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A pilot study of South African oncology pharmacy facilities: Comparison with best practice guidelines

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Abstract

Introduction: Exposure to antineoplastic drugs can lead to adverse health effects such as fetal loss and DNA damage. Oncology pharmacy facilities should implement best pharmacy practice guidelines to protect pharmacy personnel. The objective of this study was to assess South African oncology pharmacy facility workplace and personnel work practices, guided by internationally accepted best practice guidelines.

Methods: A cross-sectional pilot study was conducted in 6 oncology pharmacy facilities (one personnel member per facility) of 2 South African oncology pharmacy service providers. Using a simple checklist, comprising 7 assessment categories and 43 questions derived from best practice guidelines, work and workplace practices were scored as compliant, partially compliant, or noncompliant. Each facility and service provider were also given an overall score.

Results: Overall scores for the 6 facilities ranged from 33.1% to 79.3%. Service provider 2 pharmacy facilities (which were assessed as being compliant overall) scored higher at 78.0% ± 1.5 (76.4%–79.3%) than service provider 1 pharmacy facilities, which were noncompliant overall at 40.2% ± 21.5 (33.1%–49.9%). Categories in which performance was poor included the presence of engineering controls, use of personal protective equipment, and medical monitoring.

Conclusion: The complexities of South African oncology pharmacy facilities highlight the need for stricter regulation. Despite operating under the auspices of managed care organizations, some facilities' work practices were poor. It is recommended that service providers implement international best practice guidelines.

Keywords: oncology pharmacy, occupational survey/checklist, antineoplastic drugs

Introduction

Health risks for oncology pharmacy personnel have been described in numerous studies on workplace contamination.[1–3] Currently, there are hundreds of antineoplastic drugs (ADs) in use, globally.[4] Most ADs are classified as hazardous drugs by the US Centre for Disease Control's (CDC) National Institute for Occupational Safety and Health (NIOSH).[5] Adverse health effects from exposure to ADs range from minor to severe and include skin rashes, low birth weight, infertility, ectopic pregnancies, tumors and leukemia, and reproductive effects, such as fetal loss and congenital malformations.[6]

Published guidelines on best oncology pharmacy practices include the International Society of Oncology Pharmacy Practitioners (ISOPP) "Safe Handling of Cytotoxics,"[7] the "Quality Standards for Oncology Pharmacies (QuaPos),"[8] the United States Pharmacopoeia Chapter 800,[9] and the American Society of Clinical Oncology (ASCO) "Chemotherapy administration safety standards."[10] These guidelines extensively discuss best oncology pharmacy practices and serve as resources for oncology pharmacy personnel to develop their own guidelines.

Some managed care organizations in South Africa regulate medical oncology facilities, including the South African Oncology Consortium (SAOC) and the Independent Clinical Oncology Network of South Africa (ICON). The ICON developed a "chemotherapy administration standards and guidelines resource document" guideline in a bid to provide oncology pharmacy facilities with a pragmatic assessment approach, as described by Eedes et al[11] who noted that South African oncology pharmacy facilities did not provide input to survey.

The role of the oncology pharmacist is indispensable in today's clinical oncology environment,[12,13] and safe work practices are paramount. However, in a survey conducted by von Grunigen et al,[14] a wide variability and major gaps in safe work practices were identified in oncology pharmacies in low- and middle-income countries(LMICs), including a pharmacy in South Africa.

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The objective of this study was to assess South African oncology pharmacy facility workplace and work practices, guided by international best practice guidelines.

Methods

This was a cross-sectional pilot study. On request, the South African Society of Oncology Pharmacy Practitioners (SASOPh) provided a list of 43 oncology pharmacy personnel and their contact details. All were invited to participate in the study through email. A simple checklist (Annexure A) was developed from the ISOPP[7] and QuaPos[8] guidelines. The checklist was divided into 7 assessment categories including, engineering controls, administrative controls, use of personal protective equipment (PPE), education and training, medical, and environmental monitoring, cleaning procedures and waste handling, and spills and accidents. Each category comprised several questions (4–8 per category, 43 in total). Each question was designed to obtain a rating: noncompliant (rating = 0), partially compliant (rating = 3), or fully compliant (rating = 10). Information was obtained from the facilities by observing the workplace, perusing relevant documents, and interviewing personnel. The pilot study was conducted from March to September 2023.

Data analysis

Data were captured into Microsoft Excel 2023 (Microsoft Corporation, Redmond, WA) thereafter descriptive statistics were used for analysis. The total score for each category was converted into a percentage; and the mean score (percentage) was then calculated for all 7 assessment categories. A score >75% represented full compliance, partial compliance was assigned for scores of 50%–75%, and a score below 50% indicated noncompliance. The individual assessment category and overall scores were compared between service providers.

Ethics approval

Ethics clearance was obtained from the University of the Witwatersrand's Human Research Ethics Committee (HREC) (clearance certificate no. M190312) on September 14, 2019. Consent was obtained from all service providers and pharmacy personnel before commencing the study.

Results

Of the 43 pharmacy personnel contacted, 23 did not respond (53.5%), 2 refused (4.7%), and 18 (41.9%) expressed willingness to participate in the pilot study. However, permission to participate was required from 3 of the service providers. One service provider refused to allow their oncology pharmacy facilities to participate; 2 agreed. Consequently, only 6 pharmacy personnel (one personnel member at each facility) participated in the pilot study. Three facilities were in Gauteng province and 3 in the Western Cape province of South Africa.

All 6 oncology pharmacy personnel who were interviewed were female; 5 were pharmacists and one was a registered nurse (Table 1). The mean age of the participants was 51.1 ± 6.7 years (45–64 years). The mean duration of employment (experience) of personnel was 11.7 ± 5.7 years (4–20 years). The mean daily exposure to ADs was 6.00 ± 1.79 hours (4–8 hours).

Table 2 shows that service provider 1 facilities were "noncompliant" for 5 of the 7 assessment categories and partially compliant for 2, whereas service provider 2 facilities were fully or partially compliant for all 7 categories. Based on the mean scores, none of the service provider 1 facilities was compliant overall (with scores of 33.0%–49.9%). All facilities affiliated with service provider 2 were fully compliant overall (with mean scores of 77.0%–79.3%).

Table 1

Sociodemographic profile of oncology pharmacy staff.

Characteristic	n (%)
Sex	
Male	0 (0)
Female	6 (100)
Age (years)	
45–54	3 (50.0)
55–64	3 (50.0)
Experience (years)	
0–5	1 (16.7)
6–10	2 (33.3)
11–15	1 (16.7)
16–20	2 (33.7)
Role	
Pharmacist	5 (83.3)
Registered Nurse	1 (16.7)
Exposure (hours/day)	
4–5	2 (33.3)
6–7	2 (33.3)
8 +	2 (33.3)

None of the 6 facilities was fully compliant regarding engineering controls, that is, all scores were <75% (Table 2). Three of the 4 facilities that were partially compliant were affiliated with service provider 2. Points were lost for not having an "anteroom" next to the mixing room in the facilities and for having containment primary engineering controls (C-PEC) that did not comply with international guidelines. Nevertheless, service records for the C-PEC were present in every facility, and all were equipped with an external extraction fan (although none had pressure differentials between the anteroom and the C-PEC as recommended in the ISOPP and QuaPos guidelines).

Only the facility that implemented staff rotation (service provider 2) was compliant regarding the implementation of administrative controls. All facilities lost points for inappropriate facility design. Although all used centralized preparation, none was designed to optimally handle ADs (i.e., movement of ADs did not follow the shortest route through the facility). In one facility (service provider 1), the consumables, for example, syringes and needles, were not appropriately placed to facilitate efficient use.

The scores for PPE compliance for the facilities affiliated with service providers 1 and 2 differed by a factor of 4 (21.7% and 88.3%, respectively). Personnel at service provider 1 facilities used disposable latex gloves but no other PPE. The 3 facilities affiliated with service provider 2 were rated as fully compliant for the use of PPE, which was specifically designed for use when mixing and preparing ADs.

Personnel associated with service provider 2 were fully compliant (85.7%) regarding education and training. A lower score was obtained by service provider 1 personnel (47.1% ± 25.1) as 2 of the 3 were noncompliant. One personnel member from service provider 1 scored higher than the other 2, for attending workshops/conferences and/or masterclasses, being affiliated with a professional body, and having training records available.

Of the 7 categories, all 6 facilities scored lowest for medical and environmental monitoring. All 3 pharmacy facilities from

Table 2

Facility scores per assessment category.

Assessment category	Service provider 1 scores (%)				Service provider 2 scores (%)			
	Facility 1	Facility 2	Facility 3	Mean ± SD	Facility 4	Facility 5	Facility 6	Mean ± SD
Engineering controls	31.4	41.4	65.7	46.2 ± 17.6	65.7	65.7	51.5	61.0 ± 8.2
Administrative controls	52.0	66.0	52.0	56.7 ± 8.1	52.0	66.0	86.9	68.3 ± 17.6
PPE	21.7	21.7	21.7	21.7 ± 0.0	88.3	88.3	88.3	88.3 ± 0.0
Education and training	28.6	37.1	75.7	47.1 ± 25.1	85.7	85.7	85.7	85.7 ± 0.0
Medical and environmental monitoring	0.0	0.0	0.0	0.0 ± 0.0	66.7	66.7	66.7	66.7 ± 0.0
Cleaning procedures and waste handling	60.0	60.0	90.0	70.0 ± 17.3	90.0	90.0	90.0	90.0 ± 0.0
Spills and accidents	38.0	38.0	44.0	40.0 ± 3.5	86.0	86.0	86.0	86.0 ± 0.0
Overall score (%)	33.0	37.8	49.9	40.24 ± 8.7	77.0	78.4	79.3	78.2 ± 1.2

service provider 1 facilities scored zero. All service provider 2 facilities conducted medical monitoring and were partially compliant because environmental monitoring was not conducted.

Four of the 6 facilities scored 90% for cleaning procedures and waste handling (one from service provider 1 and 3 from service provider 2). Two facilities from service provider 1 scored 60% because they had no training records for cleaning procedures and waste handling and no cleaning schedules or records of cleaning. For waste handling, all 3 facilities affiliated with service provider 2 scored 86.0% in contrast with those affiliated with service provider 1, which scored 38.0%–44.0% because no training records or written procedures were available. One facility affiliated with service provider 1 was able to provide documentation of accidents; however, no corrective measures were recorded.

Discussion

Response rate/participation

The initial response to the invitation to participate in the study was relatively positive; only 2 of 43 oncology pharmacy personnel contacted declined. This indicates a general interest and willingness among oncology pharmacy personnel to contribute to research about their work practices. However, this positive response was thwarted by the requirement for permission to participate in the study from service providers, and limited the number of pharmacies that ultimately participated. Service provider 1 permitted all 3 of its pharmacies to participate in the study while service provider 2 permitted participation by 3 of its many oncology pharmacies, without indicating how they selected them.

Demographic and work characteristics

The mean duration of employment was 11.7 years, indicating a relatively experienced group of participants in oncology pharmacy practices. All 6 pharmacy personnel interviewed were female, and the majority were pharmacists; one was a registered nurse. In South Africa, oncology pharmacy personnel are not required to be registered pharmacists, although the majority of AD mixing is performed by pharmacists.

Overall performance

The 3 facilities from service provider 1 performed inconsistently and relatively poorly overall, while those from Service Provider 2 performed more consistently and achieved higher scores overall for each of the 7 assessment categories. Service provider 1 did not have all the recommended controls in place. DeJoy et al[15] found that the "recommended use of engineering controls and PPE were variable" in a study among 1800 nurses who administered ADs in the United States. Another survey of nurses and pharmacy practitioners in the United States, published in 2015, revealed a lack of universal adherence to recommended national safe handling guidelines.[16]

Engineering controls

The facilities did not perform as well as expected in this category as engineering control measures recommended in international guidelines can be expensive in LMICs. However, less expensive but effective measures (such as extraction fans) were in place in all the oncology pharmacy facilities.

Although no facility's C-PEC complied with international best practice, all facilities had a vertical flow class II C-PEC device installed with a service schedule that complied with ISOPP and QuaPos requirements. Each facility was equipped with an external extraction fan, although pressure differentials were not installed. The absence of anterooms, which are necessary for the donning of PPE and preparation of vials and ampoules containing ADs for mixing in the C-PEC, was probably due to the significant capital investment required.

International and local guidelines specify that the C-PEC should be in a separate room to avoid environmental contamination. However, only 3 of the facilities conformed to this recommendation. Unfortunately, the air-conditioning provided was unable to reduce the heat generated by the C-PEC to a level that was comfortable for the pharmacy personnel who were mixing ADs. Unlike the installation of external extraction fans and anterooms, it is easy and cost-effective to isolate the C-PEC in a separate room. Discomfort due to high temperatures could lead to reduced concentration on the task at hand and an increased risk of errors.

Administrative controls

There were mixed results regarding administrative controls. Although all facilities used centralized preparation (where the pharmacy is located within an oncology out-patient department), some facilities were not ideal for handling ADs. In some facilities, for example, ADs did not follow the shortest route through the facility, increasing the risk of contamination. The facility with the highest score for this assessment category had the advantage of having 2 oncology pharmacy personnel employed. This allowed for staff rotation and, consequently, a higher score.

PPE

One service provider felt that the use of PPE was unnecessary, while the other implemented and enforced PPE requirements. The lack of use of PPE in the facilities of service provider 1 was possibly due to poor understanding of good oncology pharmacy practice. Some oncology pharmacy personnel renounced the use of PPE, stating that the risk of exposure was of no concern to them. Those who renounced the use of PPE were also unaware of the requirements for PPE when mixing ADs. The only PPE that service provider 1 supplied was latex gloves, which have been proven to be inferior in the mixing of ADs when compared with those approved for use in chemotherapy, such as EN374 gloves.[7] In comparison, service provider 2 employed recommended chemotherapy approved gloves (EN374 gloves), masks, overcoats, and coverings.

Education and training

The difference between the 2 facilities in their scoring in the "education and training" category was in line with findings in the other categories in that service provider 2 facilities scored higher than service provider 1 facilities, mainly because service provider 1 personnel did not attend continuous professional development (CPD) courses. None of the facilities had comprehensive details about training on record. Anecdotally, on-the-job training was provided by experienced oncology pharmacists. Two participants from service provider 1 were not affiliated with a professional or other relevant body such as the South African Pharmacy Council (SAPC) or the SASOPh (which provides training and education through seminars and workshops). Although this is not a requirement, affiliation with such organizations could potentially improve work practices. The training provided by the SAPC (not oncology pharmacy specific) and the SASOPh (oncology pharmacy specific) is accredited for CPD purposes. In-house CPD-accredited training is also provided by company representatives employed in the pharmaceutical industry.

Medical and environmental monitoring

Medical and environmental monitoring in oncology pharmacies is essential. Medical monitoring includes baseline blood tests when employment commences and routinely thereafter as well as liver function and other tests to screen for adverse health effects for exposure to ADs, as recommended internationally. Only service provider 2 did medical monitoring despite the relatively low cost compared with environmental monitoring. The high cost of environmental monitoring, which includes checking for AD contamination of surfaces, may have been the reason that none of the service providers adhered to this international requirement.

Waste management

Waste management companies remove medical waste from facilities such as oncology pharmacies, including PPE. Although all the facilities in this study had contracts with pharmaceutical waste management companies, build-up of AD waste was observed in all of them. Nevertheless, all facilities were fully compliant in this category because they had the required cleaning/disinfectant chemicals/materials, waste management and containers, cleaning procedures, and waste handling. The scores for this category were thus the highest of all the categories. Training on cleaning procedures and waste handling is paramount but no such training was documented. This was in line with the observations made regarding the education and training assessment category.

Spills and accident management

Similarly, training on spills and accident management was not documented in service provider 1 facilities. This is a concern because spills increase exposure to ADs and therefore the risk of adverse health effects.

Facilitators of safe handling of ADs

Robust policies (SOPs) and stakeholder knowledge of service provider 2 led to better outcomes than the service provider 1 facilities. This is possibly due to service provider 2 being a corporate service provider with many oncology pharmacy facilities, which may result in a more thorough scrutiny of processes.

Barriers to safe handling of ADs

Service provider 1 did not have appropriate controls in place to ensure the safe handling of ADs. Fazel et al, in a Canadian study, found that organizational factors (such as poor training, safety culture, and inconsistent policies) were substantial barriers to the safe handling of ADs.[4] These and other factors contributed to the overall poor performance of service provider 1. Service provider 1 is a small business (in contrast to service provider 2, which is a multipharmacy business) and is therefore less likely to comply to occupational health and safety requirements.[17]

Study limitations

The study had several limitations. The sample size was very small and the poor response rate, as a consequence of the facilities needing permission from the service providers to participate, potentially led to response bias, thereby reducing the validity of the results. Facilities with good health and safety practices might have been more willing to participate in the study. These issues raise questions about the representativeness of the participants and the generalizability of the findings. Although, the facilities did not allow direct observation of work practices, which could have led reporting bias, it was possible to assess the implementation of engineering and administrative controls, and the use of PPE. The participating pharmacies were in large urban areas, where work practices may be very different to those in smaller towns and rural areas. Another limitation is that the checklist was not validated or piloted. However, it was based on checklists previously used in similar studies and experts were consulted to ensure that it captured relevant issues pertinent to the study.

Recommendations

At the very least, all oncology pharmacists should be provided with PPE to minimize exposure to ADs, including gloves specifically designed to prevent dermal absorption, masks to prevent exposure through inhalation, and body coverings such as impermeable long-sleeved aprons and overshoes. Policies regarding the provision and use of PPE should be developed and enforced. The use of PPE is at the bottom of the hierarchy of controls for health and safety but is a cost-effective and affordable control.[18]

One level up in the hierarchy of controls is administrative controls, which include training. Oncology pharmacy personnel must be encouraged to actively participate in continuous professional development courses, workshops, and conferences to stay updated on best practices to protect their health. Guidelines for medical and environmental monitoring must be implemented to ensure a proactive approach to health and safety. As not all facilities are registered with the SAPC, Good Pharmacy Practice (GPP) is not necessarily enforced. The registration of all oncology facilities with the SAPC will improve practices to safeguard pharmacy personal. Section 2.17.3 of the GPP, concerning cytotoxic preparation and reconstitution services, should be reviewed and revised to specify the need for regulation of oncology pharmacy. This section is consulted by organizations like SAOC and ICON to develop guidelines and standard operating procedures (SOPs).

Engineering controls are third in the hierarchy of controls. In the case of oncology pharmacies, engineering controls such as anterooms and cleanrooms (ventilation controls) are prohibitively expensive in LMICs. However, the placement of the C-PEC in a separate room is easy and cost-effective. All oncology pharmacies should ensure that they are fitted with optimal ventilation (e.g., effective air-conditioning) and extraction systems that are regularly inspected and maintained by ventilation experts. Records of checks and maintenance should be appropriately filed.

Recommendations for further research

It is recommended that societies like the SASOPh, private oncology service providers, and the SAPC should assist in encouraging participation in future, larger studies on the health and safety of oncology pharmacists and the facilities to improve response rates. Future studies should be extended to other provinces in the country and should include oncology facilities in rural areas. Direct observations should be included in such studies, to reduce information bias.

Conclusion

Some of the gaps identified in this pilot study included the lack of training for oncology pharmacists the lack of best practice guidelines and inadequate controls to minimise exposure. This study highlights the need for stricter regulation of South African oncology pharmacy facilities and the implementation of national guidelines and standardization of workplaces and procedures. The findings contribute to the discourse on the complexities of South African oncology pharmacy facilities, shedding light on organizational factors. Differences in performance between service providers identified issues to be considered for the health and safety of oncology pharmacy personnel, particularly engineering controls and PPE usage. Although all the facilities were, in theory, subject to scrutiny by South African managed care organizations, work practices in some of the facilities were found to be poor. The reason for this requires further investigation. Work practices in South African oncology pharmacies should be investigated to protect employees from adverse health effects.

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