



卫生技术评估简讯

Newsletter of Health Technology Assessment

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编者按：

实验室师生参与我国经济学评价的报告质量分析研究；卫生技术评估应用于医保管理决策
本期简讯为您呈现我国经济学评价报告的质量分析和医保管理专题资讯

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我国经济学评价论文质量评析

药物经济学已成为我国医药卫生研究的热点，受到决策者、研究者的重视，能够为政府宏观决策、价格管理、相关医保政策制定等提供经济学证据支持，是提高医疗资源利用率的重要工具。国内已发表的药物经济学评价文献，已从前期的理论研究逐步过渡到实证研究，研究数量也呈逐年上升趋势，卫生政策制定者如何评价和应用这些评价研究结果，取决于结果的真实性和可靠性；来自不同学科背景的研究人员对药物经济学的理解不一，导致评价的设计、分析方法和结果解释差异较大。对我国药物经济学评价研究的质量进行评估，是充分发挥药物经济学评价在卫生决策中的作用以及实践价值的前提与保障。

国家卫健委卫生技术评估重点实验室（复旦大学）老师与学生共同参与，分别从疾病筛查技术、肿瘤药物、冠脉支架、中医药、糖尿病药物和癌症筛查 6 个方面研究我国经济学评价的报告质量及影响因素，为规范相关卫生经济学研究提供借鉴和参考。上述研究中使用的经济学评价工具为 CHEERS（Consolidated Health Economic Evaluation Reporting Standards）2013 版。6 个主题中，肿瘤药物、中医药和糖尿病主题针对的是中国 2020 年国家药品谈判目录中对应的药物。检索的数据库包括 PubMed、Embase、Web of Science、知网、万方、维普和 SinoMed，时间范围集中于 2000 年至 2021 年。检索词包括中国、各主题对应的关键词（筛查、支架、药物名称等）和成本效果分析（CEA）、成本效用分析（CUA）、成本效益分析（CBA）、最小成本分析（CMA）、经济学评价、增量成本效果比（ICER）等药物经济学评价相关词汇。

结果检索到 8000 多篇经济学评价文章，最终纳入 412 篇。结果显示纳入研究的报告质量总体呈逐年上升趋势，且英文文章通常比中文文章报告质量高。回归分析显示，发表年份、发表期刊类型、通信作者机构、研究类型等与报告质量显著相关，可能原因在于（1）早期还没有推广药物经济学评价报告的标准，导致发表年份较早的研究报告质量较低；（2）不同期刊对于篇幅和结构的限制不同，报告内容的丰富程度可能会受此影响；（3）通信作者机构为大学或研究机构，比医院的文章报告质量更高，可能原因在于研究机构人员接受过更多的药物

经济学专业培训；（4）CUA 的报告质量更高，可能原因在于 CUA 的效果指标，质量调整生命年（quality-adjusted life years, QALYs）是 CHEERS 的关注要素，《中国药物经济学评价指南（2020）》等权威指南中也推荐使用 CUA。

总体而言，中国药物经济学评价报告的质量呈上升趋势，但仍有提高的空间，尤其要注重完整报告研究视角、贴现率、模型选择等关键信息。可通过推广 CHEERS 等标准化报告指南，来提高相关报告的质量。

部分文章已完成撰写并进行投稿，摘要如下图所示。另外，筛查、冠脉支架和中医药 3 个主题的内容在 2022 年 HTAi 年会上进行了海报展示，见下图。

（作者：翁俊岭，刘柳）

我国卫生经济学评价的报告质量影响因素分析 ——以癌症筛查类为例

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摘要： **目的** 本研究旨在评价我国癌症筛查的经济学评价研究的报告质量，并探究其影响因素。**方法** 检索 2000 年到 2021 年内，PubMed、Embase、中国知网、万方等数据库在收录的相关文献。研究者筛选文献、提取资料并使用《卫生经济学评价综合报告标准》（Consolidated Health Economic Evaluation Reporting Standards, CHEERS）量表评价文献质量，使用广义线性回归来确定文献质量的影响因素。**结果** 初步检索到 658 篇文献，最终纳入 78 篇。纳入文献中占比较多的为中文文献(69.2%)，基于模型的研究(61.5%)，成本效果研究(53.8%)。平均标准化质量得分为 0.57(SD=0.13)。与研究视角、贴现率、效果测量、贴现率、分析方法、异质性有关的 CHEERS 条目得分相对较低。广义线性回归发现文章语言、第一作者单位、评价类型与报告质量相关 ($P < 0.05$)。**结论** 本研究提示我国以癌症筛查为主题卫生经济学研究的报告质量有待提升，癌症筛查的卫生经济学评价研究报告质量的主要影响因素包括文章语言，第一作者单位，经济学评价类型。研究者在开展经济学评价时应该参考 CHEERS 规范等报告指南以规范文章报告质量。

Were economic evaluations well reported for the newly listed oncology drugs in China's national reimbursement drug list

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Abstract

Purpose: To assess the reporting quality of published economic evaluations of the negotiated oncology drugs listed for China's 2020 National Reimbursement Drug List (NRDL).

Methods: A comprehensive search was conducted to identify economic evaluation studies of negotiated oncology drugs listed in China's 2020 NRDL using the PubMed/MEDLINE, Embase, Web of Science, CNKI, SinoMed, and Wan-Fang Database up to March 31, 2021. The Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist scored the reporting quality between 0 and 100. A linear regression analysis was employed to examine the influence of various characteristics on the reporting quality scores.

Results: Eighty papers were included in the study, with the majority published during the past decade. Furthermore, more than half of the articles (57.5%, or 46 out of 80) were written in English. The average CHEERS score was 74.63 ± 12.75 and ranged from 43.48 to 93.75. The most inadequately reported items included choice of model, characterization of heterogeneity, and discussion, as well as currency, price date and conversion. Higher scores were associated with articles published from 2019 to 2021 and English publications.

Conclusion: The economic evaluation studies of negotiated oncology drugs listed in 2020 NRDL had moderate reporting quality. The Chinese economic evaluation publications could improve the reporting quality if the CHEERS checklist is consistently implemented. Also, the Chinese journals maybe explore introducing a reporting standard for economic evaluations.

Keywords: China, Economic evaluation, Oncology drugs, Price negotiation, Reporting quality assessment

The quality of published health economic evaluations on screening programs in China: a systematic review and quantitative appraisal

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ABSTRACT

Background: This study seeks to assess the quality of HEEs reporting on screening programs over the last 20 years in China, to identify potential predictors of reporting quality.

Methods: We performed a literature search of HEE studies published in PubMed, Embase, CNKI, and WANFANG from 2000 to 2021. The search terms included 'screening,' 'China,' 'CEA,' 'CBA,' 'CUA,' and all other names for health economic evaluation. Two reviewers independently extracted data and assessed the reporting quality using CHEERS checklist. A generalized linear regression analysis was used to identify the predictors of reporting quality.

Results: 133 of 1,281 identified studies was included. The reporting quality scores showed an increasing trend and the mean score was 0.56. Some items were underreported, such as study perspective, discount rate, measurement of effectiveness, analytical methods, uncertainty, heterogeneity etc. Five factors (year of publication, journal type, first author's affiliation, economic evaluation type, specialty journals or not) predicted a higher score of reporting quality in the regression analyses ($P < 0.05$).

Conclusions: Overall, the quality of HEEs on screening programs in China showed an improving trend. Given the significance of reporting quality, it is advisable to report HEE results following standard evaluation guidelines to improve their transparency.

Quality Assessment of Health Economic Evaluation on Screening Programs from China

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UTRECHT, NETHERLANDS

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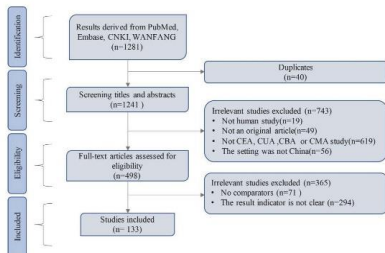
Introduction

- With the increasing use of **health economic evaluation (HEE)** in decision-making and policy designing for health resource allocation and management, there is mounting HEE studies from China on screening program as well.
- In addition to the quantity of HEE, the quality may be of particular concern as it influences the reliability of HEE evidence adopted in policy formulation.
- This study sought to **assess the reporting quality of HEE on screening programs over the last 20 years** in China, and identify **potential predictors** and **relevant recommendations** to improve the quality of study reporting.

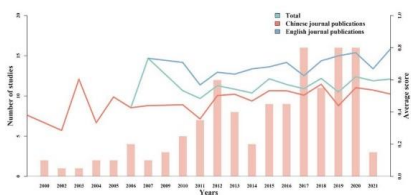
Methods

- A search of HEE studies published in PubMed, Embase, CNKI and WANFANG from **2000 to 2021** was performed.
- Two reviewers independently extracted data and assessed the reporting quality using the 24 item **Consolidated Health Economic Evaluation Reporting Standards (CHEERS)** checklist. Score of 0, 0.5, 1, or N/A was assigned to each CHEERS item, and the total CHEERS score for each study was converted into a **standardized 0-1 point scale**.
- The **general linear regression analysis** was used to identify the predictors associated with the reporting quality.

Flow chart of search process



Number of studies published and average score by year



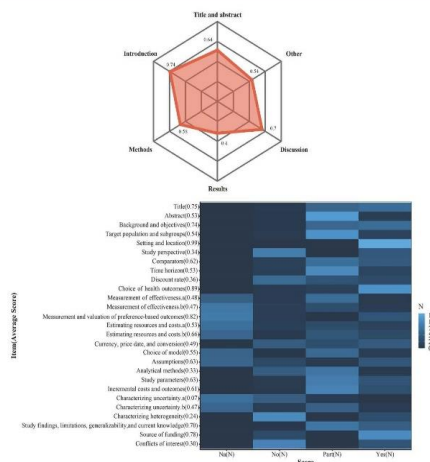
Results

- **One hundred and thirty three studies** met the inclusion criteria. The mean standardized score of included studies was **0.56(Title), 0.64(Abstract), 0.74(Introduction), 0.58(Methods), 0.40(Results), 0.70(Discussion), and 0.54(Other section)**.
- The number and reporting quality of articles published each year showed an overall upward trend. A greater proportion of studies were published in Chinese journal(69.2%), modelling-based (54.9%), conducted by universities/research institutions (45.9%), focused on non-infectious disease (84.2%), using cost-effectiveness analysis method (50.4%), published in non-specialty journal (60.2%), and declaring the funding support (76.7%) accounted for a relatively greater proportion.
- Items related to **study perspective, discount rate, measurement of effectiveness, currency and price, analytical methods, uncertainty, heterogeneity and conflicts** were under-reported.
- **Published year, journal type, the first author affiliation and economic evaluation type** predicted higher score in regression analyses ($P < 0.05$).

Discussion & Conclusions

- Overall, the quantity and quality of HEE on screening program in China showed an improving trend, yet it is highlighted that concentration should be put on specific reporting items following the CHEERS criteria.
- Given the significance of reporting quality, it is advisable to refer to the suitable evaluation guidelines to promote decision making process more scientific.

Quality assessment of studies per item for CHEERS



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Quality Of Economic Evaluation Of Coronary Stents Based On CHEERS: A Scoping Review

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Introduction

- Although numerous economic evaluations (EEs) in selecting the most appropriate coronary stenting intervention strategies for different medical scenarios of coronary artery disease (CAD), there is a lack of quality assessment and review of these EEs for stenting interventions.
- The study aims to systematically review all articles on the economic evaluation (EE) of coronary stenting, to critically assess the reporting quality, and to summarize the results.

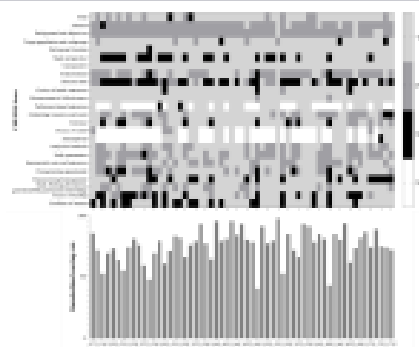
Results

- A total of 3622 articles were retrieved, 59 articles were included in this review. The quality of the reports varied between studies, with a standardized mean score of 0.76 (0.40-0.98).
- "Introduction" had the lowest overall score (0.53), with many articles deficient in the description of the study's perspective; "Discussion" had the highest overall score (0.86), with nearly three-quarters of the articles reporting the full content; "Title and abstract", "Methods", "Results", and "Other" scored 0.71, 0.78, 0.74 and 0.66, respectively.
- "Published year", "National type", and "Type of economic analysis" were significantly associated with the quality of literature (P < 0.05).

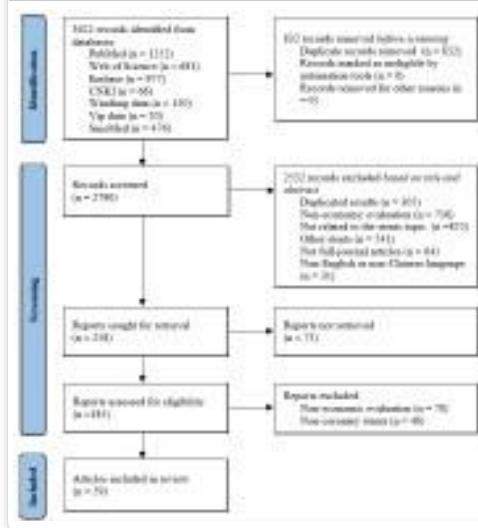
Methods

- A systematic search was undertaken through seven databases (PubMed, Web of Science, Embase, CNKI, Wanfang data, Vip data and SinoMed.) from inception until March 2021, to identify economic evaluation articles comparing coronary stenting with other therapies among different stenting procedures.
- The methodological quality was assessed using the CHEERS (Consolidated Health Economic Evaluation Reporting Standard) checklists.
- The literature scores were standardized as a proportion of the total score and stepwise multiple regression was constructed to verify the factors that might influence the quality of literature.

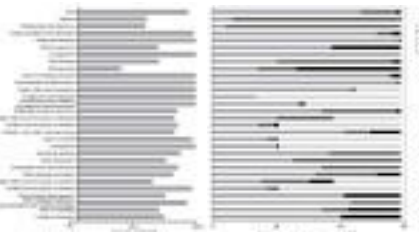
The score composition and standardized scoring rate of 59 articles



PRISMA flowchart for studies selection



The score composition and standardized scoring rate of 24 items



Discussion & Conclusion

- The quality of current research reports on the economics of coronary stenting is generally satisfactory, but there is potential for improvement and high quality reports can provide evidence to support decision making for policy makers.

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A systematic Review Of Reporting Quality Of Economic Evaluations In TCM In NRDL Of China Based On CHEERS

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Introduction

Traditional Chinese Medicine (TCM) has become a common kind of health care in several countries, with increasing demands. In China, Traditional Chinese Medicine (TCM) has been a common kind of primary health because of its many beneficial effects.

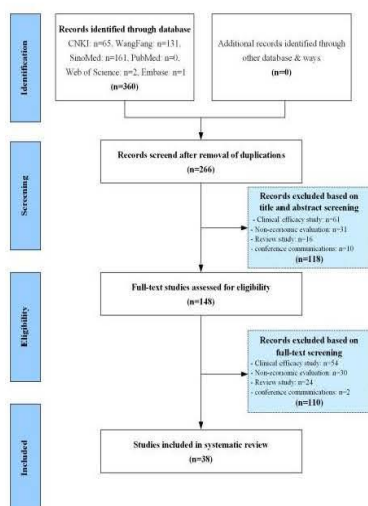
Objectives

This review aimed to identify and appraise the reporting quality of economic evaluations of TCM in the National Reimbursement Drug List (NRDL) of China (2020 version), based on the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.

Methods

Electronic databases were searched for economic evaluation articles of TCM in NRDL (2020 version) published in Chinese or English from 2001 to 2021, including PubMed, Web of Science, Embase, CNKI, WanFang, and Sinomed. The reporting quality of included economic evaluations was assessed by two independent reviewers using the CHEERS statement.

PRISMA flowchart for studies selection



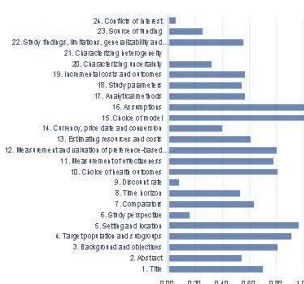
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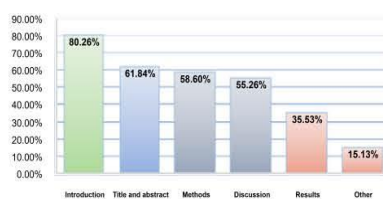
Results

A total of 360 articles were retrieved, but only 38 economic evaluations met the inclusion criteria. No articles were compliant with all items of the CHEERS checklist. On average, the included economic evaluations satisfactorily met 10.93 of the CHEERS items (51.31%). The least reported CHEERS checklist items included: "Characterizing heterogeneity", "Conflicts of interest", "Discount rate", and "Study perspective", with an average score of 0.00, 0.05, 0.08, and 0.16, respectively.

The average CHEERS score of 38 included articles



The average scoring rate of included articles in different sections



Discussion & Conclusion

The economic evaluation of TCM is still at an early stage, with an urgent need for improving the reporting quality. To promote the reporting quality of economic evaluations and further development of TCM, multiple measures focusing on reporting formula, policy, training, and new methodology are required.



卫生技术评估应用于医保管理决策的国际经验荟萃及启示

近年来，随着医保药品报销目录调整过程中卫生技术评估（Health Technology Assessment, HTA）与药物经济学作用的不断强化，以HTA为基础的医保价值购买、医保准入决策及目录调整机制已初步建立。但与HTA发展较为成熟的国家和地区相比，HTA应用于我国医保管理决策的工作仍面临诸多挑战，如HTA组织体系尚待健全、HTA机构评估能力有待提升、评估评审指南尚需开发、创新药医保支付标准制定方式相对单一等。本文通过对典型国家或地区HTA应用于医保管理决策经验进行总结，以期为进一步优化我国医保目录调整过程中HTA的科学应用提供经验借鉴，促进我国HTA辅助医保管理决策工作的高质量发展。

一、国际经验荟萃

总结HTA组织体系建设相对完善的英国、加拿大、澳大利亚、德国、韩国、日本和中国台湾地区关于HTA应用于医保管理决策的经验如下：（1）HTA组织管理体系，在“行政主管机构-HTA整体流程负责机构-评估机构-评审机构-定价机构”各个环节均设有相应的责任主体机构。如英国的NHS和NICE、加拿大的CADTH、澳大利亚的DoH、德国的G-BA和IQWiG、韩国的MOHW、HIRA和NECA等；（2）HTA参与方，除了开展HTA工作的官方机构外，大学、独立学术研究机构以及医疗卫生机构等社会主体也广泛参与到各个国家和地区HTA的整体发展中。如英国NICE的技术评估项目往往由与其合作的13家高校和研究机构承接开展；（3）HTA实施指南与标准，系统的操作指南与标准化的操作流程是各国和地区HTA体系高效运行的重要抓手，贯穿于HTA辅助医保管理决策的全流程，包括卫生技术的评估、材料递交、结果评审等各环节。如英国、加拿大、澳大利亚、韩国等国均发布了官方的药物经济学评估指南，英国NICE于2000年制定了首部应用于多项卫生技术评估的技术评审指南；英国NICE、加拿大CADTH、澳大利亚药品福利建议委员会与医疗服务建议委员会等HTA机构均向企业申请方公布了特定的材料递交模板与递交流程；（4）创新技术医保准入定价，基于HTA的谈判定价是各国和地区制定创新技术医保支付标准的主要方式。其中，英国、澳大利亚和中国台湾地区由HTA评审机构与企业方进行价格谈判，加拿大则是由各省卫生厅负责，韩国和德国是由国家医疗保险机构承担具体的价格谈判工作。在医保准入及支付标准制定的方法方面，英国、加拿大、澳大利亚和韩国主要关

注创新技术的增量成本效果比；德国更加关注技术的临床附加效益；日本则采用成本定价法或比较定价方法为产品制定医保报销价格。

二、启示及建议

根据HTA用于支持我国医保管理决策过程中面临的主要痛点与挑战以及典型国家或地区在相应问题上的应对经验，现总结如下启示及建议：（1）创机制，探索建立由医保管理部门为主导，医疗卫生机构、大专院校、科研院所、行业协会、非营利组织、医药企业、患者群体等多方参与的HTA发展模式，进一步压实HTA辅助医保管理决策的应有之功；（2）建体系，自下而上逐步构建我国HTA专业体系和管理架构，夯实HTA工作基础，包括设立国家层面的HTA专业管理机构，探索组建由医保管理部门牵头的国家级和区域化HTA专家委员会，加强HTA团队和专业机构的能力建设与人才培养和探索建立HTA机构协作网；（3）设标准，制定官方的HTA操作指南和标准，加强HTA工作的技术指导，保障HTA项目研究质量，促进HTA辅助医保管理决策工作高质量发展；（4）促推广，在医保准入环节，分别设立药品、医用高值耗材、医疗服务项目评审工作组对相应申报技术进行审查，切实强化医保准入环节HTA评审工作的专业性；（5）攻难点，对于肿瘤免疫治疗等多适应症的药品、医疗器械、高值耗材以及社会广泛关注的卫生技术项目，建议由医保管理部门或未来可能建立的国家HTA主管机构主动发起项目评估需求，并委托社会第三方HTA机构开展具体评估，保障HTA评估结果的客观公正；（6）重价值，对于创新技术的医保支付标准制定，应重点关注卫生技术的临床附加效益。可根据谈判、临床附加效益原则对医保目录内有、无对照技术的创新产品规定支付标准；对于生命终末期及肿瘤类治疗技术，可考虑适当提高其医保准入阈值，并给予其合理的医保支付标准。

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