



# 卫生技术评估简讯

Newsletter of Health Technology Assessment

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## 编者按：

第七届 HTAsiaLink 年度会议于 2018 年 5 月在泰国清迈召开。本期简讯将为您呈现此次 HTAsiaLink 年度会议的最新资讯，及实验室成员在本次会议上的精彩汇报。

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## 第 7 届 HTAsiaLink 年度会议专题报道

### 专题分享

#### (一) 不安全或无效的卫生技术及干预的使用

该专题会议由新加坡卫生部 Daphne Khoo 的主持，泰国 Cochrane 协作网的 Pisake Lumbiganon 教授、中国兰州大学的陈耀龙教授和南非金山大学公共卫生学院的 Karen Hofman 教授分别就剖腹产手术、感冒药“克流感”和补充免疫计划三方面分享当前技术和干预的使用情况及对卫生体系和人群的影响。

Pisake Lumbiganon 教授介绍了剖腹产手术的使用与母婴死亡率的关系之间的研究。研究显示在人群水平中，若剖腹产手术率小于 10% 时，可帮助减少母婴死亡率，但超过该阈值则不再有相应的联系，该研究结果也推动了相关领域的指南修订。但由于部分利益驱使的因素，使得世界多地的剖腹产手术率普遍偏高。为了减少不必要的剖腹产手术，Lumbiganon 教授从患者和服务供方两个角度给出了相应的建议和干预措施，建议应通过增加产妇信息帮其做出更合适的选择。

陈耀龙教授分享了感冒药“克流感”使用的研究现况。发现低质量的文献以及药企资助研究对感冒药“克流感”效果的评估会产生较大偏倚，从而影响政策决策。为解决这一问题，陈耀龙教授提出了提高文献报道的透明化；对证据和建议进行评级；结合患者和公众的力量帮助评测，三个解决方法。

Karen Hofman 教授以麻疹为例，介绍麻疹补充免疫计划对南非麻疹防疫及卫生体系的影响。由于各地贫富间的差异，导致补充免疫的覆盖呈现明显的地区性差异，但是补充免疫能带来更高的机会成本，因此建议未来将补充免疫的范围进一步聚焦在高风险和脆弱人群，同时进一步优化补充免疫的计划。对于麻疹的控制策略，Hofman 教授建议可以优化国家对相关领域的规划，加大对常规卫生

体系和基础免疫的投资，平衡常规免疫和补充免疫计划的使用。

## （二）评估未经实证的技术所需的努力和面临的挑战

该专题会议由来自三个国家（日本、韩国、英国）的研究者分别向我们介绍了新技术评估在各自国家的一些发展情况。

日本国家儿童卫生发展中心卫生政策部门的主任 Rintaro Mori 教授，主要介绍了在日本医疗保险中的新技术评估。在日本，医疗卫生费用主要由社会保险覆盖 70-80%，由于日本的人口老龄化严重，医疗保险制度在日本的卫生发展中尤为重要。日本社会医疗保险中心委员会的主要功能是每两年核查一次保险付费制度，其主要由卫生服务提供者、使用者、社会利益方等组成。对于新技术，日本主要由 PMDA 审批，由国家医疗保险组织定价，并由专业的组织机构进行相关的临床技术指导。PMDA 主要进行一些临床研究，聚焦在药品和设备的安全性，并且与 FDA 和 EMA 合作。卫生技术评估中的专业组织 Minds 主要由政府资金投入，由日本卫生服务质量委员会主持主要工作。

韩国 NECA 卫生循证中心的 Seok-Hyun Kim 教授，介绍了韩国的卫生新技术评估。近年来，卫生服务提供者、利用者、企业、卫生政策制定者等对于新技术的需求越来越大，因此高质量的循证依据将会成为解决这些问题的关键。韩国的循证证据收集体系主要由各种不同的卫生技术研究机构成果共同组成，当新技术出现时，先由 nHTA 进行审批，如果低质量，则不进行卫生技术评估，但若被 nHTA 的 temporary exemption 同意通过，则会被再次进行审批；若高质量但是证据不足，则进行预评估；若高质量且证据充分，则直接被国家医疗卫生系统覆盖。

全球发展中心的 Kalipso Chalkidou 教授，主要介绍减少全球卫生费用浪费的方法。因为卫生资源的不公平与不可持续性，每年全球卫生服务费用的 20-40% 是被浪费的。其中，有不够成熟的卫生技术与治疗设备被大量资金投入造成了资源浪费，因此对新技术进行针对人群/因素的研究和价格协商是避免资源浪费的重要途径。但是单独的价格调控是不能解决卫生费用浪费，需多方共同努力合作。

### （三）解决当前困境的潜在解决方案及所面临的责任

该专题会议由 Tony Culyer 教授主持，马来西亚大学的 Su May Liew 教授，韩国大学的 Hyeong Sik Ahn 博士，台湾卫生福利委员会的 Jasmine Pwu 博士分别就卫生技术评估中问题的解决途径和措施及未来的发展目标进行汇报。

Su May Liew 介绍了溶栓剂在治疗急性缺血性中风的应用现状。1997 年溶栓剂就已被收入指南推荐疗法，且具有高质量的成本效果优势，但在临床中应用却很少，而且疗效上不如溶栓剂的吡拉西坦却被广泛使用。Liew 教授认为卫生技术评估不仅要关注有效性低技术的使用，更要关注有效性高技术的未使用问题。卫生技术评估的工作需所有利益相关者共同参与。患者及公众需参与卫生技术评估中问题提出、方法确定、结果和评估的各个环节中；服务提供者需将诊疗标准化；研究人员通过现实数据、多部门研究从而提供高质量的证据；卫生技术评估者需保持独立性，更加关注研究的意义和价值而不仅是费用；管理者需参与循证和卫生技术评估知识的相关培训，关注于价值，并为其他利益方提供足够的支持。

Hyeong Sik Ahn 教授主要介绍了研究证据向实践的循证转化。目前 30-40% 的患者没有获得有效的治疗，20-25% 的患者存在过度医疗或接受的治疗存在一定的风险。因此循证转化对改善服务、效果和成本具有重要的意义。循证转化主要包括 2 个阶段，阶段 1 由实验室向临床试验运用转化，阶段 2 由临床试验向临床医疗服务提供转化。循证转化有利于解决理论与实践之间的不对称问题。现阶段循证转化工作存在的障碍，一方面证据繁杂且质量参差不齐；另一方面循证转化中的结构、组织、成员、专业化等方面也存在问题。循证转化工作就是要实现技术评估人员将评估证据转化为医技人员的临床实践，并通过监管与反馈、培训活动和反复提醒来改变临床人员的行为。

Jasmine Pwu 教授介绍了当前台湾防控丙肝的情况。台湾通过病人治疗注册系统，实现药物安全性的监管。尽管有超过 20 万的病人获得治疗，但仍存在大量的潜在病人。未来的工作需进行成本效果分析，来选择合适的筛查技术。此外，Pwu 教授提出了以治疗带领预防、以筛检支持治疗、以预防巩固成效，实现防治一体化、本地化和精准化的丙肝防治工作的政策方向。认为台湾丙肝防治仍存在基础设施、缺乏卫生技术评估工作和合作不足等问题，未来要实现管理、决策和卫生技术评估的有机结合。

## 实验室风采

本届 HTAsiaLink 年度会议设有三个平行分会场，以卫生经济评估和卫生体系研究为两大主题。实验室的参会成员共进行了 9 场口头汇报。其中，卫生经济评估类共计 5 场，讲者分别围绕宫颈癌筛查、非小细胞癌治疗、肝癌治疗以及子痫前期预测等领域的新兴技术评估以及相关技术的卫生经济学评价展开。另有卫生体系研究类口头汇报共计 4 场，讲者们就新兴医疗技术监测评估的水平扫描系统建立、住院医师规培项目评估、疟疾快速诊断试验技术推广以及非营利性民营医疗机构的医疗费用等卫生体系框架下各领域的研究内容进行了详细的介绍。实验室参会成员们精彩的口头汇报获得了现场专家评论组的广泛好评，同时也收获了专家们给出的指导建议，进一步启发了未来的研究方向。其中，金嘉杰硕士获得了此次大会卫生体系研究类口头汇报的二等奖，也是此次会议中唯一获奖的中国代表。



## Cost-effectiveness of cervical cytology and HPV DNA testing for cervical cancer screening in Eastern China

Zhou Ping



**OBJECTIVE:** This study aims to evaluate the cost effectiveness of general screening strategies from government perspectives and provide decision-making reference for the implementation of cervical cancer screening strategies.

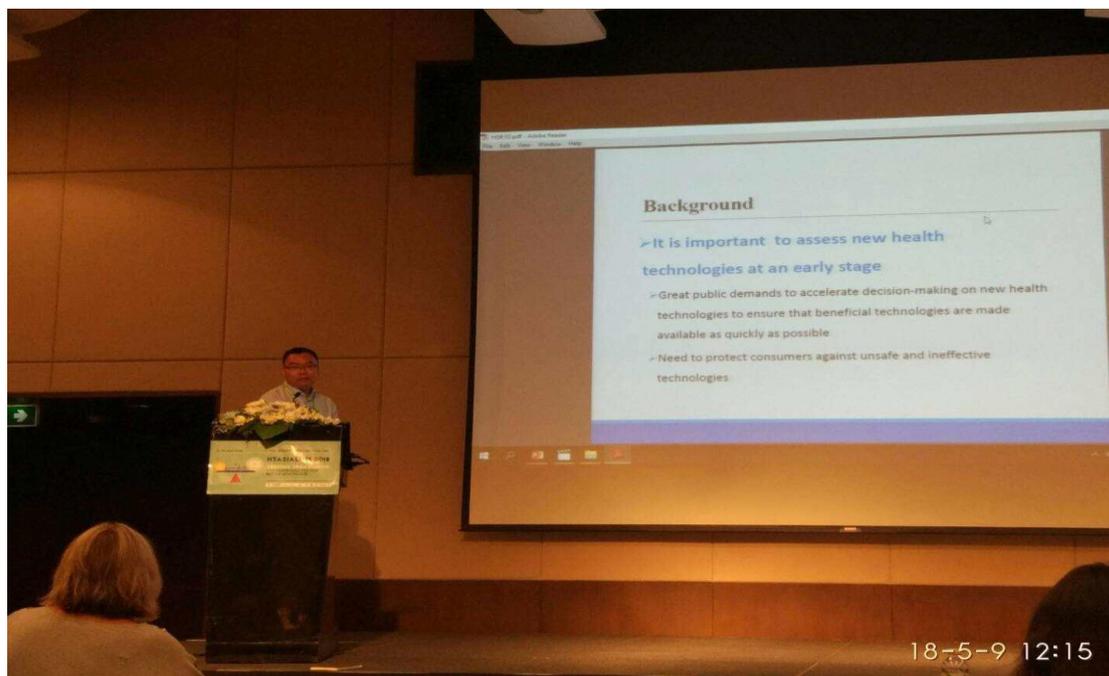
**METHODS:** A decision tree model was used to estimate the cost effectiveness of the various screening strategies. Decision tree models, operated by using data based on the literature review, expert interview and local investigation, are used to represent the sequence of chance events and decisions that occur during 5 years. We estimated the cost-effectiveness of three screening strategies (Pap smear every three years; TCT testing every three years and HPV DNA testing every five years) for women above 30 years-old, and screening efficacy, coverage, cost, and screening regular review rate were varied in sensitivity analyses.

**RESULTS:** Compared with no screening, the cost to exactly diagnose one histopathology positive case of Pap smear every three years, TCT testing every three years and HPV DNA testing every five years was 5.32 million yuan, 7.70million yuan and 4.01 million yuan respectively. The CE ratios of these strategies to detect one positive cases was 2485 yuan, 8844 yuan and 1415 yuan and the average cost of a single screening was 36.35 yuan, 101.60 yuan and 154.70 yuan. Thus when considered from the accuracy and cost-effectiveness, HPV DNA testing every five years would be recommended at current price. According to the one-way sensitivity analysis, the cost of the screening test had a great effect on the cost-effectiveness results.

**DISCUSSION AND CONCLUSIONS:** This CEA indicates that HPV DNA testing could be a cost-effective screening alternative for large-scale organized screening.

## Pilot study of establishing a horizon scanning system in China

Zhiyuan Xia



**OBJECTIVE:** This study aimed to identify existing best practices and effective methods for health technology horizon scanning system (HSS), and collect the needs and recommendations for the proposed HSS in China from potential users. Establish a pilot HSS in China and conduct trial assessment.

**METHODS:** A comprehensive search for literature and a targeted search of web sites of the HSS organizations were performed to identify existing horizon scanning methods. 20 potential users including policy makers, health insurance administrators, food and drug administrators, clinical experts, were invited to participate the face to face interview to collect their needs and recommendations. A pilot HSS was established, 5 new health technologies trial alerts were produced and published in the institution's website.

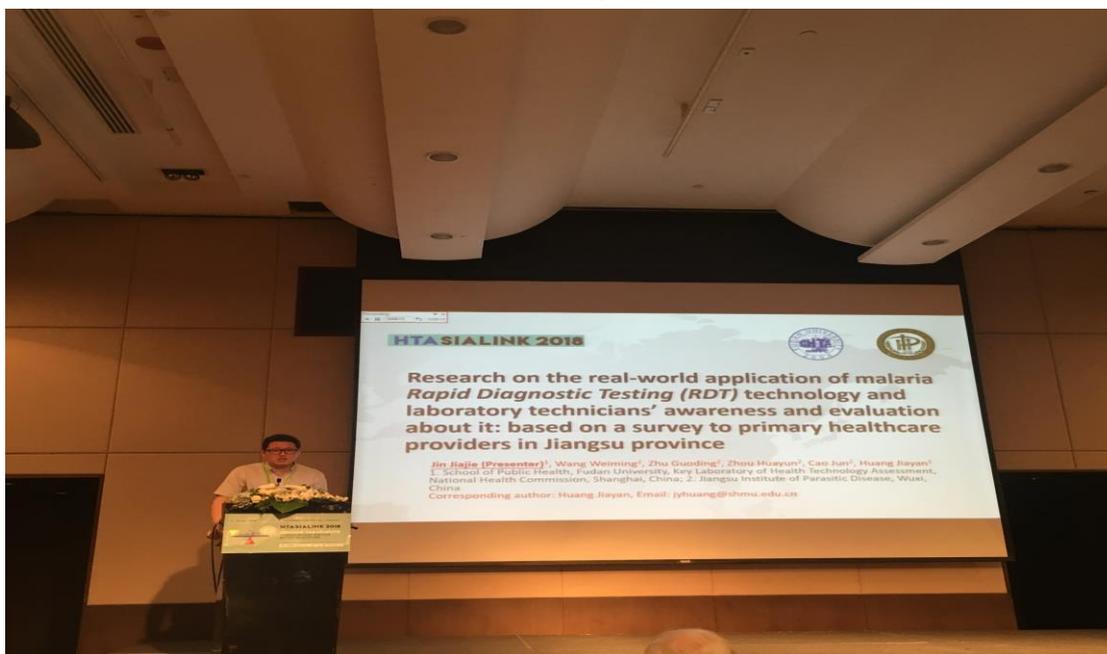
**RESULTS:** Most of formally established HSSs in the world are members of EuroScan and they share common functions and structures defined by EuroScan, all HSSs aim to “identify, filter and prioritize new and emerging health technologies to assess or predict their impact”. However, it is necessary to adjust the common stages to the needs of the individual HSS. The interview results showed that potential users thought HSS would be helpful for their decision making. The feedback results showed that the alerts were helpful and we need work with decision makers closer to produce evidences to meet their demands.

**DISCUSSION AND CONCLUSIONS:** We could establish a HSS in China by

adopting the international experience and localizing it according to the needs of Chinese health system. It was necessary to disseminate the knowledge of HSS in China in the first step. To acquire the government support and more resources, improve the HSS method, work with decision makers and clinical experts closer are important for HSS future sustainable running.

## **Research on the real-world application of malaria rapid diagnostic testing (RDT) technology and laboratory technicians' awareness and evaluation about it: based on a survey to primary healthcare providers in Jiangsu province**

JIN Jia-jie



**OBJECTIVE:** To investigate the real-world application of malaria Rapid Diagnostic Test (RDT) technology and laboratory technicians' awareness and evaluation about it at primary healthcare provider level in Jiangsu province, thus providing empirical evidence and policy suggestions for RDT's future application and promotion.

**METHODS:** We first analyzed the malaria surveillance data of the year 2012 to 2016 to describe the overall disease background for malaria microscopy and RDT application in Jiangsu province. Valid questionnaires were collected from 817 health institutions and 800 laboratory technicians at prefecture city, county and town level in Jiangsu province respectively to be included in the data analysis.

**RESULTS:** (1) The annual task load of malaria microscopic testing in Jiangsu remained comparatively high. Health institutions at county and town-level are faced with limited laboratory professional resources and heavy workload. (2) The supply of

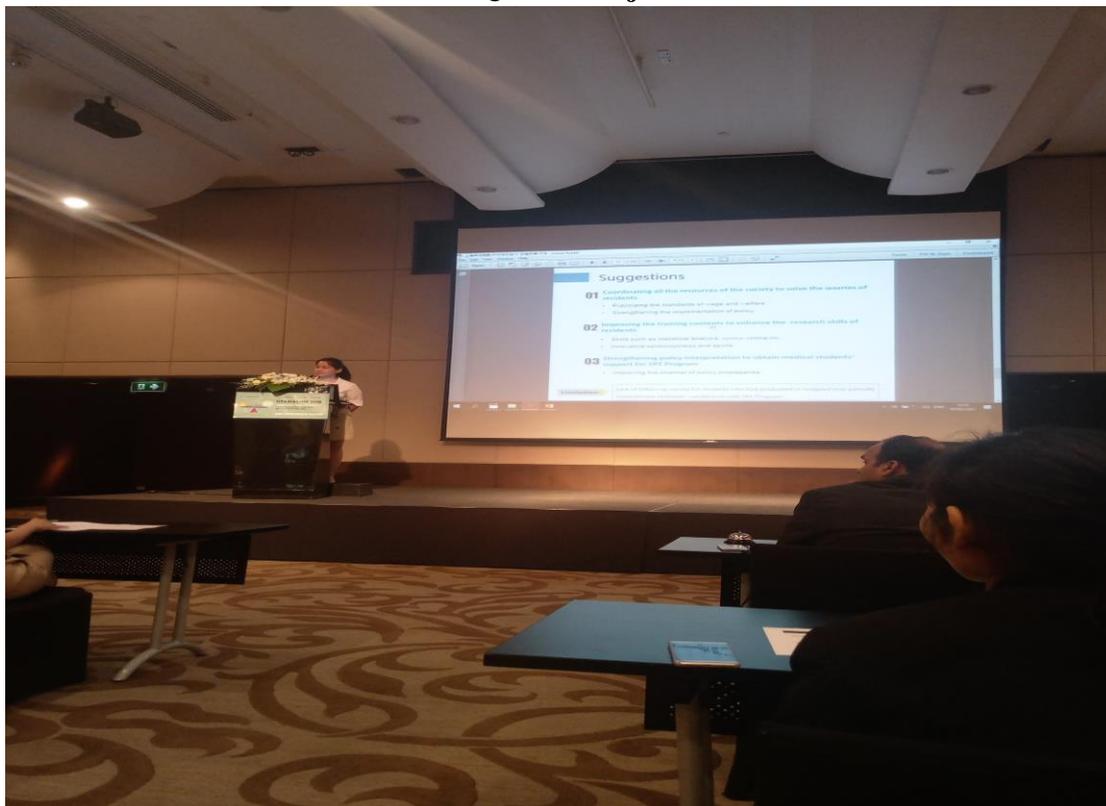
RDT test strips has been rapidly increasing during 2012 to 2016. RDT testing has been performed in 76.87% of the investigated institutions. (3) The investigated institutions gave higher scores for RDT in terms of testing time and professional personnel needed while giving lower scores for it in terms of testing accuracy and supporting measures. The investigated individuals gave higher scores for RDT in terms of operational difficulties and patient acceptance while giving lower scores for it in terms of plasmodium differentiation capacity and substituted value to microscopy.

**DISCUSSION AND CONCLUSIONS:** RDT technology has been widely performed in health institutions in Jiangsu province but it has been used under insufficient guidance and with non-standard operation. In the future, more needs to be done in terms of RDT professional training, quality control measures and process management to exploit the potential value of RDT in the field of malaria testing and diagnosis.

## Evaluating the effect of Shanghai Standardized Resident Training

### Program: from the perspective of residents

QIAN Wen-ji



**OBJECTIVE:** To evaluate the effectiveness of Shanghai Standardized Resident Training Program from the perspective of residents, and to provide evidence and recommendations for the further promotion of the program.

**METHODS:** Questionnaires were administered to residents who had accepted the

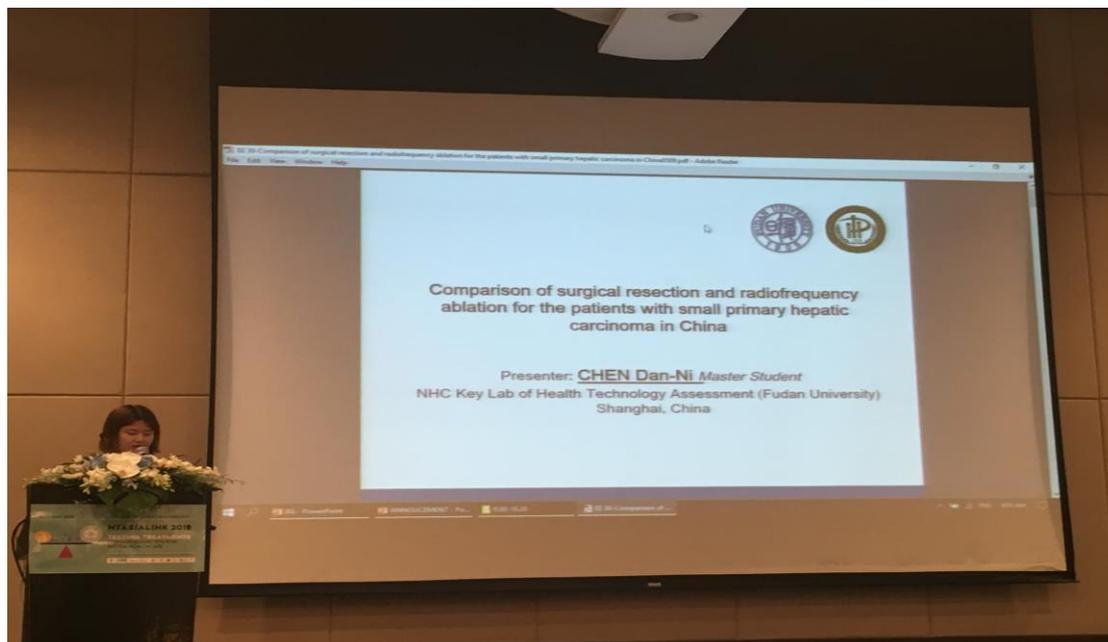
standardized training from 2013 every year in June from 2014 to 2016. The survey included the basic information of residents, their understanding and attitude toward the training program, their satisfaction with the program and the assessment of self-improvement. Using random effect model to analyze the data.

**RESULTS:** There were significant improvements in residents' attitude and satisfaction. Residents have high self-rated score in most respects, especially in clinical skills. However, the self-rating of theoretical knowledge is relatively low.

**DISCUSSION AND CONCLUSIONS:** The effectiveness of Shanghai Standardized Resident Training Program has already shown up and has been approved by all stakeholders. Shanghai Standardized Resident Training Program sets up an expert group to conduct regular supervision of the training bases in order to find and solve problems in time. This measure helped to improve the training environment and living conditions of residents which finally led to the improvements in residents' attitude and satisfaction. The program has effectively improved the clinical skills of residents by continuous improvement of the top design and faculty. It is suggested that welfare treatment and research ability training should be strengthened in the following work. It is also proposed that the government develop effective policy interpretation to attract medical students to enroll the resident training.

## Comparison of surgical resection and radiofrequency ablation for the patients with small primary hepatic carcinoma in China

Danni Chen



**OBJECTIVE:** To compare the effectiveness, safety, length of stay after surgery, and cost of inpatient care of surgical resection and radiofrequency ablation (RFA) for the inpatients with small primary hepatic carcinoma (PHC) (maximum diameter < 5cm) in

China.

**METHODS:** According to criteria, references related to eligible clinical researches were searched and selected from PubMed, Cochrane Library, EMBASE, and two Chinese databases (CNKI and CBM) from January 2010 to December 2015. Two reviewers (Danni Chen and Kun Xiong) independently extracted the data and assessed the methodological quality of the included studies. Descriptive statistics, t tests and Meta analyses were used to compare the effectiveness, safety, length of stay after surgery, and cost of inpatient care of the inpatients with small PHC.

**RESULTS:** Totally 31 original papers with 5898 cases, 3002 received surgical resection and 2896 received RFA, were reviewed and analyzed. The study showed that, compared with surgical resection, inpatients with small PHC who received RFA had higher survival rates and tumor-free survival rates in 1 year, 3 years, and 5 years, and had lower tumor recurrence rates in 3 years and 5 years. However, inpatients with small PHC after RFA had shorter average length of stay after surgery, lower medical costs and lower rates of adverse events, mainly in pain, pleural effusion, celiac effusion and pulmonary infection.

**DISCUSSION AND CONCLUSIONS:** According to the newest native and international clinical guidelines, including NCCN (2017), AASLD (2017), EASL/EORTC (2012), APSAL (2010), and Standard for diagnosis and treatment of Primary Liver Cancer (2011 Edition, China), there is no agreement on whether RFA should be as an alternative treatment to inpatients with small PHC. Based on recent clinical evidences in China, surgical resection is the first choice.

## **Oncologists' preference for treatment for non-small cell lung cancer: an empirical study of discrete choice experiments**

**Gongru Wang**



**OBJECTIVE:** Although efficacy, tolerability, and cost are classical criteria for choosing treatment for nonsmall cell lung cancer (NSCLC), patient adherence and tariff issues related to novel oral anticancer drugs may also influence therapeutic decisions. This study aims to estimate the relative importance of efficacy, tolerability, mode of administration, and cost of a NSCLC chemotherapy on the preferences of Chinese physicians through a Discrete Choice Experiment (DCE).

**METHODS:** The DEC instrument was developed based on literature review and consultation with clinical experts. We identified six treatment attributes to describe the NSCLC treatment alternatives in this study, i.e., time without tumor progression, disease control rate, risk of moderate side effects, risk of severe side effects, treatment cost, and mode of administration. The choice profiles were determined by a main-effects D-efficient experimental design in SAS, and 16 DCE scenarios were selected for each doctor. Face to face DCE survey was conducted among 50 NSCLC oncologists in Beijing, China. Random-parameters logit model was used to evaluate the preference

weight (PW) as well as the relative importance (RI) of treatment attributes.

**RESULTS:** 50 oncologists completed the DCE survey. The PW and RI for each attribute were as follows: time without tumor progression (PW= 1.91, RI= 60.4%); disease control rate (PW=0.69, RI=21.9%); mode of administration (PW= 0.20, RI= 6.2%); risk of severe side effects (PW= 0.19, RI= 6.0%); treatment cost (PW=0.14, RI=4.4%); and risk of moderate side effects (PW=0.03, RI=1.0%). The results varied significantly by length of practice of the oncologist.

**DISCUSSION AND CONCLUSIONS:** The results suggest that time without tumor progression and disease control rate were the primary attributes that were taken into consideration by oncologists. These two attributes comprised over 80% of the total RI. Mode of administration was rated as the third most important attribute, preceding side effects and treatment cost.

## **Effect of sFlt/PlGF ratio on the prediction of pre-eclampsia: a systematic review and meta-analysis**

**Zhen Huang**

**OBJECTIVE:** Pre-eclampsia, characterized by new-onset hypertension and proteinuria, is a severe obstetric complication leading to maternal and foetal mortality. In women with pre-eclampsia, the level of anti-angiogenic soluble fms-like tyrosine kinase 1 (sFlt-1) is increased, and the maternal serum concentration of angiogenic placental growth factor (PlGF) is decreased. The study aims to investigate the capacity of sFlt/PlGF ratio to predict pre-eclampsia.

**METHOD:** We conducted literature retrieval on PubMed, Web of Science, CNKI, and Wanfang and searched for published articles in English and Chinese about the relationship between serum levels of sFlt-1 and PlGF and their ratio in predicting pre-eclampsia. We excluded non-compliant articles and conducted meta-analysis of

the results of included studies using Stata 14 version.

**RESULT:** Among the 19 studies that were included in this research, 14 studied pre-eclampsia prediction, and nine studied early-onset pre-eclampsia prediction. Meta-analysis revealed that the pooled sensitivity and specificity were 81% (95% CI, 70%-89%; I<sup>2</sup>=95%) and 91% (95% CI, 81%-96%; I<sup>2</sup>=99%) respectively; that the positive and negative likelihood ratios (PLR and NLR) were 9.0 (95% CI, 4.1-19.7) and 0.21 (95% CI, 0.13-0.34) respectively; and that the diagnostic odds ratio was 43 (95% CI, 16-117) in predicting pre-eclampsia. For predicting early-onset pre-eclampsia, the pooled sensitivity and specificity were 90% (95% CI, 82%-94%; I<sup>2</sup>=74%) and 94% (95% CI, 86-97, I<sup>2</sup>=95%) respectively; the PLR and NLR were 14.2 (95% CI, 6.4-31.4) and 0.11 (95% CI, 0.06-0.20) respectively; and the diagnostic odds ratio was 131 (95% CI, 44-391) respectively.

**DISCUSSION AND CONCLUSIONS:** Our analysis indicates that sFlt/PIGF ratio is a useful index for predicting pre-eclampsia, especially in early-onset pre-eclampsia. However, this conclusion must be interpreted cautiously due to high heterogeneity among the included studies.

## **Evaluating the influence of non-for-profit status of private health care facilities on their medical costs of long-term care in Shanghai**

**Wei Fang**

**OBJECTIVE:** To facilitate the development of private long term care to meet the needs of an ageing population, Shanghai Social Medical Insurance (SSMI) authorized many private health care facilities for their long-term care. Our study aims to evaluate the influence of nonfor-profit status of private health care facilities on their medical costs of long-term care in Shanghai.

**METHODS:** All data related to inpatients discharged from every private SSMI long-term care facilities in 2016 were extracted from the information system of the Shanghai Municipal Medical Insurance Office. Multilevel linear regression models were used to

compare total daily medical costs between private, non-profit SSMI long-term care facilities and private, for-profit SSMI long-term care facilities.

**RESULTS:** The study showed that 20,777 inpatients were discharged from 54 private SSMI long-term care facilities. Non-profit SSMI long-term care facilities had more female inpatients, more inpatients aged 80 or older, more inpatients with basic medical insurance for urban employees (BMIUE), and more inpatients with primary diagnoses of four surveyed diseases than did for-profit SSMI long-term care facilities. The average total daily medical cost in private SSMI long-term care facilities was 930.91 yuans. The cost was higher in for-profit facilities than in non-profit ones, even after controlling for inpatient characteristics, size of long-term care facilities, and types of diseases.

**DISCUSSION AND CONCLUSIONS:** The high burden of medical costs of private

SSMI long-term care facilities will limit the public's access to them. Possible patient selection and supplier-induced services in private, for-profit SSMI long-term care facilities should be supervised and regulated.

## **Patients' preference for treatment of non-small cell lung cancer: an empirical study discrete choice experiments (DCEs) in China**

**Hui Sun**

**OBJECTIVE:** The aim of this empirical study is to evaluate patients' preference in relation to treatment of non-small cell lung cancer (NSCLC) in China using a discrete choice experiment (DCE).

**METHODS:** Face to face DCE instrument was developed by the research team, and the survey was carried out involving 148 NSCLC patients in August 2017 in one city. The following attributes were used to describe hypothetical choice sets: 1) time without tumor progression, 2) disease control rate, 3) side effect of skin 4) nausea and vomiting, 5) fatigue and tiredness, 6) treatment cost and 7) mode of administration. The combination of attribute levels included in each NSCLC treatment profile was determined by a main effects D-efficient experimental design and the experimental design resulted in 18 choice questions. Random-parameters logit model was used to evaluate the preference weight (PW) and relative importance (RI) of treatment attributes.

**RESULTS:** The most important attributes for patient were time without tumor progression (PW=1.04, RI=47.8%), followed by disease control rate (PW=0.40, RI=18.3%), fatigue and tiredness (PW=0.27, RI=12.4%), mode of administration (PW=0.20, RI=9.2%), side effect of skin (PW=0.16, RI=7.4%), nausea and vomiting (PW=0.11, RI=5.0%).

**DISCUSSION AND CONCLUSIONS:** The results suggest that effectiveness was most important attributes for patients. In addition, side effects and mode of administration had significant influence on patients' treatment preference. The survey results can be used in designing, assessment, and decision in NSCLC treatment regimes, in order to provide more effective and efficient care of patients, thereby increasing adherence.

## **HTAsiaLink 2018 获奖体会及课题分享**

本次在泰国清迈举办的 HTAsiaLink 年会是亚太地区卫生技术评估 (HTA) 领域研究者交流学习的一次盛会。来自高校、研究机构、政府部门、医疗机构以及非政府组织 (NGO) 的参会者围绕卫生政策、卫生技术评估、卫生体系研究、

卫生经济学评价等主题，通过摘要汇报、主旨演讲、论坛讨论等形式，就 HTA 在实现全民健康覆盖（Universal Health Coverage, UHC）过程中的作用和意义展开了深入的讨论。金嘉杰硕士获得了此次大会卫生体系研究类口头汇报的二等奖，也是此次会议中唯一获奖的中国代表。因此，我们特地采访金嘉杰，谈谈其获奖感受及课题内容在 HTA 和 Global Health 方面的意义。

金嘉杰硕士的汇报题目是《疟疾快速诊断（Rapid Diagnostic Test, RDT）技术现场应用及检验人员的认知与评价：基于江苏省基层医疗卫生机构调查分析》。对于能够在 HTAsiaLink 年会的卫生体系研究类研究中获得优秀论文汇报二等奖感到非常荣幸，既欣喜于自己的研究成果得到了相关领域内专家的肯定，也再次深深感受到在 HTA 及全球卫生研究领域中，国际交流和成果传播活动所发挥的重要意义。



作为由复旦大学公共卫生学院和江苏省寄生虫病防治研究所合作开展的“江苏省疟疾快速诊断技术（RDT）使用与管理优化策略实施与评价研究”（以下简称“江苏省 RDT 优化策略研究”）课题产出之一，该研究采用分层随机抽样方法，选取江苏省 878 家医疗机构和 118 家疾控机构作为机构调查对象，同时由每家机构选派一名疟疾检验人员作为个人调查对象参与问卷调查，调查内容包括各机构 2015 年疟疾检测工作开展情况、RDT 试纸使用情况以及受调查机构/个人对于 RDT 试纸的评价情况。研究发现，RDT 试纸已在江苏省基层医疗卫生机构广泛

应用，疾控机构的 RDT 试纸使用量高于医疗机构；疾控机构及其疟疾检测人员对于 RDT 试纸的单次检测时间、检测操作及结果判定难度方面的评价高于医疗机构及其疟疾检测人员。上述结果作为重要的基线调查信息，为“江苏省 RDT 优化策略研究”课题的后续有效实施打下了良好的基础。“江苏省 RDT 优化策略研究”课题通过在江苏省选取 4 个设区市作为干预地区实施 RDT 使用与管理优化策略（以下简称“优化策略”），其余 9 个设区市作为对照地区维持原有疟疾诊断工作体系，开展了为期一年的干预-对照研究。优化策略主要包含 4 项主要干预措施，即保障 RDT 试纸供应、RDT 使用人员定期专业培训、重点人群疟疾防治知识宣传、RDT 试纸发放与使用全面过程管理；同时配以研究数据复核、患者回访及现场督导等配套质控措施，以保证研究按照研究方案顺利推进。干预措施实施一年后，课题组从医疗卫生机构疟疾诊断及基层专业技术人员 RDT 相关知-信-行（KAP）与满意度等 2 个角度评价优化（干预）策略的实施效果。同时，“江苏省 RDT 优化策略研究”课题也通过建立决策树模型，模拟并分析了 4 种疟疾检测与诊断策略应用于实际疟疾诊断工作的成本-效果，为 RDT 技术的现场应用提供了卫生经济学评价证据。课题证实了 RDT 使用优化策略对于实施策略地区的疟疾病例初诊至确诊时间间隔的缩短、重症疟疾病例占比降低、基层专业技术人员的 RDT 相关知-信-行及满意度水平的改善具有显著影响，且具有较好的成本-效果优势。课题研究成果在一定程度上填补了我国疟疾诊断技术现场评价和 RDT 技术的系统化现场应用模式的研究空白。

疟疾防控是全球卫生的重点关注领域，2016 年全球范围内仍有 2.16 亿报告疟疾病例，44.5 万人因疟疾而死亡。随着越来越多的国家/地区的疟疾防控目标逐步从控制（Control）走向消除（Elimination），如何在发病例数急剧降低、疟疾病例不典型症状及外周血地疟原虫密度造成的疟疾诊断难度增加以及人员流动性增加的背景之下，利用便捷有效的检测工具保障疟疾病例的及时诊断和规范治疗，同时杜绝输入性疟疾病例发生本地继发传播成为了现阶段疟疾防控领域关注的重点问题之一。“江苏省 RDT 优化策略研究”课题即希望从中国江苏省在维持疟疾可消除状态的现场工作实践出发，围绕 RDT 技术在实际疟疾诊断工作中的合理有效应用建立 RDT 使用与管理优化干预策略，针对疟疾消除阶段的疫情特征，通过干预-对照研究设计及干预效果评价，在实践中积累总结中国在提升疟疾诊断工作效率、实现疟疾消除目标过程中积累的有效经验，从而为面临相似

情况的国家/地区提供模式参考和经验借鉴。必须注意到，HTA 在某一国家/地区的实践经验总结和评价中能够发挥出至关重要的作用。作为一种从安全性、有效性、经济性、社会影响、伦理影响等多个维度对卫生技术开展综合评价的系统性方法，HTA 方法所得到的评价证据显然在国与国、地区与地区之间的模式借鉴方面具有更高的参考价值 and 实践意义。“江苏省 RDT 优化策略研究”课题面对国内相关领域尚无针对疟疾 RDT 技术的系统性评价证据的现状，采用了 HTA 的研究思维框架，即从安全性、有效性、经济性等多个维度，考量 RDT 技术实际应用于疟疾诊断工作所能够发挥的价值。HTA 作为一种综合性评价方法，也使得研究者和政策制定者能够将中国江苏省的实践经验在多个维度加以分析、考量、评价和总结；未来若其他国家/地区借鉴或引入相关中国经验时，也将由此关注到除技术本身特性外，社会、经济、文化、伦理、风俗等外部环境可能对于 RDT 技术的合理有效应用所产生的潜在影响，从而令全球卫生领域内疟疾诊断工作的先进经验的交流、输出和引入显得更为有据可循。



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