

# Health economic evaluations of medical devices in the People's Republic of China: A systematic literature review

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**Background:** The objective of this study is to identify and review the methodological quality of health economic evaluations of medical devices performed in the People's Republic of China. To our knowledge, no such investigations have been performed to date.

**Methods:** A systematic literature review involving searches of Medline, Medline In-Process, the National Health Service Economic Evaluation Database, the Cost-Effectiveness Analysis Registry of the Tufts Medical Center, and the Wanfang Database was performed. The search spanned the period from 1990 to 2013. Studies on health economic evaluations of medical devices, in-vitro diagnostics, procedures, and the use of medical devices in Chinese health care settings were included. Full-text articles and conference abstracts in English and Chinese were included.

**Results:** Fifty-seven publications were included, 26 (46%) of which were in English and 31 (54%) of which were in Chinese. The included publications covered a wide range of clinical areas, such as surgery (n=23, 40%), screening (n=9, 16%), imaging use (n=6, 11%), kidney intervention (n=4, 7%), and nine other technological areas. Most of the studies (n=31, 54%) were cost analyses. Among the others, 13 (50%) studies used modeling, and another 13 (50%) were within-trial evaluations. Among studies that used modeling, eleven (85%) conducted sensitivity analyses, six of which had one-way sensitivity analysis, whereas one conducted both one-way and two-way sensitivity analyses; four of these eleven modeling-based analyses included probabilistic sensitivity analyses. The incremental cost-effectiveness ratio was reported in ten (18%) studies, eight of which were screening studies. The remaining two modeling studies were in areas of imaging and oncology.

**Conclusion:** This study indicates that there are major limitations and deficiencies in the health economic evaluations on medical devices performed in the People's Republic of China. Further efforts are required from different stakeholders – academic, governmental, and privatized – to improve health economic research capacity and to put it to use when informative decisions are made in the health care setting.

**Keywords:** health economics, cost-effectiveness analysis, cost-utility analysis, cost-consequences analysis, medical devices, People's Republic of China

## Introduction

Health economics helps to compare different health technologies, taking into account clinical and cost consequences, and supports resource allocation decisions.<sup>1</sup> After safety, efficacy, and effectiveness, cost-effectiveness has been recognized as the major “fourth hurdle” to secure market access in many developed countries around the world.<sup>2,3</sup> Health economics is successfully used to support decision making in medical device use, in-vitro diagnostics, and medical procedure areas.<sup>4</sup>

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While having a long history of use in the United States, Europe, Canada, Australia, and other countries, health economics has only recently emerged as a decision-making supportive tool in Asian countries.<sup>5-8</sup> The People's Republic of China, with a population of >1.3 billion people and with a growing economy, is an attractive market for manufacturers of medical devices and pharmaceuticals.<sup>9</sup> The People's Republic of China's medical device market has become the world's second largest in 2010, with a market size having exceeded 15.8 billion US dollars (USD).<sup>10</sup> However, reimbursement for medical devices is limited and complex, especially for innovative products.<sup>11</sup> With the growing role of health economic evaluations, it is important to evaluate the status of this area in the People's Republic of China in terms of quantitative data, characteristics, and methodological approaches for evaluations of devices.

There is a lack of information concerning how the People's Republic of China performs as a stakeholder in terms of health economic evaluations revolving around medical devices and whether or not, or how cost-effectiveness is addressed in the Chinese health care setting. Therefore, the objective of this study was to review the methodological quality of health economic evaluations of medical devices performed in the People's Republic of China.

## Methods

### Literature search and citation screening

A systematic literature search was performed in the following databases: Medline, Medline In-Process, the National Health Service Economic Evaluation Database (NHS EED), and the Cost-Effectiveness Analysis (CEA) Registry of the Tufts Medical Center,<sup>12</sup> as well as the Wanfang Database<sup>13</sup> for studies published in Chinese. The Wanfang Database is an affiliate of the Chinese Ministry of Science and Technology and provides access to a wide range of data, including medical and scientific areas. The full-search strategy for each specific database is presented in the [Supplementary materials](#). The searches were conducted on February 20, 2013 for Medline, on February 25, 2013 for the NHS EED and the CEA Registry, and on March 1, 2013 for the Wanfang database. The search spanned the period from January 1, 1990 to January 31, 2013.

Screening of abstracts and evaluations of full-text publications was performed by a single reviewer using the inclusion/exclusion criteria provided below. A second reviewer checked the appropriateness of inclusion of studies. Disagreements were resolved by consensus.

## Study selection

The following inclusion criteria were used:

1. Type of studies: CEA, cost-utility (CUA), cost-benefit (CBA), cost-minimization (CMA), cost-consequences (CCA), and budget impact analyses. Economic evaluations as a part of published health technology assessments were also considered.
2. Type of interventions: Medical devices, in-vitro diagnostics, and procedures using medical devices were considered.
3. Language: Publications in English or Chinese were included.
4. Type of publication: Full-text publications in peer-reviewed journals and abstracts of conference proceedings were included.
5. Setting: The study should have been conducted in a Chinese setting.

## Data extraction and analysis

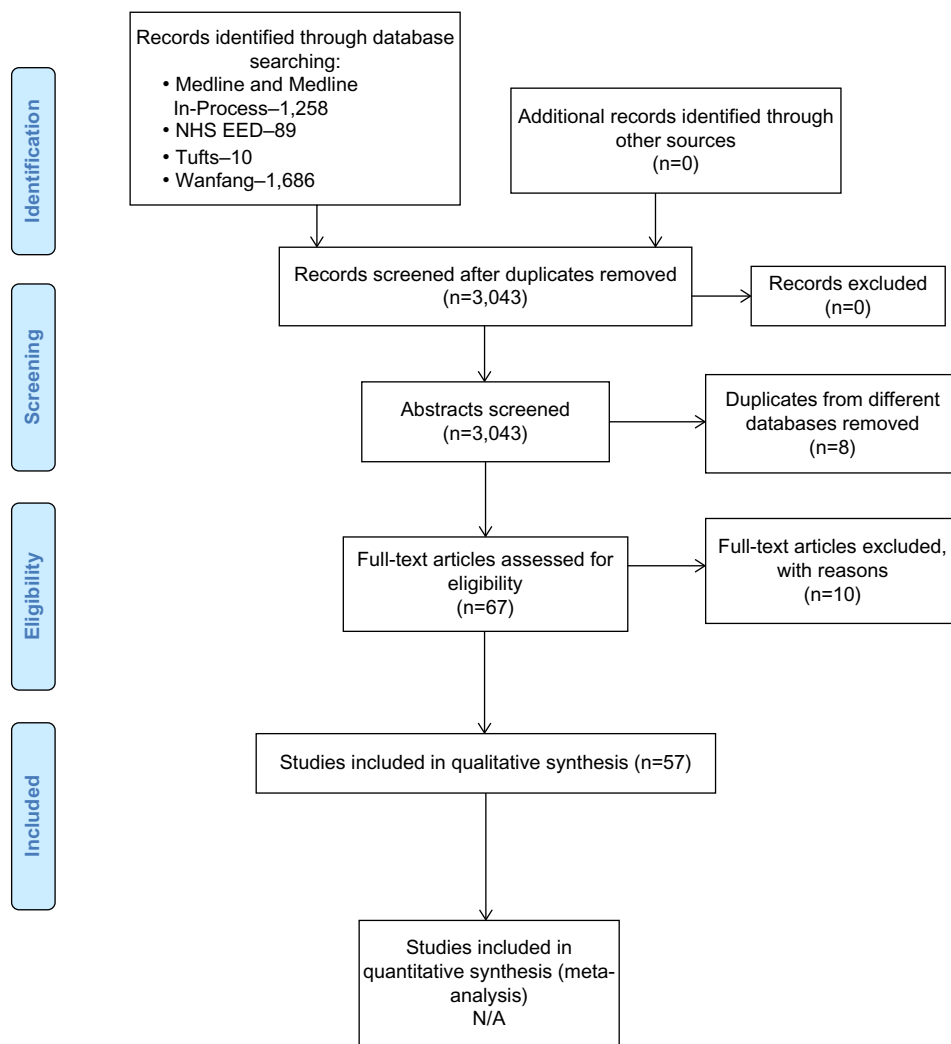
Data from included publications were extracted by one reviewer and presented in the format outlined below. The following information was extracted: title, first author, payer perspective, population/settings, intervention, comparator, time horizon, type of economic evaluation, type of study (economic evaluation alongside clinical trial, modeling), type of analysis (CEA, CUA, etc), cost and cost categories (direct, indirect, etc), source of unit cost, year of costing, resources used and their quantity reported separately (yes/no), clinical outcomes, economic outcomes, discounting, sensitivity analysis (one-way, two-way, etc), regression analysis of cost, source of funding, results (incremental cost-effectiveness ratio [ICER] or total cost per intervention), main conclusion, and language of publication. A second reviewer assessed the quality of the data extraction.

Summary statistics were calculated. No formal statistical analysis was used due to the descriptive nature of this study.

## Results

### Literature search and citation screening

The literature search of electronic databases returned 3,043 initial hits. In total, 57 publications were included in the study. Detailed information about the search process is presented in Figure 1. A list of excluded publications with the reasons for exclusion is presented in the [Supplementary materials](#).



**Figure 1** PRISMA flow chart.

**Abbreviations:** N/A, not applicable; NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

## Description of identified studies

Fifty-seven studies in total were available, 26 (46%) of which were in English and 31 (54%) of which were in Chinese. Methodological characteristics of included publications are presented in Table 1.

## Design and methodology of economic evaluations

Most of the studies ( $n=31$ , 54%) were cost analyses of routine care. Among the others ( $n=26$ , 46%), 13 (50%) used decision analytic modeling, whereas the other 13 were trial-based evaluations. Thirty-two studies (56%) adopted a hospital perspective, whereas five (9%) adopted a third-party payer perspective, while the remaining studies ( $n=20$ , 35%) were from a societal perspective.

Time horizon was reported in 36 (63%) articles. Most studies ( $n=25$ , 44%) used the respective study's follow-up as the time horizon. There were 22 (39%) and three (5%) studies that used hospital stay and lifetime as time horizons, respectively.

Discounting was applied in 12 (21%) studies; four of these discounted future costs with 3% of the annual rate, one discounted future costs with 5% of the annual rate, and seven discounted both future costs and benefits with 3% of the annual rate.

The source of funding was reported in 19 (33%) studies. Of these, three articles had funding from academia, ten studies had funding by the government, three articles had funding by both government and academia, one study had personal support, and two studies specified that there was

Table 1 Methodological characteristics of publications included in the analysis

Author, reference	Type of intervention	Type of evaluation	Type of analysis	Perspective	Time horizon	Cost categories	Year of costing	Discounting	Economic outcomes	Sensitivity analysis	Source of funding
Wang and Huang <sup>14</sup>	Imaging	M	CEA, CUA	H	-	DM	2010	C-5%	ICER, total cost	One-way	A
Zhang and Yang <sup>15</sup>	Screening	TBE	CCA	HCP	-	DM	-	-	Total cost	-	-
Wei et al <sup>16</sup>	Surgery	CA	CCA	H	Hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
Kim et al <sup>17</sup>	Screening	M	CUA	S	Lifetime	DM, DNM, I	1999/2000	CB-3%	ICER, total cost	-	-
Woo et al <sup>18</sup>	Screening	M	CEA, CUA	S	Study follow-up	DM, DNM, I	-	CB-3%	ICER, total cost	Prob	P
Wong et al <sup>19</sup>	Screening	M	CEA, CUA	S	Study follow-up	DM	2005	CB-3%	ICER, lifetime costs, QALY	Prob	G
Wong et al <sup>20</sup>	Screening	M	CEA, CUA	S	Study follow-up	DM, DNM	2005	CB-3%	ICER, lifetime costs	Prob	G
Wong et al <sup>21</sup>	Oncology	M	CEA, CUA	S	Study follow-up	DM	2010	CB-3%	ICER, lifetime costs	Prob	G, A
Chen et al <sup>22</sup>	Cardiac surgery	CA	CCA	H	Hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
Cheng et al <sup>23</sup>	Imaging	M	CCA	H	-	DM	2007	C-3% after 5 years	Total cost	One-way, two-way	-
Gong et al <sup>24</sup>	Surgery	TBE	CCA	H	Study follow-up, hospital stay	DM	-	-	Total cost	-	-
Feng et al <sup>25</sup>	Surgery	TBE	CCA	S	Study follow-up, hospital stay	DM, I	-	-	Total cost	-	G
Chen et al <sup>26</sup>	Cardiac surgery	CA	CCA	H	Study follow-up, hospital stay	DM	-	-	Total cost	-	-
Zang et al <sup>27</sup>	Surgery	CA	CCA	H	-	DM	-	-	Total cost	-	-
Gurbanov et al <sup>28</sup>	Life support	CA	CCA	H	-	DM, DNM	-	-	Total cost	-	N
Zhang et al <sup>29</sup>	Kidney intervention	TBE	CCA	H	Hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
Liu et al <sup>30</sup>	Imaging	TBE	CCA	H	Study follow-up	DM, DNM	-	NA <sup>a</sup>	Total cost	-	-
Wong et al <sup>31</sup>	Surgery	TBE	CCA	H	Study follow-up	DM	-	-	Total cost	-	G, A
Xie et al <sup>32</sup>	Bone surgery	CA	CCA	H	Study follow-up, hospital stay	DM	-	-	Total cost	-	N
Lu et al <sup>33</sup>	Surgery	CA	CCA	H	Study follow-up, hospital stay	DM, DNM	-	-	Total cost	-	-
Yang et al <sup>34</sup>	Screening	M	CBA	S	Lifetime	DM, I	2008	CB-3%	ICER, total cost	One-way	G
Sheng et al <sup>35</sup>	Surgery	TBE	CCA	H	Study follow-up, hospital stay	DM	-	-	Total cost	-	-
Wang et al <sup>36</sup>	Screening	M	CEA	S	Study follow-up, hospital stay	DM	2010	CB-3%	ICER, total cost	One-way	-
Huang et al <sup>37</sup>	Screening	M	CEA, CUA	S	Lifetime	DM, DNM, I	2009	-	ICER, total cost	One-way	-
Wu et al <sup>38</sup>	Surgery	CA	CCA	H	Study follow-up, hospital stay	DM	-	-	Total cost	-	-
Xia et al <sup>39</sup>	Obstetrics	CA	CCA, CMA	H	Study follow-up	DM	-	NA <sup>a</sup>	Total cost	-	-
Chen et al <sup>40</sup>	Kidney intervention	TBE	CUA	S	Study follow-up, hospital stay	DM, DNM, I, recessive cost	2003	-	ICUR, total cost	One-way	G
Chen et al <sup>41</sup>	Surgery	CA	CCA	S	-	DM, DNM, I	-	-	Total cost	-	-

Fan <sup>42</sup>	Imaging	CA	CEA	HCP	-	DM	-	-	Total cost	One-way	-
Gu et al <sup>43</sup>	Imaging	M	CCA	HCP	-	DM	-	-	Total cost	-	G, A
Fu et al <sup>44</sup>	Vascular surgery	CA	CEA	H	-	DM	2007	C-3%	Total cost	-	-
Guan et al <sup>45</sup>	Surgery	CA	CCA	S	-	DM, DNM, I	-	-	Total cost	One-way	-
Guo et al <sup>46</sup>	Screening	M	CEA	S	-	DM	2002	C-3%	ICER, total cost	One-way	-
Han et al <sup>47</sup>	Respiratory support	CA	CCA	HCP	Hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
He et al <sup>48</sup>	Surgery	CA	CCA	S	Study follow-up, hospital stay	DM, DNM, I	-	NA <sup>a</sup>	Total cost	-	-
Hou et al <sup>49</sup>	Imaging	CA	CCA	H	-	DM	-	-	Total cost	-	A
Gen <sup>50</sup>	Kidney intervention	CA	CCA	HCP	-	DM	-	-	Total cost	-	-
Guo <sup>51</sup>	Surgery	CA	CCA	S	Study follow-up, hospital stay	DM, DNM, I	1999	-	Total cost	-	-
Lan et al <sup>52</sup>	Respiratory support	TBE	CCA	H	-	DM	-	-	Total cost	-	-
Li and Liu <sup>53</sup>	Surgery	CA	CCA	S	-	DM, DNM, I	-	-	Total cost	-	-
Liu et al <sup>54</sup>	Bone surgery	TBE	CEA, CUA	H	Study follow-up	DM, DNM	-	-	Total cost	One-way	-
Ma et al <sup>55</sup>	Vascular surgery	CA	CCA	H	Study follow-up, hospital stay	DM	2010	NA <sup>a</sup>	Total cost	One-way	-
Peng et al <sup>56</sup>	Surgery	M	CUA	S	-	DM, DNM	-	-	Total cost	One-way	G
Tan et al <sup>57</sup>	Surgery	CA	CCA	H	Hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
Tan <sup>58</sup>	Surgery	CA	CCA	S	Hospital stay	DM, I	-	NA <sup>a</sup>	Total cost	-	-
Wang et al <sup>59</sup>	Surgery	CA	CEA	H	Study follow-up	DM	-	NA <sup>a</sup>	Total cost	-	G
Wang et al <sup>60</sup>	Bone surgery	CA	CCA	H	Study follow-up	DM	-	NA <sup>a</sup>	Total cost	-	-
Wei et al <sup>61</sup>	Surgery	CA	CCA	S	Hospital stay	DM, DNM, I	-	NA <sup>a</sup>	Total cost	-	G
Wen et al <sup>62</sup>	Kidney intervention	CA	CCA	H	Study follow-up	DM	-	-	Total cost	-	G
Xia <sup>63</sup>	Surgery	CA	CCA	H	Hospital stay	DM, DNM	-	NA <sup>a</sup>	Total cost	-	-
Yu <sup>64</sup>	Surgery	CA	CCA	S	Study follow-up, hospital stay	DM, DNM, I	2005	C-3%	Total cost	One-way	-
Zhou et al <sup>65</sup>	Surgery	CA	CCA	H	-	DM	-	-	Total cost	-	-
Wu and Zen <sup>66</sup>	Ophthalmology	TBE	CCA	H	-	DM	-	-	Total cost	-	-
Liu et al <sup>67</sup>	Surgery	TBE	CCA	H	Study follow-up, hospital stay	DM	-	NA <sup>a</sup>	Total cost	-	-
Han et al <sup>68</sup>	Ophthalmology	CA	CCA	H	-	DM, DNM	-	-	Total cost	-	-
Liu et al <sup>69</sup>	Airway surgery	TBE	CCA	H	-	DM	-	-	Total cost	-	G
Ly et al <sup>70</sup>	Surgery	CA	CCA	H	-	DM	-	-	Total cost	-	A

Note: <sup>a</sup>NA, not applicable for studies with duration of < 1 year.

Abbreviations: A, academia; CA, cost analysis of routine care; CCA, cost-consequence analysis; CEA, cost-effectiveness analysis; CMA, cost-minimization analysis; CUA, cost-utility analysis; C-%, cost discounted - annual discount rate; CB-%, cost and benefit discounted - annual discount rate; DM, direct medical cost; DNM, direct nonmedical cost; G, government; H, hospital; HCP, health care payer; I, indirect cost; ICER, incremental cost-effectiveness ratio; M, modeling; N, none; NA, not applicable; P, personal; Prob, probabilistic; QALY, quality-adjusted life year; S, society; TBE, trial-based evaluation; -, not reported; CBA, cost-benefit analysis.

no supporting funding. There was no single study reporting funding from the industry.

Among all studies involving a health economic analysis, 40 (69%) used a CCA; seven (12%), both a CCA and a CEA; five (9%), a CEA; three (5%), a CUA; one (2%), a CBA; and one (2%), both a CCA and a CMA.

Concerning studies in clinical areas, 23 (40%) involved surgery, nine (16%) involved screening, six (11%) involved imaging, four (7%) involved kidney intervention, three (6%) involved bone surgery, two each involved cardiac surgery/vascular surgery/respiratory support/ophthalmology (3% each), and one each involved oncology/life support/obstetrics/airway surgery (2% each).

## Resource use and cost inputs

Among 44 nonmodeling studies, only 14 (32%) reported resources used and the quantity used for each resource. Thirty studies reported the source of unit cost, 16 (53%) of which adopted local unit costs from hospitals, ten (33%) used regional unit costs, one (3%) used national unit cost as a reference, and three (10%) used both local and regional sources. There was only one study (2%) with a regression analysis on cost available. All (n=57) studies reported direct medical costs. Direct nonmedical costs were reported in 19 (33%) studies, and indirect costs were reported in 14 (25%) studies.

## Sensitivity analysis

Among the 13 studies that used modeling, eleven (85%) conducted sensitivity analyses; six (55%) of these had a one-way sensitivity analysis, one (9% of 11) conducted both one-way and two-way sensitivity analyses, and four (36% of 11) reported a probabilistic sensitivity analysis.

Among nonmodeling studies that conducted one-way sensitivity analyses, there were two (4%) that conducted trial-based evaluations and four (7%) that conducted cost analyses of routine care.

## Outcomes of economic evaluations

The ICER was presented in ten (18%) studies, eight (80%) of which were screening studies, while the remaining two (20%) were studies in imaging and oncology areas. The reported ICER (with year of costing available) ranged from 12 USD per life-year saved (USD/LYS) for the single colonoscopy screening strategy to 6,014 USD/LYS for an additional positron emission tomography/computed tomography (CT) screening when compared with conventional CT staging.

Detailed information on population, settings, comparators, results, and conclusions is provided in the [Supplementary materials](#).

## Discussion

The present study is one of the first attempts to evaluate the status of health economic evaluations of medical devices in the People's Republic of China. This study complements existing literature on methodological quality of the health economic evaluations in regions by raising the issue of application of this concept in decision making.<sup>71–73</sup> While other systematic reviews are focused on health economic evaluations in general and mainly include evaluations of pharmaceuticals, our review is aimed on research in medical device and in-vitro diagnostic areas. Specifics of economic evaluation of medical devices in comparison with pharmaceuticals have been extensively reviewed elsewhere.<sup>74</sup> This includes difficulties in conducting randomized controlled trials, “learning curve” and usability aspects, wider organizational implications, a shorter life cycle, fast price erosion, etc. Moreover, reimbursement and funding for medical devices differ significantly than for pharmaceuticals, as a special approach is required for the evaluation of medical device studies.

This study reveals that literature on health economics of medical devices in the People's Republic of China is limited (57 publications in total from the year 1990), and the majority of the publications (53%) include cost or CCAs of routine care. Decision analytic modeling and within-trial evaluations have been used equally.

To include the majority of relevant studies, the search was also conducted using a local Chinese bibliographic database. Although locally published studies bring value in terms of having a complete picture of available research, they may have different methodological quality. Interestingly, the majority of the studies published in Chinese (24 out of 31) used CCAs, mainly at the hospital level. On the other hand, nine out of the ten studies that reported ICER and nine out of 17 studies that conducted sensitivity analyses were published in English, while all the Chinese studies with sensitivity analyses conducted only one-way sensitivity analysis. Among the 13 studies that applied modeling approaches, ten studies were published in English. In addition, among 42 studies with study follow-ups longer than 1 year, only 13 had discounting available. Among these 13 studies, nine were published in English. This may reflect both interests from authors to increase exposure to international literature and to have the influence of international recommendations on good reporting

practice on content of published articles. The development of clear guidelines for economic evaluations is clearly considered part of the strategy to increase application of these studies in decision making.<sup>75</sup> Recently, Consolidated Health Economic Evaluation Reporting Standards were issued by the International Society for Pharmacoeconomics and Outcomes Research Task Force, which may help improve the quality of reporting of economic evaluations.<sup>76</sup>

A sensitivity analysis was also conducted to account for the time that passed after the primary analysis was completed (January 2013 to December 2014). The analysis was performed using Medline and Medline In-Process on January 15, 2015, with the same search strategy that was used during the primary analysis. Among the 181 hits generated from the search, eight studies were identified.<sup>77–84</sup> Most of the studies (n=4, 50%) were trial-based evaluations, and the remainder were cost analyses of routine care (n=2, 25%) and decision analytic modeling (n=2, 25%). Discounting was not applied in any article (it was not applicable to one study). Apart from one study published in Chinese, the remaining studies were published in English. Six studies (75%) used CCA, and both CEA and CUA were used in two studies (25%). In the two studies that used modeling, both conducted sensitivity analyses – one study conducted only one-way sensitivity analyses, while the other performed one-way, two-way, and probabilistic sensitivity analyses. However, it is worth mentioning that the study that conducted a CEA and CUA with decision analytic modeling and sensitivity analyses (one-way, two-way, and probabilistic) was conducted in the setting of Hong Kong,<sup>83</sup> which runs a different health care system and medical device funding system than Mainland China. With these results, it appears that over the extent of the latest time period specified, the quality of the health economic studies performed in the People's Republic of China remains the same.

This systematic review reveals several areas in which improvements in methodology and reporting are possible for Chinese health economic studies. These include reporting of resource used, sensitivity analysis, presentation of study's results with ICER, both internal and external validation of decision analytic models, transparency on source of funding, etc.

The limited role of economic evaluations in reimbursement for medical devices in the People's Republic of China should be taken into account while interpreting the findings of our study. On the national level, the health care system was financed through out-of-pocket payments (35%), social insurance schemes (35%), and government subsidies

(30%).<sup>85</sup> However, tier III hospitals (highest tier with highly specialized services) dominated 70% of the medical device market among the top 12 cities (including Shanghai, Beijing, and Guangzhou). They have a different purchasing pattern due to a different source of revenue than tier II hospitals.<sup>86</sup> Tier III hospitals are expected to generate at least 40% of their revenue from out-of-pocket payments, while tier II hospitals have 20% of revenue coming from out-of-pocket payments.<sup>86</sup> This also drives tier III hospitals to procure the most advanced products to boost demand for high-end medical devices, as well as to attract complex disease treatment to enhance out-of-pocket revenue. Thus, with a demand for top medical products, the scarcity of health economic evaluations in the People's Republic of China needs to change, to determine which of these, eg, are cost-effective so that the rural areas could also consider which of these products may be accessible for them. Fee-for-service remains the main and basic payment mechanism. In most cases, reimbursement does not cover the cost of medical devices completely and there is no established mechanism for evaluating the long-term benefits and cost-effectiveness of technologies. If the role of reimbursement from public sources grows in future, it may lead to increased demand for clinical and economic evidence of benefits of medical technologies.

## Conclusion

This study indicates that there are a limited number of economic evaluations of medical devices existing in the People's Republic of China, and these are mainly focused on cost analysis and have methodological deficiencies. Further efforts are required from different stakeholders, including academia, state institutions, and the private industry, to improve health economic research capacity and to put the results of analyses into practice to ensure that decisions in health care are based on the best available clinical and economic evidence.

## Disclosure

The authors report no conflicts of interest in this work.

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