

Compliance of Private Primary Health Care Facilities on the Requirements of Labelling of Dispensed Medicine in Sarawak



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Introduction

Compliance on the requirements of labelling of dispensed medicine (LDM) among private primary health care facilities (PPHCF) were crucial in promoting appropriate use of medicines

Objective

This study aimed to examine the rate of compliance on the requirements of LDM among retail pharmacies (RPs) and private medical clinics (PMCs).

Methods

1. A cross-sectional study was conducted from April 2019 to January 2020 across all inspected premises in Sarawak.
2. Minimal sample size RPs and PMCs needed for this study were found to be 90 and 150 respectively
3. Proportionate Stratified random sampling was employed to select premises.
4. Publics who attended RPs and PMCs and having medicines dispensed, were consented to participate in the study upon exiting the premises.
5. Only products sold or dispensed that are listed in the poison list in Poison Act 1952 were included, and those who refused to give out consent would be excluded from the study.
6. Subsequently, the dispensed medicines of participants were examined for its compliance on the requirements of LDM, and recorded into self-developed data collection form.
7. Compliance score was the percentage of LDM that fulfil the requirements under the Regulation 12 of Poisons Regulations 1952.

Discussion & Highlights

1. PMCs more comply to the LDM requirements under regulation 12 of Poison Regulation 1952.
2. Full compliance rate toward the requirements **were concerning (<50%)**, which indicate more than half of the patients received incomplete medicine labels when received medicine supply.
3. Three of the errors (patient's name, name & address of facilities, and date) were significant higher among RPs; as **Medicine was found dispensed without labels [14 RPs & 6 PMCs]**
4. **Avoid pre-packing or repacking** to avoid incomplete or missing of medicine name
5. **Limitation:** Data were collected in the state of Sarawak thus it might not be generalizable to whole Malaysia

Results

1. A total of 414 LDM were examined, with 135 from RPs and 279 from PMCs [Table 1].
2. The median compliance score of PMCs significantly higher than RPs [Table 2]; the full compliance on the requirements of LDM among RPs and PMCs were 23.7% and 41.6%, respectively [Table 3].
3. The requirements of LDM with least compliance was labelling of medicine name (53.1%), followed by patient name (31.9%) and date of dispensing (25.6%) [Graph 4].
4. Among the LDM for external used preparations reviewed (n = 22), half of them were not labelled with "not to be taken" or "for external use".

Table 1: Background Data

Variables	Retail Pharmacy n(%)	Private Medical Clinic n(%)
Premise Area	96 (100.0)	154 (100)
Kuching	43 (44.8)	78 (50.6)
Sibu, Sarikei, Kapit	21(21.9)	35 (22.7)
Bintulu	8 (8.3)	12 (7.8)
Miri, Limbang	24 (25.0)	29 (18.8)
Labelling of Dispensed Medicines Screened	135 (32.6)	279 (67.4)

Table 2: Median compliance score on labelling of dispensed medicine screened

Variables	Retail Pharmacy	Private Medical Clinic	Z statistic (df) ^a	P Value ^a
Median Compliance score (IQR)	0.67 (0.33) ^b	0.83 (0.17) ^b	-7.14	<0.001

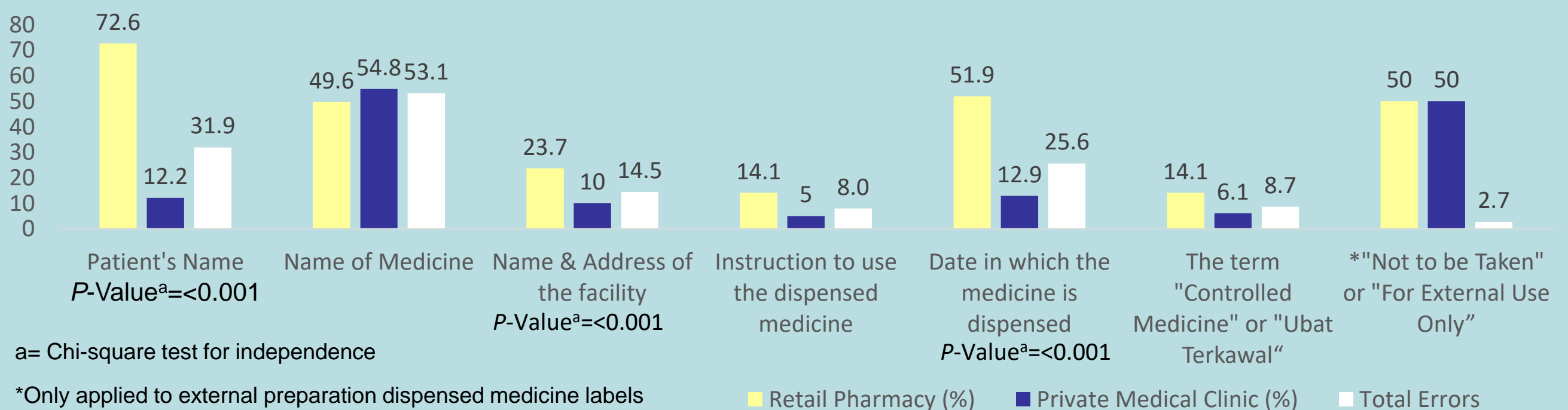
^aMann-Whitney test; ^bskew to the left; df=Degree of Freedom

Table 3: Fully compliance rate on labelling of dispensed medicine screened

Variables	n	Fully comply n (%)	Not fully comply n (%)	X Statistic ^a (df)	P Value ^a
Retail Pharmacy	135	32 (23.7)	102 (76.3)	12.6	<0.001
Private Medical Clinic	279	116 (41.6)	163 (58.4)		

^a Chi-Square Test; df=degree of freedom

Graph 4: Common Errors Found on Labelling of Dispensed Medicine Screened (%)



Conclusion

1. The full compliance rate on the requirements of LDM among RPs and PMCs were low.
2. More stringent enforcement inspections reviewing filled medicine envelope labels are necessary
3. Public education about their rights demands for fully complied LDM could be the solutions.

References

1. Ting CY, Loo SC, Ting H, Ang WC, Jabar AHA. Compliance of Community Pharmacists and Private General Medical Practitioners With Malaysian Laws on Poisons and Sale of Drugs. Therapeutic Innovation & Regulatory Science. 2017;51(4):439-445
2. Neoh C, Hassali M, Shafie A, Awaisu A, Tambyappa J. Compliance Towards Dispensed Medication Labelling Standards: A Cross-Sectional Study in the State of Penang, Malaysia. Current Drug Safety. 2009;4(3):199-203