Methodology and Results Analysis of Effect and Economic Evaluations Related to Pharmaceutical Care Practice in China: A Recent Review

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ABSTRACT

Background: To evaluate the value of pharmaceutical care, and sort out the existing problems in the current researches. **Materials and Methods:** We established the research strategy and searched seven databases. Two reviewers independently screened the studies, extracted data, conducted the statistical analysis and assessed the quality of full economic evaluations. The pharmaceutical care was divided into 9 types based on the relevant standards of Chinese Hospital Association. **Results:** 332 studies were included. The methods were mainly cohort studies (*n*=187, 56.32%), and followed by randomized controlled trials (*n*=124, 37.35%). Only 23 studies were conducted as full economic evaluations. The Quality of Health Economic Studies score was 61.22±12.80. The most commonly used effect indicators included length of hospital stay (*n*=166, 50%), prescription rationality rate (*n*=166, 50%), incidence of adverse reactions (*n*=117, 35.24%) and course of medication (*n*=107, 32.23%). For economic indicators, the cost of medication (*n*=269, 81.02%) and hospitalization (*n*=113, 34.04%) were the most frequently used indicator. The research results showed that pharmaceutical care could improve the therapeutic effect. 91.45% and 81.42% of the studies revealed that pharmaceutical care could reduce the cost of medication and hospitalization. **Conclusion:** Pharmaceutical care can improve the therapeutic effect and save the cost. However, the methodology of pharmaceutical care effect and economic evaluation needs to be further improved.

Keywords: Review, Pharmaceutical care, Effect, Economic evaluation, Methodology.

INTRODUCTION

Pharmaceutical care is represented by that pharmacists use pharmaceutical expertise to provide direct, responsible and drug-related services to the public, so as to ensure the safety, effectiveness, economy and appropriateness of drug treatment.[1] Different from medical services provided by doctors and nurses, pharmaceutical care focuses on rational drug use and guidance to patients.[2] Due to the differences of economic conditions and medical service level in different countries, the value and social status of pharmacists are also different.[3-5] The development of pharmaceutical care in developed countries is relatively mature, while the recognition of pharmacists in less developed countries is generally low, which fails to fully reflect the professional value of pharmacists.

More than ten years ago, the main content of pharmacy service in Chinese hospitals was to ensure the supply of drugs.[6-8] In recent years, with the development of economy and medical technology, the focus of pharmaceutical care in China has changed from "drug-centered" to "patient-centered". Pharmacists need to strengthen pharmaceutical professional technical services.[9] At present, China is reforming its public hospital policy, and the "Zero Markup Drug Policy" and "Centralized Drug Procurement Policy" are being implemented in Chinese hospitals in 2017 and 2018, respectively. These policies prevent hospitals from getting extra revenue from selling drugs.[10,11] How to prove the value of them has become a common problem faced by pharmacists in China. In 2022, Fujian province in China started to pay for pharmaceutical services, and it's covered by insurance.[12] In September 2023, National Health Commission of the Peoples Republic of China issued an important document to promote charges for three pharmaceutical services nationwide. Including pharmacy outpatient clinics, drug dispensing, and individualized pharmaceutical care for inpatients. This is a good experiment, but there are still many problems before it can be fully rolled out

in China. For the insurance payer, how to define whether the pharmacists have played the value, this is the most important problem. Therefore, Chinese researchers want to prove the effectiveness and economy of pharmaceutical care provided by pharmacists through scientific methods.

Pharmacoeconomic methods have been widely used to evaluate the economics of drug therapy, such as cost-effectiveness analysis.[13-15] These methods have also been used to evaluate other public health problems, including pharmaceutical care.[16-18] However, there are still some problems in the researches on the effect and economic evaluation of pharmaceutical care in China, such as imperfect research methods, non-standard inclusion indicators, limited types of pharmaceutical care and most studies adopted partial economic evaluations.[19] The purpose of our study was to evaluate the value of pharmaceutical care, and summarize the research methods and experience. To provide references for optimizing the evaluation of pharmaceutical care value.

MATERIALS AND METHODS

Study selection

Since the main settings of pharmaceutical care in China are hospitals, we only included the study placed in hospitals. The researches needed to evaluate the clinical effect and economy of pharmaceutical care without limiting the type of research design. We excluded the following studies: (1) pharmaceutical care provided by non-medical institutions (e.g. community and social pharmacies); (2) pharmaceutical care were not provided by pharmacists (e.g. doctors or nurses); (3) only effect evaluation without economic evaluation; (4) evaluation of drugs rather than pharmaceutical care; (5) the studies were not conducted in China; (6) intervention measures involve administrative intervention or punishment, in consideration of the effects of these measures were often greater than the intervention of the pharmacist; (7) secondary studies; (8) not published in full or not available in full; (9) duplicate publications.

Data sources and searches

Relevant studies were identified by electronically searching the following databases from their inception until December 2021: PubMed, Embase, the Cochrane Library, China National Knowledge Infrastructure, WanFang Database, VIP Database for Chinese Technical Periodicals, Chinese Biomedical Literature Database. The search terms including "pharmacy", "pharmacist", "pharmaceutical", "pharmaceutical care", "pharmaceutical services", "pharmacy service", "pharmacal services", "cost", "cost analysis", "economics", "economic evaluation", "economic analysis", "cost effectiveness", "cost benefit", "cost utility" and "cost minimization". Because we only wanted to include researches conducted in China, we also set the search term as "China", "Chinese", "Asian", "Taiwan", "Hong Kong" and "Macao". More

details about the search strategy are listed in supplementary Table 1.

Data extraction and quality assessment

Titles and abstracts were independently screened against inclusion and exclusion criteria by two investigators. Disagreements were resolved by discussion or consulted a third independent investigator to reach a consensus. The full texts were read after excluding obviously irrelevant studies to make a final decision on inclusion. The extracted data included: author information, diseases and medicines involved, study design, setting, sample size, type of pharmaceutical care, health outcome indicators, economic indicators, and economic evaluation methods. The pharmaceutical care was divided into 9 types based on the guideline of hospital pharmacy management and pharmaceutical care published by Chinese Hospital Association,[20] including prescription checking, centralized dispensing of intravenous drugs, medication therapy management, medication reconciliation, pharmaceutical ward round, pharmaceutical intervention, pharmaceutical monitoring, medication education, therapeutic drug monitoring. For those involving multiple pharmaceutical cares that unable to be categorized clearly, we defined them as comprehensive pharmaceutical care.

The overall quality of the full economic evaluations, including Cost-Minimization Analysis (CMA), Cost-Benefit Analysis (CBA), Cost-Effectiveness Analysis (CEA) and cost-utility analysis (CUA), was assessed by Quality of Health Economic Studies (QHES).[21]

Data analysis

We conducted descriptive statistics on literature publication information, types of study design, types of involved diseases and drugs, types of pharmaceutical care, health output and economic indicators, and economic evaluation methods. Excel 2017 (Microsoft, Redmond, Washington, USA) was used for data manage and analyze. Percentages were used for statistical analysis of the data.

RESULTS

General characteristics of studies

Of 11265 articles were under screened, we reviewed the full text of 595 studies. 332 studies met all of the inclusion criteria for analysis. The literature screening process was showed in Figure 1. The detailed description of these studies is provided in Table 1. The first study was published in 2004, and the number of studies has increased significantly over time. The study authors were mainly from tertiary hospitals (*n*=230, 69.28%), and most of them were pharmacists (*n*=240, 72.29%). 93.67% of the literatures were published in Chinese journals. Most of the diseases involved in the studies were perioperative (*n*=64, 19.28%), infectious diseases (*n*=63, 18.98%) and respiratory system diseases (*n*=33, 9.94%).

More than half of the drugs involved were antibacterial agents (*n*=174, 52.41%). 212 (63.86%) studies could not accurately classify the types of pharmaceutical care, so they were classified as comprehensive pharmaceutical care. Beyond that, pharmaceutical intervention was the most involved pharmaceutical care (*n*=77, 23.19%).

The methodology used in the studies

As shown in Table 2, the participants included were mainly hospitalized patients (*n*=173, 52.11%). However, 43.07% of the studies did not provide the participants background information. The study sample size mainly focused on 100-500 cases (*n*=178, 53.61%). The largest one had a sample size of 412, 782 cases, which was a database-based analysis.[22] Unfortunately, no study has introduced the calculation method of sample size. Randomization was performed in 159 studies. The period of research was mostly within 12 months, and the longest was 78 months.[23] The methods were mainly Randomized Controlled Trials (RCTs) (*n*=124, 37.35%) and cohort studies (*n*=187,56.32%). Nevertheless, 86.09% of the cohort studies could not be determined to be prospective or retrospective.

Only 23 studies were conducted as full economic evaluations (13 in CEA, 8 in CBA and 2 in CUA), and merely 8 of them introduced the research perspectives (3 on society, 3 on medical institution, 1 on medical insurance and 1 on patient). Among the economic evaluation methods, only 10 studies used incremental analysis. Two studies used model analysis methods (one in Markov model and one in decision tree model). Sensitivity analysis was performed in 11 studies. Threshold value setting was performed in only 5 studies, including two in CBA, two in CEA and one in CUA. However, in addition to CBA, the cost-benefit ratio was used as the threshold value, while the other three studies used different methods to set the threshold value. Only one study set the discount rate at 3%.[24]

Results of the effect and economic evaluation

We counted the relatively frequently-used indicators of effect and economic evaluation (as shown in Table 3). The most commonly used effect indicators included length of hospital stay (*n*=166, 50%), prescription rationality rate (*n*=166, 50%), incidence of adverse reactions (*n*=117, 35.24%) and course of medication (*n*=107, 32.23%). The results of 5 indicators (prescription rationality rate, patient satisfaction, patient compliance, antibiotics use density and quality adjusted life years) showed that pharmaceutical care had 100% improvement rate. The worst improvement rate was in mortality (30%). However, only 10 studies included mortality as effect indicator, while 7 found no difference in mortality, and no deaths occurred in three of those studies. The improvement effect was reported in 57.14%~95.33% of other effect indicators. On the other hand, one study showed that the pharmaceutical care group had a higher incidence of adverse reactions (14 vs. 36, *p*<0.05).[25] The author of this study considered that this might be due to the timely monitoring of patients by pharmacists, which improved the detection rate of adverse reactions. The result of one study showed that the pharmaceutical care group had longer medication duration (13.32±8.63 days vs. 9.60±6.83 days, *p*=0.003), which may be related to the more complex conditions of the subjects in this group.[26]

For economic indicators, the cost of medication was the most frequently used indicator (*n*=269, 81.02%), 91.45% of the studies revealed that pharmaceutical care could reduce the cost of medication. The second commonly used indicator was the cost of hospitalization (*n*=113, 34.04%), 81.42% of the studies showed improvement. Proportion of drug costs was an evaluation index of public hospitals in China, which refers to the proportion of drug expenses in the total expenses. Therefore, 52 studies have taken it as an economic evaluation indicator, and 49 of them were improved by pharmaceutical care. The total treatment cost was included in 20 studies, but none of them explained it in detail. We think the total treatment cost in these studies mainly refers to the cost of hospitalization, while 70.00% of the studies showed
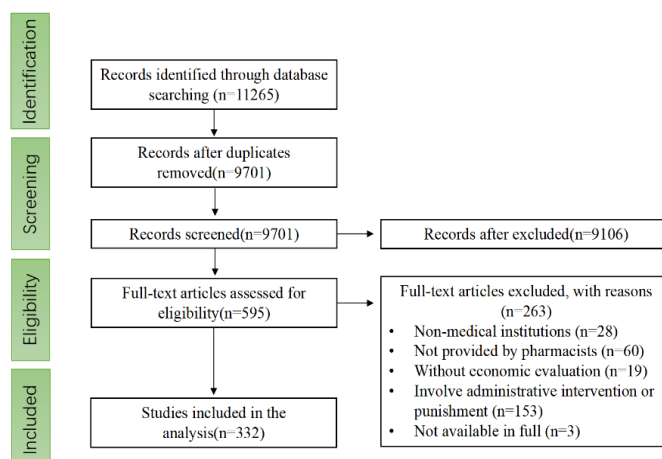

Figure 1: Literature screening process.

Table 1: General characteristics of effect and economic evaluation of pharmaceutical care in China.

Characteristics	Number (n)	Percentage (%)	Characteristics	Number (n)	Percentage (%)
Year			Respiratory system	33	9.94
2004-2006	2	0.60	Cardiovascular	12	3.61
2007-2009	9	2.71	Diabetes	12	3.61
2010-2012	20	6.02	Digestive system	10	3.01
2013-2015	63	18.98	Others	138	41.57
2016-2018	111	33.43	**Classification of drug**		
2019-2021	127	38.25	Antibacterial agents	174	52.41
Author Affiliation			TCM	14	4.22
Tertiary hospitals	230	69.28	Antineoplastic drugs	12	3.61
Secondary hospitals	78	23.49	No restrictions	86	25.90
Primary hospitals	13	3.92	Others	46	13.86
Hospitals in SAR	5	1.51	**Type of Pharmaceutical care**		
Others	6	1.81	PC	4	1.20
The identity of the corresponding author			CDID	1	0.30
Pharmacist	240	72.29	MTM	8	2.41
Unspecified	88	26.51	MED-REC	4	1.20
Others	4	1.20	PWR	12	3.61
Type of journal			PI	77	23.19
Chinese journal	311	93.67	PM	5	1.51
English journal	21	6.33	ME	7	2.11
Classification of disease			TDM	2	0.60
Perioperative	64	19.28	Comprehensive pharmaceutical care	212	63.86
Infectious diseases	63	18.98			

SAR-Special administrative region; TCM-Traditional Chinese medicine; PC-Prescription checking; CDID-Centralized dispensing of intravenous drugs; MTM-Medication therapy management; MED-REC-Medication reconciliation; PWR-Pharmaceutical ward round; PI-Pharmaceutical intervention; PM-Pharmaceutical monitoring; ME-Medication education; TDM-Therapeutic drug monitoring.

improvement. Pharmacist labor cost was only calculated in 13 studies. Unsurprisingly, 12 studies showed that pharmaceutical care would increase this economic indicator, 1 study showed that the pharmacist time spent in the pharmaceutical care group was higher, but there was no statistical difference (3.1±1.0 hr vs. 2.5±1.1 hr, $p>0.05$).[27]

Quality evaluation of economics literature

We used QHES score to evaluated the literature quality of 23 full economic evaluation studies (as shown in Supplementary Table 2). The scores ranged from 41 to 86, with an average of 61.22±12.80. The lowest scores were found in the absence of a subgroup analysis, the absence of reasons for model selection and limitations of model assumptions, and without explaining the bias that exist in the studies. Of these, 17 studies were published in Chinese journals, and the average score was 62.88±12.61. Six studies were published in English journals with an average score of 56.50±13.25. Independent sample t test was conducted

between the two groups, and the result showed no statistical difference ($p=0.887$).

DISCUSSION

Since 1988, American College of Clinical Pharmacy (ACCP) began to search and summarize the literatures of pharmaceutical care economic evaluation every 5 years,[28-32] as to provide suggestions for the economic evaluation method of pharmaceutical care, and prove the rationality of the implementation of pharmaceutical care and medical insurance reimbursement. The newly study published by ACCP included literatures of pharmaceutical care economic evaluations conducted in the United States between 2011 and 2017.[32] In recent years, there have been more and more studies on the effect and economic evaluation of pharmaceutical care in China. The previous systematic evaluation has shown that pharmaceutical care has a good effect.[28-35] Our research shows that, almost all studies proved that pharmaceutical care could improve the treatment effects and reduce treatment costs. Such as reduced the length of hospital stay, improved the prescription

Table 2: The methodology used in the studies.

Methodology	Number (n)	Percentage (%)	Methodology	Number (n)	Percentage (%)
Participant			Research Method		
Outpatient	16	4.82	RCT	124	37.35
Inpatient	173	52.11	Cohort study	187	56.32
Unspecified	143	43.07	Prospective	6	3.21
Special group [a]	38	11.45	Retrospective	20	10.70
Sample size			Unspecified	161	86.09
≤600	72	21.69	Database-based analysis	21	6.33
100-500	178	53.61	Reference to ethical approval		
≥e00	75	22.59	Yes	67	20.18
Unspecified	7	2.11	No	265	79.82
Calculation method of sample size			Indicator of health outcome		
Yes	0	0	Data source	143	43.07
No	332	100.00	Calculating method	164	49.40
Sampling method			Indicator of economics		
Randomization	159	47.89	Data source	103	31.02
Stratified sampling	10	3.01	Calculating method	34	10.24
Whole group sampling	4	1.20	Economic evaluation method		
Unspecified	159	47.89	PEE	309	93.07
Description of the inclusion and exclusion criteria			CEA	13	3.92
Yes	139	41.87	CBA	8	2.41
No	193	58.13	CUA	2	0.60
Period of study			Research perspective		
≤e2 months	164	49.40	Society	3	0.90
12-24 months	59	17.77	Medical insurance	1	0.30
≥.4 months	102	30.72	Medical institution	3	0.90
Unspecified	7	2.11	Patient	1	0.30

RCT-Randomized controlled trial; PEE-Partial economic evaluation; CEA-Cost-effectiveness analysis; CBA-Cost-benefit analysis; CUA-Cost-utility analysis.[a]Special group: Including children, pregnant and breastfeeding women, elderly patients, and patients with liver or kidney insufficiency.

rationality rate, reduced the incidence of adverse reactions, The reduced costs mainly included the cost of medication and hospitalization. Therefore, pharmaceutical care provided by pharmacists is worth promoting.

However, there are still many problems in the studies of pharmaceutical care effect and economic evaluation. First of all, in terms of research content. Many studies (63.86%) did not categorize the types of pharmaceutical care clearly, which may not be conducive to the evaluation of which pharmaceutical care content played a major role. 41.57% and 39.76% of the studies did not specify the disease and type of drugs. This may result in a mismatch between patients enrolled in the research groups and control groups. Secondly, in terms of research methods. Although, only one study did not set a control group, there were still some problems in most studies. Such as did not introduce the

sampling methods, failed to distinguish between prospective and retrospective studies, the lack of inclusion/exclusion criteria, and did not calculate the sample size in advance. We suggested that these areas worth improving in the future methodology. Finally, the differences in results may be related to differences in study methods and judgment of outcome measures.

In the economic evaluation methods. Most studies only roughly calculate the cost saving without comprehensive economic evaluation. Just 23 out of 332 studies conducted full economic evaluations, and only 2 studies used models. These studies had a QHES score of 61.22±12.80, lower than the 77.3 QHES score reported by ACCP for the economic evaluation of pharmaceutical care in the United States, which included 9 studies in 2011-2017. Ten studies performed incremental analysis, but only three of them set thresholds. Two studies used one time and three times Gross

Table 3: Effect and economic evaluation results of pharmaceutical care.

Indicators	Number (n)	Percentage (%)	Results		
			Improve (%)	Worsen (%)	NSD (%)
Indicators of health outcomes					
Length of hospital stay	166	50.00	127 (76.51)	0 (0.00)	39 (23.49)
Prescription rationality rate	166	50.00	166 (100.00)	0 (0.00)	0 (0.00)
Incidence of adverse reactions	117	35.24	99 (84.62)	1 (0.85)	17 (14.53)
Medication duration	107	32.23	102 (95.33)	1 (0.93)	4 (3.74)
Utilization rate of antibiotics	54	16.27	49 (90.74)	0 (0.00)	5 (9.26)
Types of drug combination	48	14.46	43 (89.58)	0 (0.00)	5 (10.42)
Effective rate of treatment	47	14.16	36 (76.60)	0 (0.00)	11 (23.40)
Patient satisfaction	34	10.24	34 (100,00)	0 (0.00)	0 (0.00)
Patient compliance	34	10.24	34 (100.00)	0 (0.00)	0 (0.00)
Infection rate	28	8.43	16 (57.14)	0 (0.00)	12 (42.86)
Antibiotics use density	16	4.82	16 (100.00)	0 (0.00)	0 (0.00)
Mortality	10	3.01	3 (30.00)	0 (0.00)	7 (70.00)
QALYs	3	0.90	3 (100.00)	0 (0.00)	0 (0.00)
Indicators of economic evaluation					
Cost of medication	269	81.02	246 (91.45)	5 (1.86)	18 (6.69)
Cost of hospitalization	113	34.04	92 (81.42)	1 (0.88)	20 (17.70)
Proportion of drug costs	52	15.66	49 (94.23)	0 (0.00)	3 (5.77)
Total treatment cost	20	6.02	14 (70.00)	3 (15.00)	3 (15.00)
Pharmacist labor cost	13	3.92	0 (0.00)	12 (92.31)	1 (7.69)
Cost of outpatient	4	1.20	4 (100.00)	0 (0.00)	0 (0.00)
Cost of medical examination	3	0.90	1 (33.33)	1 (33.33)	1 (33.33)
Adverse reaction disposal cost	2	0.60	1 (50.00)	0 (0.00)	1 (50.00)

NSD-No statistical differences; QALYs-Quality adjusted life years.

Domestic Product (GDP) per capita as thresholds, respectively, and the other used 3 times of the 10-year Medication Therapy Management (MTM) cost as threshold. More accurate threshold setting methods need to be identified, especially surveys based on patients' willingness to pay. This is also very important for the subsequent formulation of pharmaceutical service fee standard in China. Finally, in the setting of indicators. Primary outcomes such as mortality and Quality Adjusted Life Years (QALYs) were rarely used. Many studies included the incidence of adverse reactions as an effect indicator, but did not calculate the adverse reaction disposal cost. The calculation of pharmacist labor cost varies greatly due to the different income of pharmacists in different regions. Only one study used 3% as a discount rate, this might due to with the fact that most studies were short-term evaluations. We think long-term economic evaluations are worth carrying out.

Our review has several limitations. Although we utilized seven different databases to conduct our search, we might not have identified or included all relevant manuscripts. We did not add record identified through other source and search for unpublished work, which may increase the risk of publication bias. For subsequent studies, we suggest that more randomization methods should be adopted, and the sample size of the study should be estimated in advance to meet the statistical needs. It is suggested that more long-term economic evaluation should be carried out, and more full economic evaluations should be adopted, the threshold of research needs should be strictly set.

CONCLUSION

Pharmaceutical care provided by pharmacists can improve the therapeutic effect and save the cost. However, the methodology of pharmaceutical care effect and economic evaluation needs to be further improved. Full economic evaluation is recommended.

FUNDING

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

CMA: Cost-minimization analysis; **CBA:** Cost-benefit analysis; **CEA:** Cost-effectiveness analysis; **CUA:** cost-utility analysis; **QHES:** Quality of Health Economic Studies; **RCTs:** Randomized controlled trials; **ACCP:** American College of Clinical Pharmacy; **QALYs:** Quality adjusted life years; **SAR:** Special administrative region; **TCM:** Traditional Chinese medicine; **PC:** Prescription checking; **CDIC:** Centralized dispensing of intravenous drugs; **MTM:** Medication therapy management; **MED-REC:** Medication reconciliation; **PWR:** Pharmaceutical ward round; **PI:** Pharmaceutical intervention; **PM:** Pharmaceutical monitoring; **ME:** Medication education; **TDM:** Therapeutic drug monitoring, **PEE:** Partial economic evaluation, **NSD:** No statistical differences.

SUMMARY

In China, the content of pharmaceutical care is undergoing an important change, and the value of pharmaceutical care needs to be redefined. Based on the results of our study, pharmaceutical care is worth promoting, because the effects of pharmaceutical care on patients of pharma outcomes and treatment costs have been proven to be positive. The research design and report integrity of pharmaceutical care effect and economic evaluation need to be further improved. Therefore, we also provide a reference for the improvement of subsequent researches.

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