

EVIDENCE-BASED PHARMACOECONOMIC EVALUATION OF
TRADITIONAL CHINESE MEDICINES:
PROGRESS, DILEMMAS AND EXPLORATION

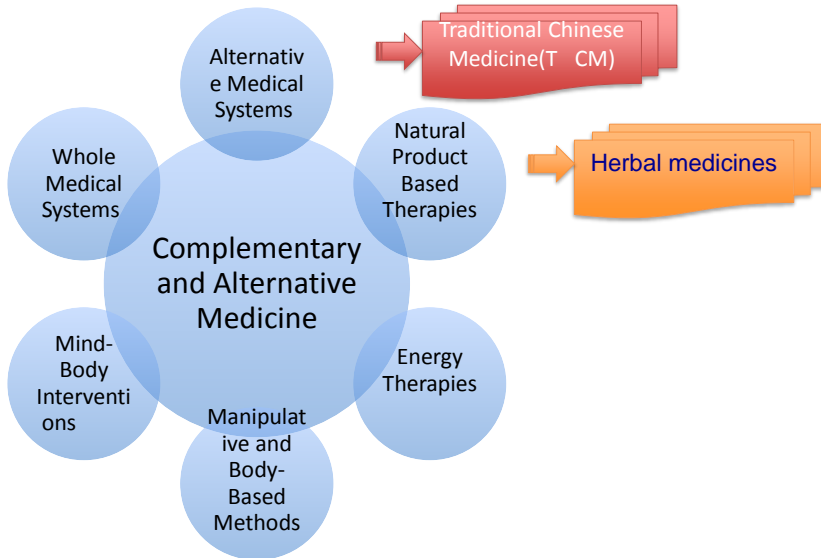
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- Progresses and problems in evidence-based PhE studies of TCM in China
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Complementary and Alternative Medicine in China



Wieland et al. Development and classification of an operational definition of complementary and alternative medicine for the Cochrane Collaboration. *Altern Ther Health Med*. 2011 ; 17(2): 50–59.

Traditional Chinese Medicines in China



Draft of *Traditional Chinese medicine law* is put for 2nd review by Standing Committee of the National People's Congress on August 29, 2016

Dilemmas of TCMs in China

- Post-market evaluation of TCM for selection and elimination
 - 60430 approval products of TCM
 - Effect? Safety? Economics?
- Formulated by traditional Chinese medical theory, while evaluated by modern western medical theory?
 - 君臣佐使 monarch; minister; minister; assistant and guide;
 - 升降沉浮 ascending, descending, sinking and floating;
 - 性味归经 nature, flavour, channel, tropism
- the relationship between the function and the effect of TCMs?
 - Need appropriate method to qualitative and quantitative measure the effect of TCMs
- The need of proving, explaining and promotion of TCM on the international platform

Progresses and problems in evidence-based PhE studies of TCM in China

- PhE clinical Studies
- literature PhE studies based on meta-analysis
- PCT
- Piggyback RCT
- Developing guideline of TCM PhE studies

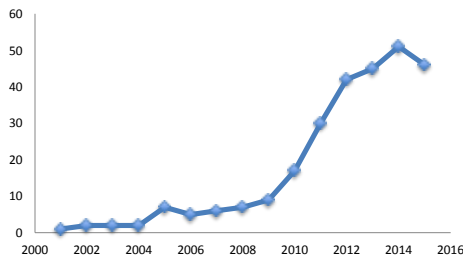
PhE Clinical studies

First PhE research Paper on TCM issued in 2001

WANG Y, LI L, HE B, et al. **CEA Comprehensive Evaluation for Western and Traditional Chinese Hypotensive Drugs**. Chinese Journal of Integrated Traditional and Western Medicine, 2001(09)

- 4 medicines:
 - Ling jiao Jiangya Pill , benazepril , amlodipine and indapamide
- 294 patients with mild to moderate hypertension , 6 weeks therapeutic course.
- Effectiveness indicators:
 - QOL was measured with SF-36 questionnaire
 - Efficacy policy model was applied for comprehensive evaluation of CEA .

PhE Clinical studies 2001-2015



- Comparison:
 - TCM1 vs TCM2 vs
 - TCM vs Chemical drugs
 - Chemical drug +TCM vs chemical drugs

Analysis methods used in PhE

	total	CEA	CUA	CBA	CMA	CEA+CUA	CEA+CM A
TCMs	69	65	1	0	2	0	1
TCM vs Chemical drugs	203	194	0	1	6	2	0

Sun L, et al. Application Status and Prospect of Pharmacoeconomics in Evaluation of Traditional Chinese Medicine. China Pharmacist, 2015, 18(6)

- Common shortcoming of PhE clinical studies:
 - Design:
 - Most is Retrospective Cohort Study, or cased reports, seldom Perspective study
 - Methods:
 - Most is CEA, seldom CUA
 - Indicators:
 - Most are simple intermediate indicators, seldom endpoint indicators
 - Study length:
 - Short term within several weeks, lack of long term follow up, lack of model using.

PCT

- The First grant PCT research program of TCM in China
 - In 2007, under the support of The National High Technology Research and Development Program of China (863 Program) in “the 11th 5-year Project” , Peking University and Zhongyi Pharmaceutical Co set up the “Evidence- based Research of Xiaoke pill for diabetes disease”
 - In 2010, the program of “Pharmaceconomic evaluation of Xiake Pill for diabetes disease” was set up lead by Prof Gardon Liu.
 - Follow-up investigation of 3000 patients in 1 year, to collect and calculate the basic information, disease cost and health outcomes, systematic evaluate the marketed antidiabetic agents.



Piggyback RCT

- RCT+ Pharmacoeconomic evaluation
 - E.g. PhE evaluation based on a multi-center double-blinded randomized clinical study of Jingshu granule for cervical spondylotic radiculopathy
 - 240 patients from 10 clinical study centers
 - double-blinded randomized
 - 3 years research, 1 year's follow-up
 - Indicators:
 - The Neck Disability Index, NDI
 - Pain VAS score
 - QOL by SF-36
 - QALY by SF-6D(transfer from SF-36)

The development of PhE study guidelines of TCM

- 2012.10, committee of TCM evidenced-based PhE, China Associate of TCM set up
- 2012-2014, committee issued 3 Technical Essentials of Evidence-based Pharmacoeconomics Evaluation on Traditional Chinese Medicines:
 - Technical Essentials of Evidence-based Pharmacoeconomics Evaluation on Traditional Chinese Medicine in Treating Stroke.
 - Evidence-based Review of the Pharmacoeconomic Evaluation Technical Essentials of Chinese Material Medica in Treating Pelvic Inflammatory Disease Sequela (Chronic Pelvic Inflammation). 2013
 - Technical Essentials of TCM Pharmacoeconomics Evaluation in Treatment of Children Recurrent Respiratory Infection. 2014



中药治疗脑卒中循证药物经济学评价技术要点

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摘要 中药治疗脑卒中循证药物经济学评价技术要点。首先介绍循证药物经济学评价技术要点, 然后结合脑卒中循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。其次介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。最后介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。

关键词 循证药物经济学评价技术要点; 循证药物经济学评价技术要点; 循证药物经济学评价技术要点

Technical Essentials of Evidence-Based Pharmacoeconomics Evaluation in Traditional Chinese Medicine in Treating Stroke
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Abstract Technical Essentials of Evidence-Based Pharmacoeconomics Evaluation in Traditional Chinese Medicine in Treating Stroke. First, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation. Then, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation in traditional Chinese medicine. Finally, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation in traditional Chinese medicine.

Key Words Evidence-based pharmacoeconomics evaluation; Evidence-based pharmacoeconomics evaluation; Evidence-based pharmacoeconomics evaluation

中药治疗小儿反复呼吸道感染药物经济学评价技术要点

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摘要 为探讨小儿反复呼吸道感染中药治疗的药物经济学评价, 结合循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。其次介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。最后介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。

关键词 循证药物经济学评价技术要点; 循证药物经济学评价技术要点; 循证药物经济学评价技术要点

Technical Essentials of TCM Pharmacoeconomics Evaluation in Treatment of Recurrent Respiratory Infection in Children
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Abstract Technical Essentials of TCM Pharmacoeconomics Evaluation in Treatment of Recurrent Respiratory Infection in Children. First, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation. Then, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation in traditional Chinese medicine. Finally, we introduce the technical essentials of evidence-based pharmacoeconomics evaluation in traditional Chinese medicine.

中药治疗盆腔炎性疾病后遗症(慢性盆腔炎)循证药物经济学评价技术要点

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摘要 为探讨中药治疗盆腔炎性疾病后遗症(慢性盆腔炎)循证药物经济学评价技术要点, 结合循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。其次介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。最后介绍循证药物经济学评价技术要点, 介绍循证药物经济学评价技术要点。

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Technical Essentials of Evidence-Based Pharmacoeconomics Evaluation in Treating Pelvic Inflammatory Disease (Chronic Pelvic Inflammatory Disease)
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Thinking and methodology exploration of TCM PhE study

Study design: Transfer from disease-center to syndrome-center?

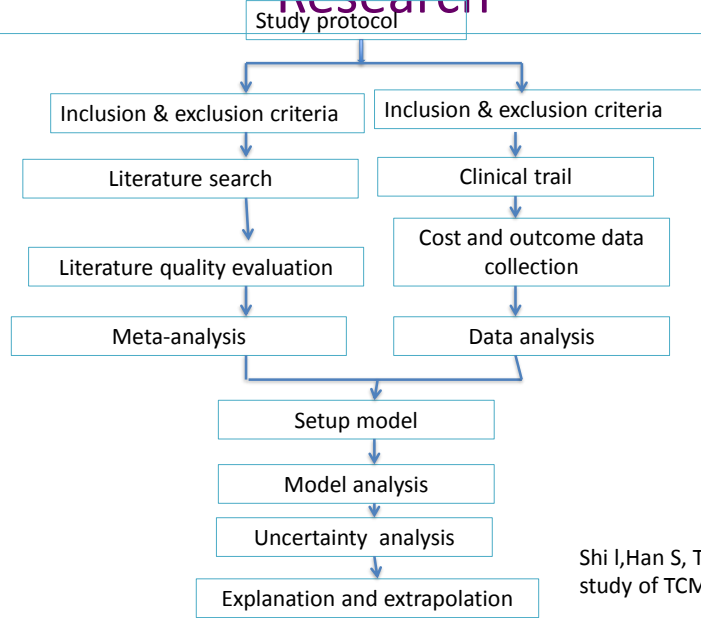
Highlights of Evidence-based Pharmacoeconomics Evaluation on TCM

- Study design:
 - PCTs or piggyback RCTs, instead of low-quality case studies
- Outcome:
 - QALY by EQ-5D or SF-6D..., instead of common/fuzzy effective percentage
- Combine TCM theory and principle with outcome research

Transfer from disease-center to syndrome-center

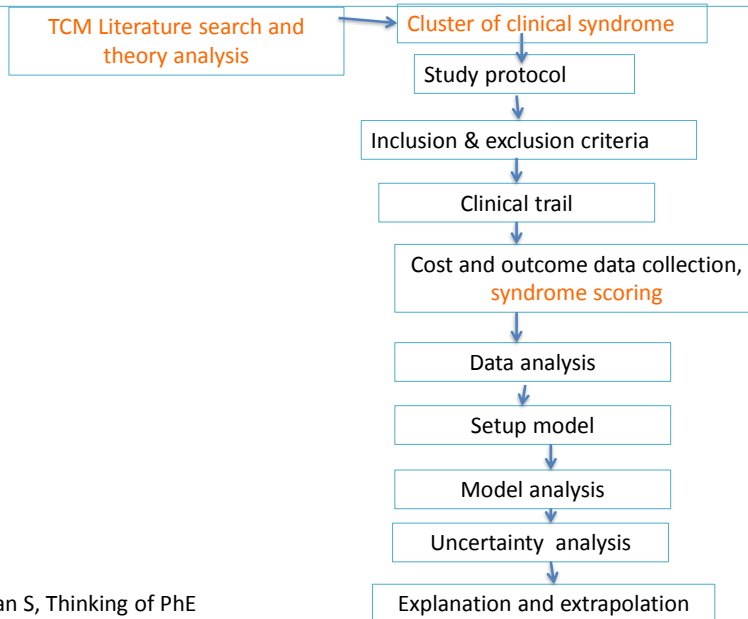
– Prof Shi Luwen
• Peking University

Pathway of Disease-center PhE Research



Shi I, Han S, Thinking of PhE study of TCM .

Pathway of syndrome-center PhE Research



Shi I, Han S, Thinking of PhE study of TCM .

- E.g. Liuweidihuan Pill for gestational vertigo with syndrome of yin deficiency of liver and kidney(肝肾阴虚证)

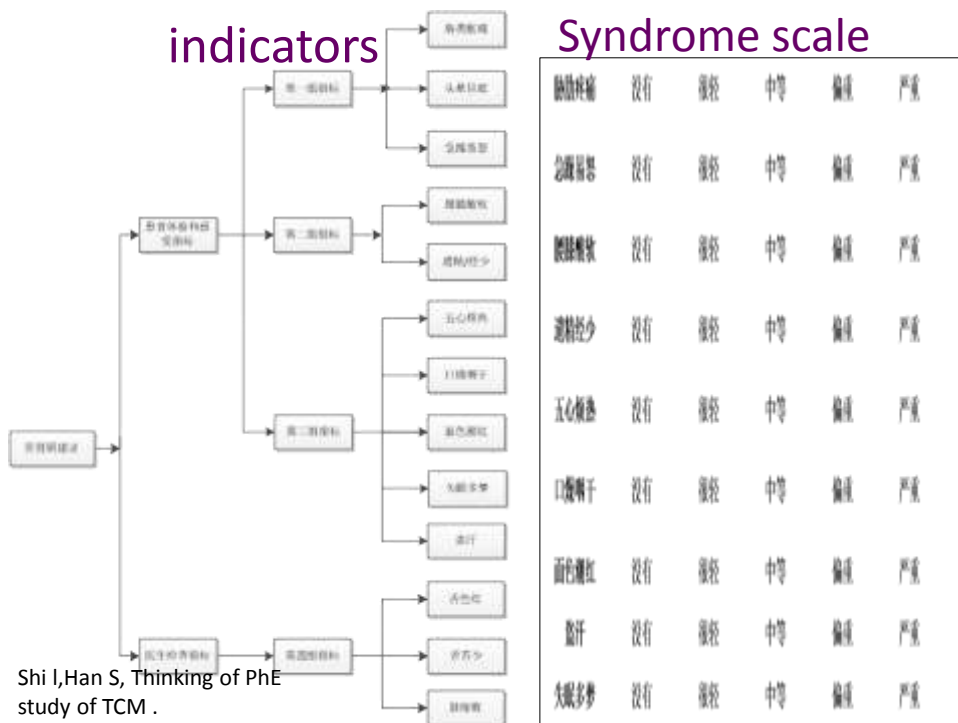
TCM theory & literatures



Cluster of syndrome



Shi J, Han S, Thinking of PhE study of TCM .



Score calculation (Pre-Post test)

- Score value(100%)
 - $S_{100} = (X - S_{min}) / (S_{max} - S_{min}) * 100$
- syndrome score
 - $S_{100} = (X - 13) / (65 - 13) * 100$

Shi I, Han S, Thinking of PhE
study of TCM .

Thank you for your attention!

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