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

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• Complementary and Alternative Medicine in China
• Progresses and problems in evidence-based PhE studies of TCM in China
• Thinking and methodology exploration of PhE study of TCM
Complementary and Alternative Medicine in China

- Whole Medical Systems
- Manipulative and Body-Based Methods
- Energy Therapies
- Natural Product Based Therapies
- Alternative Medical Systems
- Herbal medicines


Traditional Chinese Medicines in China

- Part 1 of ChP(2015)
- 1493 TCMs
- TCMs, 987
- National insurance Medicine lists(2009)
- TCMs, 203
- NEMLos

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


- 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

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• 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:
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

Study protocol

Inclusion & exclusion criteria
- Literature search
- Literature quality evaluation
- Meta-analysis

Inclusion & exclusion criteria
- Clinical trail
- Cost and outcome data collection
- Data analysis

Setup model

Model analysis

Uncertainty analysis

Explanation and extrapolation

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

Pathway of syndrome-center PhE Research

Study protocol

Inclusion & exclusion criteria
- Clinical trail
- Cost and outcome data collection, syndrome scoring
- Data analysis
- Setup model
- Model analysis
- Uncertainty analysis

Cluster of clinical syndrome
- TCM Literature search and theory analysis

Explanation and extrapolation

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

**indicators**

**Syndrome scale**

Shi L, Han S, Thinking of PhE study of TCM.
Score calculation
(Pre-Post test)

• Score value (100%)
  – \( S_{100} = \frac{(X - S_{\text{min}})}{(S_{\text{max}} - S_{\text{min}})} \times 100 \)

• Syndrome score
  – \( S_{100} = \frac{(X - 13)}{(65 - 13)} \times 100 \)

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

Thank you for your attention!

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