

Role of Drug Labeling in Promoting Rational Dispensing: A Literature Review

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Abstract: One of the major roles of healthcare professionals is to reduce the incidence of medication errors at healthcare facilities. Poor labeling is one of the major causes contributing towards medication errors and irrational dispensing. The aim of this literature review is to summarize the research findings among developed and developing countries as well as Pakistan related to labeling practices and its role in promoting rational dispensing. A total of 52 published articles were reviewed regarding current labeling practices and factors contributing towards poor labeling practices. The review concluded that labeling practices are in its preliminary stages in many developing countries including Pakistan and is the most neglected area at hospital as well as community pharmacies. There is a need for developing policy regarding devising and implementing standard labeling guidelines on national level. Stakeholders should design the right model to be adopted for dispensing practices in the healthcare system of Pakistan.

Keywords: Drug labeling, extemporaneous preparations, dispensing, pharmacist, medication error

I. Introduction

Dispensing process involves preparation and dispensing of medicines according to a prescription to a person. It also involves proper preparation and labeling of medicines for patient according to the instructions of prescriber [1]. Dispensing is crucial process for assuring rational use of drugs as a small mistake can lead to wrong drug, wrong dose, wrong advice, therefore it is important that drug should be dispensed correctly [2]. One of the important factors affecting dispensing includes labeling of drug products. One of the major causes of medication errors worldwide are related to poor drug labeling. There are different barriers to adequate labeling of the medicines. For instance, in case of unit dose of drug, the one mentioned on the medicine is not similar to the one used by the nurses and practitioners in general. This creates ambiguity and as a result, the nurse relies on his/her knowledge for the unit dose [3]. Another important issue is misreading the label. Nurses in general have a very tough schedule and thus misread the information i.e. overlook the decimal points in the dosage [4]. Not only wrong labeling on medicine is harmful but incomplete labeling information can also cause medication errors. Most of the medication errors are reported when the drug label does not have proper warning signs [5]. Another factor that could lead to medication error is improper labeling font and writing style. This could prevent patient from reading the labeling information properly and may lead to handling errors as well [6]. The label helps the practitioner and the patient to differentiate between look alike and sound alike medicine. This paper focuses upon the different labeling practices followed by dispensers at healthcare facilities worldwide by reviewing past and present literature [7]. The main objective is to systematically identify and review the different labeling practices and their role in improving rational dispensing around the globe.

II. Methodology

The electronic databases PubMed, Google Scholar and Science direct were searched for articles published from January 2005 to June 2015. The search terms used with each database were drug labeling, pharmacists, dispensing and medication error. Full text papers as well as abstracts were retrieved and included in review. A total of 52 studies were retrieved from databases related to drug labeling and medication errors. The studies were categorized on the basis of their country of publishing into developed countries, developing countries and Pakistan. Thirty five studies from developed countries, 14 from developing countries and 3 studies from Pakistan were included in this review (Table 1). Quantitative cross sectional surveys as well as qualitative studies were also included.

Table 1 Details of Country and Number of Included Papers

Regions	Number of studies	Countries
Developed countries	35	USA, Australia, UK, Japan, Germany, Switzerland, Canada, Denmark, Greece, Spain, Italy, Finland, Netherlands
Developing countries	14	Turkey, China, Ghana, Malaysia, India, Taiwan, Qatar, Jordan
Pakistan	3	-
Total		52

III. Results and Discussions

Drug Labeling: A Tool to Promote Rational Dispensing in Developed Countries

The first evidence of study conducted on drug labeling was found in 1996 by Sansgiry, Cady and Patil. They assessed over-the-counter (OTC) medication labels to determine compliance with the Label Readability Guidelines recommended by the Nonprescription Drug Manufacturers Association (NDMA). They also assessed the use of pictures on OTC medication labels. They found that in many cases NDMA guidelines are not followed. Though, the product name was shown in visible font but the indicators and warnings were not written in visible font. The use of pictures was also found to be limited which reduced the visibility of indicators [8].

A study reported large numbers of drugs present in market are not approved by FDA for children usage and only a small number of drugs are duly approved. Many drugs were also not available in correct pediatric dosages increasing the vulnerability of neonates and infants. The liquid formulation of pediatric drugs also lacks making them difficult for pediatric usage. To increase drug compliance pharmacies prepare the liquid formulation of pediatric drugs but they are not tested for expiry, efficacy and stability [9]. A study reported that they found that labeling revision has no significant effect on medication errors and the only options left to reduce the drug contradictions and patient death due to ADRs of any particular drug is to remove the general usage of drug and restrict its availability in market [10]. A study suggested, reasons for medicine labeling are description, identification, avoiding medication errors by providing detailed therapeutic instructions, storage and inventory, thus helps in dispensing [11]. Another study indicated that only the trained dispensing staff was able to dispense medicines properly [12].

Another study conducted in Netherland highlighted that even strict regulations and labeling of drugs before marketing do not fully reduces the chances of medication error incidence prevail [13]. A case study from France explained the clinical view of medication errors due to confusing blisters of drugs. The case study analysis revealed that the French general practitioners hesitate to prescribe generic drugs due to confusing blisters caused by drugs. It is claimed that labeling of generic drugs can reduce the confusions and incidence of ADRs can be reduced [14]. A study from United States reported that due to similar sounding names and look alike pharmacists, nurses and doctors often get confused [15]. In order to solve this problem the researchers used the orthographic (look-alike), phonetic (same sounds) and other similarities to develop a novel system of drug evaluation. It claimed that their system is able to act as preliminary system for confusable drug identification by FDA however, adding more factors of similarity can improve the performance of their tool. Another researcher presented his tool for warning label and prescription information verification. He claimed that his invention is a unique tool for labeling verification and it can help consumers to verify the drugs accurately when it will be printed on one side of drug packages [16].

A review study in Australia claimed that labeling of medicines is the only vital information source for patients. The labeling should therefore be consumer focused. All stakeholders must cooperate with each other in order to achieve the possible benefits of goof medicine dispensing [17]. Studies conducted in different countries revealed that literacy level of patients is directly related to their understanding of drug labeling. In addition, a direct link between number of drug prescriptions and labeling understanding was also found [6]. A similar relationship between literacy and prescription labeling misunderstanding was reported from a study conducted in the United States [18]. It is claimed in a study from the USA that improving the labeling printing can increase medication safety [3, 19]. Limited health literacy of patients is linked to prescription drug misunderstanding and it is due to their inability to understand labels and they get wrong dosage information. In order to reduce this problem the vague and inconsistent labeling must be altered with clear and detail information of drugs [20, 21]. The concurrent injectable drugs in Canada lack adherence to Canadian food and drug regulations due to which labeling of these drugs in Canada is termed unsatisfactory.

The study of the issues related to ampoules and vials labeling in Canada recommended that the subjective and objectives measures taken for drug labeling must be standardized to make drug identification easier, improve labeling designs and make all the drugs in compliance with Canadian food and drug regulations [22]. The analysis of formats used by the U.S. drug manufacturing companies and found that due to lacking standardization of drug labeling formats the number of medication errors is quite high. A comprehensive research to analyze and standardize the labeling system is required to minimize the ADRs and medication errors in the U.S [23].

Use of explicit language usage in drug dosage and frequency information can create a positive influence on less literate patients of the United States. There find a positive relation between the factors and claimed that using more explicit language can assist to improve prescription drug labeling to less literate consumers [24, 25]. The dispensing system lacks standardization due to which studying labeling in different study settings is difficult [26, 27]. The medication labeling improvement is directly related to health literacy of the patients. A standardized system of medication labeling can be used to meet the goal of medication errors reduction [28, 29].

Drug Labeling: A Tool to Promote Rational Dispensing in Developing Countries

The study on Indian professional pharmacists and the frequency of medication errors revealed that medication errors can be broadly of two types that are medication errors that are detected while patient counseling and those that are reported by the patients themselves. Having said this it was claimed that patient counseling can be valuable in reducing the frequency of medication errors. Additionally, it can also help patients to understand the labeling as the information will be given to them by the trained professional pharmacists [30].

The perceptions of consumer groups regarding the OTC labeling readability revealed that consumers prefer the large line and white spacing labels. However, the influence of white spacing was less as compared to the line spacing; while, complementary use of large line spacing and white spacing had a significant impact [31]. It is claimed that dispensing and prescription are important for good drug dosage. There is a lack of studies related to prescription and dispensing in India [32]. A review suggested that a standardized label format with understandable font and language help patient understand the directions and information regarding drug, improving labeling practices leads towards safe medication use and printing of labels using different software could prove crucial in minimizing risks involved in hand made labels [33]. A study from Nigeria revealed that pattern of prescriptions in addition to the formulation methods is very important to improve provision of health services to the patients. The most important reason to label the medication is to help the prescription agents to understand the maximum time of usage in case of extemporaneously used medication like pyridoxine, spironolactone and distilled water etc [34, 35].

Inadequate labeling was reported as source of discrepancy in providing improved patient care. Drugs with similar labeling pose greater risk of dispensing errors so requires strict consideration and monitoring to minimize dispensing errors for this it is important to adopt standard guidelines. Color coded labels could prevent dispensing errors of lookalike sound alike drugs [36, 37]. Literature review of different countries showed that errors in labeling of medicines compromise patient safety and needs to be improved to assure error free dispensing of drugs [26, 38, 39].

Labeling of medications dispensed in hospitals is done in order to give comprehensive and detailed information of medicine and give ease of identification to the patients. Name of medicine, identification of patient, dosage, storage and frequency information, date of manufacturing and expiry in addition to administration route are labeled [40]. The inconsistency of labeling practice may result in inadequate information for the patients and in return increase the chances of medication errors. There can be a number of factors causing inconsistent labeling like absence of pharmacist, look alike drugs, lack of trained dispensers, erroneous prescription and verification [7, 41-43].

The literature shows that most of the studies conducted were to evaluate the medication errors due to inadequate prescribing, dispensing and administration of medicines and how medication errors can be reduced by adopting different strategies. Few studies have been conducted on medication errors due to inadequate dispensing including labeling at community pharmacies. Very few studies have been conducted on assessment and evaluation of current labeling practices at pharmacies situated in healthcare facilities. More studies are required to assess compliance with labeling guidelines and proposed strategies to improve labeling practices [44-47].

Drug Labeling: A Tool to Promote Rational Dispensing in Pakistan

Labeling practices are in its preliminary stages in Pakistan. It is the most neglected area at hospital as well as community pharmacies. The dispensing practices at community pharmacies are not up to the mark in Pakistan [48]. The factors causing medication errors of clinical significance result in serious patient morbidity or mortality. The naming, labeling, and packaging of lookalike and sound alike drugs contribute to errors that can cause injuries and deaths. Laws exist but their implementation is major factors contributing towards inappropriate labeling practices, same is true for the hospital pharmacies [49, 50].

No study to the best of our knowledge has been conducted to evaluate labeling practices at hospital pharmacies till date. There is an urgent need to devise a plan and strategies to identify the gaps in labeling practices in Pakistan. Improvements can be made by educating the dispensers regarding good dispensing practices [51, 52].

IV. Conclusion

The review concluded that safe use of medications requires a team-based approach focused on medication safety with effective 2-way communication, use of technology to prevent and identify errors, diligent monitoring of the medication's effects on the patient, and use of standardized protocols to decrease the likelihood of a medication error. There is a need for developing standard labeling guidelines on national level which incorporates a standardized format of label along with specifications for label layouts and instructions to be mentioned along with pictograms. Furthermore studies should be conducted in future to ascertain the status of adherence to labeling guidelines in the country. Moreover, qualitative studies should be conducted to identify the various barriers for effective labeling practices in Pakistan. Intervention studies based on implementation of particular model, color coded labels for labeling and its impact on overall adherence might be conducted. Different studies can be conducted which can assess the need and acceptability of the right model to be adopted for dispensing practices in the healthcare system of Pakistan.

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