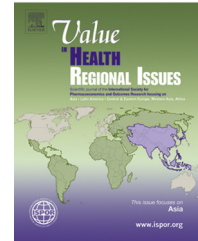




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## Mapping and Analyzing Stakeholders in China's Essential Drug System by Using a Circular Model: Who We Should Deal with Next?

Hui Shao, MHA<sup>1</sup>, Shixue Li, PhD<sup>2</sup>, Lingzhong Xu, PhD<sup>2</sup>, Shuang Yang, MHA<sup>2</sup>, Nicholas J. Thomas, MPH<sup>1</sup>, Mohammed Umer Mir, MS<sup>1</sup>, Zhen Guo, MHA<sup>2</sup>, Bo Ning, PHD<sup>2</sup>, Lizheng Shi, PhD<sup>1,\*</sup>

<sup>1</sup>School of Public Health and Tropical Medicine, Tulane University, New Orleans, LA, USA; <sup>2</sup>School of Public Health, Shandong University, Jinan, Shandong, China

### ABSTRACT

**Objectives:** To predict the prospects of the essential drug system by using the Stakeholder Impact Index (SII) and evaluate the current performance of each main stakeholder and suggested dangerous stakeholders and dormant stakeholders. **Methods:** A Delphi method was used, involving 36 experts with experience in implementation and evaluation of the essential drug policy, to construct the circular model as well as evaluate the performance of each stakeholder. **Results:** The central government was a dominant stakeholder of the whole essential drug system. The provincial governments were definitive stakeholders, whereas local governments and medical institutions were dependent stakeholders. Furthermore, media and drug stores were dormant stakeholders and pharmaceutical manufacturers and delivery enterprises were dangerous stakeholders. Patients, community residents, and medical insurance programs were discretionary stakeholders. The SII for the essential drug system was positive ( $SII_{proj} = 2.72$ ). **Conclusions:** The overall anticipation of the essential drug policy is optimistic.

Letting definitive stakeholders (provincial governments) having more autonomy can efficiently accelerate the pace of implementation of the essential drug policy in the current situation. Central government, however, also needs to construct an experience exchange platform with the aim of building versatile methods for running the essential drug system in all provinces. Pharmaceutical manufacturers and delivery enterprises were dangerous stakeholders for the essential drug policy. Because of their potential threat to the implementation of the policy, the central government should motivate them to support the construction of the essential drug system spontaneously. In that case, provincial governments need to construct a fair, balanced, and self-stabilized bidding platform.

**Keywords:** essential drug, system evaluation, stakeholder analysis, Delphi method.

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### Introduction

Essential drugs, as defined by the World Health Organization, are “those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford” [1]. Within the last 30 years after this definition was put forward, many countries started to construct their own Essential Drug Operation System (EDOS) [2].

China's central government's “Measurements for Implementing Essential Drug Policy” and “Essential Drug List (EDL),” introduced in August 18, 2009 [3], have had a profound influence on Chinese citizens in terms of improving physical and financial access to basic medication. The national EDL is categorized into three broad categories: Chemical Drugs and Biological Products, Chinese Patent Drugs, and Chinese Medicinal Decoction Pieces.

There are 317 subcategories of drugs under Chemical Drugs and Biological Products, whereas Chinese Patent Drugs contain 207 subcategories. Every province is authorized to construct a provincial EDL that can work as a supplement to the national EDL. Drugs are included in the EDL for the purpose of fulfilling citizens' basic medical needs by providing fair and cheap medicines and promoting universal access. The essential drug policy reduces medication costs for citizens through more governmental financing and introduction of a provincial drug-bidding platform. It reshapes profit distribution among all stakeholders in the EDOS by altering the net benefits among pharmaceutical manufacturers, delivery enterprises, and health care providers [4].

The current EDOS, including its bidding, pricing, and delivery system, required full cooperation of stakeholders, and citizens would gain benefits only if most of the stakeholders are willing to participate in the EDOS. For example, more pharmaceutical

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\* Address correspondence to: Lizheng Shi, Department of Global Health Systems and Development, School of Public Health and Tropical Medicine, Tulane University, 1440 Canal Street, New Orleans, LA 70112.

E-mail: [lshi1@tulane.edu](mailto:lshi1@tulane.edu).

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manufacturers bidding for a class of essential drugs would increase the drug quality and reduce its price. Therefore, if some of the stakeholders lose benefits under the implementation of the essential drug policy, there would be foreseeable motivations for them not to participate in the system for their own good, and it was where the potential risk for the EDOS came from [5].

Figure 1 shows the ordinary operation system for medicines: it has a structure of radiation diagram with a central piece marked “Medical institutions.” In this system, medical institutions were the dominant stakeholders. They have the power to decide not only which drug to buy from a drug manufacturer but also the prescription behaviors.

This ordinary operation system for medicines has certain drawbacks: by letting providers have the autonomy of buying and selling medicine, economic factors often outweigh other concerns, such as social responsibility and service quality, with for-profit pharmaceutical companies having more control of the drug market [6]. Information asymmetry, where patients often do not have adequate information relevant to choosing or using medicine, can increase the burden on patients if the market is left unregulated [2]. Compared with the radiation diagram we drew in Figure 1, the EDOS presents a different picture (Fig. 2). In this system, the Chinese provincial governments are in charge of purchasing medicines for the medical institutions instead of letting medical institutions buy medicines themselves. They set up bidding platforms to modify the behavior of pharmaceutical manufacturers and implement prescription standards to regulate the medical institutions’ drug-prescribing practices. By doing so, pharmaceutical manufacturers must lower their price and enhance the quality of their products to compete in the bidding process. Simultaneously, medical institutions are not allowed to use more expensive and unnecessary drugs when an essential drug can be used in the situation. These regulations enhance the governments’ ability to exert control in the drug market and ensure provision of drugs to ordinary citizens at minimal costs [7].

Stakeholder analysis has a history of almost 30 years and is one of the current important methods to help decision makers get a clear understanding about the operation system as a whole [8]. Because of the diversity of stakeholders, some of them may influence the project far greater than do others. We browsed six

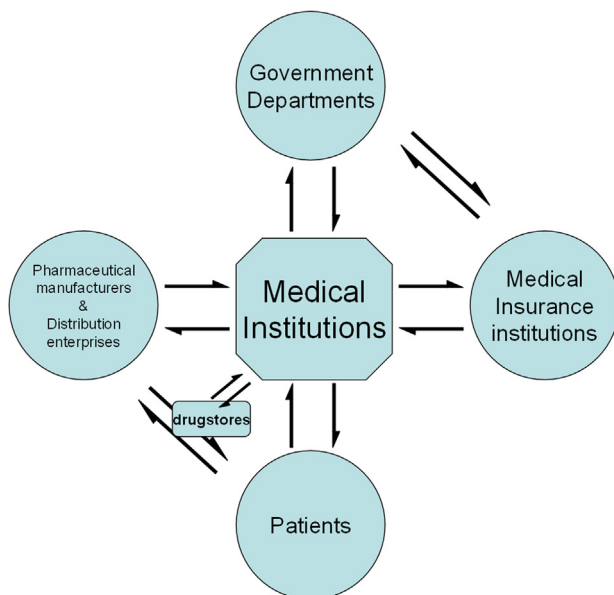


Fig. 1 – Operation system for medicines out of the essential drug list.

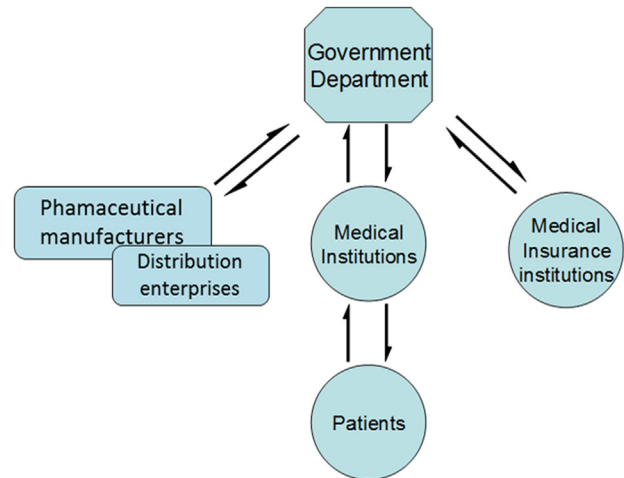


Fig. 2 – Essential drug operation system.

authoritative articles and screened out 11 major stakeholders for the EDOS [9–14]. The primary purpose of this study was to categorize diverse stakeholders in the EDOS by using three key attributes: power, legitimacy, and urgency. The “power” of stakeholders is their ability to mobilize and withdraw social and political forces. The “legitimacy” is constructed by both normative legitimacy and derivative legitimacy: normatively legitimate stakeholders are those to whom the organization has a moral obligation based on fairness; derivatively legitimate stakeholders are those whose actions might affect normatively legitimate stakeholders and thus need to be accounted for by managers [15]. The “urgency” is based on sensitivity and criticality: the former is the degree to which managerial delay is unacceptable when dealing with claims; the latter is the importance of the claim to the stakeholder [16]. According to the definition by Mitchell et al. [16], dangerous stakeholders were those who have power and urgency but no legitimacy. Therefore, this category of stakeholders tended to chase their own interest (i.e., profit) without concern for social outcomes and needed to be paid serious attention. Other categories of stakeholders are presented in Table 1. For more details related to the characteristics of each category of stakeholders, we refer readers to Mitchell et al.’s article [16].

The primary objective of this study was to evaluate the current role and its performance of each major stakeholder in the EDOS. Through the stakeholder analysis, we would be able to get a clear picture of how each stakeholder would react in response to the implementation of the essential drug policy. After that, certain stakeholders that are more influential in the EDOS would be further discussed. Our ultimate goal was to evaluate and predict the likelihood of success for this new essential drug policy through a thorough evaluation of the compliance of all the major stakeholders involved.

## Methods

### Data Source

Literature articles and expert opinion related to stakeholders for the essential drug policy were used to identify 11 main stakeholders. These were central government, provincial governments, patients, mass media, community residents, pharmaceutical manufacturers, delivery enterprises, medical insurance institutions, local governments, medical institutions, and pharmacies.

**Table 1 – Classification method for stakeholders.**

Categories	Power	Legitimacy	Urgency	Alert level
Dormant stakeholder	1	0	0	Middle
Discretionary stakeholder	0	1	0	Middle
Demanding stakeholder	0	0	1	Low
Dominant stakeholder	1	1	0	High
Definitive stakeholder	1	1	1	High
Dangerous stakeholder	1	0	1	High
Dependent stakeholder	0	1	1	Middle

Data were collected between April 2012 and June 2012 using the Questionnaire survey method and the Delphi method. The Delphi experts group had 36 experts from Shandong University, Provincial Hospital, Academy of Medical Science, Bureau of Health, and Provincial Center of Disease Control (CDC). We set up an authority self-evaluation test with two indexes: Ca (How confident you are about your viewpoint?) and Cs (How familiar you are with the topic?). Authority index  $Cr = (Ca + Cs) / 2$ . Scholars whose values of Cr are higher than 0.7 pass the authority examination [17] and are accepted into the next step. Twenty-six (72.2%) experts passed the authority examination. Kendall’s concordance coefficient showed that all scholars had reached an agreement ( $P < 0.01$ ) after three rounds of the Questionnaire survey and the proportion of satisfaction for every index was more than 70%.

**Critical Index Calculation**

Bourne and Walker [18] develop the vested interest–impact index (ViII) to illustrate both the probability and the level of stakeholder impact on project execution. The formula is as follows:

$$ViII = \sqrt{v \times i / 25}$$

The vested interest levels (*v*) and the influence impact levels (*i*) were valued numerically as follows: 5 = very high, 4 = high, 3 = neutral, 2 = low, and 1 = very low.

In this research, we used Stefan Olander’s Stakeholder Impact Index (SII) [19] to evaluate the actual effects of stakeholders on the whole project. The formula is as follows:

$$SII = ViII \times A \times P$$

The stakeholder attribute value (*A*) was assessed by weighing the total score of power, legitimacy, and urgency. Under usual conditions, these three indexes weighed 0.4, 0.3, and 0.3 separately. The stakeholder position value (*P*) was qualitatively assessed as active opposition (–1), passive opposition (–0.5), not committed (0), passive support (0.5), and active support (1). The higher the value the single stakeholder has, the stronger the impact is on the whole project. All the critical values used to calculate ViII and SII were extracted from results of the Delphi analysis. The value of ViII indicates the potential impact of stakeholders on the whole project; however, how much of the potential impact could be fulfilled still depends on those stakeholders’ attribute and position. Thus, SII measures the actual impact of the stakeholders on the project.

**Model Structure**

Lynda and Derek [20] proposed the initial theory for constructing the stakeholder circle model in 2005 with the purpose of setting up a clear, efficient, and comprehensive model for decision makers even without specific knowledge of the field. We designed the circular model for EDOS on the basis of their theory. In this model, the concentric line indicated the urgency of stakeholders. Patterns of stakeholder entities indicated their homogeneity. The stakeholder who has patterns with different colors indicated heterogeneity within its group. The size of the area represented the value of ViII; however, whether this impact power can be fully used depends on the attitude consistency of the stakeholders. Color density indicated the influence impact level (SII) of stakeholders.

**Results**

Power, legitimacy, and urgency were qualitative indexes with only two options (exist or not); therefore, scholars reached a highly consistent agreement on them in the first round of the Delphi survey. It takes three rounds, however, to complete the discussion on the rest of indexes (*v*, *i*, and *P*). The results of the uniformity test are presented in Table 2.

Table 2 presents homogeneity within scholars in the Delphi group. Based on our analysis, Table 3 presents the survey findings on the attributes of the stakeholders and their relative importance (ViII score and SII score) to the EDOS.

**Central Government, Provincial Governments, and Local Governments**

“Who should lead the implementation for essential drug policy?” has been argued among academic circles for a considerable period, and studies have tried to come to conclusive results [21]. Our results presented in Table 3 indicate that the central government may not be the best choice due to a lack of urgency in handling such important matters at the central level. Time delays and information barriers are common resistance for the central government handling immediate problems. On the contrary, provincial governments have power, legitimacy, and urgency, and it would likely be highly efficient letting them lead the implementation of the essential drug policy. The ViII score for the central government is higher than that for the provincial governments (1.00 vs. 0.8), indicating that the central government

**Table 2 – Results of the uniformity test for *v*, *i*, and *P* in the Delphi group.**

Indexes	W	$\chi^2$	df	Significance
Vested interest level ( <i>v</i> )	0.429	90.119	10	0.000
Influence impact levels ( <i>i</i> )	0.752	157.991	10	0.000
Stakeholder position value ( <i>P</i> )	0.766	160.931	10	0.000

W, Kendall’s concordance coefficient.

**Table 3 – Index system of stakeholder analysis for essential drug operation system\*.**

Stakeholder	Attribute			Class	Indexes related to stakeholder analysis					
	Power	Legitimacy	Urgency		A	v	i	P	Viii	Sii
Central government	0.4	0.3		Dominant	0.7	5	5	1	1.00	0.70
Provincial governments	0.4	0.3	0.3	Definitive	1.0	4	4	1	0.80	0.80
Local governments		0.3	0.3	Dependent	0.6	5	4	1	0.89	0.53
Medical institutions		0.3	0.3	Dependent	0.6	3	2	0	0.49	0.00
Pharmaceutical manufacturers	0.4		0.3	Dangerous	0.7	4	3	0	0.69	0.00
Delivery enterprises	0.4		0.3	Dangerous	0.7	4	3	0	0.69	0.00
Patients		0.3		Discretionary	0.3	5	1	1	0.45	0.14
Medical insurance institutions		0.3		Discretionary	0.3	4	3	1	0.69	0.21
Mass media	0.4			Dormant	0.7	1	4	1	0.40	0.28
Community		0.3		Discretionary	0.3	4	2	1	0.57	0.17
Drug stores	0.4			Dormant	0.4	4	2	-0.5	0.57	-0.11

\*  $SII_{proj} = \sum SII_k$ . [19].

still has a higher potential impact on the EDOS. Because of lack of urgency, however, the actual impact of the central government is lower than that of the provincial governments (SII score 0.7 vs 0.8). The local governments are dependent stakeholders in the EDOS. Because of limited power, their functions largely rely on provincial and national drug policies. Thus, even though they have a large potential impact (Viii score 0.89), their actual impact on the EDOS is limited (SII score 0.53).

#### Medical Institutions

As major providers, medical institutions play an essential part in the general drug market. Recent studies have found that the essential drug policy has harmed physicians' interests, especially those physicians who worked at peripheral-level clinics (e.g., village clinic) because of reasons such as delayed reimbursement [4]. This finding is in accordance with our results in Table 3. With limited motivation, the position score dropped to zero (P score = 0) for medical institutions, indicating a neutral position in the EDOS. Also, as a dependent stakeholder, the only way the medical institutions can achieve their needs is by relying on the other stakeholders. In China, most medical institutions, especial major hospitals, are funded and supported by the government. Therefore, government policy usually has a major impact on medical institution benefits. Compliance with the essential drug policy could potentially be against the pursuit of personal interests in their case. Because prescribing essential drugs to the patients would reduce provider benefits, it could also lead to a reduction in provider motivation in complying with it [22]. As we can see in Table 3, medical institutions have a large potential impact (Viii = 0.49), but their actual impact on the EDOS is low (SII = 0), potentially due to a lack of motivation.

#### Pharmaceutical Manufacturers and Delivery Enterprises

Pharmaceutical manufacturers and delivery enterprises are two dangerous stakeholders in the system. They became potential threats not only because they lack legitimacy but also because the policy reduces their possible benefits [23]. In the present situation, their benefits with the introduction of the essential drug policy are uncertain. Large and middle-sized pharmaceutical manufacturers and delivery enterprises see potential profits and have the motivation to engage the EDOS by actively participating in the provincial bidding. There is no certainty, however, whether those stakeholders will retain such interest or will take countermeasures promoting failure of the EDOS. Both pharmaceutical manufacturers and

delivery enterprises have potentially large impacts (Viii score = 0.69); thus, their effects could be devastating for the policy if they turned their position against the system.

#### Drug Stores

Drug stores are the only class of stakeholders that have a negative position toward the EDOS. Because of the nature of drugs on the EDL, drug stores would profit less from selling them compared with selling drugs not on the EDL. The actual negative impact of drug stores on the whole system, however, is relatively small (SII = -0.11).

#### Others

Medical insurance institutions, patients, and community are three discretionary stakeholders in the EDOS. They all have a positive impact on the system. Mass media is a dormant stakeholder and has a positive impact (SII = 0.28) on the implementation of the essential drug policy.

Table 3 also showed that the EDOS has an overall large positive SII score (2.72), indicating that the system would run smoothly in the near future. We constructed the circular model for essential drug policy (Figure 3) by using data in Table 3. As we mentioned above, provincial governments are the best choice for running the essential drug policy. Therefore, we circle the central government (dark spot in the middle) with provincial governments in Fig. 3, indicating that the central government is still in charge of the whole program but providing provincial governments with more autonomy would accelerate the implementation of the essential drug policy. After that, three stakeholders with colorful patterns should raise decision makers' attention: these are pharmaceutical manufacturers, delivery enterprises, and local governments. Both pharmaceutical manufacturers and delivery enterprises showed a neutral attitude on the whole because the essential drug policy brought great benefits to large pharmaceutical manufacturers and delivery enterprises but eliminated almost all small and middle-sized stakeholders out of the game. Therefore, stakeholders in these two categories had different attitudes toward the essential drug policy (colorful pattern). Local governments were a special class in the system. It contained different layers including city, county, village, and district, which possess different attitude toward the essential drug policy. Therefore, we marked this class of stakeholders with circles of different color density. Even though their interests and attitudes were different, their overall position should be supportive because

## Circular Model for Essential Drug Policy

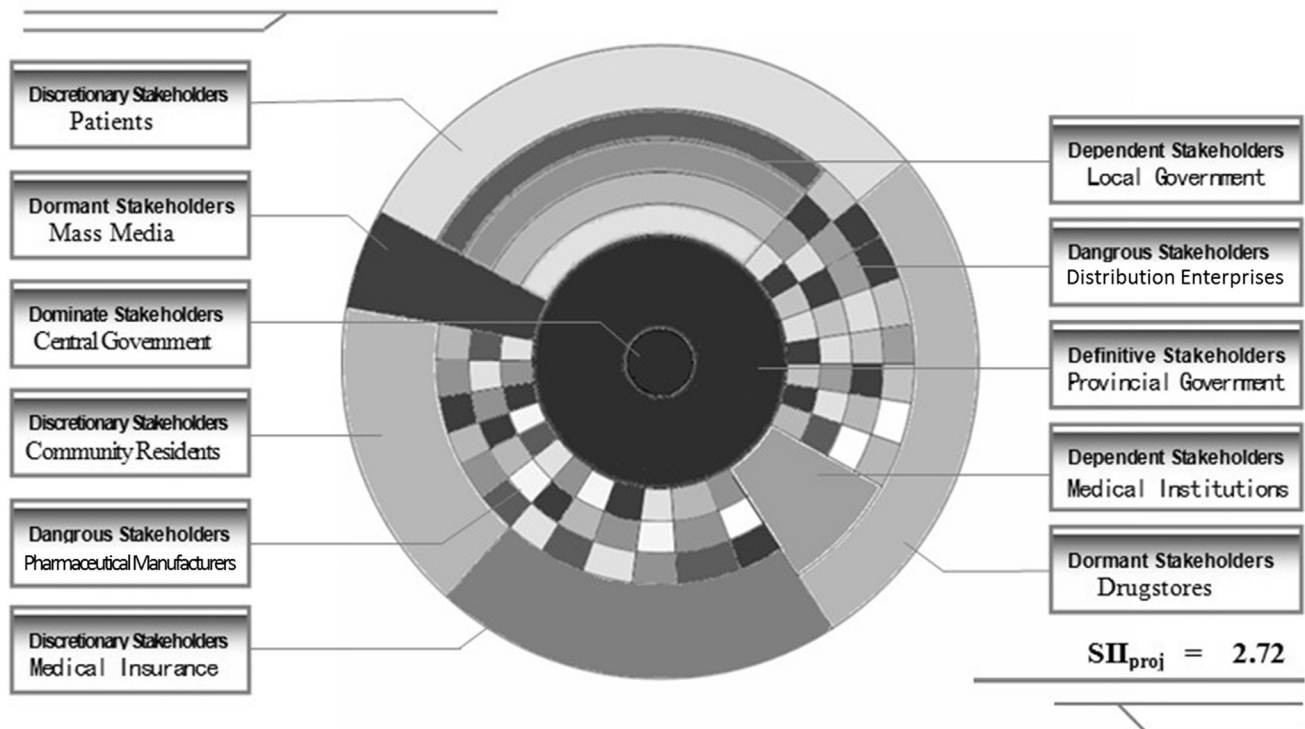


Fig. 3 – Circular model for essential drug policy.

the essential drug policy was a government-implemented policy. Medical institutions, who had a high level of VIII, should make great contributions to the project but remain unused ( $SII = 0$ ).

### Discussion

On the basis of high impact score ( $SII_{proj} = 2.72$ ) as well as the large proportion of supportive stakeholders ( $SII > 0$ ), we believe that this system would operate smoothly in the near future. We predict, however, that modifications are still needed to improve the performance of the system. For one thing, the definitive stakeholders play the most important roles in the system. To make the system run smoothly, it is essential to ensure that those definitive stakeholders (provincial governments) have enough power and resources to achieve their as well as the policy goals. For another, the dangerous stakeholders have potentially uncertain effects on the policy results. Letting them function without restriction or supervision would risk the entire system. The government must constantly supervise and motivate them to make sure they do not shift their position and compromise the system objectives. These two categories of stakeholders are further discussed below.

#### Definitive Stakeholders

The general strategy for the Chinese government was to provide provincial governments with more autonomy and the central government acts only as a directorate, leading the whole project by issuing acts and supporting policies [24]. Provincial governments could potentially benefit from more autonomy in decision making relevant to policy implementation and modification because this could make the process more efficient owing to the consideration of the local context. Also, because of the lack of experience for implementing the essential drug policy in specific

countries such as China, letting provincial governments develop their own ways of implementation could effectively help the Chinese government explore an appropriate method for running the EDOS in China. Giving more autonomy, however, does not mean a total control of all issues. In the last 2 years after the beginning of the implementation of the policy, provinces all across China have shown different capacities for achieving the policy goal [25]. Some of them constructed an outstanding EDOS with a rational and fair drug-bidding platform. On the contrary, some of the others destroyed the EDOS by letting inferior medicines win the bidding and dominate the drug market [22]. Under these circumstances, the central government should construct a platform for provinces to exchange experience. The platform could be created in the form of an annual symposium, seasonal meeting, learning class, video conferences, or any other forms, but should have a singular theme: developing versatile methods for running the EDOS. Decision makers should not appreciate letting stakeholders on the grassroots level have too much autonomy. Although having autonomy could efficiently raise the reactivity for the EDOS, it would also provide them with more access to make personal profits, and this would sharply raise the possibility of an unexpected cost increase for both government and patients. A later, ultimate structure of this EDOS might be a consolidating of power back to the central government by issuing a rational guideline for running the EDOS for all provinces to abide by [26]. If decision makers could realize that this would happen in the next phase of implementation of the essential drug policy, they would be willing to start constructing versatile methods through exchanging experience among provinces in the current phase.

#### Dangerous Stakeholders

Pharmaceutical manufacturers and delivery enterprises are the two classes of dangerous stakeholders in the EDOS. Because of

having power and urgency but no legitimacy, there is a high possibility that they pursue their own goals through violent behavior [27]. In the last 2 years, different provinces encountered various problems caused by dangerous stakeholders. The worst incident happened in the Anhui province where smaller pharmaceutical manufacturers trumped large pharmaceutical manufacturers in the bidding and poured inferior medicines into the market, completely staining essential drugs' reputation [28]. It prompted a deep thought about "how do we make stakeholders willing to compete within the range of policy and laws rather than finding illegal ways to achieve their own profits?" In our previous study [29] we indicated that self-motivation is the key solution for the question above. In the circular model for EDOS, both pharmaceutical manufacturers and delivery enterprises have a large impact on the EDOS ( $V_{II} = 0.69$ ). The only reason they contributed nothing to the project ( $S_{II} = 0$ ) was because stakeholders in each category had different attitudes (patterned color). If their attitudes turned uniformly supportive ( $P > 0$ ), dangerous stakeholders could make a great contribution to the project. To motivate pharmaceutical manufacturers, a fair, balanced, and self-stabilized bidding system should be constructed. The Chinese government tried to improve the rationality of the bidding process by focusing on both quality and price of drugs through a screening method called "Double Envelopes" [30], which required that pharmaceutical manufacturers pass the technique evaluation before they participate in price competition. This method, however, has certain flaws: Who should be in charge of evaluating the technique score of drugs and how to evaluate? The Chinese government currently evaluates the technique score of each bidder through expert evaluation and mainly on the basis of prescription preference and producers' production capacity. This method is subjective and improperly eliminates two essential categories of bidders: nonlocal pharmaceutical manufacturers (less favored by local physicians) and excellent middle-sized pharmaceutical manufacturers (low production capacity) who had been in the essential drugs market for years. The Chinese government, especially provincial governments, should be dedicated to exploring more objective indicators for evaluating the technique score. This goal could be achieved through specific evidence-based medical experiments; however, this bidding platform should have continuous attraction for bidders to participate in (self-stabilization) [31]. The Chinese government was happy to see the byproduct of implementing the essential drug policy-industry integration both in pharmaceutical manufacturers and in delivery enterprises. This integration had great social benefits even for the ordinary drug market [32]. There remain potential, however, concerns that the Chinese government should take into consideration: today's bidding platform was not a self-stabilized one. We could find that pharmaceutical manufacturers who win the bidding are getting more likely to win again. Because of scale expansion and technology promotion after winning, they could gain advantages on costs, prices, and qualities, and therefore raise their possibilities for becoming the next winner. As we all know, additional cost was required for changing industries into producing essential drugs. If pharmaceutical manufacturers are unlikely to win the bid, they might lose the participation enthusiasm. Therefore, a decline in the number of bidders can be foreseen. On the contrary, a fair bidding platform requires perfect competition. More participants in a single bidding could reduce the drug prices as well as motivate the bidders to improve their technology. This paradox explains why the current platform is not a self-stabilized platform. The Chinese government should design a rational protection policy for pharmaceutical manufacturers who are willing to participate in the bidding even if they are less likely to win. And stakeholders who are willing to explore innovations in manufacturing technique, pharmaceutical formulation, and even new

categories of essential drugs should be encouraged, protected, and rewarded [33]. The Chinese government had shortened the period for the admission of new drugs recently, which was a good start. For delivery enterprises, avoiding single delivery enterprises dominating the whole provincial delivery industry is a primary requirement [34].

To sum up, the circular model for essential drug policy is a highly efficient model for decision makers. Stakeholders close to the project's center were provincial governments, followed by pharmaceutical manufacturers, delivery enterprises, and local governments. An experience exchange platform is required for the Chinese government to coordinate implementation progress among provinces. And this platform can also contribute to exploring a uniform method for running the EDOS. After that, the government should put more focus on constructing a fair, balanced, and self-stabilized bidding system. Exploring more objective indicators while protecting innovations in manufacturing technique, pharmaceutical formulation, and even new categories of essential drugs would contribute to the whole project. Besides the above stakeholders, there were some other stakeholders that the Chinese government should take care of, such as medical institutions.

### Limitations

It is widely acknowledged that the Delphi expert panel method often suffers from selection bias and by selective inclusion of experts from certain fields [35]. In our study, we included experts only from colleges, medical providers, and governmental departments, which might not represent the perspective of all stakeholder entities. It is possible that this expert selection process has biased our results. Considering the scope and complexity of the EDOS, however, it is unlikely that people from other fields such as mass media, drug stores, and patients would pass the authority test at the beginning of the study. Therefore, we had to compromise under the given situation with a narrowed source of experts to conduct our study.

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