

BUILDING THE NATIONAL DRUG POLICY ON EVIDENCE – A CROSS SECTIONAL STUDY ON ASSESSING IMPLEMENTATION IN LAO PDR

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Abstract. The National Drug Policy (NDP) of Lao PDR, endorsed in 1993, has since 1995 been implemented through an intervention program in five pilot areas out of 18 provinces, including training of health personnel. The aim was to assess the impact of the NDP program to get evidence for revising the policy. In a cross sectional design, comparisons were made between the pilot province of Luangphrabang (LPB) and the non-pilot province of Sayabury (SBR). In each province, three districts were purposively chosen. Four pharmacies at the public hospitals were included, while 20 private pharmacies were randomly selected. A set of 29 combined indicators was utilized. One hundred and ten prescriptions for under-five children with simple diarrhea and 240 adult outpatient prescriptions were sampled. Furthermore, twelve health care managers were interviewed on knowledge and attitudes. LPB health managers had better knowledge of NDP concepts. Significantly more essential drugs (ED) were available in the private pharmacies in the pilot province. The proportion of prescriptions of ED in hospitals was higher in the pilot province (95% in LPB vs 86% in SBR; $p < 0.001$). Fewer drugs per patient were prescribed in the pilot province (2.7 vs 3.3, $p < 0.001$), and the management of simple diarrhea in children was significantly more in accordance with Standard Treatment Guidelines. The pilot province performed significantly better regarding several aspects of quality and rational use of drugs, probably related to the implementation program. National as well as regional and global diffusion of research findings is recommended towards evidence-based national drug policies.

INTRODUCTION

The mushrooming of private pharmacies, and the lagging behind of regulatory and control mechanisms have contributed to irrational use of drugs and deprivation of access to affordable drug treatment in many developing countries (Cederlof and Tomson, 1995; Goel *et al*, 1996; Paphassarang *et al*, 1995). According to WHO (2000a) less than one half of the 90 countries that have developed National Drug Policies (NDPs), also have active implementation plans, and fewer than 20 operate systems for monitoring their progress. Successes and failures depend to some extent on the country-

specific political, economic and socio-cultural context (Stenson *et al*, 1997; 2001a), but evidence-based policy and decision making also have a global aspect (Hogerzeil *et al*, 1993; Hamrell and Nordberg, 1995; Muir Gray, 1997; Le Grand *et al*, 1999; WHO, 2000a; Laing *et al*, 2001).

Lao PDR is a poor country with a GNP per capita of US\$ 370 in 1996, and a government expenditure on health of not more than US\$ 4 for each of its 4.5 million citizens (National Statistics Center, 1998). About 60% of the adult population is illiterate. The life expectancy is one of the lowest in the region; 57 and 61 years for men and women, respectively. A high infant mortality rate of 82/1,000 live births, and a maternal mortality rate of 530/100,000 live births are indicators of one of the worst health situations in the world (Boupha,

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2001; WHO, 2000b).

The Lao NDP was adopted by the Ministry of Health (MOH) in 1993 and comprised 13 elements for achieving availability, affordability and rational use of safe and effective essential drugs (ED) of good quality for all people in the 18 provinces of the country (Paphassarang *et al*, 1995). To support the implementation, a special program was carried out, from 1993 in three and from 1996 in five pilot provinces with the assistance of the Swedish International Development Cooperation Agency (SIDA) (Helling-Borda and Andersson, 2000). The program has included both the private and the public sector in the form of training of private drug sellers, training of inspectors and development of monitoring indicators for good pharmacy practice (GPP) and rational use of drugs (RUD), establishment of therapeutic drug committees (DTCs), development of standard treatment guidelines (STGs) for prescribers, and information, education and communication for and with the general public on the rational use of drugs. Key persons at central and pilot provincial level have been the main focus for human resource development. Pharmacists have had the leading role in program implementation, but in close collaboration with medical doctors and other stakeholders, like the Lao Women Union and national drug manufacturers. The study presented here is one of six operational research projects that have been conducted, including the public and private sector, communities and health facilities, modern and traditional medicine (Boupha *et al*, 2000; Stenson *et al*, 1997; 2001b).

This study aims at using monitoring indicators to assess the effectiveness of the NDP program implementation in one pilot province compared to a non-pilot province.

MATERIALS AND METHODS

Luangphrabang (LPB) and Sayabury (SBR) were chosen as the pilot and control provinces, respectively, on grounds of being similar geographically and regarding the pharmaceu-

tical privatization process. Three districts of each province were purposively selected to represent three types of areas: urban, rural and remote. The amount of information that should be retrieved from these three districts was calculated to be adequate for the comparison. The field study was conducted in 1999.

The following data were collected in each province:

- 12 health care managers were purposively selected to represent the decision-makers at provincial and district level, and were interviewed with semi-structured questionnaires on the NDP concept, including objectives, as well as the essential drugs concept, standard treatment guidelines and inspection principles. Their answers were scored according to level of correctness.
- 24 pharmacies (20 randomly selected private pharmacies and four public pharmacies at the provincial and the three district hospitals) were surveyed with structured questionnaires, including a check-list of the ten most commonly used essential drugs and essential materials (available from the first author on request). In focus of attention were the availability of ED, and the observed quality of keeping and dispensing drugs, including the quality of any oral or written information given regarding the name, strength, dosage, duration and side-effects. At the private pharmacies, 45 customers per province were also observed during transaction and interviewed regarding their knowledge about the drug and the information received.
- 50-60 prescriptions for children under five with simple diarrhea and 120 prescriptions for adult OPD patients were collected retrospectively from the record book of the child and outpatient departments of the provincial and the three district hospitals in each province. The prescriptions were checked using the following indicators for: a) diarrhea: percentage of ORS, percentage of antibiotics, and percentage of anti-diarrhea drugs; b) prescribing at the OPD: number of drugs per prescription, percentage ED prescribed, percentage injections, percent-

age of antibiotics.

The selection of the 29 indicators was firstly based on WHO manual of the indicators for monitoring the NDP (WHO, 1994) which is composed of four sets of indicators, namely: background information indicators, structural indicators, process indicators and outcome indicators. These indicators were already tested and utilized in many countries to assess the pharmaceutical situation and to compare this among countries, especially developing countries. We selected 15 of these indicators for reasons of accuracy for our study objectives; a few of them were slightly modified for adaptation to the situation in Lao PDR. The second kind of indicators used were the ten indicators for inspecting pharmacies, called GPP indicators (Johansson and Suren, 1997), developed by the Food and Drug Department (FDD) with assistance of a SIDA expert. These indicators have been tested and utilized in the whole country by the drug inspectors to assess the quality performance of the private pharmacies in relation to the pharmaceutical legislation. Finally, four extra indicators were

developed to measure the knowledge of NDP and its components (the two main objectives of the NDP; principles of the essential drugs concept; the use of STGs; and inspection principles).

Descriptive data analysis, including statistical analysis, was performed using the EPI6 and SPSS10 programs. Significance testing was performed at the 95% level, and confidence intervals were calculated.

RESULTS

Among the twelve health care managers interviewed in the pilot province, ten had at least half of the maximum score on each of the four indicators, versus five in the control province.

In Tables 1, 2 and 3, the most important similarities and differences related to Good Pharmacy Practice between the pilot and control province are shown. The results of all indicators are not shown, but are available from the first author on request.

Table 1
Availability of essential drugs (EDs) and materials, frequency of inspections and observed quality of drugs and services at 24 pharmacies (20 private, 4 public) in each of the Luangphrabang (pilot) and Sayabury (control) Province.

	Pilot	Control	p-values	95% CI of the difference
	Total nos.	Total nos.		
No. of inspections per year	1.5	0.5		
No. of pharmacies with ED list available	19	3		
No. of pharmacies with banned drug list available	17	18	ns	
No. of pharmacies with no advertising posters	19	18	ns	
No. of pharmacies dispensing from original package	4	0	ns	
No. of ED available in public sector out of ten EDs	9.0	6.5	ns	
No. of ED available in private sector out of ten EDs	8.5	7.3	p=0.03	0.11;1.89
	percent	percent		
Observed quality indicators:				
-Percentage of essential drugs being registered	70	54	p<0.001	10;23
-Percentage of EDs with bill of purchase	42	18	p<0.001	14;34
Percentage of informed customers (n=45/per province)	18	7	ns	

Table 2

Physicians' prescribing practice as percentages for children under five with simple diarrhea at public outpatient departments (OPD) in the Luangphrabang (pilot) and Sayabury (control) province. Total no. of prescriptions: 110 (Luangphrabang: 50, Sayabury: 60).

	Pilot province percentage	Control province percentage	p-values	95% CI of the difference
ORS (oral rehydration solution)	100	82	p=0.001	0.08;0.28
Anti-diarrheals	0	0	ns	
Antibiotic	22	50	p=0.002	-0.45;-0.11

Table 3

Physicians' prescribing practice at public OPDs in the Luangphrabang (pilot) and Sayabury (control) province (n=120 patients per province).

	Pilot province	Control province	p-values	95% CI of the difference
Number of drugs per patient	2.68	3.33	p<0.001	
Percentage ED of all prescribed drugs (pilot: n=320; control: n=403)	96.5	85.8	p<0.001	0.07;0.14
Percentage injections of all prescribed drugs	1.3	8.9	p<0.001	-0.11;-0.05
Percentage antibiotics of all prescribed drugs	13.1	14.6	ns	

Similarities: Both the pilot and control provinces had low indicator scores on dispensing practices such as little dispensing from the original package and not giving information to customers. On the other hand they had fairly high scores on availability of essential drugs (in particular in the public sector), on the availability of the banned drug list, and on the absence of unapproved drug advertising materials on their walls, such as posters and stickers.

Differences: Compared with the pharmacies in the control province, the pharmacies in the pilot province had been visited more frequently by the inspectors, had more essential drugs available in the private sector, had better observed quality of essential drugs, better prescribing practices in general (lower number of drugs prescribed per patient; lower rate of injections), as well as more accurate case management of

simple diarrhea among under-five year old patients (all received ORS and less than one quarter received an antibiotic).

DISCUSSION

In the pilot province compared with the control province, there was better knowledge on NDP concepts, and essential drugs (ED) were more often available and regularly distributed in the private health facilities. The proportion of prescriptions of ED in public hospitals was higher in the pilot province, and these drugs are assumedly of better quality as the stricter regulations to ensure good quality drugs were followed. Prescribing practices were also of a higher standard with more correct treatment of childhood diarrhea, and better overall prescribing for adult patients.

The better knowledge of the NDP concepts among decision-makers in the pilot province, including its two main objectives, is probably due to the intensive training and the distribution of drug bulletins by the program to the pilot province. This is comparable with a study in Nigeria (Adiku and Osundo, 1991) which found that all the health professionals interviewed were aware of the essential drugs list (EDL) four years after intervention of a WHO program. Availability of EDL and the higher rate of inspections per year in the pilot province may also be linked to the improvement of the knowledge of the health officers of the essential drugs and the inspection concept, and their awareness of the need to promote the use of the EDL. The significant improvement of the availability of essential drugs in the public and private sectors is similar to findings from Yemen (Hogerzeil *et al*, 1989).

Unethical marketing, including advertising through stickers at the pharmacy, provinces was low in both. This improvement is probably due to the implementation of WHO Ethical Criteria for Drug Promotion (WHO, 1988). This document was translated, printed and distributed to health decision-makers across the country during the NDP development workshop in 1992, introduced into regulation on drug advertising, and included in the inspections of private pharmacies.

The low rate of dispensing from original packages can be explained by lack of awareness of drug sellers of the quality of drugs, which is supported by previous findings (Stenson *et al*, 1998), as well as by the weaknesses of the regulatory system (Stenson *et al*, 2001b). Our findings showed significant differences between the pilot and the control province regarding the existence of information about registration status and the source of procurement. It has been shown previously that effective drug registration may improve the quality of drugs (Hogerzeil *et al*, 1993; WHO, 1997). However, findings in the control province coincided with the high prevalence of substandard quality of drugs found in the Savannakhet Province, Lao PDR, and in some neighboring

countries (WHO, 1997; 1999).

Regarding rational use of drugs, our findings showed significantly better results in the pilot province both for case management of simple diarrhea and for OPD prescriptions. This may be attributed to an impact of the intensive training on the use of Standard Treatment Guidelines (STGs), and to the development of Drug Therapeutic Committees. Similar effects have been found in other countries when STGs have been introduced (Hogerzeil *et al*, 1993). Compared with the findings from a quick survey in 1992 in the same pilot province, polypharmacy (4.5-6.0 prescriptions per patient) and the overuse of antibiotics and injections have improved (Paphassarang *et al*, 1995). There are no comparative figures for the situation in the control province, but it can be assumed that it has probably also decreased since 1992. However the present level of prescribing is similar to the situation in Vietnam, Sri Lanka and Indonesia (WHO, 1997), and higher than in some other developing countries (Hogerzeil *et al*, 1993).

Although we have shown significantly better performance in the pilot province, we are aware that randomized controlled trials provide more rigorous evidence (Muir Gray, 1997; Le Grand *et al*, 1999). Such a study on regulatory enforcement at private pharmacies showed initial low levels of drug information to customers and mixing of drugs at dispensing, but a significant improvement after the intervention (Stenson, *et al*, 2001b).

The Lao NDP has recently been revised and further adapted to the Lao situation during the 5th National Conference on Pharmaceuticals in February 2001. Over one hundred decision makers participated, including representatives from other ministries and health institutions across the country, and from main private drug suppliers. Findings from the six operational research projects were presented at the conference and the evidence was discussed in relation to the revised policy. However, the main results had been known already before this occasion, and had been shown at a dis-

semination conference in August 2000 when the revision process started (Stenson *et al*, 2001; Boupcha *et al*, 2000; Stenson *et al*, 1998; 2001b).

The majority of participants at the National Drug Conference found operational research useful to solve their problems and accepted to include it in the new NDP formulation. In the revised NDP, health systems research (operational research) became one of the 13 components beside other new elements such as human resource development and pharmaceutical economic strategy. The main objectives were formulated as ensuring the availability and affordability of safe and efficacious essential drugs of good quality to all in need, in particular the poorest populations in remote areas, and to promote rational use of drugs and traditional medicines.

The MOH of Lao PDR has thus ensured that the future implementation and revisions of the NDP will build on evidence from the Lao context. This experience may contribute to a better understanding of the process of implementing a National Drug Policy and serve as an inspiration for other countries, rich and poor. In addition to robust methods *for* policy, including health information indicators, research must also be performed *on* policy to ensure that data are utilized in evidence-based decision making.

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