**Study Protocol**

**Assessment of competency among private clinics and community pharmacies towards requirements of labelling of dispensed medicine in Federal Territory of Labuan, Malaysia**

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**Study site/s:**

Community Pharmacies & Private Clinics in Federal Territory of Labuan

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**List of Abbreviations**

-NOT APPLICABLE-

# **RESEARCH SYNOPSIS**

| **Study title** | Assessment of competency among private clinics and community pharmacies towards requirements of labelling of dispensed medicine in Federal Territory of Labuan, Malaysia. |
| --- | --- |
| **Study Population** | All inspected private clinics and community pharmacies by the Labuan Pharmacy Enforcement Branch involving a total of 5 community pharmacies and 17 private clinics. |
| **Study Design** | A cross-sectional study reviewing compliance of the private clinics and community pharmacies on the labelling of dispensed medicines.  A data collection form will be used to collect data prospectively from January 2023-January 2024. The form needs to go through face and content validations and pre-tested. Briefing and training sessions must be conducted with all data collectors to assure the validity and reliability of the data collected. The appointed data collectors are Pharmacy Enforcement Officers from Labuan Pharmacy Enforcement Branch.  The compliance level of community pharmacies and private clinics towards medicine labelling requirements were measured by scoring the medicine labels obtained from the staff of community pharmacies and private clinics. The labels were scored according to the Regulation 12 (1) and Regulation 12 (2) of Poison Regulations 1952.  Descriptive statistics in numbers and percentages were used to report the compliance level of retail pharmacies and private medical clinics. The compliance level was analysed based on the following formula:  Compliance rate R = [Score for reviewed medicine labels/Total score of the labels based on the requirements] x 100% |
| **General Objective** | To assess the competency of staffs among private clinics and community pharmacies towards the requirements of labelling of dispensed medicine |
| **Specific Objectives** | 1. To identify the most highly absent requirement on the dispensed medicine labels. 2. To compare compliance rate towards the requirements of labelling of dispensed medicine between private clinics and community pharmacies. |
| **Study endpoints/outcomes** | 1. All private clinics and community pharmacies in Federal Territory of Labuan, Malaysia achieving 100% compliance towards the requirements of labelling of dispensed medicine. |
| **Sample Size** | All private clinics and community pharmacies in W.P. Labuan |
| **Study Duration** | 1 year (February 2023 - February 2024) |

**1.Background and Significance**

Dispensing labels which are pasted on prescribed medicines by the clinic or community pharmacy provide administration instructions and important warnings for the patient. A poor label will result in confusion of the patient and in serious cases may lead to a medication error. In previous studies, labelling errors – for example, wrong patient name, drug name, strength or form – and wrong/incomplete instructions on a dispensing label represent a significant proportion of dispensing errors.

A study conducted by Boonstra et al. in the year 2003 in Botswana observed that the mean score of 6461 dispensed medicine labels reviewed was 2.75 out of 5 (95% CI 2.71; 2.78). The requirements reviewed are dosage of drug,name of drug, strength of drug, name of patient, and volume of drug. A dispensed medicine label with a score of 2.70 and above was regarded as satisfactory. However, the rate of dispensed medicine labels that were fully compliant was not reported. While another study conducted by Athuraliya et. al in Sri Lanka in the year 2016 observed that out of 5756 dispensed medicine labels reviewed, only 43.3% were found to be adequately labelled. The interpretation of an adequate labelling of dispensed medicine varies depending on the countries’ laws and regulations as well as their social norms.

In Malaysia, the legal requirements for labelling of dispensed medicine are enforced under Regulation 12(1) of the Poison Regulation 1952. The regulation states that “where any poison is sold or supplied as a dispensed medicine, or as an ingredient in a dispensed medicine, the container of such medicine shall be labelled, in a conspicuous and distinct manner”. A medicine label must include the name and address of the supplier or seller, the name of the patient or purchaser, the name of medicine, adequate directions for the use of such medicine, the date of delivery of such medicine, and where such medicine is sold or supplied and entered in a prescription book, with reference to the serial number of the entry in such book relating to such sale or supply. Under Regulation 12(2) of the same regulation, “any poison or medicine containing any poison is sold or supplied as a dispensed medicine, or any medicine in any container ready for sale as a dispensed medicine, there shall be labelled on the container the words “Controlled Medicine” or “Ubat Terkawal”. For medication intended for external use, Regulation 12(3) states that “any poison or medicine containing any poison is sold or supplied as a dispensed medicine for external use, the container of such poison or medicine shall be labelled conspicuously and distinctly with the words “Not to be Taken” or “For External Use Only” in English, Malay, Chinese and Tamil printed in red or on a red background” . This regulation governs the Malaysian law on medicine labelling. These criteria should be present on a label of a dispensed medicine.

In fact, the Pharmacy Enforcement Branch of the Ministry of Health conducts annual audits on community pharmacies and private medical clinics to ensure that their labels comply with the above-mentioned regulations.

A study in Sarawak showed that the full compliance towards the requirements of labelled dispense medicine among community pharmacies (CP) and private medical clinics (PMC) were 23.7% and 41.6%, respectively. The median compliance score of PMCs (0.83) was significantly higher (P<0.001) than RPs (0.67). The requirements of LDM with the lowest compliance were name of medicine (53.1%), followed by name of patient (31.9%) and date of dispensing (25.6%).

There are no similar studies conducted in Labuan hence it is with great interest that the investigators conduct a similar study. (1)

**2. Objective**

## To assess the competency of staffs working at the community pharmacy and private clinics towards the requirements of labelling of dispensed medicine

# **3.Methodology**

Private clinics and community pharmacies inspections are part of a routine work for Enforcement Pharmacists. During the routine inspections, the investigator will produce a medical prescription which clearly states the name of a fictional clinic, fictional patient name and address, total amount of medicine to be supplied and the dose in accordance to Section 21, Poisons Act 1951, and request staffs at the clinic or pharmacy who is in charge of medication dispensing to produce a label in accordance to Regulation 12, Poisons Regulation 1952. The investigator will then cross check the medicine label's compliance with the law and score it accordingly.

**3.1 Study Type and Design**

Cross sectional study

**3.2 Study Population**

Staffs involved in medication dispensing process working at private clinics and community pharmacies in W.P. Labuan during the study period 1 March 2023 - 31 December 2023.

## **3.3 Inclusion Criteria**

## Staffs involved in medicine dispensing at community pharmacies and private clinics in the Federal Territory of Labuan, Malaysia.

## **3.4 Exclusion Criteria**

* Staffs working at Veterinary Clinics

## **3.5 Withdrawal Criteria**

Not applicable.

**3.6 Sample Size**

Universal sampling of staffs working at5 community pharmacies and 17 private clinics

**3.7 Study Duration and Timeline**

* Stage 1, inspection of clinics and community and assessing compliance- 4-6 months
* Stage 2, data collection and data analysis - 3 months
* Stage 3, presentation and publication - 6-12 months

**3.8 Study Visits and Procedures**

Not applicable.

# **3.9 Statistical Analysis Plan**

Descriptive statistics in numbers and percentages were used to report the compliance level of retail pharmacies and private medical clinics. The compliance level was analysed based on the following formula:

Compliance rate R = [Score for reviewed medicine labels/Total score of the labels based on the requirements] x 100%

## **3.10 Risk and benefit to study participants**

This study does not present any direct benefit to the participants. However the study does provide a better understanding of their compliance towards the law.

# **3.11 Risk Benefit Assessment**

As stated above, there is minimal risk from the investigational product and study procedures. Study findings shall potentially greatly improve compliance towards the law. The expected benefit outweighs the minimal risk to subjects and thus this study should be supported.

# **3.12 Ethics of Study**

Study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and approved by the Medical Research and Ethics Committee (MREC).

# **3.13 Informed Consent/Assent Process**

No consent will be taken from participants as they are bound by the law to demonstrate their competency on the matter.

# **3.14 Privacy and Confidentiality**

Subject’s names will be kept on a password-protected database and will be linked only with a study identification number for this research. The identification number instead of patient identifiers will be used on subject data sheets. All data will be entered into a computer that is password protected. On completion of study, data in the computer will be copied to CDs and the data in the computer erased. CDs and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study. The CDs and data will be destroyed after that period of storage. Subjects will not be allowed to view their personal study data, as the data will be consolidated into a database. Subjects can write to the investigators to request access to study findings.

# **3.15 Conflict of Interest**

None

**3.16 Publication Policy**

No personal information will be disclosed and subjects will not be identified when the findings of the survey are published.

**3.17 Termination of Study**

# The sponsor may decide to terminate the study at any time.

# **References**

1. Loo, Shing Chyi, et al. “Compliance of Private Primary Health Care Facilities Towards Requirementsof Labelling of Dispensed Medicine in Sarawak.” *Current Drug Safety*, vol. 17, no. 3, Bentham Science Publishers Ltd., Aug. 2022, pp. 176–82. *Crossref*, https://doi.org/10.2174/1574886316666211006113948.
2. Ting, Chuo Yew, et al. “Compliance of Community Pharmacists and Private General Medical Practitioners With Malaysian Laws on Poisons and Sale of Drugs.” *Therapeutic Innovation & Regulatory Science*, vol. 51, no. 4, Springer Science and Business Media LLC, July 2017, pp. 439–45. *Crossref*, https://doi.org/10.1177/2168479017699531.