REDUCING THE EXTERNAL GALENICAL PREPARATION ERRORS AMONG NORTHERN SEBERANG PERAI CLINICS

Wan Y¹, Nurul Jannah S², Ooi HL³, Nor Aishah I⁴, Anis Humaira M², Suriati S⁵, Nursyafikah MS³, Muhammad Alif Halimi AK³ ¹Butterworth Clinic, ²Tasek Gelugor Clinic, ³Mak Mandin Clinic, ⁴Sungai Dua Clinic, ⁵Kepala Batas Clinic

1. SELECTION OF OPPORTUNITIES FOR **IMPROVEMENT**

| Problems | S | М | Α | R | Т | Score |
|--|-----------------------------------|----|----|-----------|----|-------|
| High rate of unclaimed medications among Value Added Services (VAS) patients | 16 | 15 | 11 | 8 | 10 | 60 |
| High rate of repeated intervention in pharmacy | 15 | 15 | 14 | 15 | 12 | 71 |
| High incidence of errors in external galenical preparation (EGP) among Northern Seberang Perai (SPU) clinics | 16 | 18 | 15 | 23 | 20 | 92 |
| Overlapping medication due to multiple follow up in different clinic. | 18 | 11 | 15 | 20 | 18 | 82 |
| Total Members: 8 | Score: 1: Low 2: Moderate 3: High | | | e 3: High | | |

EGP errors cause medication error, reduce efficacy in treatment, increase wastage and medical cost Detecting no. of errors via observing EGP and checking

galenical preparation labels Prevention of medication preparation errors can improve medication safety and optimization of treatment

Standardization of protocols for preparation and label, education and training

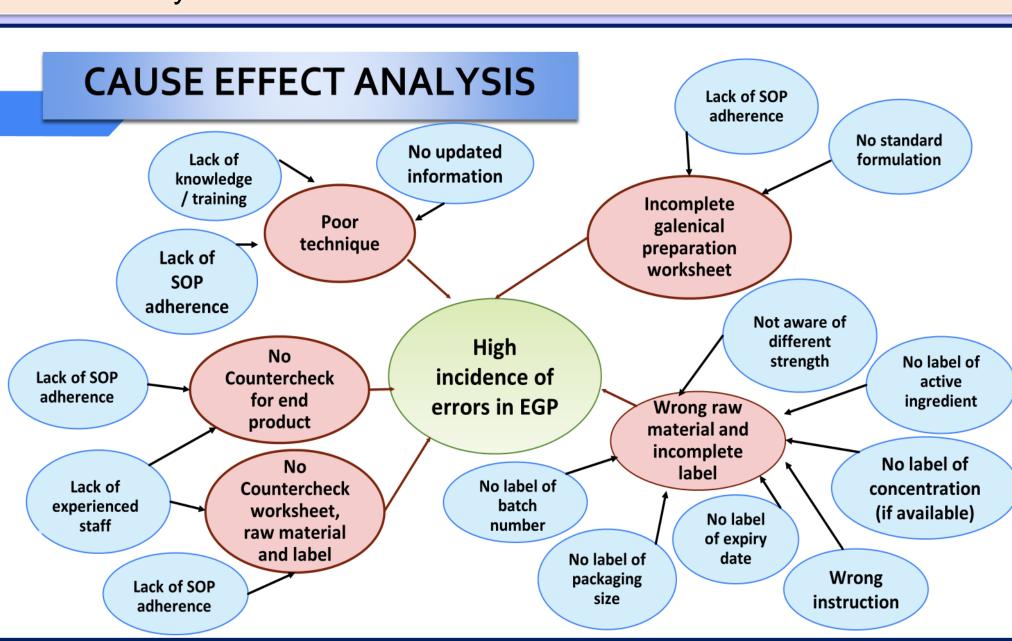
Study and remedial measure can be completed in 1 year time

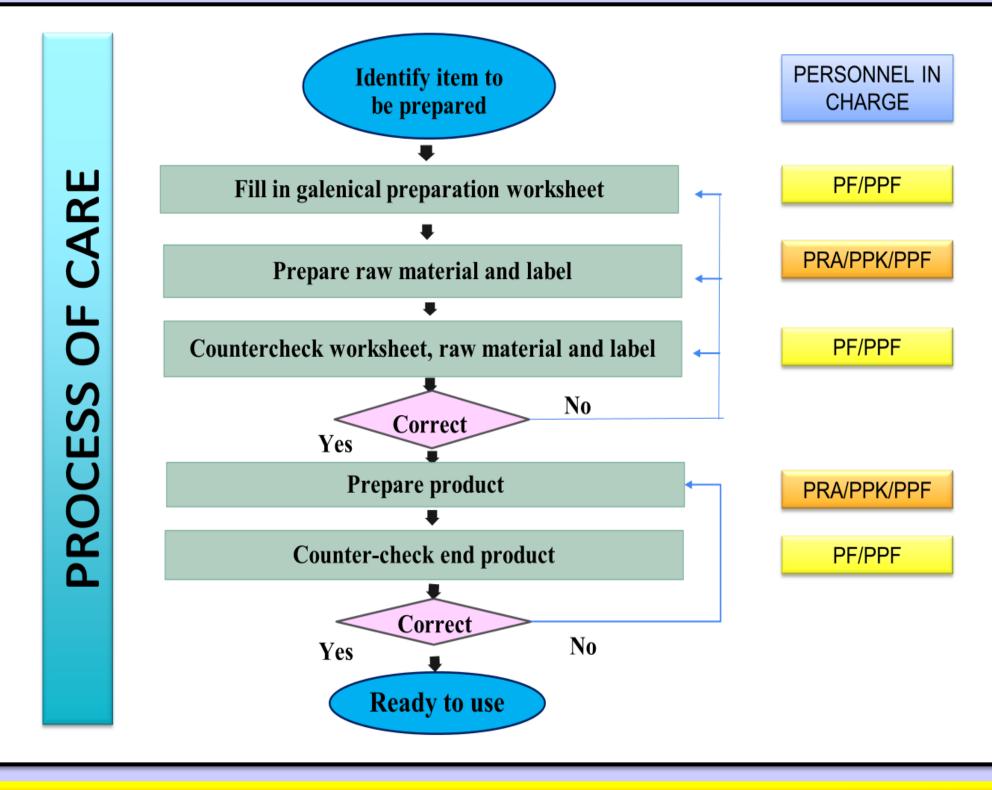
LITERATURE REVIEW

Medication errors may be due to human errors, but it often results from a flawed system with inadequate backup to detect mistakes³. Lack of standardization formula can lead to formulation failure². In addition to monetary cost, patients experience psychological, physical pain and suffering as a result of medication errors⁴.

PROBLEM STATEMENT

- > A retrospective study (2022) found out that 58.3% of the EGP across 6 clinics in SPU had varying in-use expiry dates and incomplete labels.
- > This unstable EGP may lead to ineffective treatment, longer hospitalization, and increased cost of treatment.
- > An error in the preparation will lead to the entire batch of product to be rejected, increasing the EGP waste and medical expenditures
- > Factors contribute to the errors include lack of knowledge, lack of product information updates and non-adherence to work procedures.
- > This study aims to reduce incidence of error in EGP.





2. KEY MEASURES FOR IMPROVEMENT

General Objective

Specific

To reduce incidence of error in EGP from 61.1% in May 2022 to 0% in July 2023

To verify the incidence of EGP errors in SPU clinics from May 2022 to July 2023

To identify the contributing factors attributing of EGP errors To formulate and implement the necessary remedial

Objectives measures to reduce EGP errors

implemented.

To reevaluate the effectiveness of the remedial measures

STANDARD = 0% preparation error

INDICATOR

Percentage of preparation with error(s) detected:

Total number of preparation with errors *

X 100%

Total number of external galenical preparation

*1 preparation might have few errors, considered as 1 preparation error

Definition Term

Preparing creams, lotions, oral solutions that are not Galenical available commercially preparation

Medication Any preventable event that may cause or lead to inappropriate medication use or harm the patient, at any error phase of drug therapy

Indicate that something is on the outside of a surface or **External** body

The end of the application period, in which a medical **In-use expiry** product may be taken or applied after the package has been date opened, respectively after a first dose of the medicinal product has been taken from the package

3. PROCESS OF GATHERING INFORMATION

Study Design

Remedial:

Post-remedial:

C1: Feb 23

Process

C2: June 23

Study Period

Study Tools

Data collection

 May 22 – July 23 Cross-sectional study

Study Frame

• Pre-remedial: July 22

C1: Aug 22- Jan 23

C2: March 23 – May 23

Inclusion Criteria

✓ All the EGP prepared.

- - Questionnaires

Study Samples

form

- No. of EGP prepared
- No. of EGP labels

Exclusion Criteria

χ All the EGP which might be used internally (eg: Liquid paraffin)

Cycle

Cycle

4. ANALYSIS AND INTERPRETATION

Standard

MODEL OF GOOD CARE

Criteria

| Fill in galenical preparation worksheet before proceeding worksheet 2. Fill in PhIS system (If available) 100% 10.5% 1 | | | | | Remediai | Cycle | Cycle |
|--|--------------|----------|---|--------------|----------------|--------------|--------------|
| Prepare raw material and label 100% 10 | galenical | 1. | worksheet before | 100% | 93% | 100% | 100% • |
| material and label Correct raw material, aware of different strength preparation Complete label with 1. Active ingredient 2. Concentration (if available) 3. Correct instruction 4. Batch number 100% 92.6% 100% 100% 5. Expiry date 100% 95.3% 98% 100% 6. Packaging size 100% 63.9% 86.9% 100% 6. Packaging size 100% 63.9% 86.9% 100% 76.8% 100% 94.4% Countercheck worksheet, raw material and label before proceeding to preparation 2. Staff involved (PF/PPF) have good knowledge for counterchecking (n=42) Prepare Product 1. Prepare the product following the worksheet generated 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product Counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecked by a Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking counterchecking (PF/PPF) have good knowledge for counterchecked by a Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking | • | 2. | Fill in PhIS system (If | 100% | 10.5% | 43.4% | 74.2% |
| 1. Áctive ingredient 2. Concentration (if available) 3. Correct instruction 4. Batch number 5. Expiry date 6. Packaging size Countercheck worksheet, raw material and label before proceeding to preparation 2. Staff involved (PF/PPF) have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product Countercheck 1. Countercheck the worksheet, raw material and label before proceeding to preparation 2. Staff involved (PF/PPF) have good knowledge for counterchecking (n=42) Prepare 1. Prepare the product following the worksheet generated 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product Countercheck and product Countercheck by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking | material and | 1. | correct raw material, aware of different | 100% | 100% | 100% | 100% |
| 3. Correct instruction 4. Batch number 5. Expiry date 6. Packaging size Countercheck worksheet, raw material and label before proceeding to preparation 2. Staff involved (PF/PPF) have good knowledge for counterchecking (n=42) Prepare 1. Prepare the product following the worksheet generated 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product Countercheck end product Countercheck end product 2. Staff involved (PF/PPF) have good knowledge for counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking | | 1. | Active ingredient Concentration (if | | | | |
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| raw material and label before proceeding to preparation 2. Staff involved (PF/PPF) have good knowledge for counterchecking (n=42) Prepare 1. Prepare the product following the worksheet generated 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product Countercheck end product 2. Staff involved (PF/PPF) have good knowledge for counterchecking | | 1. | | 100% | 42.2% | 76.8% | 97.7% |
| following the worksheet generated 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product 1. End products counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking | raw material | 2. | material and label before proceeding to preparation Staff involved (PF/PPF) have good knowledge for counterchecking | | | | |
| 2. Personnel prepare external galenical product have good knowledge on EGP (n=11) 3. Personnel prepare based on updated information Countercheck end product end product 1. End products counterchecked by a Pharmacist / Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking 100% 54% 65% 69% 4.7% 100% 100% 52.8% 76.2% 100% 71.3% 81.8% 89% | • | 1. | following the | 100% | 100% | 98.7% | 100% |
| 3. Personnel prepare based on updated information Countercheck end product end product 1. End products counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking 100% 52.8% 76.2% 100% 71.3% 81.8% 89% | | 2. | Personnel prepare external galenical product have good knowledge on EGP | 100% | 54% | 65% | 69% |
| end product counterchecked by a Pharmacist / Pharmacist assistant 2. Staff involved (PF/PPF) have good knowledge for counterchecking | | 3. | Personnel prepare based on updated | 100% | 4.7% | | |
| Pharmacist assistant 2. Staff involved 100% 71.3% 81.8% 89% (PF/PPF) have good knowledge for counterchecking | | 1. | counterchecked by a | 100% | 52.8% | 76.2% | 100% |
| | | 2. | Pharmacist assistant Staff involved (PF/PPF) have good knowledge for counterchecking | 100% | 71.3% | 81.8% | 89% |
| | | | | | | | |

Pre-remedial, ABNA was 61.1%

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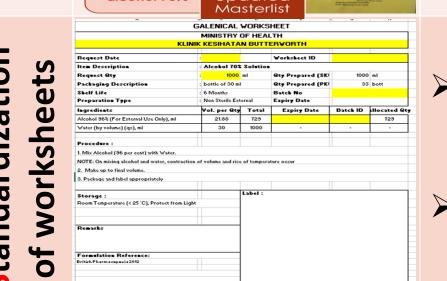
7. WHO guideline Poster ini dibentangkan di Konvensyen QA Kebangsaan Kali ke-12, 8-10 Oktober 2024, Negeri Sembilan

5. STRATEGY FOR CHANGE

First Cycle Remedial **ViMaSSS**

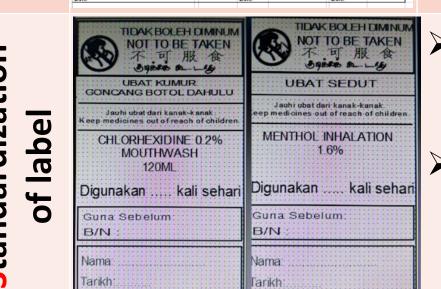


- ➤ Virtual CME involve 6
- > To improve SOP adherent
- To improve knowledge of staff (PF/PPF) for counterchecking
- > To improve knowledge of personnel involved (PRA/PPF) on stability data
- > Through JKUT meeting, delist some preparations & update current practice
 - > Update master list to get updated information



of preparations

- > 6 New External Worksheets made available in M. Excel & shared among clinics in a shared folder > To
- formulation improve documentations in EGP



- ➤ All the labels made available in Argox label & shared all clinics in a shared folder. To complete labelling of active
- ingredient & conc. (if available), correct instruction, BN, expiry date & packaging size

Second Cycle Remedial



Added

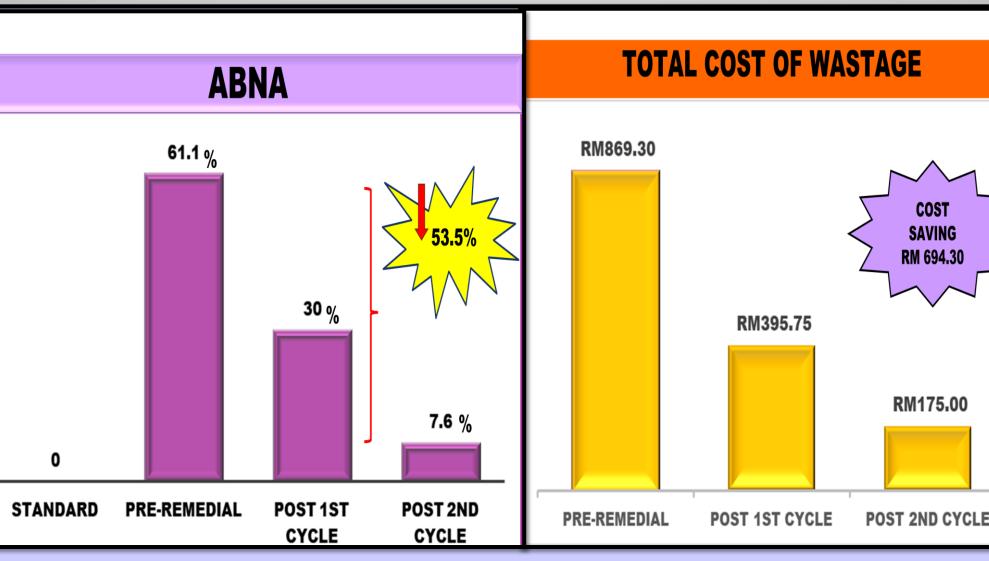




6. EFFECTS OF CHANGE

PERCENTAGE OF LABEL ERRORS

7.4 2.2 0.0 1.8 1.0 0.0 0.0 0.0 CONCENTRATION PACKAGING EXPIRY CORRECT BATCH SIZE DATE INSTRUCTION NUMBER (IF AVAILABLE) ■ Pre-Remedial ■ Post 1st Cycle ■ Post 2nd Cycle



Conclusion

- ABNA was successfully reduced from 61.1% to 7.6%.
- The main contributing factors were incomplete documentation, lack of a counterchecking system before preparation and after production, followed by incomplete labelling.
- Remedial measures (Virtual CME, Master list, Standardization of worksheet, Standardization of label & Sticker gun label) capable of resolving EGP errors
- The cost of wastage from EGP was decreased from RM869.30 to RM175.00

7. THE NEXT STEP

- Continuous education on galenical preparation and product updates annually to staff especially new staff
- ViMaSSS will be updated periodically and shared among SPU clinics
- Audit will be done by pharmacist periodically
- Remedial measures may share with other facilities

ACKNOWLEDGEMENT

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