

# Does the Essential Medicines Policy Succeed in China? Empirical Study on Rational Medicine Use in Primary Health Care Institutions

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## Abstract

This study investigated outpatient prescription medicines use in primary health care institutions to evaluate the impact of the essential medicines policy on rational medicines use. Data were collected from primary health care institutions in 4 province-level areas of different socioeconomic status in China. Around the policy implementation, the numbers of various medicines used per prescription were compared by *t* test and 1-way analysis of variance, and the proportions of prescriptions with antibiotics, injections, or hormones were compared by chi-square test. After the policy implementation, the numbers of all medicines and antibiotics used per prescription dropped, and the number of essential medicines used per prescription increased in all 4 areas. The percentage of prescriptions with injections declined in all 4 areas, but the percentages of prescriptions with antibiotics or hormones witnessed different status in different areas. To a certain degree, the essential medicines policy in China has taken effect on rational medicines use but needs development.

## Keywords

health care system reform, essential medicines policy, rational medicine use, primary health care, China

## Introduction

Incorrect use of medicines can be found all over the world. According to the World Health Organization's (WHO's) estimation, more than half of all medicines are improperly prescribed, dispensed, or sold, and half of all patients take them incorrectly. This incorrect use may commonly take the form of excessive use of medicine species, excessive use of antibiotics and injections, prescribing medicines not in accordance with clinical guidelines, and inappropriate self-medication.<sup>1</sup> These issues are very often seen in China. The Center for Drug Reevaluation of China Food and Drug Administration investigated medicine treatment for children in 26 hospitals from Beijing, Wuhan, Chongqing, Guangzhou, and so on, in 2004, finding that the rational use of medicines for diarrhea accounted for only 5.4% and that merely 12.3% of the medicine treatments for pneumonia were appropriate. Overuse of antibiotics was the most common and severe incorrect medicine use in China; for instance, the patients who suffered respiratory disease mainly died of pulmonary infection, but the proportion of the rational use of antibiotics treating pulmonary infection was <50%.<sup>2</sup>

“Essential medicines,” as defined by the WHO, are drugs that satisfy the priority health care needs of the population, which were brought forward in 1970s.<sup>3</sup> A major mission of essential medicines and pharmaceutical policy is to improve rational medicines therapy, and the policy is currently globally implemented in developing countries.<sup>4-6</sup> The availability of the essential medicines list is one cornerstone for rational prescribing. On this basis, the implementation of a formulary and medicines use guideline, tailored to the local medical needs and mediciners' skills, could bring about improvements in the availability and rational use of medicines in primary

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health care institutions (PHCs) and, hence, the quality of health care provided.<sup>7-10</sup>

China launched its new health care reform program in 2009, which aimed to settle a series of problems that existed in the health system of the time. One of the 5 core parts of the program is that efforts should be made to establish the national essential medicines system in order to secure pharmaceutical supply and ensure medicine safety.<sup>11,12</sup> The 2009 Essential Medicines List<sup>13</sup> released at the time of the program launching, comprised 307 medicines with more than 2000 specifications—medicines that should be used with high priority and rationally in health institutions throughout the country in accordance with the policy requirement. This requirement had not appeared in any official document before and would change the prescribing behavior and using habit of medicines. The medicines that have been selected for the list were carefully evaluated and screened to ensure their necessity, safety, effectiveness, and cheapness so that using the essential medicines may lead to a relatively rational medicine use.

This study investigated outpatient prescription medicines use in terms of essential medicines utilization and the rational use of antibiotics, injections, and hormones to evaluate the implementation effect of the policy, and it attempted to provide information for developing the implementation of the essential medicines policy in the next-stage health care reform in China.

## Materials and Methods

### Data Source

The raw outpatient prescriptions were collected from 176 PHCs in 4 provincial-level areas of different socioeconomic status: Zhejiang Province, Anhui Province, Shandong Province, and Ningxia Hui Autonomous Region. Calculated by dividing the local population by the regional gross domestic product, which is available on the website of National Bureau of Statistics of China (<http://www.stats.gov.cn/>), the gross domestic products per capita of Zhejiang, Anhui, Shandong, and Ningxia in 2009 were 43,575.34 CNY, 16,413.02 CNY, 35,793.72 CNY, and 21,652.96 CNY, respectively, and the rank of gross domestic product per capita among these 4 areas was unchanged from 2009 to 2011.

Materials from Zhejiang and Anhui were collected through the program “Mid-term Evaluation on Implementation Effect of Essential Medicines Policy,” organized by the National Development and Reform Commission in the end of 2010. The program was conducted in 12 counties of 4 prefecture cities—Hangzhou and Shaoxing in Zhejiang and Hefei and Bengbu in Anhui—3 counties for each prefecture city, respectively, and involved 139 PHCs in total. We randomly selected 10 pieces of prescriptions for each day between August 21 and August

30, 2009, and between August 21 and August 30, 2010, from each involved PHC, so there were 100 prescription samples for each institution each year.

Materials from Shandong and Ningxia were collected by our group with local academic institutions’ cooperative efforts through some field works in 2011. The on-site investigation in Shandong was conducted in Ju County, involving all 21 PHCs, and that in Ningxia was conducted in 16 PHCs, of which 8 were in Xiji County, 4 were in Tongxin County, and the other 4 were in Qingtongxia County. We received the outpatient prescriptions spanning January to June 2009, January to June 2010, and January to June 2011, and 100 pieces of prescriptions were randomly selected for each institution each year.

Since the implementation of the essential medicines policy in these areas began in 2010, we considered 2009 as being before the policy implementation period and 2010 and 2011 as being after the policy implementation period.

### Data Content

According to the manual *How to Investigate Drug Use in Medical Facilities: Selected Drug Use Indicators*,<sup>6</sup> which was contributed by Action Programme on Essential Drugs and the International Network for the Rational Use of Drugs, 3 groups of 12 core indicators and another 7 complementary indicators were proposed to evaluate the rational medicines use for both outpatients and inpatients, including prescribing indicators, patient care indicators, health facility indicators, and so on (Table 1). The selected drug use indicators system, which is an objective and scientific analytic technique and research model, was introduced into China<sup>14</sup> in 1995 and has been proven adequate for the research on rational medicines use in China.<sup>15</sup>

In order to monitor the outpatient antibiotics use in health institutions, the Ministry of Health of China proposed 5 indicators for outpatient prescription medicines use in 2005; among them are the average total number of medicines used per prescription, the percentage of prescriptions with antibiotics, the percentage of prescriptions with injections, the average prescription charge, and the average antibiotics cost per prescription.<sup>16</sup>

Based on the information from the outpatient prescriptions that we collected and referring to the guidelines mentioned above, the following 6 details were extracted from each selected prescription as our research indicators: the total number of medicines used, the number of essential medicines, the number of antibiotics, whether antibiotics were used or not, whether injections were used or not, and whether hormones were used or not.

**Table 1.** Drug use indicators.

Core Indicators	
Prescribing indicators	
1	Average number of drugs per encounter
2	Percentage of drugs prescribed by generic name
3	Percentage of encounters with an antibiotic prescribed
4	Percentage of encounters with an injection prescribed
5	Percentage of drugs prescribed from essential drugs list of formulary
Patient care indicators	
6	Average consultation time
7	Average dispensing time
8	Percentage of drugs actually dispensed
9	Percentage of drugs adequately labeled
10	Patients' knowledge of correct dosage
Facility indicators	
11	Availability of copy of essential drugs list or formulary
12	Availability of key drugs
Complementary Indicators	
13	Percentage of patients treated without drugs
14	Average drug cost per encounter
15	Percentage of drug costs spent on antibiotics
16	Percentage of drug costs spent on injections
17	Prescription in accordance with treatment guidelines
18	Percentage of patients satisfied with the care they received
19	Percentage of health facilities with access to impartial drug information

### Data Processing

The prescription data were coded and organized in Microsoft Office Excel 2007 for checking to ensure that there were no errors and omissions. By applying SPSS 19.0 software, independent samples *t* test and 1-way analysis of variance were used to compare the mean values of the total number of medicines, the number of essential medicines, and the number of antibiotics for individual prescription before the policy implementation with those after the policy implementation, and chi-square test was used to compare the proportions of prescriptions with antibiotics, injections, or hormones before the policy implementation with those after the policy implementation. Statistical significance was set at  $P < .05$ . The results were compared with the standard of rational medicine use for medical institutions in developing countries recommended by the WHO, if any.<sup>6</sup>

## Results

### Average Total Number of Medicines per Prescription

The average total number of medicines per prescription is an indicator for the excessive use of medicines. As is shown in Table 2, compared with the average total number of medicines

**Table 2.** Average total number of medicines per prescription.

	2009	2010	2011	$\Delta^a$	<i>P</i>
Zhejiang	3.56	3.27		-0.29	.000*
Anhui	4.19	4.05		-0.14	.125
Shandong	3.37	3.28	3.36	-0.01	.584
Ningxia	3.23	3.12	3.15	-0.08	.296

<sup>a</sup>The difference between the values for the last available year and 2009.  
\* $P < .05$ .

**Table 3.** Average number of essential medicines per prescription.

	2009	2010	2011	$\Delta^a$	<i>P</i>
Zhejiang	2.11	2.72		0.61	.000*
Anhui	3.13	3.52		0.39	.000*
Shandong	1.71	1.62	2.21	0.5	.000*
Ningxia	2.47	2.5	3.01	0.54	.000*

<sup>a</sup>The difference between the values for the last available year and 2009.  
\* $P < .05$ .

per prescription for 2009, that for the last available year dropped in every province. In Zhejiang, the richest province of these 4 areas, this decline was the largest, with a difference of 0.29, and was statistically significant ( $P < .000$ ), although the other 3 areas were not. It can also be seen in Table 2 that in Shandong and Ningxia, the average total number of medicines per prescription increased from 2010 to 2011.

In comparison with the WHO's recommended standard—that it is reasonable to prescribe 1.6 to 2.8 medicines per prescription for outpatients—the mean values of the total number of medicines used per prescription in the PHCs of these 4 areas are all still relatively high even after the policy implementation.

### Average Number of Essential Medicines per Prescription

The average number of essential medicines per prescription is an indicator for the use of essential medicines to evaluate the direct effect of the essential medicines policy. According to Table 3, compared with the average number of essential medicines per prescription for 2009, that for the last available year in every province increased, and each difference was statistically significant. In Zhejiang, the difference was the largest, with a value of 0.61. In Shandong, there was a slight drop of the value between 2009 and 2010; then the value went up by 0.6 between 2010 and 2011.

### Average Number of Antibiotics per Prescription

The average number of antibiotics per prescription is an important indicator for the rational use of medicines. Table 4 shows that there was a slight fall of the average number of antibiotics

**Table 4.** Average number of antibiotics per prescription.

	2009	2010	2011	$\Delta^a$	<i>P</i>
Zhejiang	0.8	0.75		-0.05	.000*
Anhui	0.93	0.91		-0.02	.198
Shandong	0.73	0.71	0.66	-0.07	.135
Ningxia	0.72	0.81	0.70	-0.02	.002*

<sup>a</sup>The difference between the values for the last available year and 2009.

\**P* < .05.

**Table 5.** Proportion of prescriptions with antibiotics.

	Year	Proportion	$\Delta^a$	$\chi^2$	<i>P</i>
Zhejiang	2009	60.89	-5.62%	62.820	.000*
	2010	55.27			
Anhui	2009	65.04	-1.59%	1.738	.187
	2010	63.45			
Shandong	2009	51.43	-4.29%	4.883	.087
	2010	51.43			
	2011	47.15			
Ningxia	2009	53.15	1.14%	13.788	.001*
	2010	60.28			
	2011	54.29			

<sup>a</sup>The difference between the proportions for the last available year and 2009.

\**P* < .05.

per prescription for the last available year in every province compared with that for 2009. The differences in Zhejiang and Ningxia were statistically significant. As can be seen from the table, there was a fluctuation of the value in Ningxia, and the period from 2009 to 2010 witnessed a remarkable rise in the average number of antibiotics per prescription, which was followed by a relatively sharp decrease between 2010 and 2011. With further independent samples *t* test, we found that the difference of the value in Ningxia between 2009 and 2010 as well as that between 2010 and 2011 was statistically significant (*P* = .008 and .001, respectively), but the difference between 2009 and 2011 was not (*P* = .277).

### Percentage of Prescriptions With Antibiotics

The percentage of prescriptions with antibiotics is a key indicator for the rational use of medicines. The figures from Table 5 reveal that in Zhejiang, Anhui, and Shandong, the proportions of prescriptions with antibiotics decreased from 2009 to 2010 or 2011, and this decline in Zhejiang was statistically significant. In Ningxia, the proportion went up dramatically from 2009 to 2010 and then dropped down rapidly from 2010 to 2011, although the proportion in 2011 was higher than that in 2009.

The WHO's recommended standard for the percentage of prescriptions with antibiotics for outpatient is 20.00% to

**Table 6.** Proportion of prescriptions with injections.

	Year	Proportion	$\Delta^a$	$\chi^2$	<i>P</i>
Zhejiang	2009	44.82	-4.14%	33.871	.000*
	2010	40.68			
Anhui	2009	50.75	-0.72%	0.327	.568
	2010	50.03			
Shandong	2009	30.59	-3.91%	3.884	.143
	2010	29.28			
	2011	26.68			
Ningxia	2009	28.27	-5.86%	12.590	.002*
	2010	28.01			
	2011	22.40			

<sup>a</sup>The difference between the proportions for the last available year and 2009.

\**P* < .05.

26.70%. Compared with the standard, the proportions of prescriptions with antibiotics investigated from the PHCs of these 4 areas are twice to triple as high, even after the policy implementation.

### Percentage of Prescriptions With Injections

The percentage of prescriptions with injections is another key indicator for the rational use of medicines. Table 6 illustrates that in all 4 areas, the proportions of prescriptions with injections dropped. In Zhejiang, the difference of the proportion was statistically significant, with a decline of 4.14%. In Ningxia, the proportion dropped slightly over the period from 2009 to 2010; then there was a considerable reduction of the proportion between 2010 and 2011.

The WHO's recommended standard for the percentage of prescriptions with injections for outpatient is 13.40% to 24.10%. The proportions of prescriptions with injections investigated from the PHCs of these 4 areas are higher than the standard, especially those from Zhejiang and Anhui, except for the proportion of prescriptions from Ningxia after the policy implementation.

### Percentage of Prescriptions With Hormones

The percentage of prescriptions with hormones is an indicator that we proposed to evaluate the rational use of medicines, since it was reported that the abuse of hormone in China is very common and serious.<sup>17</sup> As shown in Table 7, the proportions of prescriptions with hormones went down from 2009 to 2010 in Zhejiang and Anhui, with statistical significance. In Shandong and Ningxia, the proportions fluctuated during the period from 2009 to 2011, without statistical significance. In Shandong, the proportion decreased from 2009 to 2010 and then rose between 2010 and 2011; in Ningxia, the opposite was the case. The proportion with hormones varied greatly among the 4 areas, with >20% in Anhui and only around 2% in Ningxia.

**Table 7.** Proportion of prescriptions with hormones.

	Year	Proportion	$\Delta^a$	$\chi^2$	P
Zhejiang	2009	12.42	-2.88%	41.206	.000*
	2010	9.54			
Anhui	2009	24.44	-3.43%	10.581	.001*
	2010	21.01			
Shandong	2009	11.09	0.11%	0.153	.926
	2010	10.68			
	2011	11.20			
Ningxia	2009	1.65	0.25%	1.257	.533
	2010	2.29			
	2011	1.90			

<sup>a</sup>The difference between the proportions for the last available year and 2009.  
\*P < .05.

## Discussion

### Use of Essential Medicines

After the implementation of the essential medicines policy, the quantity of medicines used in a single prescription reduced, and the quantity of essential medicines used increased significantly; so, the proportion of essential medicines used in individual prescription should be raised. It is apparent from the results that the use of essential medicines was promoted in the PHCs of the sample areas. However, the goal of the policy is to use only essential medicines in PHCs, which has been already achieved in some other areas in China.<sup>18</sup> That is to say, the policy effect is not good enough in the sample areas such that it calls for improvement. The reasons for the defect may come to these 2 points: one is that it was just the beginning of the policy implementation and the stock of nonessential medicines needed to be consumed; the other is that the essential medicines list was probably not adequate for the basic demands of medicines in grassroots clinical practice.<sup>19,20</sup> The solution for the former is time being with supervision by government; that for the latter is to revise the essential medicines list on demand, and there has already been a revised edition of an essential medicines list, released in 2012.

### Rational Use of Antibiotics, Injections, and Hormones

The overall trend for the use of antibiotics, injections, and hormones in the PHCs of the sample areas was on the decrease, similar to research conducted in other areas in China.<sup>21</sup> Nevertheless, in 1 or 2 areas involved in our study, the decrease was not significant; the fluctuation was witnessed; or there was even a minor climb.

The risk of many infectious diseases is getting uncontrollable due to the spread of antimicrobial resistance caused by improper use of antibiotics.<sup>22</sup> Hormones can take quick effect but may cause intense and long-term harm to human bodies.

Yet, in China, many practitioners consider antibiotics and hormones as specific medicines for infections and inflammations regardless of the causations and the types of the symptoms, which may lead to a lot of overuse and misuse of antibiotics and hormones.<sup>23,24</sup> This suggests that the transmission and update of medicine knowledge to practitioners, especially to those engaging in grassroots clinical practice, are very important.

Injection is an invasive administration of medicines that increases the risk of adverse drug reactions in terms of drug allergy, infections, and physiologic imbalance, including electrolyte imbalance, hypertension, edema, and so on.<sup>25</sup> In the Western Pacific B region, where China is located, it has been suggested that injections were often used and unsafe according to the WHO's estimation.<sup>26</sup> A large number of patients in China believe that injection is the fastest way to cure disease, and many often ask the practitioners to prescribe injections for them. In that injections are usually more expensive than oral medicines, practitioners are willing to do so under the current medical system sustained by the expense of drugs. As such, it is very important to enhance the professional ethics education for practitioners and the general education of medicines use for the masses. In addition, Tang et al<sup>27</sup> have proven that the overall effect of government subsidy on the use of injection was positively significant, so it is necessary to provide appropriate financial support to PHCs to cancel practitioners' incentive of making profit.

In addition, current regulations for prescription—such as the Procedures for Prescription and Procedures for Clinical Use of Antibiotics<sup>28,29</sup>—prescribe that practitioners in violation of provisions under the regulations should be temporarily deprived of prescription privilege. However, this is determined by the health care institutions; that is, if health care institutions acquiesce in practitioners' behavior for the sake of interest, there will be no punishment for inappropriate prescription. Moreover, even if this punishment is given, it is too mild to control practitioners' prescription; therefore, punitive mechanism has to be improved to enhance the supervision of prescription.

### Variations of Medicines Use Among Areas With Different Socioeconomic Status

Change of medicine use could affect the revenue of PHCs and, hence, the sustainability and the development, which are associated with practitioners' income and government financial support. In Zhejiang, the richest province of the 4 sample areas, all changes were positive and statistically significant. A verdict can be reached that the policy took obvious effect in this rich province. In view of the change of economic interests involved in the policy implementation, we speculated that

there might be some relation between the socioeconomic status of an area and the policy effect there. However, the results from the other 3 areas could not provide clear evidence for this speculation. In Shandong, the second-richest province of these 4 areas, as well as one of the richest provinces in China, the policy failed to give a better performance than that in the other 2 less-developed areas. To verify this relation, further study is required, which should involve multiple economic indicators, including gross domestic product per capita, average income per capita, government revenue, public health expenditure, and so on, in each area.

### Other Policies That Could Affect Rational Medicine Use

Several other policies could affect rational medicine use; however, to measure the net effect of a policy is rather difficult. The policies that could directly affect rational medicine use—for instance, are the Procedures for Prescription and Procedures for Clinical Use of Antibiotics, which prescribe the medicine use in practitioners' prescriptions—were launched not in 2009 but in 2007 and 2012, respectively. Therefore, we believe that the results in this study are possibly not disturbed by these policies. Establishing and developing the basic medical insurance system is another one of the 5 core parts of the new health care reform program launched in 2009, which may affect medicine use by prescribing the scope of reimbursable medicine expenses and the proportion of reimbursement. Nevertheless, the main objective of this policy is to cover more people, focusing on the change of financing and payment model. National essential medicines system, one of the key goals of which is rational medicine use, prescribes that all the essential medicines are in the list of reimbursable medicines, and the reimbursement proportion should be higher than that of nonessential medicines, which embodies the effect of basic insurance system on medicine use.

### Conclusions and Policy Implications

To a certain degree, the essential medicines policy in China has taken effect on rational medicines use; however, it is not up to the policy goal and the WHO's recommended standard. It should be developed and then further implemented. The detailed rules of policy implementation should be drawn, amplified, and improved to monitor and control practitioners' prescribing behavior effectively. As a single policy will hardly take effect in developing countries, combined solution is needed. The education of medicines knowledge for practitioners and the public is necessary. As the essential medicines policy restrained medicines abuse, the revenue of health institutions originated from medicines may decrease so that financial support is much needed from the government to improve implementation effect of the policy, especially in those less-developed areas.

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