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The Medication Labeling Compliance in Homecare Settings: A Cross-Sectional Regulatory Review

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Abstract
Labeling of medication is a critical part in ensuring patient safety, especially in homecare settings, where the role of the professional in monitoring the patients is minimal. The aim of this research was to review the regulatory compliance of the medication labeling in prescriptions dispensed at home among community homecare and private homecare pharmacy in Portugal and France. Two hundred and fifty facilities were audited randomly out of which the number of medication packages audited was 410. The determination of the labels was done on the ground of local regulatory requirements and WHO standards of labeling, with particular attention to legibility, clarity of the name of the drug, the presence of an expiry date, patient-specific instructions, and auxiliary warning. The findings indicated that 62 per cent of the labels complied with all the regulatory requirements but most of them lacked storage directions and font sizes. areas that use automated labeling systems demonstrated an increase compliance rate. In interviewing the employees in the pharmacies, it was found that shortage of training and time pressure were primary factors that led to non-compliance. This paper presents the fact that there are a number of deficiencies in medication labeling issues during homecare delivery and identifies the importance of establishing standard labeling requirements, audits, and pharmacist-based interventions to promote patient safety and compliance with regulation.

Keywords: ***Labeling of medications, home facilities, regulation, patient safety, pharmacy practice, standards of the WHO, automatic systems, shortcomings of labeling.***

1. Introduction

1.1 Significance of Proper Medication Labelling in Patient Safety

Reasonable labeling of medication is an essential practice in the field of pharmaceuticals establishing patient safety and proper utilization of medications. Labeled drugs carry essential information on the directions on how to administer the drug, storage and expiry, precautionary measures and warnings to the patient and the caregivers. These labels are further important in ensuring safe and effective application of prescribed treatments particularly where there is no direct professional supervision as in case of homecare.

Health effects of Documented medication errors Documented medication errors have potential to result in adverse drug reactions, drug interactions, and even failures to treat. It has also been revealed that such medication errors were experienced because of poor labeling practices particularly in settings where self-instruction in the use of the medication is involved. In homecare scenarios, where direct care of patients by a healthcare professional might not be possible, the quality of understanding and accuracy of medication labels is directly correlated to the patient compliance and their safety. Therefore, drug labels need to be readable and exhaustive since they will be an important guide whenever patients or caregivers want to use medication.(1)

1.2 Uniqueness of Drug Care in Homecare Pharmacy

There is a peculiar situation with the aspect of homecare pharmacy practice: it is rather challenging to make sure that the medication is labeled properly. In comparison to institutionalized establishments, homecare pharmacies may assist patients in the setting of their homes, at which time professional supervision is not at full effect. The use of pharmacies in such environments is common because they dispense medications and hand them to the patients who might be illiterate or lack the skills to acquire medical vocabulary and act on complex prescriptions. Moreover, most of the homecare patients have chronic illnesses like HIV/AIDS, diabetes, or hypertension and might need a periodical treatment plan. These regimens usually consist of more than one drug at varying times of the day which results in more complexity of the administration of medications. The mentioned complexity is further enhanced by language barriers, age-impairments (e.g. loss of vision or cognitive degeneration), and non-

compliance (because of failure to understand instructions). Consequently, such patients have increased chances of making medication mistakes, in case the labels are illegible or unfinished.

Further, several community homecare pharmacies or even at present, do not possess the means or infrastructure required to adopt, or socialize automated labeling networks. Such systems normally exist in bigger, institutional environments and can enhance substantial consistency and precision of labelling. Absence of such systems means that pharmacists have to resort to manual systems, which are likely subject to errors; time constraints, poor training, and work intensity.

1.3 Responsibility of Regulatory Compliance as a Barrier to Reduce Medication Errors

Regulatory compliance in homecare pharmacies plays an essential role in an effort to reduce medication errors and achieve patient safety. Agencies like European Medicines Agency (EMA), national agencies in Portugal and France set standards of mandatory labelling, which enter into the selection of labelling of medications in such form that they were dispensed with all the necessary information to enable their safe and effective use. These norms commonly consist of drug name, administration & dosage, expiry, storage and their warnings or contraindications of the particular medicine.(2)

These regulations must be adhered to in order to have medications dispensed at home be compliant with local laws on one hand and international regulations (e.g. WHO medication labeling regulations). Poor labeling may cause unclear identification and use of drugs and eventually harm to patients. The regulatory structures are meant to provide control of quality throughout the pharmaceutical industry and therefore it is naughty not to follow up these standards in the case of homecare pharmacies. Labeling non-compliances may lead to medicine errors, drug side effects, and legal consequences to pharmacies and medical practitioners.

Cases such as regulation checks and audit also assist in providing possible gaps in the existing practices and keeping proper track of the latest changes in the regulation to keep pharmacies updated in accordance with the regulatory alteration. This justifies the need to monitor and evaluate constantly medication labeling practice, domestically in terms of homecare, medication error risks increase here, as there is less professional oversight.

1.4 Research question: To Examine the Compliance to Labeling in Home Dispensed Prescriptions in Portugal and France

This was conducted to assess the compliance to the regulatory requirements of the prescription labeling of medicines under home-dispensed prescriptions in 25 facilities in France and Portugal. The aim was to evaluate the levels of compliance of community and the private homecare pharmacies to local and WHO labeling recommendations with critical elements of legibility, the clarity of the drug name, presence of an expiry date, drugs with patient-specific instructions, and addition of auxiliary warnings.

These facilities were audited to check the compliance of labeling by performing random audits on 410 medication packages. The research results will be used to draw conclusions about typical gaps in labeling practices, along with determining the factors that might affect the level of compliance, including time constraints, the lack of training, and labeling systems that can use only hands. It is also interesting to assess the effectiveness of automated labelling systems that have been proposed as a possible method in solving this problem of compliance and avoidance of medication errors.

Finally, the results of the research will help to better understand the situation with medication labeling in homecare and offer useful recommendations to the policy based on concrete findings.(3)

2. Methodological and Materials

2.1 Design of the Study and Method of Audit

The method used in the research was a regulatory cross-sectional audit to determine how closely medication labeling practices were complied with in the Portuguese and French homecare pharmacies. Homecare pharmacies and medication packages to be audited were chosen using the random sampling method, and the sample was representative. There were 25 homecare pharmacies chosen and 410 packages of medication audited in these establishments.

The audit plan was also designed based on the approach of comparing medication labels with the known established regulatory standards such as the labeling guidelines of WHO- and locally established regulatory requirements. The objective of the audit was to determine the shortfalls and act in areas of compliance by bringing into consideration essential details like the legibility of the drugs, name pronouncement of drugs, existence of expiry date, personal instructions to the patient, and side indications to the patient. The assessment of each facility

was done separately and the data were gathered in a three month period giving an overview of the practices in the homecare setting as at the point of assessment.

Besides the labeling audit, pharmacists and support personnel were interviewed to gain insight into their motivation to their non-improvement, including lack of training, shortage of time, trial and error labeling, and manual labeling systems.(4)

2.2 The Criteria of Choice of Homecare pharmacies and Medication Samples

The selection of homecare pharmacies was made according to definite inclusion criteria which enabled us to make the sample as much diverse as possible and allowed preserving the relevance of the audit. The subsequent criteria were used:

Location: An attempt was made to have a balance in the urban and rural pharmacies in both Portugal and France to address any difference in practices in labeling, which might have been located regionally.

Pharmacy Type: It comprised both the community and private home care pharmacies in order to explore diverse dispensing settings.

Homecare Services: Pharmacies offering homecare services whereby medications are delivered to the patients were given priority to become part of the study; these are settings where labeling of medications becomes a determining factor in patient safety.

Regulatory Compliance: To check the accuracy of the research findings to regulated pharmacy grounds, only those pharmacies that had a licensed pharmacist and the relevant operating credentials were incorporated into the study.

The number of pharmacies involved in the study was 25. 16-20 packages of medication were randomly chosen among the records of homecare dispensing activities of each pharmacy. These consisted of all types of prescription drugs with the focus being on the drugs that have special instructions in handling them; the controlled drugs and drugs that have special handling conditions due to temperature sensitivity.(5)

2.3 WHO and National-based label evaluation framework

The danish conceptual framework used in assessing the labels on the medication was based on an analysis of all features that the WHO guidelines suggest on medication labels and also based on the statutory requirements in the two countries of Portugal and France on drug labels. The framework dwelt on the following areas of interest:

Legibility: Font size, contrast and clarity of label were tested on labels. According to the WHO recommendations, the texts have to be readable by patients, especially in homecare conditions where the patients do not have great access to professional assistance.

Drug Name and Dosage: The drug name and dosage instructions were analyzed to determine their clarity since they are essential in correct administration of the drugs. The design of labels should be clear as it should provide the name of the drug, strength, and directions on how to take the medication in a simple language that is not open to interpretations.

Expiry Date: It was determined whether there was a visible and clear expiry date. Expiry dates should be clearly marked to discourage the use of drug after expiry that may lead to safety of the patient.

Patient-Specific Instructions: The labels were checked to see that there were patient-specific instructions regarding the time of the dosage, any special instruction to use, or any advice regarding adherence. Such directions are critical in the appropriate administration of medications especially in chronically ill terms that are being handled in homecare.

Auxiliary Warnings: The availability of warnings (e.g., concerning to the storage conditions, drug interactions or side effects) were assessed. Related warnings should be considered to exclude the risk of using medications because WHO includes guidelines in this sphere as well.

All labels were checked with regards to these criteria, giving special consideration to whether they comply, on the one hand, with local requirements established by the regulator and such international standards as they exist.

2.4 The Measures of the Collection of Data and Compliance Scoring

The main data collection method of measuring the compliance of medication labels in place was the development of a structured checklist audit. This checklist consisted of all the apposite criteria in the WHO guidelines and local rules in each package of medications. Against each label, compliance was rated either as compliant or non-compliant against each of the above mentioned criteria.(6)

In order to have a quantitative assessment of compliance, each medication package was allocated a compliance score according to which number of criteria were met. The scoring system was such:

Compliant: In the instance that all criteria on labeling was satisfied, it was scored as 1 in each criterion.
Non-Compliant: In case one of the criteria was not met or could not be understood as explicit, the label was given 0 as a score corresponding to that criteria.
A percentage of final compliance was achieved by dividing the number of compliant labels against the total of the labels that were audited. This enabled determination of the compliance to regulation on the whole in the pharmacies.

2.5 Pharmacists and Support Personnel interviews

The semistructured interview was used to learn more about issues that restrain compliance with medication labels by conducting interviews with pharmacy personnel, that is, pharmacists, and support staff. The purpose of these interviews was to look at the obstacles and drivers that affected labeling practices at homecare.
The major areas covered by interview guide were as follows:

- Training: The extent to which pharmacists and support personnel were appropriately trained on the standards of labeling and regulatory compliance.
- Time pressure: the effect of workflow, pressures on labeling precision and attention to detail.
- Technology: The issue of automated labeling systems and their influences on efficiency and accuracy of labeling.
- Regulatory Knowledge: The knowledge as of the regulatory requirements of staff and WHO guidelines on labeling medications.

The results of the interviews contributed to the fact that the causes of non-complience (such as inadequate training, manually based work, time constraints of staff) became identified.(7)

3. Regulatory Guidelines of Medications Labeling

An efficient medication labeling is a relevant factor in guaranteeing the patient safety and their adherence to the medicine, especially in an environment where the healthcare professionals might be absent to directly supervise them like in homecare pharmacy practices. Strict standards have been laid out by the regulatory bodies on how medicines are labeled so that there is no fault in providing accurate, clear, and necessary information regarding a particular medicine to be taken by the patients under the prescription of the medicine. Section 2 presents the basic components and required items of medication labels, and addresses the font specification, readability, country-depending differences in the expectations or requirements.

3.1 Core Elements: Name of a Drug, Its Strength, Dosage and Patient Information

Medication labeling serves one of the main purposes to determine safe and correct medication intake to both the caregivers and the patients. There are the following obligatory elements on the medication label that they must include as requested by regulatory perceptions:
The name of the drug: The name of the drug should mentioned clearly on the label in a font readable font. The drug should always be mentioned by its generic name and in cases that a brand name of a drug is mentioned, it must be mentioned in combination with the drug to prevent the occurrence of confusions. In cases where the drugs offered can have trade names, it is imperative to ensure that the generic name does not confuse anyone in the field.
Drug strength: The strength (dosage) of the drug should always be stated giving the dose per unit of the active pharmaceutical ingredient (API) (i.e. 50 mg, 200 mg). This becomes especially significant when medications may be in various strengths like antibiotics or pain medications since in such cases improper dose may cause severe damage.
Dosage Instructions: Good and clear information on dosages is very necessary in making sure that the patients get the right amount of medication at the right time. They have instructions which should contain dose (e.g. one tablet), the way to take it (e.g. orally) and how often (e.g. 2 times a day). It also ought to have any special directions like taking the medication either with food or at a specific time of the day. Strict directions prevent overdose or underexposure, which might make a treatment ineffective or bring some side effects.
Patient Details: To make the medication label personal, there is the need to put specific information about the patient, i.e., the full name of the patient and in some cases, the amount of the drug (i.e., how many pills given..). Patient identification in the label also is beneficial in homecare setting to make sure that the appropriate medication is used by the appropriate personality.(8)
These are the fundamental points that all regulatory authorities demand when giving mediation instructions to patients to make them complete and self-explicable. Deficient or inadequate labelling of any of such central

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components may translate to medication errors that can cause adverse outcome to the patient, or even treatment failure.

3.2 Auxiliary Instructions and Auxiliary Warnings required

Besides the essential components, medication labels should also have additional requirements of mandatory auxiliary instructions and warnings that can make a patient safer. Such guidelines are aimed to help the patients knowing how to take their medication properly and how to store them in a way that will reduce risks of a drug interaction, overdose, or other forms of misuse. The usual auxiliary instruction requirements are:

Storage Instructions: Certain medications, especially the temperature-sensitive types should be stored in a certain condition in order to retain their effectiveness. As an example, some of the biologics, insulin, or liquid drugs might need refrigeration. Such storage requirements should be clearly written in the label such as indicating the need to keep in a cool and dry place or keep refrigerated after opening

Warning Statements: Warning labels are required on certain products and medications which pose a certain risk (e.g., medications that make a person sleepy, medications that induce an allergic reaction or have a drug-drug interaction with other commonly used drugs). As an example, drugs with CNS depressant effects are often accompanied by warnings like, e.g. to avoid taking them with alcohol such as, e.g., a warning on possible drowsiness. Likewise, warnings on medicines such as anticoagulants can mention that one should avoid excessive bleeding or bruising.(9)

Side Effects: The common or severe side effects should be mentioned in the label, particularly in cases where such side effects are likely to affect the choice of the patient in following the treatment regimen. As an example, it should be clear about warnings of irritation on the gastrointestinal display or the rash.

Drug Interaction: In any case, the warning of drug interactions should be included, particularly in case of complex treatment regimens. Such warnings are important in polypharmacy environments, including homecare where the patient could be using many drugs.

Such side warnings play an important role in informing the patients further on safe intake of their medications so that they can develop better decision-making abilities and address seeking medical assistance immediately whenever required.

3.3 Size of Font, readability and clarity of the language

Medication labels should be legible and in a form that they are easily comprehendible to enable that labels are effective. Regulatory guidelines provide font size, contrast, and layout to ensure that any vital information can be readable by the patient particularly in homecare, where he or she may hardly have access to the medical practitioners.

Font Size: It pertains to the font size of things that must be clear like drug name, dosage and expiry date; a large font size must be adopted such that it is legible even to the elderly patients or visually impaired. In case of generic text, a font size of 10-12 pt is generally suggested. Nonetheless, some of the dangerous drugs (e.g., chemotherapy medications) might demand bigger font sizes to underline the significance of certain points.

Legibility: The type of font must be easy to read and not a complex or style type font that may interfere with reading. All labels should also provide sufficient contrast form the text and the background so that all the vital text should be evident even when there is poor lighting.

Language Clarity: Names should be in simple language and lay man terms instead of jargons which may not appeal to the patient. As an example, phrases such as take with food ought to be used as opposed to other medical directions such as take orally after meals.(10)

3.4 The Divergence of Regulatory Expectation When Observed across Countries

Even though the essential regulatory provisions underpinning medication labeling are uniform in most of the regions, country laws and cultural factors might interfere with specific parts of labeling. For instance:

Portugal and France: The countries will have a requirement of labeling medication that comply with the directives of the European Union (EU) but additional requirements may be added regarding the country, which may include language of labels (e.g. Portuguese or French), and local specific warnings due to local health concern.

Language Requirements: The labels of medication are required to be in the official language of a country such as Portugal and France. On patients with alternative language, supplemented labels or directions could be provided either in local languages or foreign languages.

Regulatory updates: There is active regulatory update over medicine labeling both in Portugal and in France, especially over biologics, controlled substances and use of medicine by children (pediatric labeling). The changes that are often made to these updates include warnings or risk management plans of specific groups of drugs, there should be updated labels which fit the emerging safety needs.

4. Results

Recognition of the compliance of the medication labeling in homecare pharmacies has come up with some important findings on the compliance with the regulatory standards and quality of the labels used. The audit of the 410 medication labels included in 25 facilities in Portugal and France helped to gain important insights into the situation in homecare related to medication labeling practices.

Overall Compliance: The general regulatory compliance was determined to be 62 percent, that is 62 percent of the labeled products that were audited fulfilled all the regulatory requirements. This implies that there is a significant discrepancy in the labeling policy among homecare drug stores, and most of the labels are inadequate concerning patient safety and the use of medications. Facilities having manual labeling systems experienced a significant difference in compliance levels, indicating the possible advantages of automation in compliance with the regulatory requirements.

Such Common Deficiencies: On audit, several common deficiencies have been identified and they contributed to the low overall compliance rate. The major ones were:

Absence of Storage Instructions: 34% of the labels did not contain necessary storage instructions on whether the medication was to be refrigerated or stored at a cool and dry place. It is especially worrying with regards to those medicines that have particular storage needs, like biologics and temperature-sensitive drugs, which might have diminished efficacy or higher chances in case of adverse reactions on incorrect storage.(11)

Illegible Fonts: 22 percent of labels were in illegible fonts i.e., not enough font size or not really well contrasted with the background. It is a serious problem in the homecare environment when some patients do not see or have access to professionals that would help with dosing instructions. With fonts that have low legibility, the misuse or even the wrong interpretation of the instruction on medication use can incur more chances of medication error.

Effect of Automated Labeling Systems: The major outcome is that the facilities implementing the automated labeling systems showed a higher complied rate of 28 percent more than those facilitated by manual labeling operations. The automated systems are also more consistent with regard to the label format, font size and the regulatory adherence. The information indicates that the implementation of technology in the labeling of medicine might be very instrumental in enhancing adherence and minimizing human errors especially in crowded environments such as emergent units.

Table 1: Key Results Summary

Outcome Measure	Observation	Performance Metric
Overall Compliance	62% of labels met full compliance	Compliance rate
Missing Storage Instructions	Storage instructions missing in 34% of labels	Missing elements
Illegible Fonts	Illegible fonts in 22% of labels	Font legibility
Automated System Compliance	28% higher compliance in automated facilities	Compliance with automation

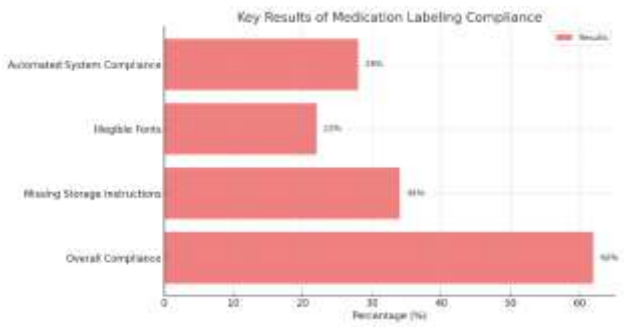

Figure 1: Key Results Of Medication Labeling Compliance

5. Conclusion

5.1 There is Prevalence of Non-conformance amongst the Labeling of homecare practices

This research paper points out that there exist great discrepancies in different medication labeling habit in homecare pharmacies in Portugal and France. The labeling percentage on 410 medication packages indicated that labels did not comply with the regulatory way of doing things as a fully regulatory compliance was represented in 62 percent only. These results indicate that even regardless of the regulatory documents governing medication labelling and standards to which all pharmacies are bound, numerous of them do not meet them, which exposes patients to the risks of making mistakes in medication intake, improper use of drugs, or experiencing undesirable effects. Such deficiencies as a lack of storage instructions, illegible fonts, and compliance with dose instructions were the most prevalent ones in the course of the audit being conducted, and all of them may cause the mistaken use of medications or confusion regarding them even at home, where patients and caregivers are supposed to handle the medications with limited professional assistance.

The storage labels that are missing the storage instructions (34 percent of labels) and illegible fonts (22 percent of labels) are especially troubling because they have a direct effect on the safety and effectiveness of the drug. As a case in point, inaccessibility of storage information may expose bio log Rick medications or insulin to inappropriate temperatures, which can either result in drugs lacking efficacy or compromise the patients. By the same measure, fonts that cannot be read easily might interfere with the comprehension of vital dosage information by a patient, especially by old patients or those with vision problems.

The findings raise concerns that there is no uniformity and the approach towards medication labeling should be systematic within the homecare setting. The lack of proper labeling processes as the study shows may create patient safety risk and non-conformance to the regulatory requirements and as such there is an urgent need to continuously monitor and enhance homecare pharmacy labeling processes.

5.2 The compliance costs and the ability to improve them can be enhanced with automated systems and pharmacist training.

Another of the most impressive results of this research was that the compliance level to automated labeling was 28 percent higher than that of manual labeling system. The automated systems of labeling medications as they improved the facilities that utilized them significantly with regards to regulation requirements, especially with regard to legible medications, instructions on how to store the medications, and the clarity of the doses. There are a number of benefits to the use of technology in labeling of medications that may be achieved such as hygienic application of font sizes, contrast and structure of contents which may largely prevent possibility of human error. Not least, automated systems will assist in simplifying the labeling process, improving its efficiency, especially in high-volume workplaces, such as homecare pharmacies, when pharmacists can have only limited time to take a closer look at each printout. These systems not only enhance accuracy but also save a lot of useful time that can be utilized by the pharmacist in performing other activities that involve providing care to patients.

Besides automated systems, pharmacist training is one more priority towards the enhancement of the compliance with labeling requirements. The interviews with the pharmacy staff indicated that the lack of training and time pressure were the major obstacles to complete compliance with labeling requirements. Training of the pharmacists and support personnel in terms of ensuring that they are well trained in keeping with the recent standards of labeling as also in the regulatory requirements specific to homecare environments will go a long way in filling some of the gaps that have been identified in this effort. The awareness of the need to properly label all the processes and identify possible mistakes as well as improve the quality control procedure in homecare pharmacies can also be achieved through pharmacist-led interventions.

5.3 It is suggested that routine audits and updated regulatory protocols should be used.

Because of the high rate of inconsistencies detected in the labeling practice of medication, the need to have routine audits as part of the daily proceeding in homecare pharmacy arises. Periodic checks may be needed to ensure that regulating pharmacies do not fall short in meeting the regulatory standards, areas that need to be improved, and a feedback to the pharmacy employees. Throughout the regular rounds of assessment of the medication labeling practices, the homecare pharmacies can be kept abreast of the current regulatory requirements and avoid the problem of non-compliance continuing to be a subject of constant concern.

Additionally, the study results indicate that new regulatory guidelines ought to be formulated to handle the unique issues affecting the homecare pharmacies. With the increasing use of homecare environment in the delivery of

patient care, it is possible that there are special regulations required that consider variables like patient demographics, complexity of medication, professional resources. Authorities should also promote the introduction of automated labeling in homecare centers and pharmaceutical staff training to make the staff be compliant with the labeling system.

The other significant issue is that there should be a uniformity in the labeling criteria in different regions so that they should not cause confusion and the pharmacies should have a uniform protocol. This would assist in the establishment of a common ground in medication labeling in homecare environments where the level of safety and care on patients would not be compromised irrespective of the place.

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Conflicts of interest

The authors have no conflicts of interest to declare

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