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Research on Quality Evaluation Method of New Medical Achievements

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Abstract: Objective: in order to explore the general quality evaluation model of new medical achievements. New drugs are the most common and main form of medical achievements. Mastering the quality evaluation indicator and quality evaluation model of new drugs will also have important reference value for other medical achievements. Methods: the quality characteristics of new drugs were analyzed by Delphi method or expert consultation method, and the quality evaluation indicator system was obtained. Then the weight coefficient of the indicator was calculated by analytic hierarchy process, and the mathematical model for quantitative analysis was obtained. And develop the technology to identify the quality of many medical achievements by using the percentage exchange algorithm and Bradford's law. Results: using the expert consultation method can get a high reliability of the quality evaluation indicator system, can implement a comprehensive quality evaluation of new medical achievements, and obtain a new quality evaluation model. Conclusion: the new quality evaluation model can fully display the level of medical achievements, and can also be used for the quality acceptance of new products and fair competition between similar products. Fair evaluation makes the evaluation results easily accepted by customers.

Keywords: New Medical Achievement, Quality Evaluation Model, Quality Management, Delphi Method, Analytic Hierarchy Process

1. Introduction

Research Background

Constant medical innovation and new medical achievements are needed to cope with the sudden outbreak of new diseases such as the Covid-19 epidemic, as well as difficult to treat diseases such as AIDS and cancer. New drugs are unquestionably the most important and in demand medical achievements, humanity's main weapon in the fight against disease. New drugs are vital to improving the overall lot of mankind. This study takes new drugs as an example to explore a new model of quality evaluation of medical achievements. In addition to curing diseases and saving lives, new drugs are also an important factor in a country's scientific and technological strength and an important way to improve its international competitiveness. In 2019, the United States was once again the most active market for new drugs, accounting for 56 percent of new products launched globally. The FDA has been trying to speed up the process of approving new drugs. The global market for new drugs is now worth hundreds of billions of dollars, and U.S. patents on new drugs account for more than half of global profits. It can be seen that new drug technology can earn a large amount of additional income for a country, which is an important way to promote GDP growth [1].

A new drug is a drug whose chemical structure, composition, and pharmacological action are different from existing drugs. According to China's Drug Administration Law and the US FDA, a new drug refers to a drug that is not on the market internationally. The target of FDA's administration is drugs and food, and it also carries out the management and law enforcement of medical devices. This further proves that the main body of medical achievements is drugs, and the registration, application and acceptance of new drugs are the main work contents of FDA. But for most consumers, new drugs are also new and unfamiliar, and there are certain risks in the process of purchase and use. Therefore, it is necessary to define the quality characteristics of new

drugs and establish a better-quality evaluation model to make it easier for customers to understand the quality level of new drugs [2]. As a kind of special commodity, the safety and effectiveness of medicine are its basic requirements, because it is related to human life and health. However, new drug development should fully consider the requirements of sociality, science, compliance and economy [3].

At present, the evaluation indicators of new drugs are relatively single. According to the Quality Control Specifications for Drug Clinical Trials issued by the State Food and Drug Administration, there are three main indicators for the certification of new drugs: effectiveness, safety and quality controllability [4]. Less quality evaluation indicator, and the evaluation criteria are vague, unable to let the customer fully understand their quality level. In this way, medical products will lose their market competitiveness and innovation value. The purpose of this study is to develop a comprehensive quality evaluation system to provide a scientific basis for improving the quality of new drugs and promoting the recognition of market customers.

Research Objectives

1. To determine the main characteristics that affect the quality of new medical achievement.
2. To establish new methods and criteria for quality evaluation of medical achievement.

2. Literature Review

2.1. Medical Achievement

Medical achievements refer to the knowledge products with certain recognized academic or economic value obtained by people through complex intellectual labor in scientific and technological activities. Clinical results with certain academic or practical significance were obtained by observing experiments, researching trial-produced or dialectical thinking activities. The medical achievements that can be used in clinical diagnosis and treatment are mainly drugs and medical devices, among which drugs are the most common and main form of achievements and the main object of government supervision [5].

2.2. Quality Evaluation

Quality evaluation is the basis of improving product quality. Establishing a perfect quality evaluation system can predict the development trend of macro-quality level, improve the market competitiveness of enterprises, Prevent potential hazards to human health, safety and living environment, and enable people to make full and reasonable choices in the market economy in which products, services and resources are exchanged [6].

2.3. Quality Characteristics

Quality characteristics must be combined with the opinions of the market and customers. Quality consists of many characteristics, each of which determines the overall quality level of the product. From the perspective of market, the quality of medical products should have the characteristics of practicability, reliability and cost performance. It also includes the efficacy and safety of government acceptance. These quality characteristics should be further refined to fully demonstrate the product quality level [7].

2.4. Medical Quality Management

Systematic management for strengthening medical quality management, standardizing medical service behavior and ensuring medical safety. The definition of medical quality management includes: whether the diagnosis is correct, timely and comprehensive; Whether the treatment is timely, effective and thorough; Length of treatment; Unnecessary (psychological or physical) pain, damage, infection and accident caused by improper medical, nursing and management measures; The level of medical work benefits; The reasonableness of the use of medical technology; The utilization benefits of medical resources and its economic benefits; Patient quality of life measures; Patient satisfaction [8].

3. Methodology

3.1. Research Objects and Sample Size

This study adopts the method of combining qualitative analysis with quantitative analysis. It mainly includes patients, doctors, nurses, pharmacists, etc. The hospital is the use terminal of all kinds of medical achievements. Doctors prescribe drugs for patients, nurses provide medication services, and patients are the main customers.

For the sample size of qualitative analysis, Glaser and Strauss (1967) recommend the concept of saturation for achieving an appropriate sample size in qualitative studies [9]. Morse (1994) suggested approximately 30-50 participants [10]. Creswell (1998) suggested only 20-30 [11]. For phenomenological studies, and Morse (1994) suggests at least six. These recommendations can help a researcher estimate how many participants they will need, but ultimately, the required number of participants should depend on when saturation is reached. Therefore, referring to the above literature, the sample size of experts in this study is N=30.

Likert scale method (Likert, 1932) is used in this research questionnaire, which is the most used quantitative evaluation scale [12]. Each state has five responses: "strongly agree", "agree", "not necessarily agree" or "disagree" or "strongly disagree", with corresponding scores of 5, 4, 3, 2, 1.

Delphi method, also known as expert survey method, was initiated and implemented by the American Rand Corporation in 1946. It is an anonymous survey method. Delphi Method process: (1) Determine the purpose of the investigation and draw up the survey outline. Provide background material to experts. (2) Select experts. It includes experts in theory and practice. (3) Send questionnaires to selected experts by means of correspondence for comments. (4) Handle expert decisions and make modifications. (5) Determine the final decision. Until the experts agree [13].

In this study, experts were tested for consistency of objectives (IOC test), The IOC developed by Rovinelli and Hambleton (1977) is a procedure used in test development for evaluating content validity at the item development stage [14]. This measure is limited to the assessment of one-dimensional items or items that measure specified composites of skills. In modern test development, items are sometimes developed to be multidimensional assessments or measures of multiple combinations of skills [15].

The analytic hierarchy process (AHP) was formally put forward by American operational research expert Thomas in the mid-1970s. It is a qualitative and quantitative combined, systematic, hierarchical analysis method. The steps include: building hierarchical structure model, constructing a contrast matrix, calculating vector for consistency test, and building weight. Its applications include economic planning and management, energy policy and distribution, behavioral sciences, military command, transportation, agriculture, education, human resources, health care, and the environment [16]. Analytic Hierarchy Process: (1) Analyze the relationship among the factors in the system and construct the pairwise comparison judgment matrix; (2) Calculate the relative weight of the compared element to the criterion by the judgment matrix, and conduct the consistency test of the judgment matrix; (3) Calculate and sort the weights of each level indicators.

3.2. Data Analysis

3.2.1. Questionnaire Reliability Analysis

Using the Reliability Analysis function of SPSS software, Cronbach's n was 0.709 and 0.921, respectively. It indicates that the reliability of the first questionnaire is acceptable and needs to be modified appropriately, while the second questionnaire is highly reliable (Ca > 0.90) and of high quality, P=0.000<0.05. As shown in table 1.

Table 1. *Reliability and consistency of questionnaires.*

	Cronbach's α	Kendall's W	*P*
First time	0.709	0.632	0.000*
Second time	0.921	0.551	0.000*

*Sig＜0.01

3.2.2. Indicator System and Score

The quality indicator is divided into three first level indicators, six second level indicators and 21 third level indicators. The score of all indicators is greater than 4.0, indicating a high score. The method to judge whether the indicator score is excellent is as follows: the method of dividing the highest score minus the lowest score by the total number of intervals is adopted to define the value of grade interval [17].

$$Spacing\ value = \frac{\text{Highest score} - \text{lowest score}}{\text{interval number}} = \frac{5-1}{5} = 0.8$$

Judgment standard of score level: 4.20~5.0 are Excellent; 3.40~4.20 are Good. As shown in Table 2.

Table 2. *Indicator code, score and ranking ($\bar{x}$±SD).*

Indicator/Code	$\bar{x}$±*SD*	Rangking
A Technical Practicality	4.88±0.32	Excellent
A1 Market Demand Rate	4.48±0.51	Excellent
A11 Market size	4.21±0.55	Excellent
A12 Residual size	4.18±0.53	Good
A13 Market Expansion Potential	4.06±0.50	Good
A2 Potency ratio	4.70±0.47	Excellent
A21 Efficacy cost advantage	4.61±0.50	Excellent
A22 Raw materials are readily available	4.52±0.57	Excellent
A3 Generality	4.36±0.55	Excellent
A31 Suitable for many diseases	4.73±0.45	Excellent
A32 Suitable for many patients	4.52±0.62	Excellent
B Technical reliability	4.85±0.36	Excellent
B1 Feasibility	4.82±0.39	Excellent
B11Production difficulty	4.64±0.49	Excellent
B12Ease of use	4.55±0.51	Excellent
B2 Curative effect	4.82±0.39	Excellent
B21 Cure rate	4.91±0.30	Excellent
B22 Significant benefits	4.06±0.61	Good
B3 Security	4.67±0.48	Excellent
B31 Structural stability	4.76±0.44	Excellent
B32Toxic side effects	4.58±0.50	Excellent
B33 Adverse reactions	4.64±0.65	Excellent
C Technical benefits	4.79±0.49	Excellent
C1 Economic benefits	4.58±0.56	Excellent
C11 Annual profit	4.39±0.50	Excellent
C12 Market share	4.24±0.44	Excellent
C2 Social benefits	4.64±0.55	Excellent
C21Patients' family satisfaction	4.76±0.44	Excellent
C22 Satisfaction of medical staff	4.55±0.51	Excellent
C3 Benefit cycle	4.31±0.67	Excellent
C31 Years of earnings	4.61±0.56	Excellent
C32 Market saturation period	4.45±1.51	Excellent
C33 Potential for continuous improvement	4.30±0.53	Excellent

3.2.3. AHP Calculation Process and Weight Coefficient Table

The calculation of analytic hierarchy process is more complicated. Comparison matrix construction method: when comparing the importance of the element and the Jth element to a certain factor at the upper level, the quantitative relative weight aij is used to describe. The value of aij in the comparison matrix is between 1 and 9 and its reciprocal. As shown in table 3.

Table 3. *Scale and significance of contrast matrix.*

Fuzzy metric level	Weight significance
aij=1	Element I am equal importance to element j
aij=3	Element I am slightly more important than element j
aij=5	Element I am more important than element j
aij=7	Element I am much more important than element j
aij=9	Element I am more important than element j
aij=2n, n=1,2,3,4, The importance of elements I and j is between aij=2n 1 and aij=2n + 1	

The weight comparison matrix is normalized and the weight value is obtained. The square root method is used here to judge the weight vector of matrix A. The steps are as follows: first, calculate the product of each row element of the comparison matrix; The NTH root of the product was calculated and normalized to obtain its weight vector Wi. The calculation formula is as follows:

$$W_i = \frac{\overline{W_i}}{\sum_{i=i}^{n} \overline{W_i}}$$

i=1,2,…n.

$$w_i = \sqrt[n]{\prod_{i=I}^{n} a_{ij}}$$

I=1,2,…n

Consistency judgment *CI* test formula:

$$CI = \frac{\lambda_{max} - n}{n-1}$$

$$\lambda_{max} = \sum_{i=1}^{n} \frac{(A_{w_i})}{nw_i}$$

$$CR = \frac{CI}{RI}$$

Where: n is the order of the matrix; RI is the indicator of randomness and consistency, which is calculated by researchers through a large number of simulation experiments, as shown in table 4.

Table 4. *Indicators of randomness and consistency.*

n	1	2	3	4	5	6	7	8
RI	0	0	0.58	0.90	1.12	1.24	1.32	1.41

When CR=0, the comparison matrix is completely consistent. On the contrary, the larger CR is, the worse the consistency of the comparison matrix is. When CR< 0.1, it is considered that the consistency of the evaluation matrix is acceptable. When CR >0. 1, the judgment matrix needs to be modified.

AHP calculation process is realized by expert evaluation and matrix. As shown in table 5.

Table 5. *Indicator judgment matrix.*

Indicators	A	B	C
A	1	1	3
B	1	1	5
C	1/3	1/5	1

Then, the judgment matrix can be obtained:

$$A=\begin{bmatrix} 1 & 1 & 3 \\ 1 & 1 & 5 \\ 1/3 & 1/5 & 1 \end{bmatrix}$$

Calculating weight

(1) Calculate the product Mi of each row element of the judgment matrix A:

$$M1=1\times1\times 3 = 3$$

$$M2=1\times 1 \times 5 = 5$$

$$M3=1/3\times 1/5 \times 1 =1/15=0.0667$$

(2) Calculate the cubic root Wi of Mi

$$W1=\sqrt[3]{3}=1.4423$$

$$W2=\sqrt[3]{5}=1.710$$

$$W3=\sqrt[3]{0.0667}=0.4055$$

(3) Vector Wi=[1.4423 1.710 0.4055] ^{T}

Next, normalization was performed:

$$V1=0.4054$$

$$V2=0.4806$$

$$V3=0.1140$$

Reliability Analysis**:** Firstly, the consistency of matrix is judged and its maximum eigenvalue is obtained.

$$\lambda_{max}=\sum_{j=1}^{3} \frac{(AV)i}{3Vi}=3.0291$$

Consistency CI=0.0145; Average random consistency CR=0.025 < 0.1, indicating that this indicator matrix has a high degree of consistency, and there is no logic error in the weight of each indicator. Therefore, the weight of the indicator is: [0.4054, 0.4806, 0.1140]. The combined weight is the weight of the second and third indicators multiplied by the corresponding higher indicator weight.

4. Results

According to the above method, through AHP calculation, we can get the weight coefficient table of each indicator. See Table 6.

Table 6. *Weight of evaluation indicator system.*

Indicator	Weight	Indicator	Weight	Synthetic weight	Indicator	Weight	Synthetic weight
A	0.4054	A1	0.4353	0.1765	A11	0.4353	0.1895
					A12	0.4869	0.2119
					A13	0.0778	0.0339
		A2	0.4869	0.1974	A21	0.6753	0.3288
					A22	0.3247	0.1581
		A3	0.0778	0.0315	A31	0.50	0.0389
					A32	0.50	0.0389
B	0.4806	B1	0.114	0.0548	B11	0.6753	0.0972
		B2	0.4806	0.2310	B12	0.3247	0.0370
					B21	0.7854	0.3775
						0.2146	0.1031

Indicator	Weight	Indicator	Weight	Synthetic weight	Indicator	Weight	Synthetic weight
		B3	0.4054	0.1948	B22		
					B31	0.4286	0.1738
C	0.1140				B32	0.4286	0.1738
		C1	0.4815	0.0549	B33	0.1428	0.0579
					C11	0.50	0.2407
		C2	0.4815	0.0549	C12	0.50	0.2407
					C21	0.6753	0.3251
		C3	0.0370	0.0042	C22	0.3247	0.1563
					C31	0.60	0.0222
					C32	0.20	0.0074
					C33	0.20	0.0074

The calculation process is more complex, but the design software can replace the manual calculation to reduce the amount of labor. Software calculation is not easy to make mistakes, and the results are fairer.

5. Discussions

The quality indicator and its weight coefficient system established can realize a single quantitative calculation of quality results, but there is still a lack of evaluation criteria for whether the calculated data can meet customer satisfaction. In addition, customers are often faced with not just one drug, but many similar drugs at the same time, and the choice becomes a problem. For the quality management department of medical results, they usually need to check and judge many medical results. For example, judge which results are qualified and which are excellent. In this study, hundred-mark algorithm and Bradford's law were used to explore the judgment mode of quality scores.

5.1. Centesimal System Judgment Method

Because the score of the actual evaluation results may be much higher or far lower than 100, it is inconvenient to judge the advantages and disadvantages quickly. The hundred-point system is a common method of data display, which is easier to reflect the quality score of an achievement. Therefore, it is more convenient and intuitive to reflect the quality level of a batch of achievements.

5.1.1. Conversion Method 1

Take the highest score achievement as the standard, convert it into 100 points, and the other items are calculated in turn according to the conversion ratio. Let Wa be the result with the highest score, Wx be the score of any other achievement, Px be the score of a certain achievement after conversion, where Pa of the highest score is 100. The conversion method is shown in Formula (1).

$$P_x=100W_x/W_a \quad (1)$$

5.1.2. Conversion Method 2

For example, in many achievements, there is a big gap between the highest score and the score of only secondary items. After conversion, the score of the second ranked achievement may be very low, which is not convenient for the display and comparison of all achievements. In this case, the average score of the top n achievements can be calculated after accumulation, and the average score is the highest score for conversion, that is, the average score is changed to 100. Suppose that the top n achievement quality scores in a certain achievement group are: W1, W2…Wn, the total score of some other achievement is Wx. If the score after conversion is set as Px, the conversion method is shown in Formula (2).

$$P_x=100\times n\times W_x \ / \ (W_1 + W_2\ldots\ldots W_n) \quad (2)$$

It should be noted that the scores of the top n achievements are all 100 points, and there is no need to convert again.

After all the results are converted by the hundred-point system, the criteria for judging excellent and qualified scores are set according to people's common sense of the hundred-point system. For example, 60 points or more are qualified, 80-90 points are good, and 90-100 points are excellent.

5.2. Criterion Based on Bradford's Law

Bradford's law was originally used as the criterion for judging core journals [18], and believed that the core distribution law was the core $1:\alpha:\alpha^2$ (α=1, 2, 3……). Calculation and processing methods are as follows:

(1) The project ranked in the top $\frac{1}{1+n+n^2}$, the result is rounded, is listed as an excellent;

(2) Ranked between $\frac{1}{1+n+n^2}-\frac{n}{1+n+n^2}$ as a good;

(3) The ranked between $\frac{n}{1+n+n^2}-\frac{n^2}{1+n+n^2}$ is listed as a qualified;

Judge: The ranked after $\frac{n^2}{1+n+n^2}$ can be regarded as unqualified achievements.

With examples, it is assumed that the Department of health will identify and accept 200 medical achievements. According to the actual situation, the value of α is 2, that is, the core distribution law is 1:2:4. The calculation and treatment methods are as follows:

(1) The results ranked in the top 1 / 7 (14.3% × 200=29, rounded) were classified as excellent in quality (First class);

(2) Those ranked between 1 / 7 and 2 / 7 (ranking 30-57) were rated as good (Second class);

(3) The results ranked between 2 / 7 and 4 / 7 (57-114) are qualified (Third class);

(4) The ranked after 5 / 7 (>143) indicated that they needed to rework and were temporarily unqualified.

According to the actual number of evaluated results, the

value range of α can be reduced or increased appropriately, and the value range can be between 2 and 10. That is to say, the less the quantity is, the lower the α value is. Conversely, the higher the α value is. The purpose of this is to facilitate screening and comparison.

6. Conclusion

In this study, the quality of new medicine is composed of 21 indicators, which is more than the previous literature. Only in this way can we show the quality of new medicine more comprehensively. Secondly, by assigning weight to the indicators, the score of new medicine quality can be calculated, to achieve a more advanced quantitative evaluation. However, this quality score can not reflect whether the quality is qualified or excellent, so this study designed two methods to judge the quality score: the percentage system replacement algorithm and Bradford law. Thus, the quality of multiple new medicine can be compared at the same time, and the fair competition between new medicine can be realized.

7. Suggestion

In this study, a new medical achievement evaluation indicator system is proposed, which is easy to calculate the weight coefficient of scores and the judgment criteria of scores, and lays a good foundation for the further research in the next stage. However, this study did not carry out a large-scale customer-based survey and focused on theoretical analysis. The research objects are relatively wide and should be new drugs as the main research object, so it has some limitations. This is an early achievement of the researcher's doctoral study, and the deficiency is expected to be remedied in the next stage of research.

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