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Research on the index system of centralized drug procurement in China--based on analytic hierarchy process

Sha Wang, Hongli Jiang*

Fudan University, School of Public Health, 200032, Shanghai, China

Abstract: This paper established a feasible index system for centralized drug procurement in China, which can be used to guide medical institutions to select the bid-winning drugs of same kinds and supervise the process of centralized drug procurement. Based on the literature and related policy documents, the index information was ranked by the relative importance, and the analytic hierarchy process method was used to construct the judgment matrix by pairwise comparison. The weight coefficient of each index was calculated and the consistency test was carried out. A hierarchical model consisting of four primary indicators (including enterprise development capability, drug quality, drug clinical use, and drug economy) and 17 secondary indicators was constructed, and the weight of each indicator to the target layer was calculated. The objective, scientific, quantitatively comparable, operative and feasible drug centralized procurement index system has been established.

Keywords: Centralized drug procurement; Index system; Delphi method; Analytic hierarchy process

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*Corresponding Author: Hongli Jiang, jianghl}@fudan.edu.cn

1. Introduction

Drug centralized procurement, the important component of the basic drug system in medicine and health care system reform in China, is set up to regulate the process of drug centralized procurement. In February 2015, the State Council promulgated "Guidelines about perfecting drug centralized procurement of public hospital" ([2015] no. 7) (hereinafter referred to as the no. 7 guidelines). In June 2015, the National Health and Family Planning Commission issued " the guidance on the implementation of the perfect public hospital drug centralized procurement ([2015] no. 70) (hereinafter referred to as the no. 70 guidance) in order to formulate specific measures[1]. After no. guidelines, all regions in China responded positively, such as Beijing (Beijing regulation of pharmaceutical equipment no. 40 [2015]), Henan (Henan regulation no. 11 [2016]), etc. However, the specific working mode of each region is different. In addition, the current implementation of the system reveals that the quality technology and access of drugs lack of the cognitive and measurable index, as well as the drug safety and drug availability issues need to be improved. In the process of drug centralized procurement, factors such as bid evaluation method, negotiation with drug manufacturers, supply of goods and distribution mode will affect the price, quality and distribution rate of drugs, which will further affect the quality, affordability and availability of drugs[2].

In Shanghai, regarding the mechanism of the public hospital drug centralized procurement as the

important content and the key link of the reform of the medical and health system, the government built the Shanghai information system for the services and regulatory of drug procurement, and innovated alliance procurement model combing the public medical institutions and drug group procurement, in order to gradually achieve the transition from centralized bidding to centralized procurement. In this transition, the management role of Shanghai government departments should also utilize more scientific methods to screen and evaluate indicators and determine the weight[3].

Therefore, this research in the perspective of the regulation of drug centralized procurement and selection of drugs, collected and analyzed the related elements of pharmaceutical production, circulation, and centralized procurement, and then accordingly put forward a set of feasible drug centralized purchasing elements of information system, which can be used to guide the medical institutions to select the winning drugs of same function and regulate drug centralized procurement, in order to ultimately ensure the quality of medical institutions, promote the benign competition and develop the pharmaceutical market[4].

2. Methods

2.1. Literature review

We search the official websites of countries and provinces (also including the municipalities directly under the central government and the autonomous regions) to collect the policies and implementation plans of the centralized drugs procurement in

different regions, and sort out and coclude the plans in different regions.

2.2. Delphi method

The Delphi method, also known as the expert method, is widely used in the establishment of various evaluation index systems and the determination of specific indicators[5]. In essence, it is a method to analyze problems that cannot be quantitatively analyzed, which acquire the related experts use their knowledge and experience and fill in the opinion form for several times[6]. In this study, government managers, academic experts, pharmacy managers in medical institutions, and procurement personnel in enterprises were selected to screen and rank the importance of the primary indicators related to centralized drug procurement, and finally determine the definition of each indicator[7,8].

2.3. analytic hierarchy process

Analytic hierarchy process[9] combines expert advice with qualitative and quantitative analysis to build an orderly index hierarchy and matrix. Experts compare the indexes in pairs of each matrix and assign relative importance values. Yaahp10.3 software is used to convert the expert's assignment into the weight of the index system[10,11].In this study, analytic hierarchy process (ahp) is used to determine the weight of element of centralized drug procurement based on expert consultation.

3. Results

3.1. Related policies after screening

By searching the official websites of the country and each province (municipality directly under the central government and autonomous region), 31 copies of centralized drug procurement policies and implementation plans in different regions were found and then checked the relevant clauses of evaluation elements related to drug bidding, which mainly focus on the scoring scheme of economic and technical standards. After the evaluation of the economic and technical aspects, we found that the 14 policies included clearly grading standard. However, there are great differences in the types, definitions and scores of various elements in economic and technical standards. In order to find regional differences, 14 documents were systematically sorted out in this study, which were classified into 4 first-level indicators (including enterprise development, drug quality, drug subjective evaluation and drug accessibility) and 31 second-level indicators. In view of the differences in the indicator systems in different regions, the indicators were discussed and screened by Delphi method, and the definitions of each indicator were clarified. For example, combination of international certification of secondary indicator preparation was concluded in the indicator of drug innovation; the annual sales volume of the second-level index overlaps the industry ranking, but the importance is degraded due to its strong retention. Finally, the name of 4 first-level indicators (enterprises development, drugs quality, drugs clinical use, and pharmaceutical economics) and 17 second-level indicators were revised. The comparison of the indicators is shown in Table 1.

Table 1. The comparison of the indicators before and after the Delphi method consulting

The first round before consulting (31 indicators)		The second round after consulting (17indicators)		
First-level	Second-level	First-level	Second-level	
	Industry ranking of enterprises		Industry ranking	
	Annual sales	Enterprises development	Annual sales	
Enterprises	Reputation		Reputation	
Enterprises development	Bad record		Bad record	
	Sampling inspection of drug quality		deleted	
	Social responsibility		Social responsibility	
	Research and development ability		deleted	
Drugs quality	Drug innovation		Drug innovation	
	Raw material source		Raw material source	
	Product sampling		Product sampling	
	GMP certification	Drugs quality	deleted	
	Electronic supervision		deleted	
	Storage conditions		Period of validity or storage conditions	
	Quality standard drafting unit		deleted	
	Product market share		market share	
	Overseas sales		deleted	
	Provincial online procurement supply situation		deleted	
	International certification of preparations		Concluded in Drug innovation	

Chronic Diseases Prevention Review

11 (2019) 33-39

Industry ranking of major varieties deleted Dosage form characteristics deleted Completeness of the declared quantity deleted Bidding group deleted

Social responsibility Concluded in Reputation

Clinical efficacy: safety and effectiveness Cure effect Drugs Convenient and practical packing Drugs clinical Safety Subjective Market credit score and brand use convenience evaluation Supply and accompanying services Supply guarantee

> unit price ranking in the same variety price ranking in the same category

unit price ranking in the same variety deleted

DDD cost ranking in the same category DDD cost ranking in the same category

The number of days counted by standard Pharmaceutical Drugs The cost of a course of treatment based on accessibility

local wages converted from the cost of a the local economic

standard course of treatment for the

disease

Definitions of secondary indicators:

- 1) industry ranking: the order of ranking is divided into following categories: comprehensive ranking of drugs :1-10, 11-30, 31-60, 61-90, 91 and later; Chemical drugs: 1-30, 31-60, 61-90, 91-120; Proprietary Chinese medicine: 1-30, 31-60, 61-90, 91-120; Biological products: 1-30, 31-60, 61-90, 91-
- 2) annual sales: there is some overlap with the industry ranking, but this indicator is more objective. The importance of the indicator can be degraded;
- 3) reputation: whether it is a well-known trademark, a famous brand in Shanghai, or an intangible cultural heritage:
- 4) bad records: the information recorded in the inquiry report of legal person's public credit information (trial version of Shanghai food, drug, medical device and cosmetics production and business enterprise) issued by Shanghai information center and Shanghai public credit information service center shall prevail;
- 5) social responsibility: whether to undertake reserve tasks at different levels of the central government, the military and local governments;
- 6) drug innovation level: Class I: compound patented drugs, national secret products, 1.1 new drugs in the monitoring period, first prize of science and technology progress; Class II: patent original developed drugs, protected varieties of traditional Chinese medicine, second-class drugs of state science and technology award; Class III: generic drugs that have passed the quality consistency assessment, domestic drugs and imported drugs that have been registered or GMP certified by the European Union, the United States, Japan, PIC/S member states; Class IV: quality standard drafting unit, first generic drugs, process patent;
- 7) source of raw materials: self-produced raw materials of the factory, or self-produced raw materials of the company, or others;

- product sampling: the drug announcement issued by the state and Shanghai food and drug regulatory authorities in the past two years shall be taken as the evidence:
- 9) period of validity or storage conditions: for the best among similar drugs, the drug manual shall prevail;
 - 10) market share: coverage in reality;
- 11) clinical efficacy: subjective opinions of clinical experts;
 - 12) safety: subjective opinion of clinical experts;
- 13) convenience: subjective opinions of clinical experts:
- 14) supply guarantee: subjective opinions of clinical experts;
- 15) unit price ranking: the ranking of the minimum price of the purchased product among the similar varieties;
- 16) DDD cost ranking: refer to the daily expense index set by NDRC;
- 17) the cost level of a course of treatment based on the local economic level: the number of days counted by standard local wages converted from the cost of a standard course of treatment for the disease

3.2. Situation of experts

In this study, a total of 26 experts including 12 procurement personnel from enterprises, 8 pharmacy managers from medical institutions, 6 government managers and academic experts were invited.

3.2.1. Authority of experts

The authority of experts has a great impact on the rationality and reliability of the indicators, which is generally determined by two factors. One is the evidence used as basis by experts to judge and evaluate the indicators, expressed as Cα. Another is the expert's familiarity with the indicators, expressed as CS. The authority of experts was expressed by the authority coefficient Cr, which can also be expressed as the arithmetic mean of the judgment basis coefficient and the degree of familiarity coefficient, namely $Cr=(C\alpha+CS)/2$.

According to the statistical analysis of the feedback results of all experts, the familiarity coefficient of most experts in the second-level indicators is more than 0.8, with an average of 0.86. The judgment basis coefficients were all above 0.6

and the mean value was 0.70. The authority coefficient of experts is 0.78 at the average level 0.73 at the lowest level and 0.83 at the highest level, indicating that the consulting experts have a relatively high degree of authority on the research issue of drug bidding and procurement elements (Table 2).

Table 2. Authority of experts

First-level indicators	Second-level indicators	Cs	Сα	Cr
	Industry ranking	0.88	0.72	0.80
Entamoissa	Annual sales	0.90	0.74	0.82
Enterprises	Reputation	0.87	0.69	0.78
development	Bad record	0.88	0.71	0.80
	Social responsibility	0.83	0.70	0.77
	Drug innovation	0.88	0.68	0.78
	Raw material source	0.79	0.67	0.73
Drugg quality	Product sampling	0.91	0.76	0.83
Drugs quality	Period of validity or storage conditions	0.91	0.75	0.83
	market share	0.91	0.70	0.80
Drugs clinical use	Cure effect	0.82	0.66	0.74
	Safety	0.86	0.68	0.77
	convenience	0.82	0.67	0.74
	Supply guarantee	0.85	0.75	0.80
Pharmaceutical economics	unit price ranking in the same variety	0.84	0.71	0.78
	DDD cost ranking in the same category	0.84	0.67	0.76
	The cost of a course of treatment based on the local economic	0.82	0.64	0.73

Table 3. The result of Kendall's W test

	coordination coefficient	c2	df	P
Total	0.180	75.020	16	0.000
enterprises	0.324	62.229	16	0.000
medical institution	0.287	41.325	16	0.000
Government or academic institution	0.391	31.318	16	0.012

3.2.2. Coordination coefficient of expert opinions

The coordination coefficient of expert opinions can be used to judge whether different experts have great disagreements on the same index, which can reflect the credibility of the consultation results. Kendall's W test can be used to indicate that the W value is between 0 and 1, and the closer to 1 the value is, the better the coordination is[12]. In view of the differences in the perspectives of experts in different fields, the coordination coefficient of experts was evaluated according to their work areas (group of enterprises, medical institution, government or academic institution).

The test shows that the coordination coefficient of each group (0.324, 0.287, 0.391, shown in Table 3) is higher than the coordination coefficient in total (0.180). The highest coefficient is in the group of government or academic institution, indicating the high degree of consistency of the opinions of the government managers and academic experts.

3.3. Weight of indicators

3.3.1. The hierarchy model

According to the analytical steps of analytic hierarchy process (ahp), the hierarchical structure model is constructed in this study, as shown in Figure 1.Among them, the general target layer is the elements of centralized drug procurement, the criterion layer is the first-level index of centralized

drug procurement, and the index layer is the secondlevel index of centralized drug procurement.

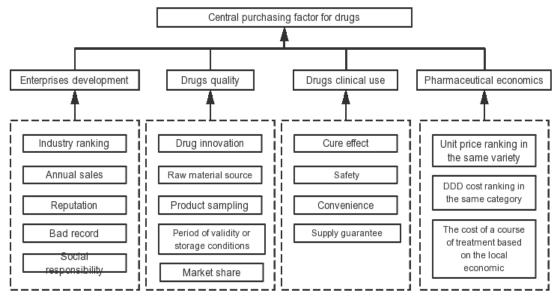


Figure 1. The hierarchy model of centralized drug procurement.

Table 4. Weight of indicators based on ahp method

First-level indicators	weight	Second-level indicators	weight
		Industry ranking	0.006
	0.076	Annual sales	0.006
Enterprises development		Reputation	0.024
		Bad record	0.019
		Social responsibility	0.009
		Drug innovation	0.054
		Raw material source	0.047
Drugs quality	0.532	Product sampling	0.243
		Period of validity or storage conditions	0.139
		market share	0.030
Drugs clinical use		Cure effect	0.093
	0.253	Safety	0.119
	0.233	convenience	0.029
		Supply guarantee	0.058
Pharmaceutical economics		unit price ranking in the same variety	0.015
	0.139	DDD cost ranking in the same category	0.036
	0.139	The cost of a course of treatment based	0.074
		on the local economic	

3.3.2. Judgment matrix

On the basis of the hierarchical structure model, all judgment matrices of each level are constructed, and a questionnaire is preliminarily formed according to the research background. A total of 5 judgment matrices were constructed in the questionnaire, among which there was 1 judgment matrix in the criterion layer, that is, each first-level index constituted a pair-wise comparison table, and the index layer under each criterion layer constituted

a pair-wise comparison table, that is, each secondlevel index under each first-level index constituted a pair-wise comparison table. A total of 26 pieces of expert consultation were sent out and 26 pieces were recovered, with a recovery rate of 100.00% and a total of 130 judgment matrices, indicating great cooperation of the interviewed experts. The recovery rate of this study meets the sample number required by statistics for inference[13].

3.3.3. Weight of indicators

Finally, the weight of the first-level and second-level indicators was calculated. Among the first-level indicators, the weight of drug quality was the largest (0.532), followed by the clinical use of drugs. Among the second-level indicators, the weight is concentrated on product sampling, period of validity and storage conditions and safety, while the other second-level indicators are numerous, but the weight value is very low, and the industry ranking weight is only 0.006. The calculation results of specific index weight coefficients are shown in Table 4.

4. Discussion

4.1. Local policies on centralized drug procurement

This study found that there were significant differences in the requirements of drug evaluation elements in the current centralized drug procurement documents of drugs in different provinces. Although many similar indicators, including enterprise development, drug quality and clinical use, are covered in different regions, the definition of specific indicators and scoring rules are quite different, resulting in different evaluations for specific drug varieties.

4.2. Methodology

The evaluation methods commonly used in China include analytic hierarchy process (ahp), fuzzy comprehensive evaluation method, grey relational degree method, BP neural network method, and evaluation method based on principal component analysis (pca). Among these methods, hierarchical analysis is often used for the determination of index weight in drug bidding procurement, Liu indicated that the level of quality, price, service, reputation weights are respectively 0.629, 0.214, 0.085, 0.072, and drug quality is more important on other indicators, which is consistent with our study. The details are shown in the case study part of index system of drug centralized purchasing in the article "the research of drug centralized purchasing evaluation index system of China". Although the second-level indicators selected in this paper are quite different from Liu's study, it can be seen that the clinical efficacy (weight: 0.639) in this study is relatively important compared with drug safety (weight: 0.361)[14]. This result is inconsistent with our study, which may be related to the subjective differences of experts.

4.3. Weight of indicators

In this paper, analytic hierarchy process (ahp) was used to construct a relatively objective, scientific, quantitatively comparable, operative and feasible drug centralized procurement index system with certain reference value. Drug centralized purchasing first-level index can be divided into enterprises development, drugs quality, drugs clinical use, and pharmaceutical economics. From the aspect of weight of first-level indicators, the order is drug quality > drugs clinical use > pharmaceutical economics > enterprise development. The weight of drug quality differs most from the weight of the other three indicators, then there is the weight of drugs clinical use, so that the drug quality and drugs clinical use are the important indicators in the centralized drugs procurement, which should be given considerable attention in the evaluation, while the other 2 indicators: enterprise development, and pharmaceutical economics can be used as auxiliary elements to assist evaluation[15].

Among the second-level indicators, the product sampling has the highest weight, followed by the period of validity, storage conditions and safety, with the weight exceeding 0.1. The three indicators are classified into the first-level indicators of drug quality and clinical use, which are consistent with the weight results of the first-level indicators. The results of this study show that for centralized drug procurement, the quality, efficacy and safety indexes of drugs are the most important, and there is a big gap with other indexes. The results are also in line with reality. It is suggested to collect the specific information and data of the bidding enterprises in the practice of centralized drugs procurement, and make quantitative scoring according to the weight of specific indicators in the hierarchical structure model established in this paper in order to select the winning enterprises more scientifically[6].

In addition, from the professional point of view, the first-level index of enterprise development and the clinical drug use will produce a great impact on the quality of drugs, can be classified as quality standard from the essence. According to this essence, the first-level index can be divided into two major categories of quality standard and economic standard, therefore, the quality standard of weight is 0.861, much higher than in table 4 special drug quality index (0.532). Pharmaceutical economics should not be limited to drug price, but also take other indicators into consideration. Therefore, drug price is standardized in this study to generate two secondlevel indicators, namely, unit price ranking and daily cost (DDDc) ranking. And it is associated with the local economic burden to produce the second-level index of the treatment course cost level based on the local economic level.

4.4. Advantages and limitations

Expert opinions are subjective, so the original data of this study are scored by experts according to certain personal scoring criteria in order to

Chronic Diseases Prevention Review

11 (2019) 33-39

quantifying the qualitative problems[16]. In addition, experts from three fields including pharmaceutical enterprises, medical institutions and researchers were selected for expert consultation and analytic hierarchy process (ahp) research, which reduced the one-sidedness and biases of expert opinions and made the analysis results more convincing. In addition, this study tested the consistency of the scoring results which can partly prevent defects caused by great difference in different experts' opinions.

5. Conclusion

However, there is some limitations. The index system of drug centralized procurement established in this paper is only based on the analytic hierarchy process method for primary research, and there are still some deficiencies, which need to be timely adjusted according to specific conditions in practical work. In addition, the definition of indicators is determined by the discussion of experts, which also needs to be further improved.

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