode and Standard Deviation of CVI Score

| CVI Score | Mean | Median | Mode | Standard Deviation |
|-----------|------|--------|------|--------------------|
|           | 0.98 | 1.00   | 1.00 | 0.11772            |

Data presented in Table 4 shows that 60 (100%) of the subjects found the features of the CSK as highly acceptable.

### Table 4. Acceptability Scores of the Chemotherapy Spill Kit as Evaluated by Nurses

| Grade               | Scores   | Frequency | Percentage |
|---------------------|----------|-----------|------------|
| Highly Acceptable   | 105-150  | 60        | 100%       |
| Acceptable          | 60-104   | 0         | 0          |
| Not Acceptable      | Less than 60 | 0 | 0          |

The data in Table 5 indicates the mean score of acceptability as 141, with a median value of 145, mode of 148 and standard deviation of 8.9067.

### Table 5. Mean, Median, Mode and Standard Deviation of Acceptability Scores of Nurses

| Mean | Median | Mode | Standard Deviation |
|------|--------|------|--------------------|
| 141  | 145    | 148  | 8.9067             |
Discussion

The findings of the present study showed very positive validation by all the experts (n=11) with mean CVI score of 0.98, median 1.00 with a mode of 1.00 and standard deviation of 0.01386. A CVI score of 0.78 to 1.00 was considered to be excellent and hence valid for the study. From an acceptability perspective, 60 (100%) of the subjects found the features of the CSK as highly acceptable and none of them found it to be in the scores of acceptable and not acceptable.
A similar study was conducted in India in 2010 by Sunita et al.12 about Operationalization of “Chemotherapy Spill Kit” in chemotherapy administration areas. The study revealed that nurses are involved both in the preparation and administration of chemotherapy drugs. While preparing or administering cytotoxic drugs there are possibilities of spillage, which pose exposure not only to the person handling the drugs but also to others in the unit. To prevent this exposure CSK has been recommended by all the leading oncology nursing agencies. All the subjects used personal protection part of the kit and 17 subjects who experienced spills, used spill management part also. Total 43 small cytotoxic spillages were experienced. Hence the usage of CSK was recommended while administrating chemotherapy.

James M. Boiano et al.13 conducted a survey study to assess adherence to safe handling guidelines by healthcare workers who administer antineoplastic drugs. The study reported that the number of spills by quantity, cause of spill, and availability of spill response kits – 12% of respondents who handled liquid chemotherapy drugs reported experiencing multiple spill episodes during administration in the past week. Nearly one of every 10 respondents reporting spills indicated that they were not always cleaned up. Some respondents reported that hazardous drug spill kits were not available at work area. ASHP (American Society of Health-System Pharmacists) recommends that hazardous drug spill kits be available in all areas where hazardous chemotherapy drugs are handled and administered.

A study conducted by Sunita et al. at Post Graduate Institute of Medical Education and Research, Chandigarh14 about “cytotoxic drug spillages among nursing personnel working in chemotherapy administration areas” to determine the patterns of cytotoxic drug spillages and exposure of the nurses to these spillages, an observational assessment is carried out in the chemotherapy administration areas. The findings of the study were that 77.3% of the nurses experienced small spills (<5 mL). The common site of the spillage for more than half (52.9%) of the subjects was surface of preparation of the drug and 47% experienced spillage over both surface of preparation and the gloves worn by them. The prevalence of spill per person in all the three research setting was 1.3, 2 and 3.6 respectively for Radiotherapy Ward, Radiotherapy and Medical Day Care Chemotherapy rooms. Results of the study suggest that drug spills are common in chemotherapy administration areas. Guidelines to manage the cytotoxic drug spills should be made available in all chemotherapy administration areas and concluded that a CSK, which is a necessity in all chemotherapy administration areas to effectively manage the spillage without posing an exposure risk to the person should be made available in all areas.

There have been guidelines provided for the management of spillage of cytotoxic drugs using CSK which have been approved by Network Governance in May 2012 and then reviewed in May 2015 in Pan Birmingham,15 endorsed by governance committee document that all personnel involved in the handling of cytotoxic drugs must be aware of the policies that are in place (in their area) for dealing with spillages and the decontamination of surfaces. These include detailed instructions on how to deal with the accidental spillage of cytotoxic chemotherapy in a ward of a hospital and in other areas of a hospital while transporting chemotherapy. According to these guidelines, all wards or clinical areas where cytotoxic chemotherapy is administered should have a cytotoxic spillage kit at a prominent location near the administration areas, with the quick guide to dealing with spillages clearly displayed.

The above-mentioned studies indicated the dire need of CSK to prevent exposure to spillages in the practice areas. The recommendations of these studies were implemented as part of this present study where the researcher has developed a valid and acceptable CSK for managing exposure to spills in the oncology settings of the hospitals.

Conclusion

The study showed a very positive validation by all the experts (n=11) with mean CVI score of 0.98, median 1.00 with a mode of 1.00 and standard deviation of 0.01386. A CVI score of 0.78 to 1.00 was considered to be excellent and hence valid for the study. From an acceptability perspective, 60 (100%) of the subjects found the features of the CSK as highly acceptable and none of them found it to be in the scores of acceptable and not acceptable. The findings revealed that there is need for safe handling of chemotherapy drugs and there are very limited provisions for nurses handling these drugs. Nurses also have limited awareness of the CSK. Therefore, hospital authority and concerned authorities should plan to conduct in-service education for the update of knowledge and must provide resources for safe handling of cytotoxic drugs, in order to prevent occupational hazards.

Acknowledgments

I express my deep sense of gratitude to my guide Ms. Bindu Shaiju, Assistant Professor, Rufaida College of Nursing, Jamia Hamdard, for the constant encouragement, precious guidance, and critical evaluation throughout the period of study. It was a great privilege to work under her guidance. I extend my immense gratitude to my co-guide Ms. Fareha Khan, Tutor, Rufaida College of Nursing, Jamia Hamdard, for the continuous support for the study. I am sincerely thankful to my co-guide Mr. Naseem M, Tutor, Rufaida College of Nursing, Jamia Hamdard, for the constant encouragement and precious guidance.

Conflict of interest: None
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Date of Submission: 2017-08-17
Date of Acceptance: 2017-10-01