

ORIGINAL RESEARCH PAPER

Pharmacology

PHARMACEUTICAL REGULATION IN CONTEXT: QUALITY OF PHARMACEUTICAL SERVICE OF PRIVATE PHARMACIES IN LAO PDR.

KEY WORDS: Quality, pharmaceutical, service, pharmacies, Lao PDR

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ABSTRACT

Quality of pharmacy services has become a major issue worldwide, especially in low-income countries which community pharmacies are becoming the first choice of people who are living in the areas that far from public health sector. Food and drug authority of Laos has putted many efforts to improve the pharmaceutical services of private pharmacy in Lao PDR. However the methods and its cost benefit should be evaluated to ensure that those methods are effective and economic. Therefore the objective of this review is to review the effort of food and drug authority on improvement of pharmaceutical service in country, and in order to find out the further studies and interventions needed.

1. Introduction

Quality of pharmacy services has become a major issue worldwide, especially in low-income countries which community pharmacies are becoming the first choice of people who are living in the areas that far from public health sector. The situation in Laos is similar to other developing countries in South East Asia [1]. The Lao PDR has faced enormous challenges in ensuring the quality of drugs that have been distributed in country. After the full opening of the trade in 1986, the number of pharmacies, especially Pharmacy Level 3, spread widely throughout the country. The pharmacy level 3 is managed by the doctors or nurses, because in that time there were no many pharmacists in Laos. Therefore, food and drug regulatory authority allowed doctors and nurses to open pharmacy as level 3 pharmacy in order to improve the essential drugs accessibility of population. After that, pharmacy become a good business, thus the major of pharmacy become more popular and later as result of an increasing pattern of level 1 pharmacy, especially in Vientiane capital. As the result of the surveys, level 1 pharmacy irrational use of drug is less than in pharmacy level 3. The one of many reasons maybe that of pharmacy level 3 is managed by doctor or nurse, therefore, they may prescribe drugs to patients without prescription. In addition, antibiotics and acetaminophen can be purchased without prescriptions are very common in Lao PDR. Furthermore counterfeit and substandard drugs are spread widely in private pharmacies, due to the increasing of pharmacies and their competition. Therefore, in 2000s food and drug regulatory authority announced to close all pharmacy level 3 in Vientiane and decrease the number of level 3 pharmacy in another provinces [1].

Now a day there is no pharmacy level 3 in Vientiane, but how to improve their pharmaceutical service is another problem that is still a major issue in Laos, therefore the objective of this review is to review the effort of food and drug authority in order to improve pharmaceutical service in country.

Figure 1 illustrates the increase and decrease of pharmacies in level 1,2 and 3 in Vientiane Capital each year. Therefore, it is necessary to have strong legislations to manage the growth of the private sector.

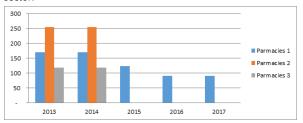


Figure 1 Graph: Expansion of private pharmacies in Vientiane Capital (2012-2016),

2. National Drug Policy

The national drug policy was established and approved in 1993 which was the Cooperation between the Government of Lao PDR and the Government of Sweden for a period of 10 years (1993-2003). The National Drug Policy covers 13 components, there are many elements that are implemented effectively, such as: The creation of a law on medicines and medical products approved in 2000 and announced in 2002, Along with the rules and regulations used to address the quality of pharmaceutical products on the market [2].

3. Pharmacy inspection indicator

The pharmacy inspection indicator was developed and effectively implemented in 1995.

The pharmacy inspection indicator consists of 10 indicators and it was used by food and drug authority inspectors for their regular inspection. Every indicator is value 1 score, in case the inspection result range from 9-10 is indicate that their pharmaceutical service is very good, 7-8 is good, 5-6 is ok, below of 5 is bad. Especially, among 10 indicators, there is one that emphasize on the knowledge of pharmacists on the use of the antimalarial, diarrhea and pneumonia drugs [3].

4. International cooperation

After the Lao PDR became a member of ASEAN in the mid-1997s, it started to have a regional and international connection. In an international connection, Laos has achieved Millennium Development Goals (MDGs). Then the country agreed to comply with the Paris Declaration, which turned into a "Vientiane Declaration" to promote and use international support budget effectively. Therefore, he Ministry of Public Health also sought for the assistant from the international organizations including government and non-government organizations for public health development. Especially in term of strengthening the capacity of public health authorities and upgrade the quality of health services to international levels [4].

5. Training

By the support from NGOs and Non-NGOs, food and drug authorities provide training on rationale use of drugs, and others regular activity that related to improvement of pharmaceutical service to the selected pharmacies at least once a year. The pre and post-test were conducted after the training in order to evaluate the effective of the training programme and the training module was improved in each year.

6. The emergency directive of MOH

Because private pharmacy is a place that people can access easily and is a source of compassion for them when they feel ill, so it is important that pharmacies need to improve their quality of pharmaceutical service to ensure the delivery of good, effective, and safe drugs. Therefore, there is a need to limit the number of

pharmacy for ensuring the effective administration of food and drug authority. In 2009 the Ministry of Health has issued a directive ordering number 699, dated 08/09/2009, Subject: Temporarily suspended licensing of Pharmacy throughout the country [5]. The purpose is to assess the situation of managing pharmaceutical retailers across the country, especially in Vientiane Capital that number of pharmacies seems to over the need of population.

7. Increase available of believable drugs information sources

The survey on health believe and treatment seeking behaviors of Lao people showed that, 97% of them prefer to go to private pharmacies rather than public health sector when they feel sick and it is the starting point of using inappropriate self-medication, which will cause side effects, drug resistance, and even worse can lead to life-threatening complications. Therefore, in order to ensure the proper use of medicines and to improve their knowledge on health and drug information, the website of food and drug authority of Laos (Food and Drug Department) was established in 2015[2], this website provide all information about drugs law, drug registration, update news and as well as health information for consumers. Addition the documents of authority which are related to drugs and health information were distributed to private pharmacy two times a year.

8. Ensure regulatory enforcements

There were evidences that strong regulatory enforcement have significant on improvement of pharmaceutical service in pharmacies [5], as an example there were widely distribution of artemisinin mono therapy and fake/substandard artemisinin in Laos between 2012 and 2015[6]. Due to artemisinin resistance has been risen in the Southeast Asia, artemisinin- mono therapy was banned, during this period under support of Global Fund, food and drug regulatory was very strict in this period, just a year after that the artemisinin mono therapy and fake/substandard artemisinin issues were solved. In addition increasing the number of times inspection also significant to improve the private sector dispensing behavior, but it is still not clear that this improvement related to the enforcement when their irrational used of drugs are found or because of the information from food and drug authority.

9. Conclusion

Food and drug authority of Laos has putted many efforts to improve the pharmaceutical services of private pharmacy in Lao PDR. However the methods and its cost benefit should be evaluated to ensure that those methods are effective and economic. There is a need to study on measuring of patient satisfaction with pharmaceutical services of pharmacy in Laos after many interventions were putted on pharmacy training programme which will help to maintain and develop a better training programme in the future.

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