REDUCING THE PERCENTAGE OF NEAR MISS CHEMOTHERAPY ERRORS IN ONCOLOGY DEPARTMENT OF HOSPITAL KUALA LUMPUR

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PRE-REQUISITE

1. Participated in 11th National Quality Assurance Convention 2022.
2. Participated in *Konvensyen Kualiti Bahagian Perkhidmatan Farmasi* Hospital Kuala Lumpur QAQI 2022.

CONFLICT OF INTEREST & FUNDING

This is an investigator initiated and self-funded research. Hence, there is no third-party involvement and the authors have no conflict of interest pertaining to the results and other parts of this study.

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ABSTRACT

Introduction: Chemotherapeutic agents have narrow therapeutic windows, where errors may result in significant harm or mortality. Between 2018 and 2020, six cases of actual chemotherapy errors resulting in adverse events were reported in the Oncology Department of Hospital Kuala Lumpur (HKL). **Objective:** This study aimed to reduce the incidence of near miss chemotherapy errors. The standard was set at 0.6%, based on findings from a previous study. **Methodology:** Near miss errors, defined as errors detected or intercepted during prescribing, preparation, dispensing, or before chemotherapy administration, were recorded using a data collection form. A survey to identify contributing factors was conducted concurrently with the baseline study in August 2020 were implemented in two cycles: November 2020 and March 2021. Cycle 1 involved updating the Cytotoxic Drug Reconstitution (CDR) request form and conducting continuous education for medical officers, pharmacists, and nurses. Cycle 2 included further refinement of the CDR request form and the introduction of the "Check-it-Right" checklist during chemotherapy dispensing. **Results:** The verification study prior to remedial measures showed a rate of near miss chemotherapy error of 1.15%. Contributing factors included incomplete documentation, lack of standardisation, staff inexperience, and inadequate counterchecking. The error rate decreased to 0.83% after Cycle 1 and further reduced to 0.52% after Cycle 2, achieving the target. **Next Step**: A multidisciplinary effort is essential in achieving 0% chemotherapy error. These strategies can be expanded to all wards using chemotherapy in HKL. **Conclusion:** This quality improvement initiative successfully reduced near miss chemotherapy errors through targeted interventions. Sustained collaboration among prescribers, pharmacists, and nurses remains essential to maintain safe chemotherapy practices and support wider implementation of these strategies.

Keywords: near miss error, chemotherapy error, oncology, cytotoxic drug reconstitution

INTRODUCTION

Hospital Kuala Lumpur (HKL), a government tertiary referral hospital, was founded more than 150 years ago, in 1870. Being located on 150 acres of prime land, it is the largest hospital under the Ministry of Health of Malaysia.[1] Housing an extensive array of 45 departments and units, encompassing 27 clinical departments and 18 clinical support services, HKL serves as a vital hub for medical care in the region. One of the main clinical departments in HKL is the Oncology Department. It is also one of the national referral centres in the field of oncology in Malaysia. The department consists of ten oncology wards as well as an oncology day-care unit collectively providing comprehensive care for cancer patients. The oncology wards are equipped with a total of 183 beds. Meanwhile, the oncology day-care unit has a maximum capacity to cater for up to 60 chemotherapy cases per day.

The oncology satellite pharmacy is one of the clinical support units that serves most of the oncology inpatients and outpatients of the Oncology Department. The oncology satellite pharmacy is currently staffed by a team of 16 pharmacists and 12 pharmacist assistants. Operational hours of the satellite pharmacy are from 7.30 am to 5.30 pm during the weekdays and 8.00 am to 2.00 pm on weekends and public holidays. The primary task of the satellite pharmacy is the production of sterile chemotherapy products for patients at the oncology day-care and wards. Other services offered by the oncology satellite pharmacy catering to the diverse needs of cancer patients which include the outpatient pharmacy, inpatient pharmacy and ward pharmacy services. Delivering optimal chemotherapy treatment to the patients requires multidisciplinary teamwork involving the oncologists, medical officers, oncology pharmacists, and the nursing team. All personnel involved in prescribing, preparation, reconstitution and administration of chemotherapy play an important role to ensure the quality, safety and efficacy of the treatment.

Chemotherapy medications are high-risk medications and usually have a narrow therapeutic range. Hence, any errors in dose, timing, rate or route can lead to significant harm, or in some cases, even death.[2,3] Several reasons for the increased susceptibility to errors in chemotherapy include the complex regimens and the requirement for dose adjustments.[4] Chemotherapy regimens may involve several different drugs which account for their complexity. For example, FOLFOX is a two-day chemotherapy regimen consisting of intravenous infusion of Oxaliplatin on Day 1, intravenous bolus and infusion of Fluorouracil as well as intravenous infusion of Folinic acid on Day 1 and Day 2. On top of that, chemotherapy doses may need to be adjusted based on individual patient's tolerability and clinical status. Several factors may influence the decision to modify chemotherapy doses in response to haematological toxicity, including the severity of blood profile derangements, the type and stage of cancer, the overall health status of the patient, and the specific chemotherapy regimen being used.

Chemotherapy medication errors may occur at any stage of the medication process. A systematic review found that chemotherapy medication errors ranged from 0.1% to 24.6% in prescribing, 0.40% to 0.50% in preparation, 0.03% in dispensing, and 0.02% to 0.10% in the administration phase.[5] A near miss error is defined as a medication error that has the potential to cause an adverse event (patient harm) but did not reach the patient because of chance or because it is intercepted in the medication use process.[6] The error is considered a near miss if the healthcare personnel detected and corrected the error before it reaches the patient.[6]

PROBLEM STATEMENT & OBJECTIVES

A brainstorming session was conducted, and five quality problems were identified as issues for improvement in the Oncology Department of HKL. The quality problems identified were the delay in processing of the special approved medication (UKK) application for cancer patients, poor stock management of direct purchased items in pharmacy, the delay in receiving prepared chemotherapy for patients in ward, increasing near miss chemotherapy errors in the Oncology Department, and lack of time on outpatient counselling by pharmacist. Based on SMART criteria (Seriousness, Measurable, Appropriateness, Remediable and Timeliness), the fourth problem; increasing near miss chemotherapy errors in the Oncology Department, was prioritised by the team members and therefore chosen to be studied.

In 2020, oncology satellite pharmacy of HKL received 15,121 chemotherapy request forms and prepared 38,045 chemotherapy preparations for cancer patients in the Oncology Department. These patients received their chemotherapy either in the oncology wards, or in day-care. There was a total of six (6) reported cases of actual chemotherapy errors that have reached patients from 2018 to 2020 in the Oncology Department. From these six cases, three errors occurred at prescribing stage, whereas another three occurred in administration stage. These errors have caused adverse events including additional monitoring and prolonged hospitalisation.

For instance, one of the errors involved prescribing of chemotherapy cycle one week earlier than intended as the date of chemotherapy interval was calculated wrongly. As a result, the patient developed neutropenia and had to be treated with subcutaneous filgrastim with prolonged hospitalisation. A second example is intravenous fluorouracil that was administered at a faster rate than intended. A potential adverse effect of fluorouracil is cardiotoxicity, which often presents with coronary vasospasm, cardiac ischemia or life-threatening arrhythmias.[8] Hence, the patient required prolonged hospitalisation and cardiac monitoring. By identifying and preventing near-miss errors, actual medication errors and patient harm can be avoided.

A verification study was conducted from August to September 2020, and the results showed that the rate of near miss chemotherapy errors in the Oncology Department was 1.15% (82/7,082). These errors were detected during the prescribing, preparation, and dispensing stages before the medicines reached the patients. Since Hospital Kuala Lumpur still uses a manual prescribing system, there is a possibility of prescribing mistakes and other process-related errors in the chemotherapy medication process. Although no patient was harmed, these incidents show weaknesses in the system that could lead to actual medication errors if not addressed. Therefore, reducing near miss chemotherapy errors is important to improve medication safety and the quality of oncology services.

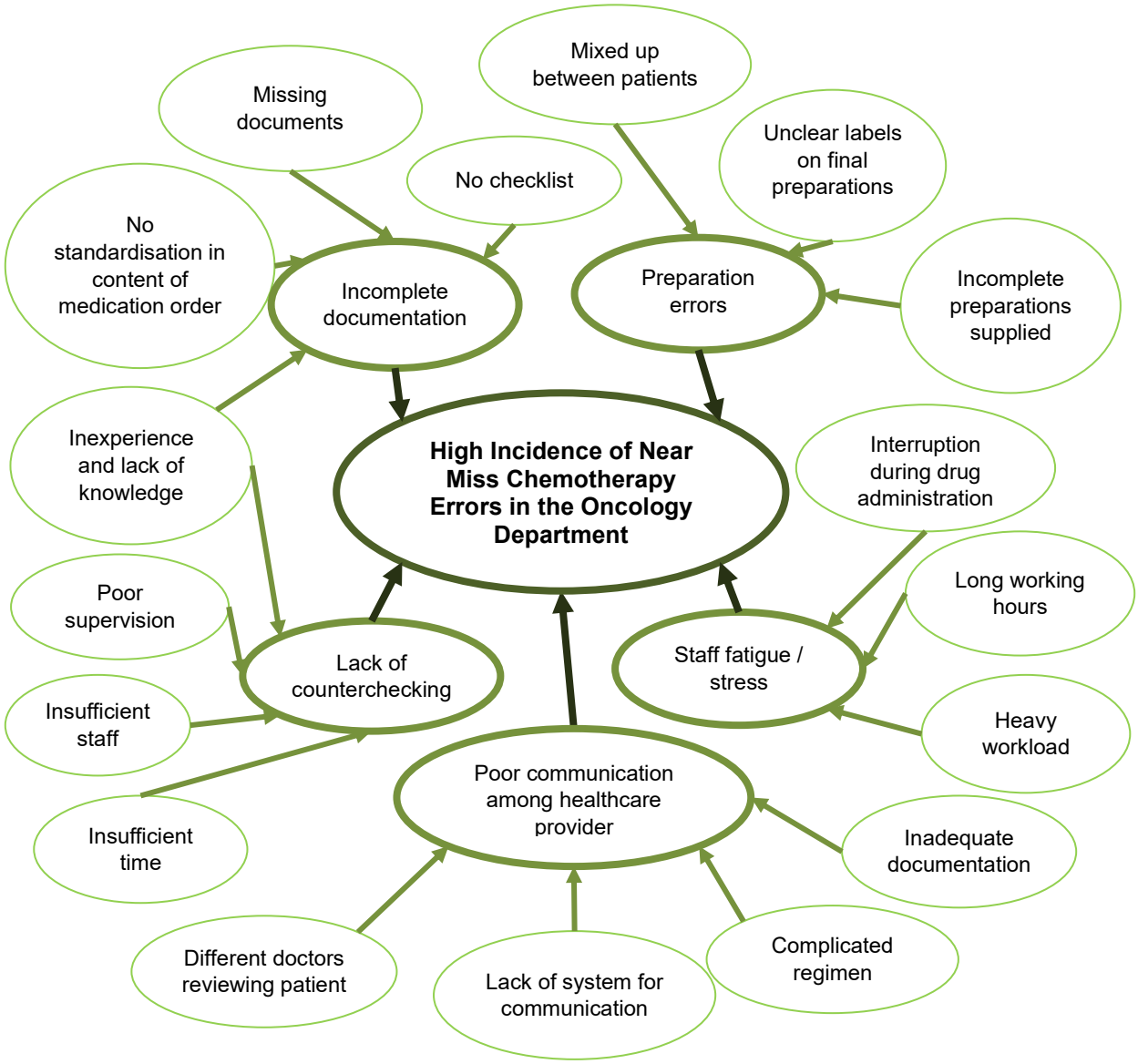

Figure 1. Problem analysis chart of increased Chemotherapy Error

To address these issues, the root causes were analysed using the Problem Analysis Chart as shown in Figure 1. The possible contributing factors based on observation that led to chemotherapy errors include incomplete documentation, lack of counterchecking, preparation errors, staff fatigue or stress, and poor communication among healthcare providers. Following this, the current process of

care was reviewed, and three critical steps were identified for targeted improvement as shown in Figure 2.

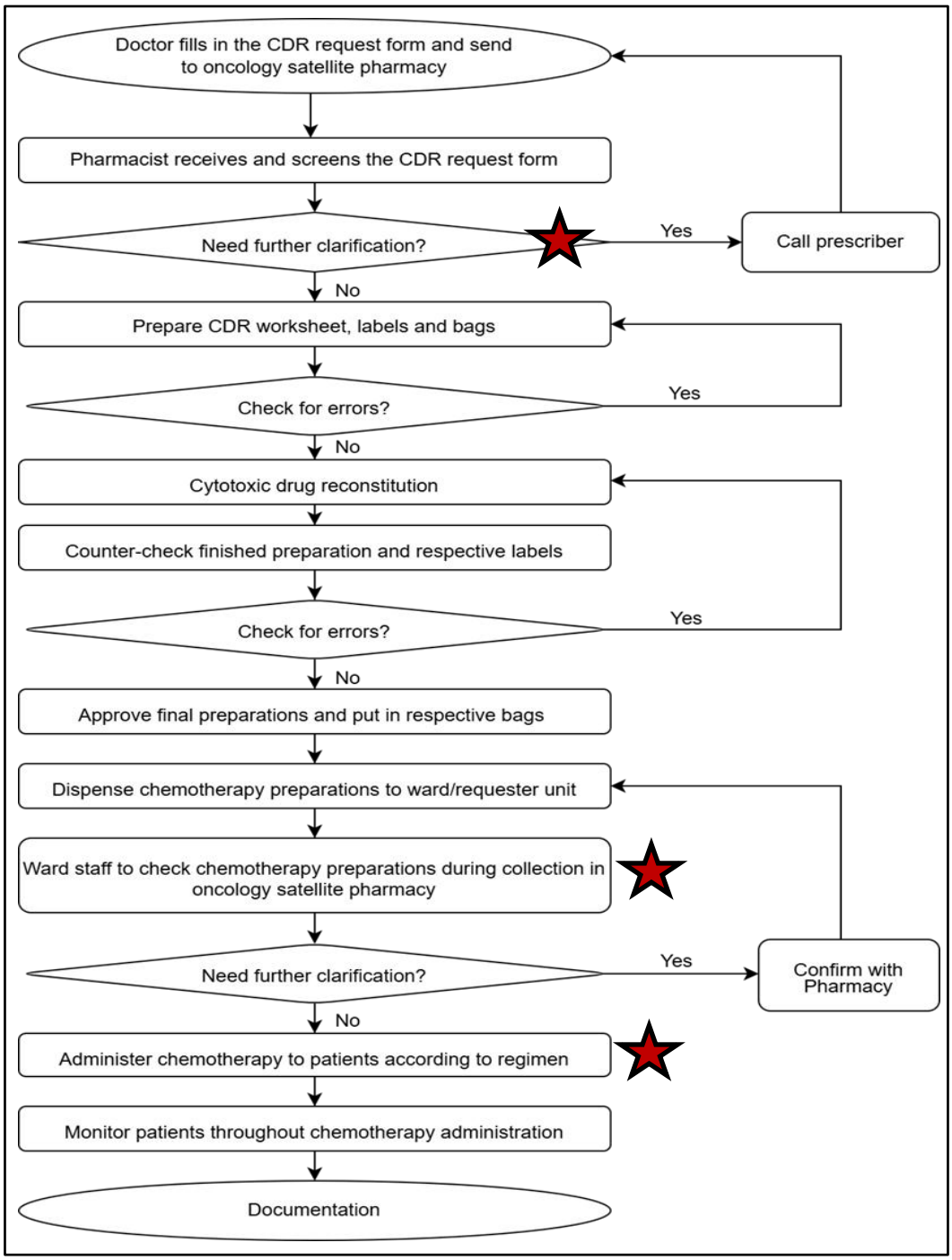

Figure 2. Process of care for preparation and administration of chemotherapy in Oncology Department HKL

The main objective of this study was to reduce the percentage of near miss chemotherapy errors in the Oncology Department. The specific objectives were to determine the percentage of near miss chemotherapy errors, to identify the causes leading to the near miss errors, to formulate and implement proper remedial measures and to evaluate the effectiveness of the remedial measures.

The key indicator for this improvement initiative was the percentage of near miss chemotherapy errors in the Oncology Department HKL. This was calculated by dividing the number of chemotherapies with near miss errors intervened by the total number of chemotherapies prepared at the Oncology Department, multiplied by 100%. Based on a study by Baldwin et al[7], which reviewed approximately 1 million orders across 700,000 chemotherapy visits, a total of 4,282 events were recorded, where 3,767 (88%) were identified as near misses errors. Since these near-misses accounted for approximately 0.6% of the total orders reviewed, the acceptable standard for near-miss chemotherapy errors in this study was set at 0.6%. The study also noted that majority of these near misses were prescribing errors, including incorrect dose, wrong drug or frequency and incomplete order.[7] By striving to meet this standard, this quality improvement study committed to achieving patient safety goals aligned with the Sustainable Development Goals (SDGs) specifically by emphasising error prevention and early detection, standardisation of care through consistent, evidence-based, and double-checked medication processes, and ensuring the delivery of safe and high-quality healthcare.

METHODOLOGY

A quality improvement study was carried out using universal sampling technique from August 2020 to April 2021. All cytotoxic drug reconstitution (CDR) requests received from Oncology Department, for oncology indications and involving parenteral chemotherapy were included in this study. The clinical trial cases were omitted from the sample.

A verification study was conducted from August to September 2020. During this period, a total of 7,082 chemotherapy preparations that met the inclusion criteria, were screened for potential near miss errors. Any errors that were detected or intervened during prescribing, preparation, dispensing or before administration of chemotherapy were recorded using a standardised data collection form. All data were compiled into Microsoft Excel spreadsheet by the investigating pharmacists. This verification study revealed that the baseline rate of near miss chemotherapy error was 1.15% (82/7,082) prior to the implementation of remedial measures.

Additionally, a survey was conducted among healthcare professionals at Oncology Department from August to September 2020 to identify the factors leading to chemotherapy errors. Methodologically, the survey utilised semi-structured interviews with open-ended questions, gathering information from 10 doctors, 20 pharmacy staff and 19 staff nurses. The perceived contributing factors to chemotherapy errors identified were incomplete documentation (43%), lack of standardisation of practices (27%), staff inexperience and lack of knowledge (12%), lack of counterchecking (8%), preparation errors (6%), and poor communication among healthcare providers (4%). A Pareto analysis demonstrated that the first three cumulative factors have contributed to 82% of the total problem. Consequently, the team decided to prioritise and formulate remedial measures targeting these factors to achieve the maximum impact on error reduction (Figure 3).

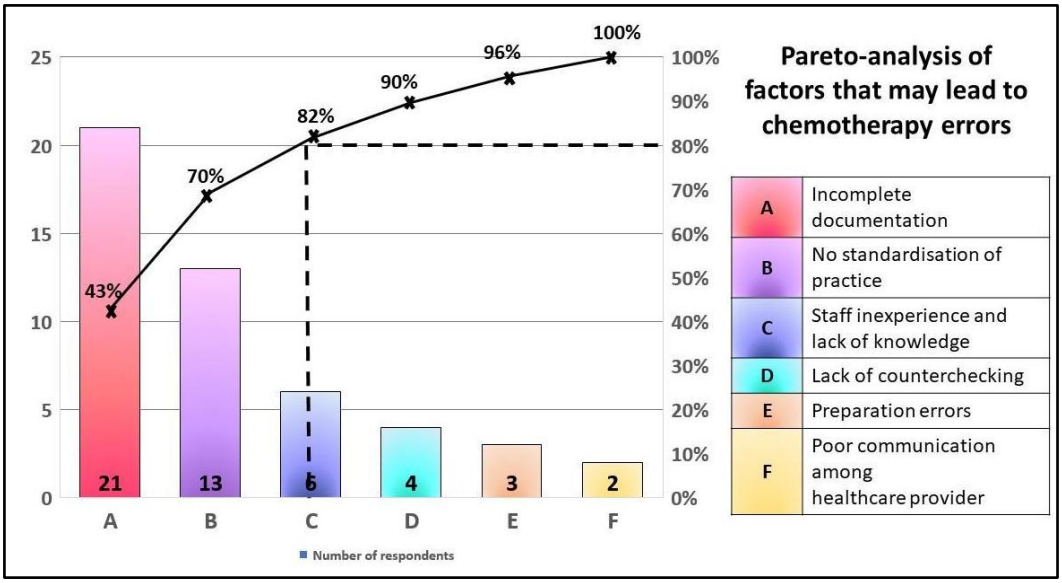

Figure 3. Pareto analysis based on survey from staff in Oncology Department

A total of four strategies for improvement were formulated and implemented across two phases; two strategies in Cycle 1 and two in Cycle 2. Cycle 1 remedial measures were carried out between November and December 2020, followed by a two-month evaluation period. Subsequently, Cycle 2 remedial measures were executed from March to April 2021, with re-evaluation conducted for over the following two months. During these respective periods, a total of 5,393 chemotherapy preparations were screened in Cycle 1, and 5,225 preparations were screened in Cycle 2.

To address the top two contributing factors identified which were incomplete documentation and lack of standardisation of practices, the first strategy involved updating the current Cytotoxic Drug Reconstitution (CDR) request form. Before the project was implemented, there were only limited chemotherapy regimens readily available in the original CDR request form template. Consequently, the prescribers frequently transcribed verified new regimens and doses manually from the specialist folders resulting in an increased risk of omitting critical clinical information or introducing transcribing errors. Another issue with the existing CDR form was that only information on the chemotherapy drugs and doses were available but it did not include any details regarding the administration. Because of this, the administration process was not standardised and may differ from personnel to personnel. Deviation from standard administration process may lead to undesirable side effects or may affect the efficacy of chemotherapy.

By updating the CDR request form, all new regimens are now available in a standard format, integrated with the complete regimens. Currently, there are 143 chemotherapy regimens that have been validated by the in-house oncologists, as compared to 31 regimens previously. The new CDR request form included the drug administration sequence and duration, route of administration, the premedication and hydration in between the chemotherapy, as well as the types of diluents used. Some regimens may also require special orders, such as highly myelosuppressive regimens which

will have remarks on its CDR request for additional subcutaneous granulocyte-colony stimulating factor (G-CSF) to be given to patient. Moreover, the updated CDR request form has allocated columns for documenting the time of administration, signatures of staff nurses who administer and countercheck at every step of administration.

Concurrently, a second strategy was implemented in Cycle 1 to address the factor of staff inexperience and lack of knowledge. In this strategy, continuous medical, pharmacist, and nursing education sessions were conducted. These sessions were aimed to brief and alert the healthcare providers regarding the structural changes made on the CDR form, while emphasising the importance of adherence to the standard protocols and reminder on the procedures of chemotherapy prescribing, preparation, and administration.

Following Cycle 1, feedback from staff nurses indicated that the updated request form lacked a method to compare previous doses of chemotherapy which existed in the old form. In response to this, the team members decided to further improve the CDR request form in Cycle 2. The improvement involved separating the administration details from the main request form into a Chemotherapy Administration Chart (CAC), which was to be attached together alongside the request form (Appendix 1.a). Hence, the CDR request form was improved to have a simpler layout that can be reused for several chemotherapy cycles (Appendix 1.b).

The final strategy in Cycle 2 focusing on the critical gaps identified during the review process of care, addressed the lack of standardised counterchecking process by staff nurses during the chemotherapy dispensing stage. The counterchecking process is a crucial step for staff nurses to detect any errors of chemotherapy preparations prior to administration. During this process, staff nurses ensure the chemotherapy preparations are prepared correctly in terms of the right patient, drug, dose, volume, dilution and final condition of the product. To overcome this problem, a “Check-it-Right” checklist was introduced as part of the chemotherapy dispensing process (Appendix 1.c). By implementing this checklist, the counterchecking process was standardized and hence, any error in chemotherapy preparation can be intervened before reaching the patient. This step also improved accountability and traceability in the event of any chemotherapy preparations being wrongly collected.

RESULTS

Following the implementation of the first cycle of remedial measures, there was a decrease in the percentage of near miss chemotherapy errors intervened or detected from 1.15% to 0.83%, representing a reduction by 0.32%. (Figure 4). Nevertheless, at 0.83%, it was still higher than the proposed standard of 0.6%. During Cycle 2 of the post-remedial study, the near miss errors were further reduced by another 0.31%. By the end of this study, the rate of near miss chemotherapy error was successfully reduced to 0.52%, below the set standard. The Achievable Benefit Not Achieved

(ABNA) gap was successfully narrowed from 0.56% to 0.23% in the first cycle, and further improved to -0.08% in Cycle 2, demonstrating that the final outcomes surpassed the established standard.. Crucially, there was zero actual chemotherapy error that reach patient reported throughout the study period.

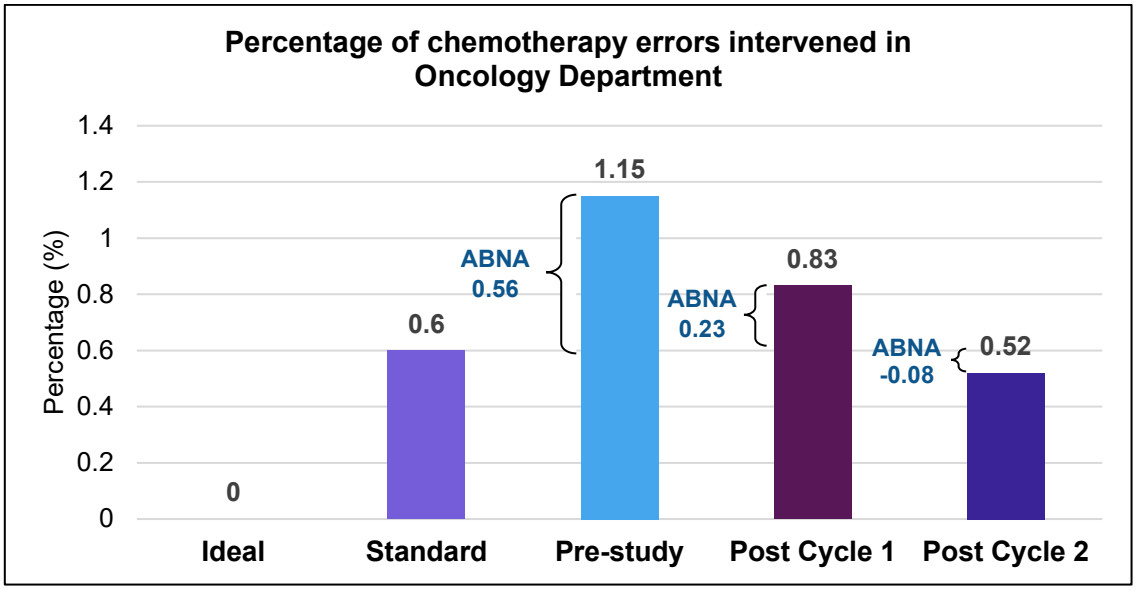

Figure 4. Percentage of chemotherapy preparations with near miss error (ABNA analysis)

A model of good care (MOGC) was developed with the criteria and standards set for all the identified critical steps and the improvement for post intervention as summarised in Table 1. Regarding the prescribing step, 95% (72/76) of doctors correctly endorsed chemotherapy regimens and doses according to the specialist's plan during Cycle 1 and continue improved to 98% in cycle 2. Furthermore, the use of the standard CDR request form specific to each regimen helps to improve from 70% (53/76) in the pre-remedial stage to 90% and 95%, in subsequent respective cycles, effectively replacing the previously manual written forms.

Table 1. Model of Good Care for reducing near miss chemotherapy error

Process	Criteria	Standard	Pre-remedial	Cycle 1	Cycle 2
Prescribing of CDR request form	a) Doctor to endorse chemotherapy regimen and doses correctly based on specialist plan.	**100%**	**90%**	**↑ 95%**	**↑ 98%**
	b) Using the CDR request form specific for the regimen	**100%**	**70%**	**↑ 90%**	**↑ 95%**
Verification during chemotherapy collection	a) Staff nurse to check chemotherapy preparations: ● correct patient ● all preparations available in the correct bag ● drugs, doses and diluents on the labels are correct	**100%**	**50%**	**↑ 70%**	**↑ 95%**
	b) Sign the record book upon receiving the chemotherapy.	**100%**	**50%**	**↑ 70%**	**↑ 95%**

Process	Criteria	Standard	Pre-remedial	Cycle 1	Cycle 2
Administration of chemotherapy	a) Staff nurse to follow regimen protocol including premedication, chemo and hydration, in the correct sequence and duration.	**100%**	**90%**	↑ 95%	↑ 98%
	b) Sign each process with time start and end of administration.	**100%**	**0%**	↑ 80%	↑ 95%

In terms of the verification during the chemotherapy collection step, compliance significantly increased from a baseline of 50% to 95% by the end of Cycle 2. This improvement was driven by the implementation of the "Check-it-Right" checklist, which mandated all staff nurses to check all chemotherapy preparations and sign the record book upon receipt. Meanwhile, for administration of chemotherapy step, adherence to protocol for each specified chemotherapy regimen by the staff nurses improved to 98% by the end of the study. Previously, there was no space for staff nurses to sign and record the timing of each administration process. This step became more refined with the introduction of CAC, improving the standard from 0% to 95% after Cycle 2 remedial measures. This chart received a very positive response from the staff nurses as it helped to ensure the administration process is standardised for everyone involved, especially for the new staff nurses. It also eliminated the possibility for omission of any pre-chemotherapy medication which the patient should receive to minimise the adverse effects of chemotherapy.

LESSONS AND LIMITATIONS

The implementation of targeted strategies led to a significant reduction in near-miss chemotherapy errors in the Oncology Department at Hospital Kuala Lumpur (HKL). Key factors contributing to the success of this initiative included strong collaboration among healthcare providers and the standardisation of clinical practices. The use of a standardised form for CDR and a structured chemotherapy administration chart played a critical role in minimising errors across prescribing, preparation, and administration processes.

During the initial phase of implementation, some nurses expressed concerns about time constraints related to adhering to and signing off on each step of the chemotherapy administration chart. This challenge was effectively addressed through continuous nursing education, which emphasised the importance and utility of the standardised chart in ensuring patient safety. All these strategies continue to be implemented in current practice to ensure the ongoing delivery of safe and high-quality healthcare.

NEXT STEP

As prescribing phase is an initial step of medical care, preventive measures at this stage may aid in alleviating consequences. It is warranted to minimise prescribing errors by implementing

computerized physician order entry (CPOE), such as e-prescription systems. E-prescription systems help physician or oncologist to send accurate, error-free, and understandable prescription. Several overseas studies documented that CPOE is one of the best tools to minimise the medication error at any following stage, including chemotherapy ordering, preparation, and administration.[9,10]

This quality improvement study is committed to achieving patient safety goals aligned with the SDGs by emphasising error prevention and early detection, standardisation of care through consistent, evidence-based, and double-checked medication processes, and ensuring the delivery of safe and high-quality healthcare. All these strategies continue to be implemented in current practice to ensure the ongoing delivery of safe and effective patient care. As of October 2025, a total of 248 CDR request form and chemotherapy administration chart specific for the regimen has been standardised for department use. According to the Malaysian Patient Safety Goals 2.0 Guidelines on Implementation and Surveillance by the Ministry of Health Malaysia, the target for medication errors leading to severe harm or death is zero.[11] Based on the findings of this study, there remains room for improvement to further reduce near-miss chemotherapy errors and enhance overall medication safety; therefore, further studies could be carried out to achieve this goal.

It is evident from the study that a multidisciplinary effort is essential in ensuring 0% chemotherapy error. As a cohesive team, continuous monitoring of the work process and strict adherence of staff to the revised policies are essential. Looking ahead, the standardised templates and double-checking strategies developed in this study can be seamlessly expanded to all wards using chemotherapy in HKL thereby, institutionalising a broader culture of medication safety.

CONCLUSION

This study identified several contributing factors associated with medication errors in chemotherapy and implemented four key strategies to address them. These strategies included: (1) updating the CDR request form, (2) conducting continuous education for medical officers, pharmacists, and nurses, (3) further refining the CDR request form along with the development of a standardised CAC , and (4) introducing the “Check-it-Right” checklist during the chemotherapy dispensing process.

The implementation of these interventions led to a measurable reduction in near-miss chemotherapy errors within the Oncology Department of HKL. The success of this initiative underscores the critical importance of ongoing collaboration and teamwork among prescribers, oncology pharmacists, and nursing staff to ensure the sustainability of safe chemotherapy practices. Overall, the strategies employed in this study have enhanced the safety and efficiency of chemotherapy delivery, thereby optimising pharmaceutical care and improving patient outcomes in cancer treatment.

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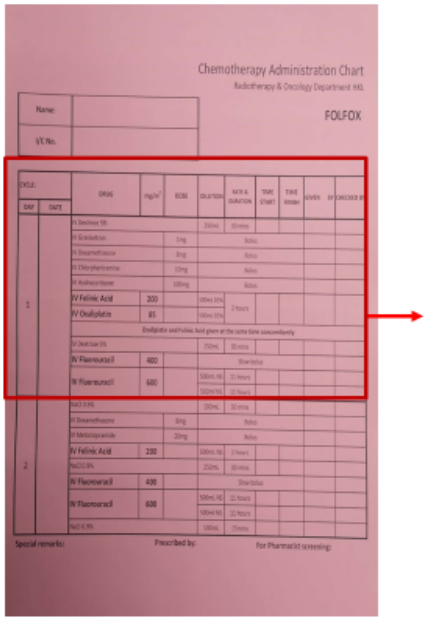
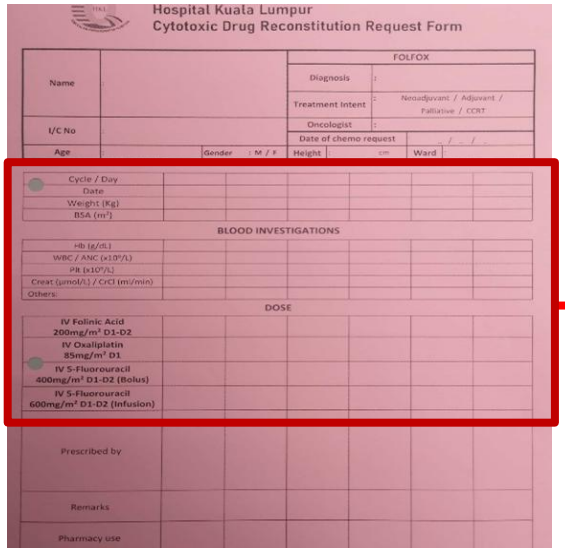
APPENDIX

Appendix 1.a: As a strategy in Cycle 2, Chemotherapy Administration Chart (CAC) was introduced, which included the complete administration details and sequences



CYCLE:		DRUG	mg/m²	DOSE	DILUTION	RATE & DURATION	TIME START	TIME FINISH	GIVEN BY	CHECKED BY
DAY	DATE									
1		IV Dextrose 5%			250mL	30 mins				
		IV Granisetron		1mg	Bolus					
		IV Dexamethasone		8mg	Bolus					
		IV Chlorpheniramine		10mg	Bolus					
		IV Hydrocortisone		100mg	Bolus					
		IV Folinic Acid	200		500mL D5%	2 hours				
		IV Oxaliplatin	85		500mL D5%					
		Oxaliplatin and Folinic Acid given at the same time concomitantly								
		IV Dextrose 5%			250mL	30 mins				
		IV Fluorouracil	400		Slow bolus					
		IV Fluorouracil	600		500mL NS	11 hours				
					500ml NS	11 hours				

Appendix 1.b: The final version of the simplified cytotoxic drug reconstitution (CDR) request form, further improved during Cycle 2 remedial measures.



Cycle / Day					
Date					
Weight (Kg)					
BSA (m²)					
BLOOD INVESTIGATIONS					
Hb (g/dL)					
WBC /ANC (x 10⁹/L)					
Plt (x 10⁹/L)					
Create (µmol/L) / CrCl (ml/min)					
Others:					
DOSE					
IV Folinic Acid 200mg/m² D1-D2					
IV Oxaliplatin 85 mg/m²D1					
IV 5-Fluorouracil 400 mg/m² D1-D2 (Bolus)					
IV 5-Fluorouracil 600 mg/m² D1-D2 (Infusion)					

Appendix 1.c:"Check-It-Right" Checklist as part of chemotherapy dispensing process

Saya mengesahkan bahawa semua kriteria berikut adalah betul dan memuaskan:

- ❑ Nama dan RN Pesakit
- ❑ Jenis Ubat
- ❑ Dos
- ❑ Amaun (ml)
- ❑ Jenis diluent yang betul bagi sediaan infusi
- ❑ Tiada kebocoran pada penutup botol infusi

Isu-isu yang telah dikenalpasti & Tindakan:

- ❑ Tiada Ada_____

Disemak & diterima oleh: Tarikh dan masa