Evaluating effectiveness of Chinese medicine treatment from patients' perspective

Seminar on Chinese Medicines
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Patient reported outcomes (PROs)

- Outcomes collected **directly from the patient**, without interpretation by clinicians or others.

- PROs use is particularly common for products developed to treat **chronic, disabling conditions** where the intention is not necessarily to cure but to ameliorate symptoms, facilitate functioning, or improve quality of life.


http://www.ispor.org/meetings/va0502/symposium.gif
TCM sector is managing substantial proportion of chronic disease burden, usually as an adjunct to western medicine.
• PROs are important endpoints in trials on chronic conditions like irritable bowel syndrome, migraine, pain, insomnia, asthma, and psychiatric disorders.

• The 2009 FDA guidance describes the use of PROs to support potential claims in product labeling.

• The claims must be supported by appropriately designed investigations using PROs that have been demonstrated to measure the concept underlying the claim.
HRQOL = Health related quality of life
PGR = patient global rating

Guidance for Industry
Patient-Reported Outcome Measures:
Use in Medical Product Development
to Support Labeling Claims

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

December 2009
Clinical/Medical

Value in Health 15 (2012) 437-442
The potential of using PROs for labeling of Chinese medicines OTC products?
Use of PROs in evaluating CAM services in the UK NHS:

The potential of using PROs for evaluating TCM services in Hong Kong?
What is MYMOP?

- Suitable for evaluating the efficacy of TCM
- May overcome the problem of the different diagnostic frameworks of different discipline
- Qualitative evaluation of MYMOP suggested that there is a good concordance between TCM patients’ personal account of clinical changes and quantified description by MYMOP.

**Profile score = Total score / 4**

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CMYMOP: Translation Process

Step 1: English to Chinese
- MYMOP Forward 1
- MYMOP Forward 2

Step 2: Chinese to English
- MYMOP Forward 3
- MYMOP Backward 1
- MYMOP Backward 2

Step 3: English to Chinese
- MYMOP Backward 3
- MYMOP Forward 4
- MYMOP Forward 5

Step 4: Expert panel assessment

Step 5: Pilot testing
- Final Chinese version
Data Collection Process

Recruitment of patient sample from TCM clinics

Informed consent and incentive acknowledgement

Baseline: CMYMOP and SF 36 \( (n=539) \)

Follow up at 2 weeks: CMYMOP, SF36 and self perceived health status change
\( (n=343, \text{ including 116 phone interview. Response rate: 63.6\%}) \)

Follow up at 4 weeks: CMYMOP, SF36 and self perceived health status change
\( (n=272, \text{ including 116 phone interview. Response rate: 50.5\%}) \)

Sample size requirement achieved

Data cleaning, entry and analysis
Quantifying usefulness of CMYMOP

1. Assessment of validity

2. Assessment of responsiveness

3. Assessment of minimally important change (MID) values
1. Assessment of validity

Criterion validity was demonstrated by negative correlation between CMYMOP profiles scores and all SF-36 domain and summary scores at baseline.

<table>
<thead>
<tr>
<th>SF-36 Profile Score</th>
<th>Pearson correlation coefficient *</th>
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</thead>
<tbody>
<tr>
<td>1. Physical Functioning</td>
<td>-0.345</td>
</tr>
<tr>
<td>2. Role, physical</td>
<td>-0.359</td>
</tr>
<tr>
<td>3. Bodily pain</td>
<td>-0.325</td>
</tr>
<tr>
<td>4. General Health</td>
<td>-0.447</td>
</tr>
<tr>
<td>5. Vitality</td>
<td>-0.454</td>
</tr>
<tr>
<td>6. Social functioning</td>
<td>-0.391</td>
</tr>
<tr>
<td>7. Role, emotional</td>
<td>-0.314</td>
</tr>
<tr>
<td>8. Mental health</td>
<td>-0.378</td>
</tr>
<tr>
<td>9. Physical Composite Summary</td>
<td>-0.368</td>
</tr>
<tr>
<td>10. Mental Composite Summary</td>
<td>-0.374</td>
</tr>
</tbody>
</table>

*All p < 0.001
2. Assessment of responsiveness

- To assess the responsiveness of CMYMOP: Cohen effect size (ES) of change at two follow ups.

  - ES values of 0.20, 0.50 and 0.80 or greater was adopted to represent weak, moderate, and strong responsiveness.

    - ES of all SF-36 domain and summary scores did not demonstrate moderate change.

    - ES of CMYMOP symptom 1, activity and profile scorings achieved moderate changes between baseline and 4th week.

    - Implies that CMYMOP outperforms SF-36 in detecting change in health condition.
Developing CMYMOP2: Part 2

1. Assessment of validity

2. Assessment of responsiveness

3. Assessment of minimally important change (MID) values

- **MID**: the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management
Interpretation of CMYMOP scoring change

• If a group patients report a magnitude of change as the following, then on average this group is experiencing a change that matters to them in the past 2 weeks:
  • Profile score = 0.516,
  • Symptom 1 = 0.894,
  • Symptom 2 = 0.580,
  • Wellbeing = 0.263,
  • Activity = 0.808
Conclusions

• The finding supports the **validity** of CMYMOP

• The finding supports that CMYMOP is more **responsive than SF 36**

• **MID values** were determined

• **Future research: Use of CMYMOP in**
  – Clinical trials of Chinese medicines products
  – Evaluation of TCM services
Thank you

Tripartite Collaboration

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