

**A comparative study of demographic grouping on patients'
satisfaction with the quality of new drug**

Peng Ruan¹

Manoch²

ABSTRACT

Compared with the old drugs, new drugs often have the advantages of good curative effect, but there are also shortcomings such as high price and low discount. The customers of new drugs are mainly patients. Patients' satisfaction with the quality of new drugs is greatly affected by that factor. The purpose of this study is to find out the differences of patients' economic income, age, education level on the quality of new drugs. To this end, the researchers surveyed 440 patients in large public hospitals. The results showed that the poor patients were satisfied with the quality of new drugs and could be loyal to the new drugs, but the poor patients were less satisfied with the quality of new drugs, and the rich patients did not care about the price of new drugs. The results showed that age, income and education of

¹ Ph.D. Candidate, Management, School of Management, Shinawatra University, Thailand

² Ph.D. Management, School of Management, Shinawatra University, Thailand

patients had significant influence on the quality satisfaction of new drugs, but the intervention of patients had no effect on the results.

Keywords: new drug quality; patient satisfaction; quality management;

1.Introduction

New drugs refer to drugs which are different from existing drugs in chemical structure, drug composition and pharmacological action. According to the "Drug Administration Law" and the new "drug registration management measures" implemented on October 1, 2007, new drugs refer to the drugs not listed in China (Chen fan, 2017). FDA's interpretation of new drugs is that there are no new drugs on the market within its jurisdiction (Mullard, 2017). The research and development of new drugs is to occupy the market and create economic value. All new drugs are accepted by the market and must face the competition with the same kind of drugs, but the final decision lies with the customers. The main customers of new drugs are patients. Their satisfaction with the quality of new drugs determines the market competitiveness of new drugs, such as sales volume and profit. But at present, there are few evaluation indexes for the quality of new drugs, and the satisfaction of the market (that is, customers) to the quality of new drugs is ignored, resulting in the quality of new drugs cannot be correctly reflected, affecting the market competitiveness of new drugs. Generally speaking,

new drugs have better efficacy and fewer adverse reactions than old drugs, but the price of new drugs is often higher (Kun, 018) However, the demographic characteristics of patients are more complex. Patients with different income, education level and age have different views on the quality of new drugs, which ultimately affects their satisfaction with the quality of new drugs. This helps managers to formulate customer hierarchical management strategy, find key customers, and formulate more reasonable new drug sales strategy. In order to understand the difference of patients' satisfaction with the quality of new drugs with different demographic characteristics, 440 patients in large public hospitals in Chengdu, China were investigated and compared according to demographic characteristics.

2. Literature review

2.1 Quality characteristics

Quality characteristics are intrinsic to the requirements of a product, process or system. It reflects the objective requirements of the use of products, reflect the main characteristics of the product quality of technical and economic parameters clearly defined. The key to the quality concept is "meet the requirements". These "requirements" must be transformed into indicators of characteristics, as the basis for evaluation, inspection and assessment. Since customer needs are diverse, the characteristics that reflect quality should also be diverse.

Quality characteristics can generally be divided into two categories: true quality characteristics and alternative quality characteristics. The so-called "true quality characteristics" refers to the quality characteristics that directly reflect the needs of users. (2) Substitute quality characteristics: generally, real quality characteristics are the overall quality characteristics of the product, but not fully reflected in the product manufacturing specifications. Moreover, in most cases, it is difficult to express directly quantitatively. Therefore, it is necessary to indirectly reflect it by identifying some data and parameters corresponding to the true quality characteristics (user requirements), which are referred to as "surrogate quality characteristics".

Product technical standard, mark the requirement that product quality characteristic should achieve, the product that accords with technical standard is qualified, the product that does not accord with technical standard is unqualified.

The characteristics of quality can be divided into timeliness, extensiveness, relativity and economy. In addition, there are virtual quality requirements, generally the quality characteristics attached, namely the quality of service. As quality management plays a more and more important role in enterprise management, quality seriously affects the survival of an enterprise.

Different categories of products, the specific form of quality characteristics are not the same. The quality requirements of hardware products

and software products are different, so this study belongs to the scope of hardware output quality (Kay,2018).

Generally, the quality characteristics of hardware products are as follows:

(1) Performance refers to the product in function to meet customer requirements, including use performance and appearance performance.

(2) Life refers to the normal service life of the product, including service life and storage life. Service life refers to the total working time of the product to complete the specified function under the specified service conditions. Generally speaking, different products have different requirements for service life. Storage life refers to the time from the beginning of storage to the specified expiry under specified storage conditions.

(3) Credibility is a collective term used to describe the availability and its influencing factors (reliability, maintainability and guarantee). The ability of a product to perform a specified function under specified conditions and within specified time is called reliability. For mechanical and electrical products, pressure vessels, aircraft and those quality accidents will cause huge losses or endanger human life, social security products, reliability is the main quality index in the use process. Maintainability refers to the ability of a product to maintain, maintain or return to a specified state under specified conditions, time, procedures and methods. Maintenance support refers to the ability to provide the necessary resources for maintenance according to the specified

requirements and time. Obviously, with the above "three", is necessarily a usable, and easy to use product.

(4) Safety refers to the product in the manufacturing, circulation and use of the process to ensure personal safety and the environment from harm. All countries in the world have given the greatest attention to product safety.

(5) Economy refers to the total cost of product life cycle, including the cost of production and sales process and the cost of use process. Economy is one of the key characteristics to ensure the survival of the organization in the competition, and it is a quality index that users are increasingly concerned about.

(6) Service In addition to physical products, product quality also includes intangible product quality, namely service product quality. Quality of service is also important. For example, pre-sale and after-sale service is also a key point of product market competitiveness.

Drug quality characteristics refer to all the external characteristics and internal characteristics that constitute the quality of drug products. All the aspects of these external characteristics and internal characteristics constitute the "applicability" of the drug, and the degree to which the drug successfully meets the Patients' goals in the process of use. Quality characteristics can be summarized as: performance, life, reliability, safety and economy. Quality characteristics have multi-dimensional characteristics (Kang,2018).

2.2 Customer satisfaction

Customer satisfaction refers to the customer's perception of the extent to which their expressed, usually implied or necessary needs or expectations have been met. Satisfaction is the feedback of customer satisfaction. It is the evaluation of product or service performance and product or service itself. Giving (or giving) a level of happiness associated with the satisfaction of spending, including a level below or above satisfaction, is a psychological experience. Customer satisfaction is a moving goal. What satisfies one customer may not satisfy another. What satisfies one customer in one case may not satisfy another. In the mid- 1980s, the U.S. government established the Malcolm Baldrige National Quality Award to encourage businesses to apply "customer satisfaction." The creation of this award has greatly promoted the development of "customer satisfaction". Of course, it is not only to evaluate the final score of the enterprise's customer satisfaction, but also to evaluate a series of total quality management measurement systems initiated by the enterprise with "customer satisfaction" as the center. IBM, MOTOROLA, FEDEX are all winners of this award, but so far, no more than five enterprises have won this award every year in the world (Rao,2005).

In this study, customer satisfaction mainly refers to medical staff and patients. Patient satisfaction refers to the subjective evaluation of the diagnosis and treatment services received after receiving outpatient and inpatient services in medical institutions (hospitals). Because of the specialty of medical service, it

is difficult for patients to make an objective evaluation of their professional service level. Medical staff, on the one hand, have to meet patients' subjective requirements, and at the same time, strictly comply with the requirements of industry norms. Therefore, compared with general service products, it is more difficult to improve patient satisfaction. Patient satisfaction evaluation should take into account peer review, public/media review, etc. A good medical worker should have professional knowledge through the patient to make proper patients in a way that is easy to understand explanation, description ability, should be based on the patient's care and win the patients understand and cooperate with, should improve the level of diagnosis and continue to study business knowledge to meet the needs of the patient and the patient has not yet realized but should provide the need. Medical workers are internal customers of medical institutions, and patient satisfaction is derived from medical staff's love and dedication to their work. Doctors' satisfaction with new drugs can often influence their recommendation and willingness to use new drugs, such as reasonably recommending new drugs to patients after comprehensive consideration of the efficacy and cost of new drugs (Liu,2018).

3.Research methods

3.1Quantitative research sample size

In this study, patients in large public hospitals in Chengdu were selected, and the researchers used a new software: G* Power was used to calculate the sample size, and the version was 3.1.9.4. G*Power is a new statistical

software developed by the university of Dusseldorf in Germany, which is specially used for statistical work and also includes the calculation of sample size. At present, it has a relatively high popularity in academic circles (Faul, 2007). The G*Power calculation interface is as follows :

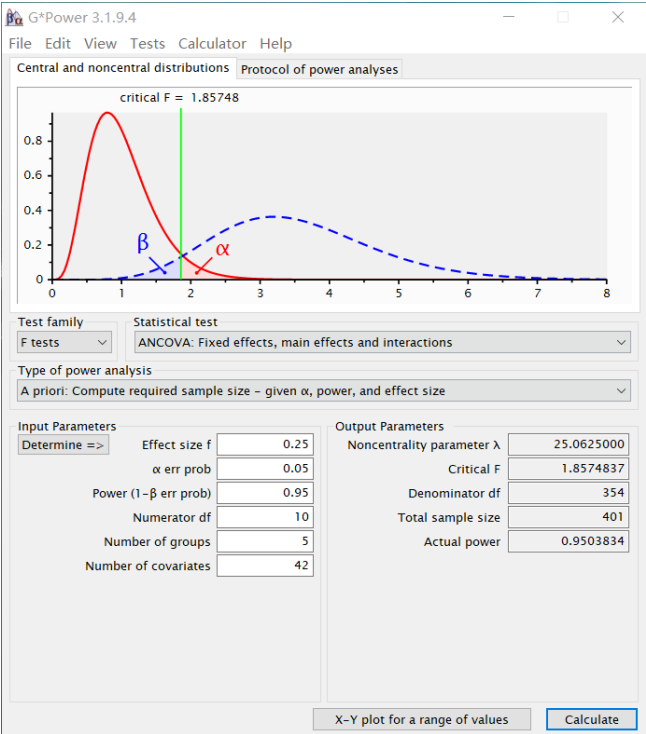


Figure 2.1 G*Power sample calculation interface

According to the calculated results of G*Power, the sample size of this study should be more than 401. However, in order to facilitate the investigation and reduce the error, the sample size of this study was set as 440 samples.

3.2 Questionnaire design and data collection

The researchers used questionnaires to collect sample data. According to a large number of documents and government medical policies, the doctors, nurses and patients in the hospital were interviewed, and the quality characteristic indexes were analyzed qualitatively, so as to obtain the evaluation index of new drug quality satisfaction.

The questionnaire consists of two parts: firstly, the demographic characteristics of patients were collected, including five contents: gender, age, income, occupation and education. Secondly, it is the evaluation content of patients' satisfaction with the quality of new drugs, including the efficacy, safety, ease of use, price, taste, smell, shelf life and other contents, so that patients can evaluate according to the quality characteristics of new drugs.

Data are collected mainly through interviews and questionnaires. Interviews were conducted with medical experts, senior hospital management experts, etc. The survey was conducted among clients of large public hospitals. In order to ensure that enough sample size can be obtained, the actual number of questionnaires is slightly more than the requirement calculated by G*Power.

The second part to the fifth part use Likert ten rating scale for measuring (Likert, 1932). A score of 10 means best, and a score of 1 means worst. Where

1, 2 and 3 represent very poor performance; 4, 5, 6, 7, said the medium level, 8, 9, 10, mean excellent.

Table 2.2 *The scales of the ten level*

Level judgment method									
1	2	3	4	5	6	7	8	9	10
Very Poor			Medium				Excellent		

3.3 *Data processing method*

In this study, qualitative and quantitative research methods are used. For the first time, using the method of literature analysis, we searched the literature database, checked the relevant research reports of journals, and asked experts to evaluate and improve the main quality characteristics of new drugs. The data were processed by Excel and spss25.0 software. Descriptive statistics of data, such as frequency and percentage, mean and variance, were performed with one-way ANOVA.

4. **Result and Discussion**

4.1 *Reliability analysis of the questionnaire*

Reliability, which refers to the degree of consistency of the results obtained when the same method is repeated for the same object. Reliability indicators are mostly expressed by correlation coefficients, which can be roughly divided into three categories: stability coefficient (consistency across time), equivalence coefficient (consistency across forms) and internal consistency coefficient (consistency across items). There are four main methods of reliability

analysis: retest reliability, duplicate reliability, half reliability and alpha reliability. Cronbach a reliability coefficient is the most used reliability coefficient at present. And its formula is as follows:

$$\text{Alpha}(\alpha) = (k / (k - 1)) * (1 - (\sum Si^2) / ST^2)$$

Where, K is the total number of items in the scale, Si^2 is the intra-question variance of item I score, and ST^2 is the variance of the total score of all items. As can be seen from the formula, the alpha coefficient evaluates the consistency among the scores of each item in the scale and belongs to the internal consistency coefficient. This method is suitable for reliability analysis of attitude and opinion questionnaire (scale). (Bland J, 1997&Cronbach,1951).

Table 3.1 *Reliability coefficient judgment criteria*

Cronbach's α	Meaning
> 0.9	Excellent
0.8~0.9	Good
0.7~0.8	Acceptable
0.6~0.7	Questionable
< 0.6	Unacceptable

The measured reliability coefficient of the questionnaire: $\alpha = 0.913 > 0.9$, indicating that the questionnaire has high reliability.

4.2 Describe analysis results

According to demographic characteristics, 440 patients were grouped and compared. It includes gender composition, age structure, income level (in

annual income in US dollars), occupation, education level, etc. Data analysis included population frequency and proportion. See the table below for details.

Table3.2

Group	Frequency	Percentage
Gender		
Male	241	54.8%
Female	198	45.2%
Age		
20-30	57	13.0%
30-40	137	31.1%
40-50	157	35.7%
>50	89	20.2%
Income		
<3500	91	20.6%
3500-7000	233	53.0%

7000-14000	65	14.8%
>14000	51	11.6%
Occupation		
Government	58	13.2%
State enterprise	174	39.5%
Private enterprise	185	42.0%
Other	23	5.30%
Education		
Below bachelor	54	12.2%
Bachelor	310	70.5%
Master	46	10.5%
Doctor	30	6.80%

Respondent Demographics

4.3 Descriptive statistical analysis of the questionnaire

This section mainly performs descriptive statistical analysis of the data, including scores of various quality characteristics indicators, customer medication experience scores, customer satisfaction scores, and loyalty scores. Get the average value, standard house difference, level and other information of each indicator. The scores of the superior indicators come from the accumulation of the lower indicators and the average value is obtained.

In this study, Likert ten-level scale method was adopted, and the method of dividing the interval number after the highest score minus the lowest score could be used to define the score grade interval (Lind Marchal,2015)

$$\begin{aligned} \textit{Spacing value} &= \frac{\textit{Highest score} - \textit{lowest score}}{\textit{interval number}} = \frac{10 - 1}{10} \\ &= 0.9 \end{aligned}$$

The grade of the score is in accordance with the criteria in Chapter 3. That is: 1, 2, 3 are very poor, are ranking 3 ,4, 5, 6, 7 are medium, are ranking 8, 9, 10 are excellent, being ranking 1. See the Table 3.3.3.

Therefore, there is one level for each 0.90 bit. Establish the level division table as follows.

Table 3.3-1 *Ranking and Level judgment*

Ranking			Level	
Score Ranging	Ranking		Score	Level
10~9.10	1		8\9\10	Excellent
8.20~9.09	2		4\5\6\7	Medium
7.30~8.19	3		1\2\3	Very Poor

Table 3.3-2 *Scores of major subordinate indicators of new drugs*

Main indicators	Mean	S.D	Level	Ranking
Efficacy	9.15	0.69	Excellent	2
safety	8.63	0.70	Excellent	2
Ease of use	8.29	0.59	Excellent	3
Price	8.35	0.62	Excellent	3
Taste	8.72	0.67	Excellent	2
Smell	8.41	0.62	Excellent	3
Shelf life	8.75	0.71	Excellent	2

It can be seen from the above table that the quality satisfaction evaluation index scores are excellent, which is of high necessity.

4.4 Patients demographics group ANOVA

According to the demographic characteristics, there was no significant difference in age, income and education, $P < 0.05$ or $P < 0.01$, except for the gender and occupation groups, $P > 0.05$

Table3.4 Results of ANOVA analysis on demographic grouping of patients

ANOVA					
	Sum of Squares	df	Mean Square	F	Sig.
Gender		438	1.565	.148	0.561
Age	4.694	3	1.565	3.846	0.010
Income	5.585	3	1.862	.600	0.004
Occupation	0.909	3	0.303	.729	0.535
Education	3.672	3	1.224	.991	0.031

The results showed that the patient's occupation and gender had no effect on the quality satisfaction of new drugs. The older the age, the lower the satisfaction of new drugs; patients with high income are more satisfied than patients with low income; people with high education level are not easy to be satisfied with the quality of new drugs.

4.5 Regression analysis of demography and quality satisfaction

In addition to gender and occupation ($P > 0.05$), the others, such as age, income, education and new drug quality satisfaction, had a strong correlation, $P < 0.05$. It shows that age, income and education of patients can have a significant impact on the quality evaluation of new drugs. This result further supports the content of Section 3.4, indicating that the quality of new drugs has different value orientation from the perspective of different types of patients. See table 3.5 for details

Table 3.5 *Multiple regression analysis*

a. Dependent Variable: New drug quality satisfaction

4.6 Summary of demographic grouping research

(1) By gender grouping, there was no difference between male and female customers in their satisfaction with the quality of new drugs, their loyalty and their judgment of quality. It shows that the characteristic evaluation of new

Coefficients ^a					
Model	Unstandardized Coefficients		Std	t	Sig.
	B	Std. Error	Beta		
Gender	.422	0.753	1.243	3.202	0.314
Age	.318	0.047	0.046	7.401	0.017
Income	.634	0.062	0.364	9.982	0.005
Occupation	.165	0.153	1.057	5.102	0.658
Education	.524	0.058	0.506	8.175	0.032

drug quality is not affected by the customer's gender. Men and women tend to have the same views, evaluations, needs, etc. The reason may be that drugs treat human diseases, often without sex differences. There was no gender difference in the treatment of diseases related to cardiovascular system, nervous system, respiratory system, etc. As a result, both men and women have similar views on drugs.

(2) In terms of customer satisfaction, there are significant differences among age groups. Specifically, the older the age, the lower the satisfaction of new drug quality. The reason may be that older patients have more clinical medication experience and have higher requirements for the quality of new drugs. They treat the quality of new drugs more deeply and strictly. As a result, elderly patients are often more difficult to satisfy than young patients.

(3) In terms of revenue group, there was a significant difference in the satisfaction of customers with new drugs at different income levels. It can be seen that customers' economic purchasing power has an impact on their satisfaction with new drugs. The stronger the purchasing power, the less economic pressure it faces. Wealthy customers are more interested in the efficacy of new drugs than in the price, discounts and so on. In addition, different groups of customers have the same views on the quality evaluation and loyalty of new drugs, indicating that the benefits of new drugs are easy to be understood and accepted by customers, and they all want to use new drugs for treatment. However, customers with low income will hesitate to buy, and they may pay more attention to the cost performance of the drug.

(4) There was no significant difference between occupational groups. Because the harm caused by the disease to the different occupation is fair, does not cause the different injury because of the different occupation. However, there are significant differences in education level grouping. The reason may be that the more educated you are, the better your understanding of the

advantages and disadvantages of new drugs, so you may be more selective about the quality of new drugs and medical services. Or people with more knowledge were more likely to see the lack of quality in new drugs, so there was a subgroup difference in satisfaction. This suggests that new drug developers, in order to grasp the quality of new drugs more shortcomings, or to understand the more accurate expectations of customers, should be inclined to survey highly educated customers.

(5) The higher the education level, the lower the satisfaction of new drugs. The reason is that patients with higher education level have more comprehensive knowledge and higher requirements for new drugs, and they understand the essence of new drug quality better, so they have more opinions on the evaluation of new drug quality. However, patients with low education level may not have a comprehensive understanding of the quality indicators of new drugs, and the methods or indicators used to evaluate the quality of new drugs are simple because of their high satisfaction.

4.7 Finding new ways to improve the quality evaluation of new drugs

First of all, the patient's gender and occupation have no impact on the quality evaluation of new drugs. If the organization personnel review the quality of new drugs, it is possible that the gender and occupational of reviewers have no negative or positive impact on the results. It is suggested that there may be

no restriction on the gender and the proportion of occupational in the review panel.

Secondly, different types of patients have different requirements for the quality of new drugs. Efficacy and safety are always important indicators for all patients. However, low and middle-income patients care more about the cost performance, price and shelf life of new drugs, while high-income patients care more about the efficacy and use experience of new drugs, such as taste, smell, ease of use, etc. Elderly patients pay more attention to the efficacy of new drugs, and they have strict attitude to various quality evaluation indicators of new drugs, just like patients with high education. This suggests that new drug developers and market managers should pay attention to the needs of different patient groups and provide new drug products targeted. For example, the exquisite degree of packaging, simple packaging may reduce costs, and is conducive to low-income patients to accept. Those with good curative effect but high price should focus on high-end market.

Third, this study also found a new way to improve the quality of new drug evaluation, which can better guide the new drug research departments and pharmaceutical factories to improve the quality of new drugs, so as to improve the market recognition and competitiveness of new drugs. This is because older people have more experience in drug use and can provide a more rigorous and profound evaluation of new drugs. Low and middle-income patients pay more attention to the cost-effectiveness of drugs. Their acceptance

of the price of new drugs often determines the market share of new drugs. Patients with higher education have a more diversified and strict understanding of new drugs. Therefore, we should improve the quality of new drugs. We should pay attention to the evaluation of such patients, because with their strict and dimensional evaluation, we can provide suggestions for manufacturers and researchers to improve the quality of new drugs, and help to improve the market competitiveness of new drugs.

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