Clinical Audit on the Practice of Labelling Multi-Dose Drugs in Ward Settings at Balik Pulau Hospital

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ABSTRACT

Introduction:

Multi-dose drugs (MDDs) are pharmaceutical products containing more than one dose. Maintaining product integrity after first opening is a key quality concern. This audit aimed to ensure that all MDDs were labelled with both the open date and correct in-use shelf life (ISL).

Methods:

This criterion-based audit was conducted across all wards at Balik Pulau Hospital over two six-week cycles. Data were collected using a data collection form. The audit standard, set by consensus, was 100% compliance with open date and correct ISL labelling for MDDs. Staff nurses' knowledge was assessed using a structured written test. Following identification of a shortfall in quality, targeted remedial measures were implemented before the re-audit.

Results:

Of the 78 MDDs identified during the pre-audit, 51.28% (n=40) were labelled with an open date, and only 2.56% (n=2) had the correct ISL. The assessment of staff nurses' knowledge on ISL of MDDs revealed that their knowledge level was below 50%. Re-audit findings following remedial actions—which included Continuous Nursing Education sessions, use of standard ISL reference list, and customized labels—demonstrated significant improvement. In the re-audit of 98 MDDs, open date labelling increased to 75.51% (n=74), and correct ISL recording rose to 51.02% (n=50). In addition, staff nurses' ISL knowledge improved significantly following the remedial measures ($P < 0.001$).

Conclusion:

The audit identified poor compliance in labelling MDDs with open date and correct ISL, posing potential risks to patient safety. Targeted remedial actions have significantly improved compliance and staff knowledge. Although full compliance was not achieved, routine monitoring of open date and the ISL of MDDs has become an essential practice during quarterly ward inspection. This practice is expected to reduce the risk of administering expired medications and enhance overall medication safety within the wards.

Keywords:

Multi-dose drugs (MDDs), drug stability, open date, in-use shelf life (ISL)

INTRODUCTION

Multi-dose drugs (MDDs) are pharmaceutical products packaged to allow multiple doses to be taken or withdrawn from a single container.[1] Such preparations often contain agents to limit bacterial growth.[1] Common forms of MDDs include bottles of capsules or tablets, liquid oral formulations in bottle form, and injectable drugs supplied in multi-dose vials. In hospital settings, MDDs are often maintained as floor stock, which are bulk supplies of commonly used drugs and used for administration to multiple patients.[2] The use of MDDs is associated with cost savings and offers practical advantages because it reduces the frequency of drugs being refilled and the amount of packaging material used which may lead to potential environmental benefits.[3]

Proper drug management is essential to ensure patient safety and optimal treatment outcome. Healthcare providers are responsible in ensuring that all drugs supplied and administered to the patients remain safe, effective and uncompromised during storage and handling. The integrity of drug products in multi-dose containers after the first opening is a key quality concern.[4] The manufacturer's expiry date on the label reflects the drug's stability in its original and unopened container.[4] Once opened, the shelf life of drugs is reduced due to the breached closure system, and repeated opening may further affect its physico-chemical or microbiological quality.[4]

To prevent administration of outdated or contaminated drugs, all MDDs must be labelled with the date they are first opened, unsealed or punctured, referred to as the open date.[5] Once opened, the expiry date set by the manufacturer is no longer applicable as the MDD's stability may be compromised. The period during which a multi-dose product remains safe and retains acceptable quality after opening is called in-use shelf life (ISL).[4,5] All drugs must be discarded upon reaching the ISL.

According to the Inpatient Pharmacy Drug Supply Guidelines issued by the Ministry of Health Malaysia, regular ward inspections must be conducted at least three times annually.[2] These inspections are performed as audits to ensure that all drugs stored in the wards are in good condition, clean, and adequately stocked.[2] At Balik Pulau Hospital (HBP), ward inspections are conducted on a quarterly basis

to ensure consistent and effective drug management across all wards.

One key criterion in the ward inspection checklist is the requirement for all opened multi-dose drugs (MDDs) to be labelled with their open date and correct in-use life (ISL). However, ward inspection reports from 2021 indicated that only 66.66% of the wards inspected complied with this requirement.

Inadequate labelling of MDDs complicates inventory management of ward floor stock and may lead to medication wastage. Furthermore, the use of expired drugs may result in suboptimal treatment outcomes, as active pharmaceutical ingredients can become chemically unstable and degrade into potentially toxic compounds, posing harm to patients and increasing the risk of microbial contamination.[6]

Therefore, an audit was conducted during routine ward inspections to assess compliance with MDD labelling requirements. The objectives of the audit were to ensure that all MDDs were labelled with both the open date and correct ISL, determine the percentage of MDDs correctly labelled, identify factors contributing to non-compliance, and formulate appropriate remedial actions to improve labelling practices. A target compliance standard of 100% correct labelling of MDDs with open date and ISL was established for this audit.

METHODS

Audit Type

This was a criterion-based audit focusing on the two components of MDDs labelling which were open date and correct ISL.

Audit Procedure and Sample

This was a two-cycle clinical audit conducted across four wards in HBP which were Female Ward, Male Ward, Maternity Ward and Paediatric Ward. A total of 19 listed MDDs (Appendix 1) were included in the audit. Two criteria were set for this study, which required all MDDs to be labelled with i) open date and ii) correct ISL. The standard for both criteria was set at 100% by group consensus in view of the deteriorating effects and consequences associated with administering expired drugs to the patient in wards.

The pre-audit was conducted from 18th April to 27th May 2022 with a total sample of 78 MDDs. The data collection form was designed and pre-tested in a pilot study with four staff nurses from each ward (Appendix 2). During the audit, the auditors reviewed all opened MDDs labelling in the designated wards and recorded the audit findings in the data collection form.

The auditors reviewed all newly opened MDDs on alternate working days between 2pm to 5pm. To ensure consistency and completeness of data collection, each auditor returned to the same ward during subsequent audit rounds, allowing all newly opened MDDs to be captured systematically.

To identify the potential causes of the shortfall in quality, a simple survey (Appendix 3) was conducted among all staff nurses in all inspected wards to further explore possible reasons for non-compliance with MDDs labelling practices. The survey focused on three main domains including knowledge and awareness barriers (Question 1, 3, and 4), time constraint (Question 2), and workflow burden (Question 5). Respondents were allowed to choose one or more reasons for non-compliance.

The survey items were developed based on direct feedback from ward supervisors who had observed recurrent non-compliance issues with MDDs labelling practices. This approach ensured that the items accurately reflected practical challenges faced by staff nurses in their daily routines.

An assessment of 42 staff nurses' knowledge on ISL of five commonly used drugs (Appendix 4) was conducted before and after remedial measures to evaluate knowledge improvement following an educational intervention.

Pre-remedial findings were discussed between auditors and the nursing representatives, including the relevant ward matrons and nursing sisters. A few remedial actions were agreed upon the discussion and one ward sister will be appointed as the representative to facilitate the implementation of the remedial action.

Change strategies were implemented from 15 June to 15 August 2022. A re-audit was subsequently conducted from 1 September to 13 October 2022.

Data Curation and Analysis

The percentage of MDDs with complete open date and correct ISL labelling was calculated based on the total number of samples audited. A paired t-test was conducted to compare pre and post-test scores, assessing the effectiveness of the remedial measures on participants' knowledge regarding ISL. Data was analysed using Microsoft Excel and IBM SPSS Statistics version 29.

RESULTS

Pre-remedial Audit Findings

A total of 78 MDDs were recorded during pre-remedial data collection. Overall, only 51.28% (n=40) of drugs were labelled with an open date and 2.56% (n=2) of drugs were recorded with the correct ISL.

Figure 1 illustrates the assessment findings of staff nurses' knowledge on ISL. The mean pre-test score was 2.10±1.08, indicating low baseline knowledge on ISL among participants.

Evaluation of Root Cause of Shortfall in Quality

The survey investigating factors that may contribute to the shortfall in quality showed that most staff were unsure of the correct ISL and there was too much information to remember as the main reasons for non-compliance to the MDDs labelling requirements (Figure 2).

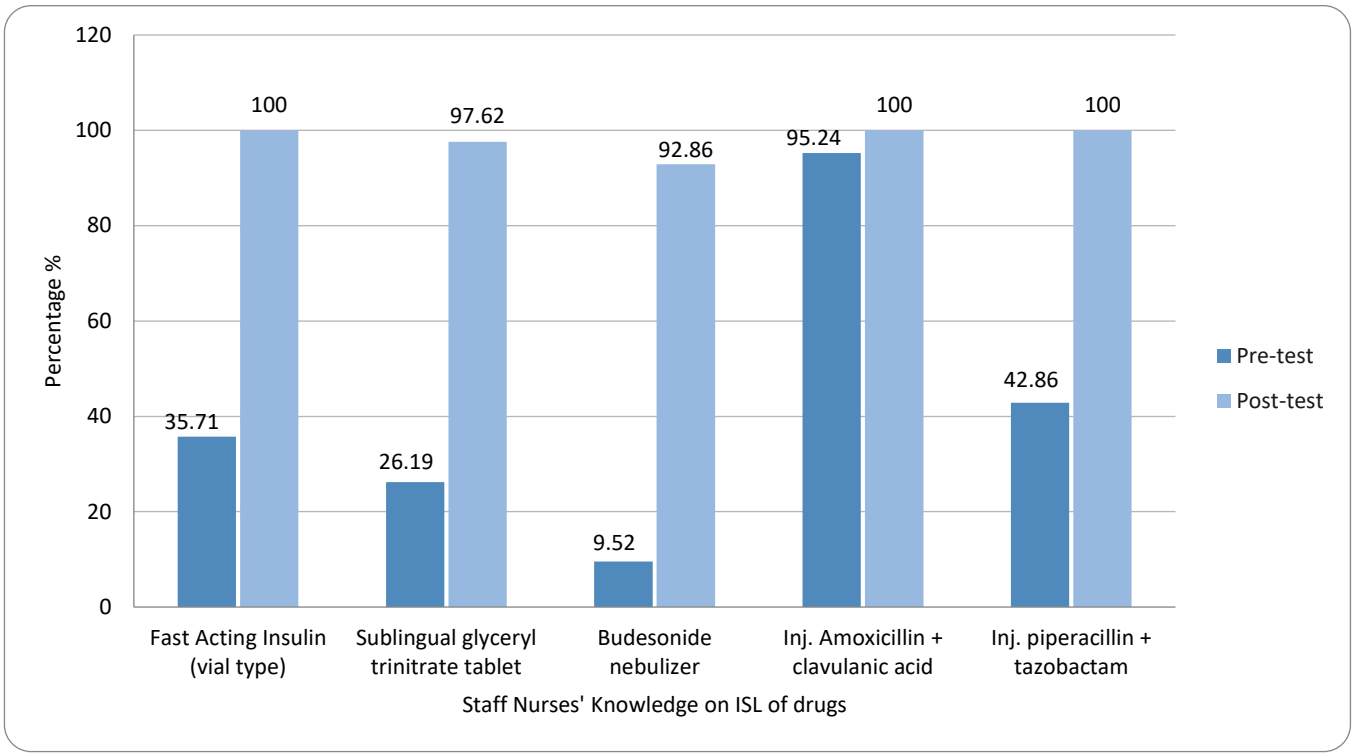

Figure 1. Pre-test and post-test scores assessing staff nurses' knowledge on ISL of MDDs (n=42)

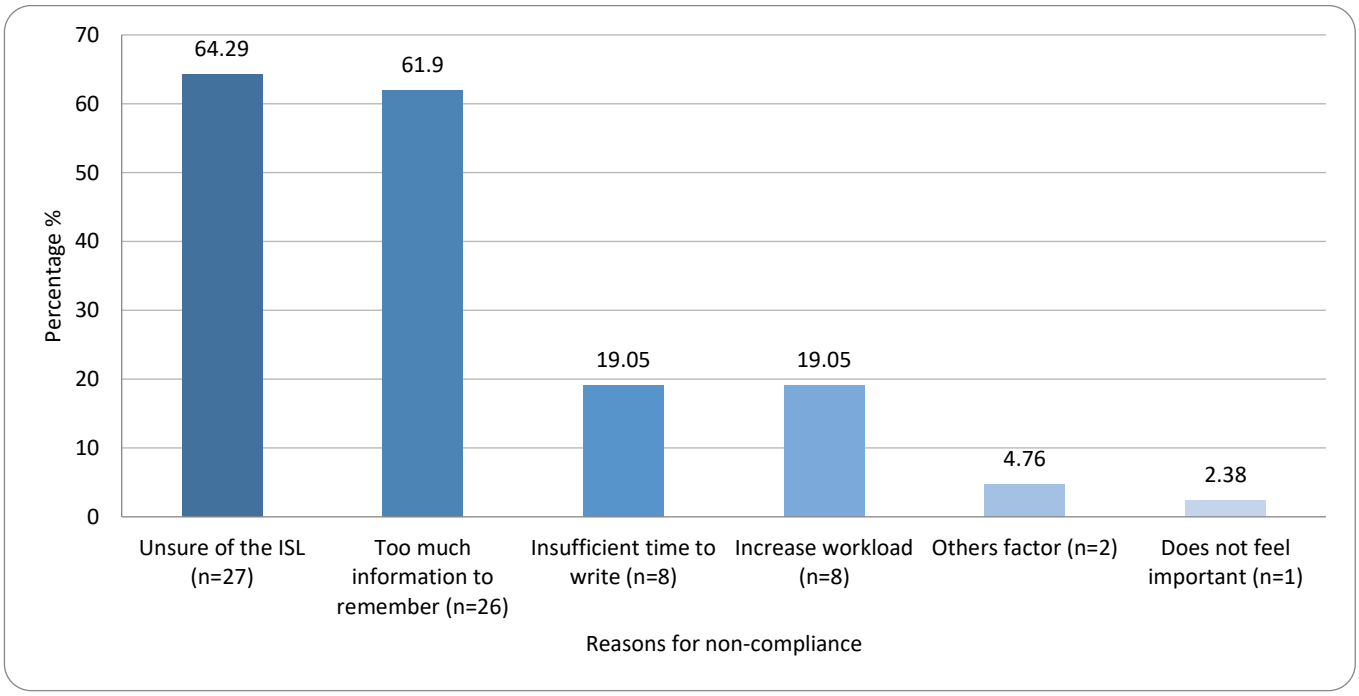

Figure 2. Root causes of incomplete labelling of MDDs

Remedial Measures/ Strategies of Change

As a remedial measure, a standard reference list of ISL was developed along with customized sticker labels (Figure 3) to support proper labelling practices. The information for the reference list was obtained from package inserts and manufacturers' recommendations which were subsequently verified by the pharmacist from Drug Information Service, Pharmacy Department of HBP. Following this, a series of Continuous Nursing Education (CNE) sessions were conducted from 15th June until 15th August 2022 to educate and raise awareness among nurses in wards on the importance of proper labelling of MDDs with both open date and the correct ISL.

Open Date
In-use Shelf Life (weeks/months after date opened):

Figure 3. Customised sticker label

Re-audit Findings

The post-remedial audit findings revealed that the percentage of MDDs labelled with open date increased to 75.51% (n=74), whereas the percentage of correct ISL labelling increased to 51.02% (n=50) (Figure 4). Following implementation of the remedial measures, a post-test on staff nurses' knowledge was conducted.

The audit findings showed that their knowledge on ISL has improved significantly post-remedial measures (*P*< 0.001) (Table 1). The mean pre-test score was 2.10±1.08, which improved significantly to 4.90±0.37 following the remedial measures. The mean difference in scores was 2.81±1.04, showing a substantial improvement in the knowledge score that was statistically significant (*P*< 0.001)

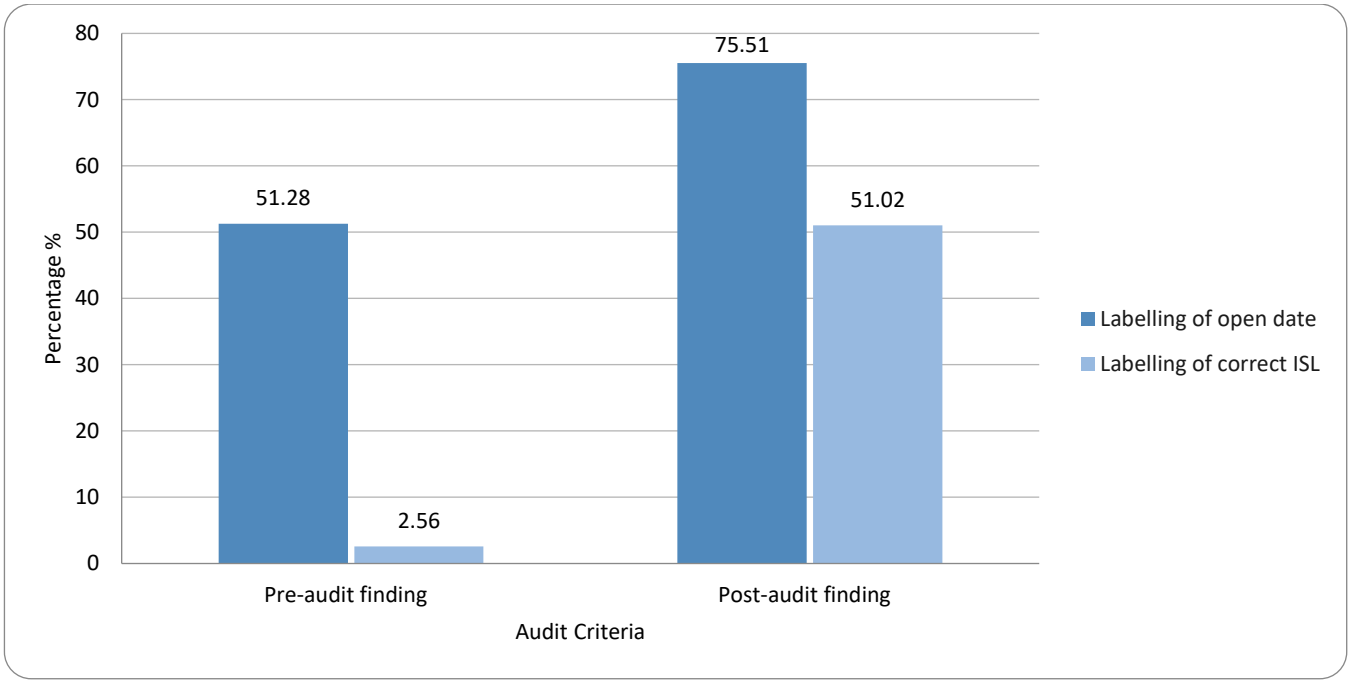

Figure 4. Pre and post-audit finding of complete labelling of MDDs

Table 1. Comparison of staff nurses' knowledge on ISL before and after the remedial measures (n=42)

Variable	Mean (SD)		Mean Difference (95% CI)	*t*-statistic (df)	P-value[a]
	Before	After			
Score	2.10 (1.08)	4.90 (0.37)	-2.81 (-3.13, -2.48)	-17.48 (41)	<0.001

[a]Paired t-test

DISCUSSION

Proper management of floor stock drugs in hospital wards helps minimise medication errors, reduce wastage, maintain product quality and improve cost-effectiveness. Most importantly, it is crucial to ensure drugs are readily available for immediate patient needs while maintaining their quality.[7]

Dispensing expired drugs in healthcare settings represents a critical safety concern.[7] The baseline audit revealed a high prevalence of incomplete labelling of the open date and ISL for MDDs. This finding aligns with a study conducted in India, which reported that some staff were unaware of the importance of recording the medication's open date. As a result, they were uncertain about when to discard drugs upon reaching the ISL.[8] These issues highlight the importance of proper labelling of MDDs to prevent the administration of expired or ineffective drugs, thereby reducing the risk of adverse effects or treatment failure.

In this audit, the written assessment on staff nurses' knowledge revealed low baseline knowledge regarding correct ISL of commonly used MDDs. This finding supports the idea that inadequate knowledge may be one of the factors contributing to the observed shortfalls in labelling compliance. As a result, several CNE sessions were conducted for all nursing staff in the wards to enhance their knowledge, which has led to a significant increase in staff knowledge regarding ISL, as demonstrated by the post-audit findings.

Labelling opened drug containers with the open date and ISL is an essential step in monitoring for expired drugs.[9] However, the absence of clear institutional policies emphasising the importance of labelling MDDs has led to inadequate knowledge among nursing staff. A pre-test finding revealed that nurses had below-average knowledge (less than 50%) regarding the ISL of commonly used MDDs in the wards.

This audit also found that most ward staff identified the unavailability of a standard ISL reference list as a major contributing factor to their non-compliance. In the absence of defined guidelines, staff may adopt inconsistent approaches to managing MDDs, leading to variations in labelling practices within the same healthcare facility.

To address these challenges, the Pharmacy Department developed and distributed a clear, standard reference list of ISL for commonly used MDDs. This list is regularly updated whenever new pharmaceutical brands are introduced. Additionally, a series of CNE sessions were conducted for all relevant staff to reinforce the importance of proper MDDs labelling and to provide step-by-step guidance on the new procedure. To further streamline the labelling process, inpatient pharmacy staff apply customised sticker labels to all MDDs containers before supplying them as floor stock.

Post-audit findings showed an increase in the percentage of MDDs with open dates and correct ISLs. Although the 100% compliance target was not achieved, quarterly ward inspections conducted by inpatient pharmacists help ensure continued adherence and identify unsafe practices, thereby minimising medication-related risks. The audit findings were presented during inter-unit meetings involving the Pharmacy Department and other departments across the facility, ensuring timely communication and prompt corrective action.

Limitations and Recommendations

The audits conducted were limited to the wards in HBP and did not include other units or departments that maintain floor stock drugs. Therefore, the findings may not reflect the practices in other facilities.

The implementation of standard labelling practice for commonly used MDDs to other units and departments within HBP are planned. Additionally, this practice will be incorporated into the facility's policy as part of the patient safety initiative.

CONCLUSION

This clinical audit identified a significant gap in the labelling practices of opened MDDs, particularly with regard to the open date and correct ISL. Such deficiencies pose a direct risk to patient safety through the potential administration of expired or unstable medications. Strengthening consistent and complete MDD labelling practices may improve inventory management and reduce the risk of administering expired drugs, thereby enhancing overall medication safety within the wards. Moving forward, these practices will be integrated into routine ward operations and may be expanded hospital-wide as part of a broader patient safety and quality improvement strategy.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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ETHICAL APPROVAL

This audit was registered with the National Medical Research Registry (NMRR-24-01831-NJF) and obtained ethics approval from the Malaysian Medical Research and Ethics Committee, Ministry of Health, Malaysia.

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Appendix 1. In-use shelf life after opening of MDDs

Item	Brand	In-use shelf life		Remarks
		At room temperature (<30 °C)	At 2-8 °C	
Inj.Actrapid 100 IU/ml in 10ml vial	Actrapid	6 weeks[1]	-	
Inj Insulatard 100 IU/ML in 10ml vial	Insulatard	4 weeks[1]	-	6 weeks when stored below 25°C[1]
S/L Glyceryl Trinitrate 0.5mg	Myonit Insta	8 weeks[1]	-	
Benzylpenicillin injection 1.0 MU	Bepen	Used immediately after reconstituted[1]	-	
Budesonide 500mcg/2ml Nebulising Solution	Pulmicort respules	12 hours[1] (Opened single-dose unit)	-	3 months when Opened from foil envelope[1]
Syrup Diphenhydramine 7mg/5ml	Uphadyl paed	6 months[2]	-	
Syrup Diphenhydramine 14mg/5ml	Royce	6 months[2]		
Syrup Bromhexine 4mg/5mL	Dysolvon	6 months[2]	-	
Syrup Lactulose 3.35g/5ml	Unilac	6 months[2]	-	
Syrup Chlorpheniramine 2mg/5ml	Alleryl	6 months[2]	-	
Syrup Paracetamol 120mg/5ml	Fepril	6 months [2]	-	
Heparin Sodium 5000 IU/ml in 5ml	Heparinol	28 days after first withdrawal provided strict aseptic technique[1]	-	
	Unihepa	28 days after first withdrawal provided strict aseptic technique[1]	-	
Inj. Hydrocortisone 100mg	Zycort	24 hours after reconstituted [1]		
Hydroxyethyl Cellulose Jelly	Q-C	1 month[3]		
Inj Tetanus Toxoid	TT vaccine	-	4 weeks[1]	
Magnesium trisilicate Syrup	Hovid	1 month[4]		
Piperacillin and Tazobactam Powder for injection 4.5g	Aurotaz-P	-	24 hours after reconstituted[1]	
Povidone iodine solution	Septidin	6 months[5]	-	
	Betadine	6 months[6]	-	
Salbutamol Respirator solution 0.5%	Pharmaniaga	-	-	3 months when stored below 25 °C[7]

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3. Information from IMEKS Pharma
4. Information from Hovid Bhd.
5. Information from Steriline Sdn. Bhd.
6. Information from product label Povidone Iodine 10% w/v (BETADINE)
7. Information from product label Salbutamol Respirator Solution 0.5% w/v
8. Information from KCK Pharmaceutical Industries Sdn. Bhd.

Appendix 2. Data collection form

Name of Drug	Open Date		Correct In-Use Shelf Life	
	Yes	No	Yes	No
Inj. Actrapid 100 IU/ml in 10ml				
Inj. Insulatard 100 IU/ml in 10ml				
S/L Glyceryl Trinitrate 0.5mg				
Neb. Salbutamol 0.5% Inhalation Solution				
Budesonide 500 mcg/2 ml Nebulising Solution (Respule)				
Syrup Paracetamol 120mg/5ml				
Syrup Lactulose 3.35g/5ml				
Syrup Chlorpheniramine 2mg/5ml				
Syrup Diphenhydramine 14mg/5ml (Adult)				
Syrup Diphenhydramine 14mg/5ml (Paeds)				
Syrup Bromhexine 4mg/5ml				
Magnesium Trisilicate Mixture 200ml				
Inj. Tetanus Toxoid (10 doses)				
Inj. Hydrocortisone 100mg				
Inj. Heparin Sodium 5000IU/ml in 5ml				
Inj. Benzylpenicillin 1MIU (600mg)				
Inj. Piperacillin & Tazobactam 4.5g				
Povidone Iodine Solution 500ml				
Hydroxyethyl Cellulose Jelly (KY Jelly)				

Appendix 3. Simple survey to identify the shortfall in quality

TINJAUAN TENTANG KETIDAKPATUHAN TERHADAP PELABELAN UBAT MULTI -DOSE DI WAD HOSPITAL BALIK PULAU

WAD :

JAWATAN :

TEMPOH BERKHIDMAT :

Sila kenalpasti sebab ketidakpatuhan dan tandakan di ruang yang disediakan:

1. Rasa tidak penting untuk ditulis ☐
2. Tidak cukup masa untuk menulis ☐
3. Terlalu banyak informasi untuk diingat ☐
4. Tidak tahu tentang tarikh luput baru untuk ubat tertentu ☐
5. Menambah beban kerja ☐
6. Lain -lain faktor: _____

Appendix 4. Test to assess knowledge of staff nurses

Ujian Pemahaman tentang Multi-Dose Drugs

Wad:_____ Jawatan: _____ Subjek: ____/___

1. Nyatakan tarikh luput *Inj. Actrapid 100IU/ml* in 10ml (vial) selepas dibuka dan disimpan pada suhu bilik (di bawah 30°C) ?

   _____

2. Nyatakan tarikh luput S/L Glyceryl Trinitrate 0.5mg (GTN) selepas dibuka dari bekas asal?

   _____

3. Nyatakan tarikh luput Neb. Budesonide 500mcg/2ml (Pulmicort) selepas dibuka dari foil envelope dan disimpan di dalam foil envelope?

   _____

4. Apakah tarikh luput Inj. Amoxicillin + Clavulanate 1.2g (Augmentin) selepas direkonstitusi?

   A. 12 jam
   B. 24 jam
   C. Diguna serta merta dan baki dibuang

5. Apakah tarikh luput Inj Piperacillin & Tazobactam 4.5g (Tazosin) selepas direkonstitusi?

   A. 8 jam jika disimpan dalam julat suhu 2-8°C
   B. 12 jam jika disimpan dalam julat suhu 2-8°C
   C. 24 jam jika disimpan dalam julat suhu 2-8°C