International Journal of Technology Assessment in Health Care, **17:4** (2001), 579–589.

PRIVATE PHARMACY PRACTICE AND REGULATION

A Randomized Trial in Lao P.D.R.

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Abstract

Objectives: The objective of this study was to assess the effectiveness of government regulation of private pharmacy practice in a low-income country.
Methods: The intervention comprised inspections of the pharmacies, information, and distribution of documents to drug sellers and sanctions. It was implemented at two different intensity levels, active and regular intervention. The methods used to assess the effect of the interventions were interviews with the district drug inspectors, drug sellers and customers, inspection of drug purchases, and indicator surveys of pharmacies. Indicators for pharmacy-specific quality as well as for dispensing quality were developed.
Results: The main finding was one of strong overall improvements from initially low levels. The improvements were particularly marked by increases in the availability of essential materials for dispensing by 34% and in order in the pharmacy by 19%. Information given to customers increased from 35% to 51% and the mixing of different drugs in the same package went down from 17% to 9%. The pharmacies in the active intervention districts showed greater improvements for four of the six indicators, although statistically significant compared with the regular intervention districts only for the essential materials indicator.
Conclusions: It was concluded that the regulatory activities have probably been an important factor behind the service quality improvements. It appeared feasible as well as effective to regulate private pharmacy practice in this particular low-income setting.

The study is closely connected to the development of the Lao National Drug Policy and could not have been implemented without the support of the Minister of Public Health, Dr. Dalaloy, and the Ministry of Health, Food and Drug Department, with its director Dr. P. Vilayvang. The leadership of the provincial health department in Savannakhet province and, in particular, the head of the provincial food and drug department, Mr. Nored and his deputy, Mr. Somphane, were crucial for the field work. Last, but not least, were the unmitigated efforts and the sense of importance demonstrated by the research assistants, Ms. Khamkhiene, Mr. Khamlieng, Ms. Mayphet, Ms. Phetsopha, and Mr. Thavy, essential for the successful implementation of the study. The Swedish International Development Cooperation Agency, Sida, through its research arm, SAREC, financed the study. The Swedish Institute provided funding for L. Syhakhang to study at Karolinska Institutet in Stockholm.

Keywords: Private pharmacies, Good pharmacy practice, Regulation, Indicators, Developing countries

In many low-income countries, pharmaceuticals make up half or more of healthcare costs (22). Pharmacies often function as outpatient clinics where patients obtain any type of drug without prescription, emphasizing the importance of the pharmacy staff as advisers to the patients and the general public (2;23;32).

The private pharmacists have a considerable public health responsibility (3). Privatization of pharmaceutical provision is a development that may compound the problems of quality as reliance on profit from drug sales contributes to overprescribing and polypharmacy (4;10).

Against the background of widespread irrational drug use, counterfeiting, and promotion of unsafe drugs in low-income countries, one would expect considerable research efforts in this area (17;31). However, even in the industrialized countries, little has been known about the effect of regulation on the quality and effectiveness of pharmacy services (5). Most published reviews of intervention research are from industrialized countries (14;15) and there is a lack of studies on the relationship between regulatory factors and pharmacy behavior (9).

In Lao P.D.R. the 2,000 new private pharmacies established during a few years after 1986 captured at least 80% of the retail market for drugs (21;28). The government runs pharmacies in public health facilities, and a number of nongovernmental organizations have set up revolving funds for drug purchases. In addition to the provision of modern drugs, traditional medicines are popular, and there is also an illegal drug market of unknown size.

Very little in the form of regulation of private pharmacies took place in the country before 1988, when basic rules for private pharmacies were established. The National Drug Policy, adopted in 1993, led to the establishment of a rudimentary structure at the provincial and district levels (19). However, the focus was mainly at the national level and in the three first pilot provinces for the National Drug Policy, not including Savannakhet province (21).

Regulation of private pharmacies in Savannakhet province began with the second phase of the National Drug Policy development program in 1996. The district pharmacists were made responsible for inspection of private pharmacies, and a unit was created at the provincial level, staffed with three pharmacists and one assistant pharmacist. Today there are nine qualified pharmacists working with food and drug issues in the province. However, before the baseline survey in 1997, only rudimentary regulatory activities were implemented.

The aim of the study is to assess whether government intervention in a low-income country in the form of regulation of private pharmacies impacts on their quality of services. This article presents and compares the impact of two intensity levels of regulatory intervention.

METHODS

Using a definition of regulation as "the public administrative policing of a private activity with respect to a rule prescribed in the public interest" (18), the study was designed as a randomized trial comparing the effects of two levels of regulatory intervention. Both levels of intervention were part of the National Drug Policy as worked out by the Food and Drug Department of the Ministry of Health and approved by the Prime Minister (19). The different components of the interventions that adhered closely to the Lao National Drug Policy were implemented over a period of $1\frac{1}{2}$ years. The project has been approved

by the Ministry of Health in Lao P.D.R. and by the ethics committee at the Karolinska Institutet.

The baseline and postintervention studies were carried out in Savannakhet province in June–July 1997 and in February–March 1999. The findings of the baseline study have been reported elsewhere (26;27).

During the intervention period the Ministry of Health, with assistance from UNICEF, also implemented a pharmacist training project directed at the private drug sellers in all provinces. The aim was to increase their knowledge on correct standard treatment for acute respiratory infections, diarrhea, and malaria. In Savannakhet province the intervention took place from December 1998 to February 1999. One-day training sessions were organized with drug sellers in all districts except one. A total of 170 of 194 pharmacies participated. In addition to the disease-specific information, the deputy provincial pharmacist held a lecture on good pharmacy behavior (personal communication, Dr. Inthong, UNICEF).

Target Population and Sample

The 214 licensed private pharmacies in Savannakhet province, Lao P.D.R., constituted the target population. All pharmacies except two belonged to class 3, the lowest class of licensed pharmacies, where the licensee does not have to be a pharmacist or an assistant pharmacist. Most of them had a nursing background.

Each pharmacy constituted a study unit. In districts with fewer than 10 private pharmacies, all were selected for the study. In the remaining districts, 10 pharmacies were randomly selected. Sampling was made by numbering the pharmacies in the district and drawing numbered squares of paper from a box under the immediate supervision of the researchers. The central district, including the provincial capital, Khanthabuli, was divided into two for the purpose of the research project. This procedure resulted in a sample of 115 pharmacies. It was estimated that a sample of this size would have about 80% power to detect changes in the quality indicators of 10%.

The selection of districts for active intervention was made through a procedure whereby the 14 districts were matched in pairs according to general socioeconomic criteria such as income level and literacy. The names of the two districts in each pair were written on identical squares of paper, and one was drawn to give the active intervention district.

The baseline study reached 92% and the postintervention study was 80% of the pharmacies in the original sample. The 14 pharmacies that were missed in the later study were excluded from the analysis, since no important deviations in the baseline study with respect to the quality indicators from the rest were observed. The reasons for missing pharmacies were mortality among drug sellers or that the pharmacy had moved or was closed for family reasons. The analysis of intervention impact is based on the 92 pharmacies (46 in regular intervention and 46 in active intervention districts) that were reached in both the baseline and postintervention studies, the customers of these pharmacies, and the drugs they purchased.

Data Collection Methods

The measurements of quality of pharmacy services is based on the concept of good pharmacy practice as defined by the International Pharmaceutical Federation (30). Two types of indicators were employed: facility specific indicators and dispensing indicators. A detailed description of each indicator was presented in a previous paper and is summarized below (27).

The three facility-specific indicators were composite indicators, each made up of 5 or 10 different components and selected from the regular 10-indicator inspection scheme. They were developed during 1992–96 by the Food and Drug Department with support

from the Division of International Health (IHCAR) at Karolinska Institutet in Stockholm (11;12).

In each pharmacy a structured interview was conducted with the drug seller. After the introduction and the interview, the pharmacy was inspected by using of these indicators. The first indicator concerned order in the pharmacy (order), including whether there were any advertisements, whether drugs were kept away from sunlight, and whether they were kept in their original container. The second indicator concerned the availability of 10 specific essential drugs (essential drugs), and the third measured to which extent the pharmacy possessed essential materials for dispensing, such as a hygienic counter (materials).

The dispensing indicators related to the drugs bought by the customers interviewed. Data were collected about the oral or written information given to the customer regarding each purchased drug (information), the packaging and labeling of the drugs (labeling) and whether different drugs were mixed in the same package (mixing). The first customers to appear in each pharmacy during the inspection, up to 10, were interviewed. The drug-specific data were obtained from inspection of each drug purchase in combination with the information provided by the customers.

All interview instruments were translated into the Lao language and are available in English from the corresponding author.

The Intervention

The intervention comprised the following components:

1. Four high-quality inspections of each private pharmacy annually in accordance with the 10-indicator inspection schedule in force (inspections);
2. Enforcement of regulation through selective punishments in case of gross violations of the rules (sanctions);
3. Ensuring the supply of up-to-date regulatory documents to the private pharmacies (documents); and
4. Using the inspections to provide information to the drug sellers about particular points needing improvement (information).

The intervention was reinforced by supervision of the district pharmacist from the provincial level (supervision) and by training provided to the district pharmacists (training). It was implemented at two different levels. The “regular” intervention package was implemented in the way and at the speed that would have taken place in the absence of this study. The aim was to let the regular intervention follow its natural course.

The active intervention package had the same legal basis and consisted of the same components. In addition to the regular intervention package, it was actively promoted through intensified supervision and additional training for the district drug inspectors. To ensure transportation and per diems for the district drug inspectors, a sum of US $1,000 was provided as extra support for the active intervention districts together. The greatest possible effort was made to standardize the intervention in these districts.

The implementation of the intervention was registered by the provincial Food and Drug Department and was compiled, checked, and cross-checked in a district profile for each district during the postintervention study.

The disease-specific intervention that was implemented in parallel with our own has been handled as an external influence of the type that occurs in real-life situations where governments and agencies undertake a variety of projects with little or no coordination.

The first and second author participated throughout the pre- and postintervention data collection, checking data for reliability.

Analysis

The unit of analysis was the pharmacy. Indicator scores were calculated for each pharmacy. Dispensing data were aggregated to the pharmacy level by calculating a proportion of customers/drugs fulfilling the criteria indicated by each dispensing indicator.

Dispensing indicator means for each pharmacy were weighted with the numbers of customers to give each pharmacy the appropriate importance. To evaluate the development over time, the differences between such pharmacy means were used. Comparisons of baseline means were made using ordinary *t* tests for independent samples. The comparisons between the pre- and postintervention periods, for the active and regular intervention, respectively, were made using one-sample *t* tests applied to the differences.

A regression model was used to evaluate the intervention impact. The dependent variables were the differences between pre- and postintervention indicator means. The independent variables were binary variables indicating regular or active intervention and the baseline indicator mean. The second variable was included since it must be suspected that the pre–post change depends on the initial level. The regression analyses of indicators were weighted to correct for the different fractions of pharmacies sampled in the districts as well as the total numbers of customers for the dispensing indicators. The possible differences between districts have been considered as nonrandom.

The data were entered using EpiInfo version 6.4b and analyzed using SPSS version 9.0.

RESULTS

Data collection was carried out successfully, and no drug seller refused inspection. Most customers were eager to be interviewed; less than 10 refused to participate in each study. Some attempts to interfere (from district drug inspector to drug seller and from drug seller to customer) were observed and actively prevented.

Only small and not statistically significant differences existed between the active and regular intervention districts before the intervention for the pharmacy and dispensing indicators.

The comparisons of all pharmacies pre- and postintervention in Table 1 show general improvement of indicator values. There are very low *p* values for the indicators for order in the pharmacies (order), in the availability of essential dispensing materials (materials), and in providing information to customers (information). The improvements were particularly strong for the indicators for order and essential materials. The only change in a negative direction was concerning labeling of drugs (labeling).

Table 1. Pre- and Postintervention Indicator Means

	Preintervention (n = 92)	Postintervention (n = 92)	*p* Value
Pharmacy indicators (scores)			
Order	5.76	6.86	.0001
Essential drugs	6.03	6.40	.1131
Materials	5.16	6.92	.0001
Sum of pharmacy indicators	17.33	20.18	.0001
Dispensing indicators (proportions)			
Information	0.35	0.51	.0001
Labeling	0.53	0.48	.5592
Mixing	0.17	0.09	.0008

One sample Student's *t* test on the pharmacy differences was used to estimate the *p* values for the change over time. Note that the mixing indicator in contrast to the others is negative, with a higher value showing worse practice.

The comparisons of changes in the indicator values during the intervention period in the active and regular intervention districts are shown in Table 2. The pharmacies in the active intervention districts showed greater improvements for four of the six indicators. For the labeling indicator there was no change in the active intervention districts and a deterioration in the regular intervention districts. The mixing indicator showed greater improvement in the regular intervention districts.

The differences in indicator scores between the active intervention and regular intervention districts are analyzed in Table 3. The *p* value for the essential materials indicator is very low. The order indicator showed a reverse trend, with the regular intervention districts improving more than the active intervention districts.

Table 2. Pre- and Postintervention Indicator Means in Active and Regular Intervention Pharmacies

Indicator	District	Preintervention	Postintervention	*p* Value
Order	Active (n = 46)	5.75	6.78	.0001
	Regular (n = 46)	5.77	6.94	.0001
Essential drugs	Active (n = 46)	6.19	6.77	.0712
	Regular (n = 46)	5.87	6.04	.4513
Materials	Active (n = 46)	5.25	7.29	.0001
	Regular (n = 46)	5.06	6.54	.0001
Sum of the above indicators	Active (n = 46)	17.78	20.84	.0001
	Regular (n = 46)	16.87	19.53	.0001
Information	Active (n = 46)	0.30	0.59	.0001
	Regular (n = 46)	0.42	0.43	.1207
Labeling	Active (n = 46)	0.53	0.53	.7474
	Regular (n = 46)	0.53	0.46	.6229
Mixing	Active (n = 46)	0.12	0.09	.1405
	Regular (n = 46)	0.23	0.09	.0025

One sample Student's *t* test on the pharmacy differences was used to estimate the *t* and *p* values.
Note that the mixing indicator in contrast to the others is negative, with a higher value showing worse practice.

Table 3. Post–pre Indicator Difference Means in Active and Regular Intervention Pharmacies

Indicator	Intervention level	Difference means	*p* Value
Pharmacy indicators			
Order	Active (n = 46)	1.03	.1175
	Regular (n = 46)	1.17	
Essential drugs	Active (n = 46)	0.58	.0969
	Regular (n = 46)	0.17	
Materials	Active (n = 46)	2.04	.0241
	Regular (n = 46)	1.48	
Sum of the above indicators	Active (n = 46)	3.06	.4399
	Regular (n = 46)	2.65	
Dispensing indicators			
Information	Active (n = 46)	0.29	.1066
	Regular (n = 46)	0.01	
Labeling	Active (n = 46)	−0.00	.9306
	Regular (n = 46)	−0.06	
Mixing	Active (n = 46)	−0.04	.5223
	Regular (n = 46)	−0.14	

The values of Student's *t* test and the corresponding *p* values for the comparison of the two groups are estimated in linear model analysis.
Note that the mixing indicator in contrast to the others is negative, with a negative difference indicating improvement.

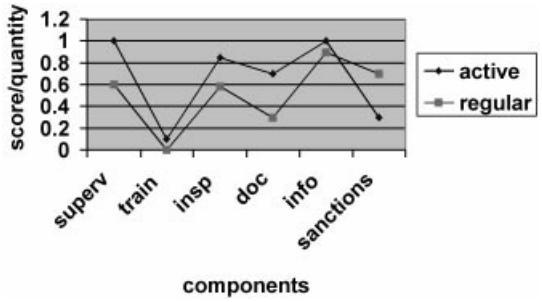

Figure 1. Regulatory interventions.

Figure 1 shows the estimated magnitude of the various components of the regulatory intervention in the two groups of districts. The scores provide rough representations of the quantity of regulatory intervention for each component of the intervention in the two groups of districts.

DISCUSSION

The main finding is that of a considerable improvement of private pharmacy service quality during the $1^1/_2$-year intervention period both in the active and regular intervention districts.

The standardization of the content and delivery of a complex intervention is a major challenge in a randomized controlled trial (29). In spite of this limitation we have been able to conclude that the intervention was implemented in all districts, with a generally somewhat higher intensity, as was planned, in the active regulation districts as compared with the regular intervention districts.

It was not possible to make the study blinded with regard to the main intervention vehicle, the district pharmacists. The research assistants who were active partners in the research team and participated in the sampling procedures were also aware of the scope of the intervention. It could not be established to which extent the drug sellers had any active knowledge of the study objectives.

The alternative of using the simulated client method could have resulted in more in-depth knowledge about certain issues, e.g., treatment of a specific disease and how drug sellers interact with their customers faced with this particular problem (16). In order to assess interventions, it would have been more specific and it also would have required a more specific intervention. However, besides being impossible to implement without causing suspicion, it would have meant a more artificial arrangement. It was therefore discarded.

It is not likely that the overall improvements could have been caused by a change in the methods with a more lenient assessment in postintervention study, since the matter was thoroughly discussed with the research assistants and problems were defined and resolved jointly. If anything, the assessment tended to become more rigorous in the postintervention study as a result of growing experience among the research assistants.

The lack of statistically significant differences in indicator scores between the active and regular intervention districts preintervention indicates that the randomization successfully dealt with interdistrict differences.

At the time of the baseline study, the private pharmacy services in Savannakhet were substandard. This was especially apparent as regards the dispensing practices, with lack

of information to customers in 59% of transactions, absence of labels on drug packages in 47% of the cases, and mixing different drugs in the same package in 26% of the cases (27).

There was an overall positive change during the intervention period in all districts taken together. The greatest positive changes were in the scores for availability of essential materials for dispensing (+34%) and for order in the pharmacy (+19%). There were also considerable improvements in the provision of information to customers and in not mixing drugs.

These factors and practices are those that could be most easily influenced. Order in the pharmacies and providing oral information can be improved at no cost. To keep drugs in separate bags is also something that can be done at a small cost, while investing in new materials for dispensing would imply additional expenditures. The availability of essential drugs is likely to be influenced more by customer demand and availability of funds to replenish stocks.

One reason why the labeling practices did not improve is that it was felt to be meaningless and was not requested by the customers, especially if only a few tablets were being sold at a time. A second reason may be that awareness of the high illiteracy rate (averaging 56.2%) in the districts of the province discourages drug sellers from labeling their products (25). Third, most pharmacies buy their drugs in bulk, not in their original packages, thus requiring writing a special label for each drug purchase. Regarding labeling, we found no studies with which to compare our data.

It has been suggested that pharmacy factors, client expectations, physician practice, and local regulating factors influence the quality of services of private pharmacies (9;20;22). We classified these factors into demand-side factors, expressing themselves through the action of the clients/customers, and supply-side factors, which impact drug sellers' behavior in other ways.

Demand-side factors:

- Changes in society (e.g., economic, social, demographic, healthcare system);
- Changes in disease burden; and
- Physician practices.

Supply-side factors:

- Marketing activities from industry, wholesalers, and agents;
- Competition, including government provision of drugs; and
- Regulatory activity, including the enforcement of legal provisions, education and training of drug sellers, and financial incentives or disincentives from government.

A change in demand is possible as a result of economic and social development, resulting in increased drug literacy and more resources among customers. But this factor would not be likely to have any impact in the short run, especially not during the intervention period, which was characterized by the Asian economic crisis.

More resources in society as a result of general economic development might work in both directions—on one hand by increasing customer demand for unnecessary drugs, but on the other hand by making a more rational behavior possible with purchases of whole courses of drugs rather than 1 or 2 days' supply at a time.

No dramatic changes in the general socioeconomic conditions in Savannakhet could be registered.

Most intervention studies regarding drug use have focused on changing prescriber behavior (1;6;24). In our study, however, most drugs were purchased without prescription.

Neither were there any signs of change in the competitive situation with regard to the number and location of private pharmacies. No dramatic changes in government provision or industry marketing activities of drugs were registered. Pressure from agents and wholesalers on one side and demands from customers on the other as well as the necessity to generate a profit in a highly competitive situation could easily provoke a further deterioration of pharmacy service quality. However, our results point in the opposite direction.

The parallel disease management intervention could have had some positive effect, although most likely in increasing general awareness of professional behavior among drug sellers rather than resulting in an immediate increase in our indicator scores. Several of these would in any case not be amenable for improvement with short notice, e.g., procuring additional materials for dispensing or increasing stocks of essential drugs. The fact that Xaybuli district, which was not exposed to the disease management intervention, does not stand out in terms of changes in the indicator score is also a sign that this project did not have a strong influence on our measurements.

There is nothing to indicate that any of the above factors would have had a decisive influence on the service quality in the private pharmacies. Therefore, the enforcement of regulatory standards in accordance with the National Drug Policy stands out as being the most likely cause for the improvement.

The interpretation of the scores for the regulatory intervention should be made cautiously since the main intervention vehicles, the district pharmacists, are different persons in the different districts. Hence the quality of the regulatory activities—that does not appear in the table—may be as important as the quantitative aspects.

Studies concerning pharmacy behavior have generally found that single interventions have been less effective than a package comprising multiple interventions (2;7;31). There is also accumulating evidence to show that providing information on its own will not lead to substantial changes in practice (8) and that legal interventions alone are insufficient to obtain the desired policy outcomes (13). In contrast with these, our study gives a more positive result with regard to the effect of government regulation.

POLICY IMPLICATIONS

The most important conclusion of the study is that great and rapid improvements of the quality of private pharmacy practice indeed are possible even in a low-income country. It is likely that the regulatory instruments were an important cause of the positive development of the quality of the private pharmacy services as measured through our quality indicators.

It could not be established that the active intervention had an overall greater effect than the regular intervention package. This may indicate that the initial effort, with the establishment of a regulatory structure and implementation of some kind of regular inspections could be important in itself. At this stage, aiming at perfection is not essential.

Great care was taken to implement a realistic and low-cost intervention. It was demonstrated that it could be implemented even in a country with scarce resources.

The result of this study is therefore a strong argument for governments in low-income countries to expand their regulatory efforts vis-à-vis the private pharmacies in order to improve the quality of their services.

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