



Sarawak Journal of Pharmacy

Journal Homepage: <http://jknsarawak.moh.gov.my/spj/>



Improving Safety in Handling Cytotoxic Drugs: Quality Assurance Project

Andy Tang Sing Ong ¹, Yeo Siaw Tze ², Teh Wey Lok ², Ong Woei Jye ², Lee Kian Choy ²

¹ *Department of Medicine, Miri Hospital, Sarawak, Malaysia*

² *Department of Pharmacy, Miri Hospital, Sarawak, Malaysia*

Corresponding author name and email: Andy Tang Sing Ong (andytangsingong@gmail.com)

ABSTRACT

Selection of Opportunities for Improvement

Cytotoxic drugs commonly prescribed for the treatment of cancer and auto-immune disorders. Many of these drugs have carcinogenic, mutagenic and teratogenic properties. Absence of or non-adherence to control measures may pose detrimental health effects to healthcare professionals through occupational exposure.

Key Measures for Improvement

There were several incidence of cytotoxic spillage reported in Miri Hospital in 2015. This study aimed at improving the adherence rate to safe handling of cytotoxic drugs checklist with the standard set at 100% adherence.

Process of Gathering Information

A cross-sectional study was conducted from April to May 2016 to assess the adherence rate of 7 wards in Miri Hospital that provide chemotherapy service. Data collection was carried out based on a safe handling of cytotoxic drugs checklist compiled according to Ampang Protocol. Implementations of remedial measures were carried out from June 2016 to March 2018. The adherence rate reassessed from April to May 2018.

Analysis and Interpretation

Pre-remedial mean adherence rate was 64.3%, which was below the standard value. The ABNA was 35.7%. Shortfalls in the adherence to safe handling of cytotoxic drugs were identified in the aspects of chemotherapy protocol availability, transport and storage, administration as well as disposal of cytotoxic preparations.

Strategies for Change

Regular seminars and continuous medical educations (CMEs) conducted and designed a protocol on the management of chemo-spillage. We appointed chemo-link nurses and doctors in each ward and made recommendation to each ward to purchase leak-proof container with larger capacity.

Effects of Change

The mean adherence rate was improved from 64.3% to 84.8% following remedial actions.

The Next Step

There is a need for continuous monitoring of adherence to safe handling of handling cytotoxic drug measures, and regular audits should be carried out to ensure sustainability of improvement.

INTRODUCTION

Cytotoxic drugs are therapeutic agents intended for, but not limited to the treatment of cancer such as rheumatoid arthritis, multiple sclerosis, and other auto-immune disorders. Due to their pharmacological action that affects cell reproduction, these drugs are highly toxic to body cells. Many of these drugs have carcinogenic, mutagenic and teratogenic properties. During the prescribing of cytotoxic chemotherapy, the risks to patients often balanced against clinical benefit. However, the risk to staff through occupational exposure remains unclear. In the absence of such data, the recommended strategy is prudent avoidance. In the workplace, control measures are necessary to minimise occupational exposure. Personnel likely to be involved in the handling of cytotoxic drugs in the wards are nurses and medical practitioners. Absence of or non-adherence to control measures is likely to cause adverse health effects through occupational exposure (1, 2).

SELECTION OF OPPORTUNITIES FOR IMPROVEMENT

In Miri Hospital, one of the clinical services provided to patients is cancer chemotherapy service. Based on the cytotoxic spillage report in 2015, there were several incidences of spillage of chemotherapy reported. A baseline audit carried out in April 2015 highlighted the shortfalls in handling of cytotoxic drugs in Miri Hospital, particularly in administration and disposal aspects. Mishandling can result in detrimental health effects through occupational exposure to nurses and medical practitioners. This study intended to improve the safety in handling cytotoxic agents.

KEY MEASURES FOR IMPROVEMENT

This study aimed to re-engineer the process involved in handling cytotoxic drugs, including the chemotherapy protocol, transport and storage, administration and disposal. Our clinical indicator was the mean adherence rate to the safe handling of cytotoxic drugs checklist among all the related wards in Miri Hospital. We set 100% as the standard adherence rate.

PROCESS OF GATHERING INFORMATION

We conducted a prospective study which involved 3 phases. The first phase (pre-remedial study) was from April 2016 to May 2016. Second phase was the implementation of remedial measures from June 2016 till March 2018. Post remedial evaluation was conducted to reassess all the wards involved from April 2018 to May 2018. A total number of seven wards

identified in Miri Hospital that provided cytotoxic chemotherapy service, including female and male surgical wards, female and male medical wards, gynaecology ward, adult day care as well as paediatric ward.

We compiled a safe handling of cytotoxic drugs checklist according to Ampang Hospital Protocol. Clinical audit based on the checklist performed by two pharmacists from Cytotoxic Drug Reconstitution (CDR) department. We inspected the wards and the clinical staff via interview and observation.

ANALYSIS AND INTERPRETATION

We assessed seven wards and the data collected was analysed using simple percentage method. The mean adherence rate was 64.3%, which was below the standard value. The ABNA was 35.7% (Figure 1). We found that cytotoxic drugs were not counterchecked before administration and administered by trained personnel. Medical staff was not appropriately gowned. No education or training was given to medical personnel, especially the new ones. Inappropriate administration and disposal of cytotoxic agents were attributable to lack of awareness and knowledge among staff. No well-designated team allocated to in charge of chemotherapy in almost all wards. The capacity of leak-proof container used was limited. These issues created the opportunity for improvement.

STRATEGIES FOR CHANGE

Regular seminars and continuous medical educations (CMEs) were carried out to improve staff knowledge on the safe handling of cytotoxic agents. A protocol focusing on the management of chemo-spillage was set up. Chemo-link nurses and doctors were appointed in each department to monitor the administration of chemotherapy, to provide orientation or training to new staff as well as to liaise with CDR pharmacists for the transport, storage and disposal of chemotherapy and the accessibility and completeness of spillage kit. Additional budget should be allocated to purchase leak-proof container of larger capacity.

EFFECTS OF CHANGE

We subsequently conducted re-evaluation after implementation of the remedial actions. There is an improvement of adherence to each parameter of handling of cytotoxic agents. The mean adherence rate of 84.8% after the implementation of remedial actions. ABNA was 15.2% (Figure 1).

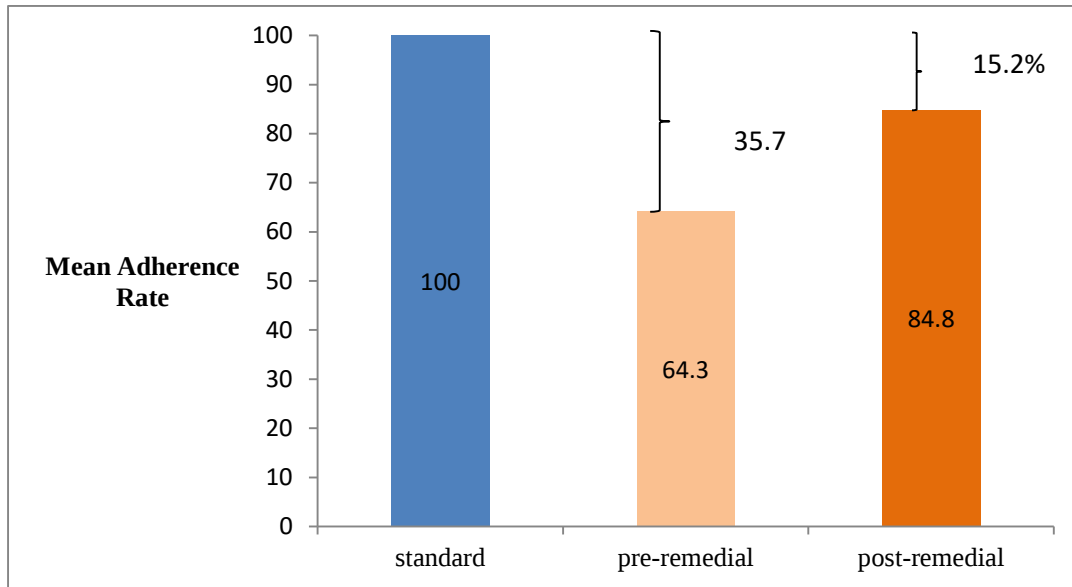


Figure 1. ABNA

THE NEXT STEP

Discussion with ward managers and head of department will be conducted to ensure a special session to be allocated for safe handling of cytotoxic drugs during orientation week to new staff. Regular CMEs will be done to emphasise the importance of adherence to the standards of practice. The role of chemo-link nurses and doctors will be re-emphasised to provide regular monitoring. Regular audits should be carried out every six- to twelve-monthly to ensure the sustainability of improvement.

REFERENCES

1. Health and Safety Executive (HSE) (2016) Safe handling of cytotoxic drugs in the workplace. Health and Safety Executive. Download available from <https://www.hse.ie/eng/staff/safetywellbeing/HealthSafetyand%20Wellbeing/HSE%20Guideline%20on%20the%20Safe%20Handling%20and%20Use%20of%20Cytotox%20Drugs%20%20Aug%202016.pdf>
2. Pan London (2011) Guidelines for the Safe Prescribing, Handling and Administration of Systemic Anti-Cancer Treatment Drugs. Download available from http://www.londoncanceralliance.nhs.uk/media/42575/PanLondonCytoPolicy_Final_v1_01.pdf

APPENDIX

1) Problem Analysis Chart



2) Model of Good Care

No	Checklist	Standard (%)	Adherence, n (%)	
			Pre-remedial Study (April –May 2016)	Post-remedial Study (April 2018)
	Protocol			
1	Is there any file for appointment book & patient chemotherapy protocol in the ward?	100	4 (57)	7 (100)
	Transport & Storage			
2	Is there any leak-proof container designated for cytotoxic drug transportation? With label 'Cytotoxic'	100	6 (86)	5 (71)
3	Is staff involved in transportation trained in Cytotoxic Drug Spillage Awareness?	100	7 (100)	5 (71)
4	Cytotoxic Drug is stored in zipped bag with Cytotoxic Caution Label in area separated from other drug.	100	7 (100)	7 (100)
	Administration			
5	Check if patient blood investigation result is reviewed by prescriber before confirmation for administration?	100	5 (71)	7 (100)
6	Check if chemotherapy is given by trained personnel or under supervision of senior?	100	1 (14)	4 (57)
7	Check if chemotherapy is counterchecked by trained personnel or under supervision of senior?	100	3 (43)	5 (71)
8	Check if chemotherapy is given in an isolated room away from hectic passage area?	100	6 (86)	7 (100)
9	If personnel is gowned up with Personal Protective Equipment (PPE) before administration?	100	2 (29)	5 (71)
10	Check if chemotherapy is given in dose and duration according to protocol?	100	6 (86)	7 (100)
11	Check if patient's chemotherapy administration record is documented according to schedule and date?	100	5 (71)	6 (86)
12	If not according to schedule, actual administration date and time is documented clearly in record and patient's book?	100	5 (71)	6 (86)

No	Checklist	Standard (%)	Adherence, n (%)	
			Pre-remedial Study (April –May 2016)	Post-remedial Study (April 2018)
13	SOP Management Chemo Spillage is available in ward?	100	1 (14)	5 (71)
14	Chemo Spillage Kit is available in ward accessible by other staff?	100	4 (57)	7 (100)
15	Education to new staff on safe handling of cytotoxic drug and chemo spillage management is carried out and documented.	100	0 (0)	5 (71)
	Disposal			
16	After administration, preparation is discarded in sharp bin solely for cytotoxic drug disposal.	100	7 (100)	7 (100)
17	The waste bin is labelled with Cytotoxic Caution Label and closed tightly.	100	6 (86)	6 (86)
18	The cytotoxic waste is collected every day.	100	6 (86)	6 (86)