Construction of Clinical Evaluation Index System of National Generic Drugs Centralized Bidding Procurement

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Abstract

Objective To establish a scientific, reliable, objective, and effective clinical comprehensive evaluation system for drugs centralized bidding procurement by government, and to conduct reliability and validity test and empirical analysis of the evaluation index system through simulated measurement. **Methods** Literature research method was used to select comprehensive evaluation indicators for drugs centralized bidding procurement. Then, Dephi method was applied to screen the final evaluation indicators, and the weight of the indicators was determined using analytic hierarchy process. **Results and Conclusion** The final clinical efficacy evaluation index system for drugs centralized bidding procurement includes 5 primary indicators and 13 secondary indicators. The experts authority coefficient in this study is high, and their opinions relatively coincide. Through the empirical research, the reliability and structural validity of the indicator system is good. This indicator system enriches methods and tools for scientifically evaluating the clinical efficacy of drugs centralized bidding procurement.

Keywords: procurement with quantity; clinical efficacy; evaluation index system; Delphi method; hierarchical analysis method; empirical analysis

The "Opinions of the Central Committee of the Communist Party of China and the State Council on Deepening the Reform of the Medical Security System" (ZF [2020] No. 5) proposed that the reform of the centralized procurement system for drugs and medical devices should be deepened, which must adhere to the integration of bidding and procurement, and linking quantity to price. The "14th Five-Year Plan for National Medical Security" (GBF [2021] No. 36) clearly proposed to establish a drug evaluation and monitoring mechanism for the medical insurance catalog, which can monitor the allocation, use, online access, medical insurance payment, and clinical efficacy of drugs, and evaluate the safety, effectiveness, and accessibility of drugs. Currently, China's comprehensive clinical evaluation of drugs has made continuous progress in monitoring drug supply assurance and rational use of drugs, and accumulated some experience. However, the comprehensive evaluation of drugs in centralized procurement is still in the exploratory stage. This study evaluates the clinical use of generic drugs in

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centralized procurement with the original drug as a control, constructing a comprehensive clinical evaluation system with Delphi method, and designing evaluation indicators to determine their weights based on analytic hierarchy process. Finally, suitable generic drug varieties for empirical research are selected.

1 Connotation of comprehensive clinical evaluation of drugs

Clinical comprehensive evaluation of drugs is a multi-dimensional and multi-level evaluation of drugs based on their clinical value [1]. In China, some researchers believe that comprehensive drug clinical evaluation should focus on data sources and decision-making methods. Data sources mainly include real-world data research, literature research, etc. Common decision-making methods include Delphi method, multi-criteria decision analysis (MCDA), etc. [2]. The comprehensive clinical evaluation of drugs provides an important evidence-based basis for drug supply assurance and rational use through a multi-dimensional drug evaluation mechanism that is patient centered and guided by the clinical value of drugs.

2 Materials and methods

In the early stage of this study, we conducted interviews with clinicians and clinical pharmacists from Beijing Third class hospitals. Combined with relevant literature on clinical efficacy evaluation of drugs centralized bidding procurement in domestic and foreign databases, we collected some policy documents on drug centralized bidding procurement and imported the above information into Nvivo 12.0 plus software. After extracting high-frequency subject words, we initially constructed an evaluation index system for drugs centralized bidding procurement, consisting of 6 first level indicators and 15 second level indicators. The letter questionnaire was developed using Likert's five-level scoring method. The final evaluation index system was formed after two rounds of Delphi expert letters, the opinions and suggestions from experts, as well as statistical indicators such as (mean), *S* value (standard deviation), *CV* value (coefficient of variation), *R* value (insignificant percentage), and full score ratio (%). The final inclusion criteria for evaluation indicators were: $x \geq 3.6$ points, $CV < 0.25$, and $R < 50\%$ [3].

Literature search, expert consultation, and Delphi method [4] were used to establish a comprehensive clinical evaluation index system for drugs. The analytic hierarchy process [5] was used to determine the weight of indicators, thereby constructing a complete clinical comprehensive scoring system for drugs. The score of each evaluation index was determined according to the weight. Some drug varieties were selected for the empirical research to verify the scientific nature and operability of this evaluation index system.

3 Construction process and results of indicator system

3.1 Basic information of experts

A total of 17 experts participated in this Delphi expert consultation, and their basic information is shown in Table 1.

Table 1 Basic information of experts

Basic information of expert	Number of people	Constituent ratio
Gender		
Male	10	59
Female	7	41

(to be continued)

Continued Table 1

Basic information of expert	Number of people	Constituent ratio
Age		
≤ 35	6	35
36–45	8	47
> 45	3	18
Industry field		
Scientific research personnel	5	29
Physician or pharmacist in a Class III hospital	8	47
Drug regulation	2	12
Medical statistics	2	12
Education background		
Graduate and above	14	82
Undergraduate course	3	18

3.2 Expert enthusiasm and authority

The recovery rate of expert consultation questionnaires is the degree of enthusiasm of experts. This coefficient directly reflects whether and how much experts pay attention to this study. When the experts' enthusiasm coefficient [6] reaches 60%, it indicates that the recovery rate is high. When it reaches 70% or above, it can be considered that the level of enthusiasm is very good. The recovery rate of the two rounds of expert correspondence questionnaires is 100%, and the experts' enthusiasm coefficient is 100%, indicating that the experts' enthusiasm is the highest.

The authority level of an expert (Cr) [7] is determined by the expert's judgment for scoring the indicator (Ca) and the expert's familiarity with the work (Cs). In this study, the authority level Cr of experts in the two rounds is 0.868 and 0.827, respectively. Generally, $Cr \geq 0.7$ indicates that the authority of experts is high [8], so the authority of correspondence experts in this study is high.

3.3 Degree of expert coordination

The expert coordination coefficient (Kendall harmony coefficient) [9] is shown in Table 2. The expert coordination coefficient is used to test the coordination degree of experts on the evaluation content. $P < 0.001$ indicates that experts' opinions on evaluation indicators relatively coincide and have a small fluctuation [10]. The coordination coefficients for the second round of experts coefficients are shown in Table 3, with P values less than 0.001, and the results are acceptable.

Table 2 Expert coordination coefficient

Item	W	x^2	P
First round	0.214	41.092	< 0.001
Second round	0.344	66.050	< 0.001

Table 3 Core and sub dimension scores for the second round of experts

Primary indicator	Secondary indicator	Maximum (Max)	Minimum (Min)	Mean value (`x)	Standard deviation (S)	Coefficient of variation (CV)	Full score ratio (%)
1 Safety		5	5	5	0	0	100
	1.1 Incidence rate of adverse reactions	5	3	4.6	0.60	0.13	65
	1.2 Severity of adverse reactions	5	4	4.9	0.32	0.07	88
2 Effectiveness		5	4	4.9	0.24	0.05	94
	2.1 Improvement degree of main clinical indicators	5	5	5	0	0	100
	2.2 Improvement degree of secondary clinical indicators	5	3	4.3	0.57	0.13	35
	2.3 Single drug replacement rate	5	3	4.4	0.69	0.16	53
	2.4 Secondary drug replacement rate	5	3	4.6	0.69	0.15	71
3 Suitability		5	4	4.4	0.48	0.11	35
	3.1 Drug compliance	5	4	4.9	0.32	0.07	88
	3.2 Convenience of drug	5	3	4.5	0.78	0.17	65
	3.3 Drug use propensity	5	2	3.9	0.90	0.23	29
4 Economy		5	3	4.3	0.57	0.13	35
	4.1 Average daily cost	5	3	4.6	0.69	0.15	71
	4.2 Single treatment cost	5	3	4.5	0.70	0.16	59
5 Accessibility		5	3	4.5	0.61	0.13	59
	5.1 Availability	5	3	4.7	0.57	0.12	76
	5.2 Supply stability	5	3	4.8	0.55	0.11	82

3.4 Expert inquiry results

In the first round of correspondence survey, experts evaluate four primary indicators. Experts believe that there is a shortage of supply of drugs centralized bidding procurement, so it is necessary to consider "accessibility". The selection criteria for comprehensive indicators and expert recommendations have led to the decision to add this indicator. Experts have evaluated 10 secondary indicators, with an average assigned value of importance between 3.8−5 points, a coefficient of variation between 0−0.26, and a full score ratio between 24% and 100%. The screening criteria for comprehensive indicators and expert recommendations lead to the final revision of 8 secondary indicators. In the first level indicator "safety", the second level indicator "drug use restrictions for special population" is deleted. In the first level indicator "effectiveness", one indicator is deleted and two indicators are added. The original secondary indicator "medication replacement rate" was deleted and two secondary indicators "medication first replacement rate" and "medication second replacement rate" are added. One secondary indicator is added to the "suitability" of the primary indicator. An indicator of "medication propensity" has been

added, while such indicators of "economy" have not been modified. Among the newly added primary indicators "accessibility", two secondary indicators "availability" and "supply stability" are new. The indicators are interpreted as "whether the drug is available" and "the stability of the drug supply". The experts in the second round of correspondence survey do not propose any modification suggestions, indicating that the experts are relatively satisfied with the existing indicators and their opinions tend to be consistent. Therefore, the third round of correspondence survey will not be conducted.

In the second round of correspondence, the five first level indicators are evaluated accordingly. The average value assigned for the importance of the indicators is between 4.3−5 points, the *CV* is between 0−0.13, and the full score rate is between 35% and 100%. One expert proposes a modification suggestion to add "innovation", but after in-depth consideration, it is not adopted. Therefore, the first level indicators are not modified in this round. The 13 secondary indicators are evaluated respectively. After comprehensive analysis, the average score of indicator importance assignment is between 3.9−5 points, *CV* is between 0−0.23, and the full score rate is between 35% and 100%. All correspondence experts have not proposed any suggestions for modifying, deleting, or adding the indicator content, so no modifications have been made.

3.5 Index weight analysis

3.5.1 Calculating index weights

The indicator weight is calculated using the analytic hierarchy process, and the consistency of the expert scoring questionnaire is checked. The unqualified questionnaire is returned to the experts for review. Then, the scores of experts are summarized. On the premise that it is determined to be a valid questionnaire, the average value of experts' scores on the same indicator is selected. The scoring method is as follows: Asking experts to compare the importance of each Element at the same level in pairs, using Saaty 1−9 scale method, and constructing a comparison judgment matrix. The scale meaning is shown in Table 4.

The steps for calculating weights using the analytic hierarchy process are as follows:

$$A_{ij} = \frac{A_{ij}}{\sum A_{ij}} \ (i = 1, 2\cdots, n).$$

Sum the normalized matrix,

$$W_i = \sum A_{ij} \ (i = 1, 2\cdots, n).$$

Normalize the vector to obtain the feature vector,

$$W_i = \frac{W_i}{\sum W_i} (i = 1, 2\cdots, n).$$

Calculate the maximum characteristic root max, and

$$max = \sum AW_i / nW_i.$$

Table 4 Analytic hierarchy process judgment matrix scale and its meaning

Mean difference	Meaning	Saaty
$A_{ij} - A_{ji} = 0$	A_{ij} is equally important than A_{ji}	1
$0.25 < A_{ij} - A_{ji} \leq 0.5$	A_{ij} is slightly more important than in A_{ji}	3
$0.75 < A_{ij} - A_{ji} \leq 1$, $0.25 < A_{ij} - A_{ji} \leq 0.5$	A_{ij} is more important than A_{ji}	5
$1.25 < A_{ij} - A_{ji} \leq 1.5$	A_{ij} is significantly more important than in A_{ji}	7
$1.75 < A_{ij} - A_{ji} \leq 2$	A_{ij} is definitely more important than a A_{ji}	9

Note: If the difference is between two scales, Saaty is taken as the reciprocal of 2, 4, 6, and 8. When comparing the values of A_{ij} and A_{ji}, one of the scale values above is assigned. The weight of A_{ij} and A_{ji} should be the reciprocal of that scale.

3.5.2 Checking the consistency of judgment matrix

The consistency of the judgment matrix can be checked by calculating the consistency ratio (*CR*) of the judgment matrix [11]. $CR = CI/RI$, $CI = (l_{max} - n)/(n - 1)$, where *RI* is the average random consistency, and *n* is the matrix dimension. The value of *CI* is calculated by the judgment matrix. *RI* is introduced

to avoid the drawback of *CI* significantly increasing with the increase of order *n*. Its value can be obtained by checking a table. When $CR \leq 0.10$, it indicates that the judgment matrix basically satisfies complete consistency [12]. If $CR > 0.10$, the judgment matrix should be modified according to the specific situation. The above calculation is implemented through online software spssau.

In this study, the maximum eigenvalue of the primary index is 5.131, and the maximum eigenvalue of the secondary index is 2.000, 4.088, 3.087, 2.000, and 2.000, respectively. All *CR* values are less than 0.1, indicating that the judgment matrix constructed in this study has good consistency. See Table 5 for details.

Table 5 Average random consistency index (*RI*) values

n	3	4	5	6	7	8	9	10	11	12	13	14	15	16
RI	0.52	0.89	1.12	2.26	1.36	1.41	1.46	1.49	1.52	1.54	1.56	1.58	1.59	1.59
n	17	18	19	20	21	22	23	24	25	26	27	28	29	30
RI	1.606 4	1.613 3	1.620 7	1.629 2	1.635 8	1.640 3	1.646 2	1.647 9	1.655 6	1.658 7	1.663 1	1.667 0	1.669 3	1.672 4

3.5.3 Combination weight of indicators at all levels

In this study, the most commonly used method for calculating combination weights – the product method [13] is used to calculate the combination weights of secondary indicators, that is, the values obtained by continuously multiplying the weights of secondary initial indicators and their parent indicators.

Based on the statistical analysis of the bidding drug indicator system for centralized procurement, it is found that the weight of safety indicators is the highest, followed by evaluation indicators of effectiveness. The weight ranking of the first level indicators in this study coincides with the weight ranking of clinical comprehensive evaluation indicators for ophthalmic drugs constructed by Wang, et al. [14]. The comprehensive evaluation level 1 index system of "direct oral anticoagulants in the prevention of atrial fibrillation stroke" established by Zhang, et al. [15] is completely the same, with similar weights. This indicates that the National Medical Security Bureau will, in accordance with the requirements of the "Opinions of the Central Committee of the Communist Party of China and the State Council on Deepening the Reform of the Medical Security System", provide high-quality generic drugs to the public, starting from three perspectives of safety, effectiveness, and quality controllability. In order to improve the quality of generic drugs, the National Medical Products Administration of the people's Republic of China has actively carried out the policy intention of evaluating the quality and efficacy consistency of generic drugs. This shows the National Healthcare Security Administration and the National Medical Products Administration attach great importance to the safety and effectiveness evaluation indicators of generic drugs. See Table 6 for details.

Table 6 Combination weights of secondary indicators

Primary indicator	Original weight	Secondary indicator	Original weight	Combination weight
1 Safety	0.40	1.1 Incidence rate of adverse reactions	0.25	0.10
		1.2 Severity of adverse reactions	0.75	0.30

(to be continued)

Continued Table 6

Primary indicator	Original weight	Secondary indicator	Original weight	Combination weight
2 Availability	0.29	2.1 Improvement degree of main clinical indicators	0.52	0.15
		2.2 Improvement degree of secondary clinical indicators	0.09	0.03
		2.3 Primary drug replacement rate	0.14	0.04
		2.4 Secondary drug replacement rate	0.24	0.07
3 Suitability	0.10	3.1 Drug compliance	0.62	0.06
		3.2 Convenience of drugs	0.28	0.03
		3.3 Medication propensity	0.10	0.01
4 Economy	0.07	4.1 Average daily cost	0.67	0.05
		4.2 Single treatment fee	0.33	0.02
5 Accessibility	0.14	5.1 Availability	0.33	0.05
		5.2 Supply stability	0.67	0.09

4 Empirical study on the clinical comprehensive evaluation index system of bidding drugs

4.1 Research object and method

Based on the established clinical efficacy evaluation index system for drug centralized bidding procurement, some drugs won the bid using sample hospital data from the National Pharmaceutical Information Network, and the clinical efficacy of centralized procurement of generic drugs and original research drugs was empirically compared. A questionnaire survey was conducted on 5 bidding drugs (including moxifloxacin hydrochloride, acarbose, atostatin, amlodipine besylate, and levetiracetam) involving 13 different product specifications based on the number of hospitals using the drug and expert opinions.

There are 5 principles for drug centralized bidding procurement. First, to ensure the scientific rigor of the questionnaire, there are five major categories of drugs commonly used in daily life, including blood pressure lowering, blood lipids, blood glucose, antibacterial drugs, and anti-epileptic drugs, which are widely collected and covered in the National Medical Information Network member hospitals. Secondly, the network member hospitals have used both bidding generic drugs and original research drugs in centralized procurement. Third, from October 2018 to September 2021, among the sample hospitals of the National Pharmaceutical Information Network, drugs were used the most extensively with a concurrent procurement record of ≥ 6 months for both centralized procurement drugs and original drugs. During this period, a total of 433 network member hospitals frequently purchased moxifloxacin hydrochloride. 345 member hospitals frequently purchased acarbose capsules. 559 member hospitals frequently purchased atorvastatin. 542 network member hospitals frequently purchased amlodipine besylate, and 310 network member hospitals frequently purchased levetiracetam. Based on the above, these five drugs were selected for research.

Criteria for questionnaire of each drug are determined. Firstly, clinical pharmacists or clinicians should be in sample hospitals. Secondly, there has been prescriptions of the studied varieties for both centralized procurement of generic drugs and original drugs. Exclusion criteria are as follows. Firstly,

assistant researchers and nurses are not included. Secondly, the department where the investee belongs does not match the department where the drugs are studied. Thirdly, the questionnaire for the bidding drug province in the centralized procurement is different from the province where the respondent is located.

Based on the evaluation index system using the comprehensive scoring method, this study constructed a clinical efficacy evaluation model for generic drugs in centralized bidding procurement. Then, the weighted total scores were used as a comprehensive indicator to evaluate each evaluation object.

Based on the established evaluation index system, with the end level indicators as the basic framework, a pool of clinical efficacy items for centralized procurement drugs is initially developed, and the end level indicators are converted into investigation questions according to their corresponding relationships. According to clinical differences, there are five levels ranging from low to high. Level I has a significant difference (1−2 points, with significant differences in clinical efficacy between the two), level II has a significant difference (2−4 points) too, level III has a moderate difference (4−6 points), level IV has a small difference (6−8 points), and level V has a small difference (8−10 points). The full score for each final indicator in the questionnaire is set to 10 points. There are two data scoring schemes for qualitative indicators. The high-quality indicators require a "yes" rating of 10 points, and "no" rating of 0 points. The low excellence indicator is assigned a value of 10 points for "none" and 0 points for "yes". In this study, the weighted method is used to calculate the total score S of the comprehensive score of bidding generic drugs for each manufacturer's centralized procurement, which is the sum of the scores of each indicator and its normalized weight. The calculation formula is S =*, where S is the weighted sum of various indicators, is the combined weight of the ith indicator, is the score of the ith indicator, and n is the number of indicators.

4.2 Results and analysis

A total of 4 683 questionnaires were collected for the five drugs in this survey. After eliminating invalid questionnaires, 3 532 were valid, with an effective recovery rate of 75.4%. According to the selection rules for each type of centralized procurement drugs, 3 532 questionnaires were divided into a questionnaire database of 13 selected manufacturers by province, and a statistical analysis was performed on them. See Table 7 for details.

Table 7 Total weighted scores of five generic drugs

Drug name	Generic drug manufacturer	Total weighted score	Mean	Standard deviation
Moxifloxacin hydrochloride	A1	7.05	6.95	0.11
	A2	7.03		
	A3	6.92		
	A4	6.81		
Acarbose	B1	7.06	7.06	—
Atorvastatin	C1	7.29	7.12	0.16
	C2	7.11		
	C3	6.97		
Amlodipine besylate	D1	7.50	7.26	0.22
	D2	7.22		
	D3	7.07		
Levetiracetam	E1	7.49	7.40	0.13
	E2	7.30		

Reliability refers to the degree of consistency of the results obtained when repeating measurements on the same object using the same method, as well as the manifestation of the consistency and stability of the response measurement results [16]. There are four main measurement methods for reliability analysis: retest reliability method, duplicate reliability method, half reliability method, and α reliability coefficient method [17]. Since this study is the first time to analyze the internal consistency of the entire scale, Cronbach's α was selected as the coefficient method, which is also the most commonly used reliability coefficient method at present. Cronbach's α coefficient range is 0−1, and it is generally considered acceptable as long as it reaches 0.7. A coefficient between 0.70 and 0.98 is considered high reliability, while a coefficient below 0.35 is considered low reliability and must be rejected [18]. The development of the scale needs to be reconsidered. This study examines the internal consistency of the scale items, as shown in Table 8.

Table 8 First-level indicator system Cronbach's α coefficient test

Dimension	Number of entries	α coefficient
Safety	2	0.950
Availability	4	0.605
Overall indicator system	7	0.844

Validity refers to the effectiveness of a measurement and the degree to which measurement tools and methods can accurately measure something [19]. The measurement results are approximately consistent with the measurement content, and the validity is high.

Content validity, also known as logical validity, refers to the appropriate degree to which a project samples the content or behavioral range to be tested, that is, the appropriateness and consistency of the measured content [20]. The content validity index is divided into two categories: an item level content validity index (I-CVI), which evaluates the content validity of each item, and the scale level CVI criterion (S-CVI) I-CVI. When the number of experts is ≤ 5, the I-CVI should be 1.00, which means that all experts believe that the item has a good correlation with the conceptual content to be measured, and then the content validity of the item is considered to be good. When the number of experts is ≥ 6, the I-CVI is ≥ 0.78 to ensure good content validity. The results of content validity analysis show that both the content validity index I-CVI and the overall content validity index S-CVI at the item level of this survey are greater than 0.8, indicating that the content validity of this questionnaire is good.

Structural validity, also known as conceptual validity or characteristic validity, refers to checking whether the test results of the measuring instrument conform to the correctness of the tested structure, that is, whether the questionnaire truly measures the clinical evaluation of bidding generic drugs in centralized procurement [21].

When criteria for determining the degree of correlation of various indicators $r = 0$, it is completely unrelated. When $0 < r \leq 0.3$, it is basically irrelevant. When $0.3 < r \leq 0.5$, it has low degree correlation. When $0.5 < r \leq 0.8$, it is significantly correlated. When $0.8 < r < 1$, it is highly correlated. And when $r = 1$, it is completely correlated [22]. The correlation analysis results are detailed in Table 9.

Table 9 Correlation analysis between secondary indicators and primary indicators

Target	1 Safety	2 Effectiveness	3 Suitability	5 Accessibility
1.1 Incidence rate of adverse reactions	0.945**	0.747**	0.814**	0.093**
1.2 Occurrence degree of adverse reactions	0.994**	0.731**	0.830**	0.090**

(to be continued)

Continued Table 9

2.1 Improvement degree of main clinical indicators	0.806**	0.901**	0.742**	0.079**
2.2 Improvement degree of secondary clinical indicators	0.779**	0.856**	0.714**	0.083**
2.3 Single medication replacement rate	0.336**	0.525**	0.305**	0.039*
2.4 Secondary drug replacement rate	0.125**	0.484**	0.099**	0.112**
3.1 Drug compliance	0.841**	0.682**	1	0.072**
5.2 Supply stability	0.093**	0.113**	0.073**	1

When ** is at 0.01 level (double tailed), the correlation is significant. When * is at 0.05 level (double tailed), the correlation is significant.

To sum up, the secondary indicators are highly correlated with their corresponding primary indicators, both of which are positively correlated, and the results are significant. It can be concluded that the consistency between the internal items of the primary and secondary indicators in the test is good. In short, the indicator system has good reliability, validity, and authenticity.

In summary, the comprehensive drug scores of each manufacturer are between 6−8 points. According to the subjective experience of clinical pharmacists and clinicians, there is no significant difference in the clinical evaluation of the original research drug and the bidding generic drugs in centralized procurement. Through empirical analysis, the reliability and validity of the indicators constructed in this article are good, which can provide reference for the drugs centralized bidding procurement. However, with the rapid development of the "patent cliff" and generic drugs, the evaluation index system should also be constantly improved. From the perspective of the production and evaluation of drug evidence, it is recommended to establish a dynamic evidence production mechanism to improve its pertinence and scientific nature.

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