



從病人角度評價中醫療效  
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>

Value Health, 6 (2003), pp. 522–531, Clin Pharmacol Ther, 84 (2008), pp. 281–283



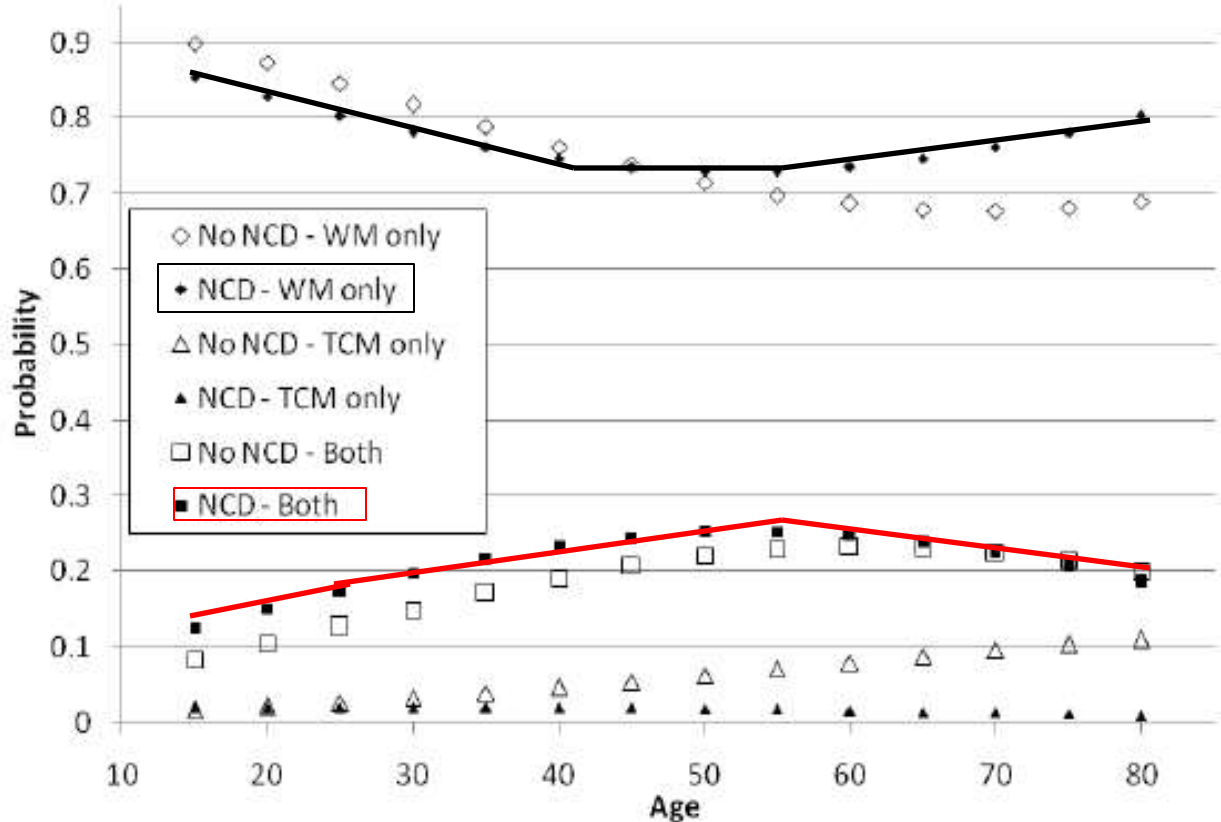
Research article

Open Access

## Age, chronic non-communicable disease and choice of traditional Chinese and western medicine outpatient services in a Chinese population

Vincent CH Chung, Chun Hong Lau, Eng Kiong Yeoh and Sian Meryl Griffiths\*

Why PROs is important for TCM in HK?



TCM sector is managing substantial proportion of chronic disease burden, usually as an adjunct to western medicine

**Figure 1** Age differences in the use of TCM as a complement or alternative to WM by NCD status\*. Key: NCD = non-communicable disease, WM = western medicine, TCM = traditional Chinese medicine. \*Estimated probability when other variables in the regression are kept constant (i.e. female, secondary education, monthly income \$HKD 10000, no WM and TCM insurance).



- 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



# PROs based claims approved by the FDA, 2006 - 10



Type of claim	All products with PRO claims (N = 28)	
	n	%
Symptoms	24	85.7
Functioning	7	25.0
HRQOL	2	7.1
PGR	3	10.7
Other	2	7.1

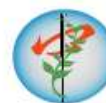
HRQOL = Health related quality of life

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

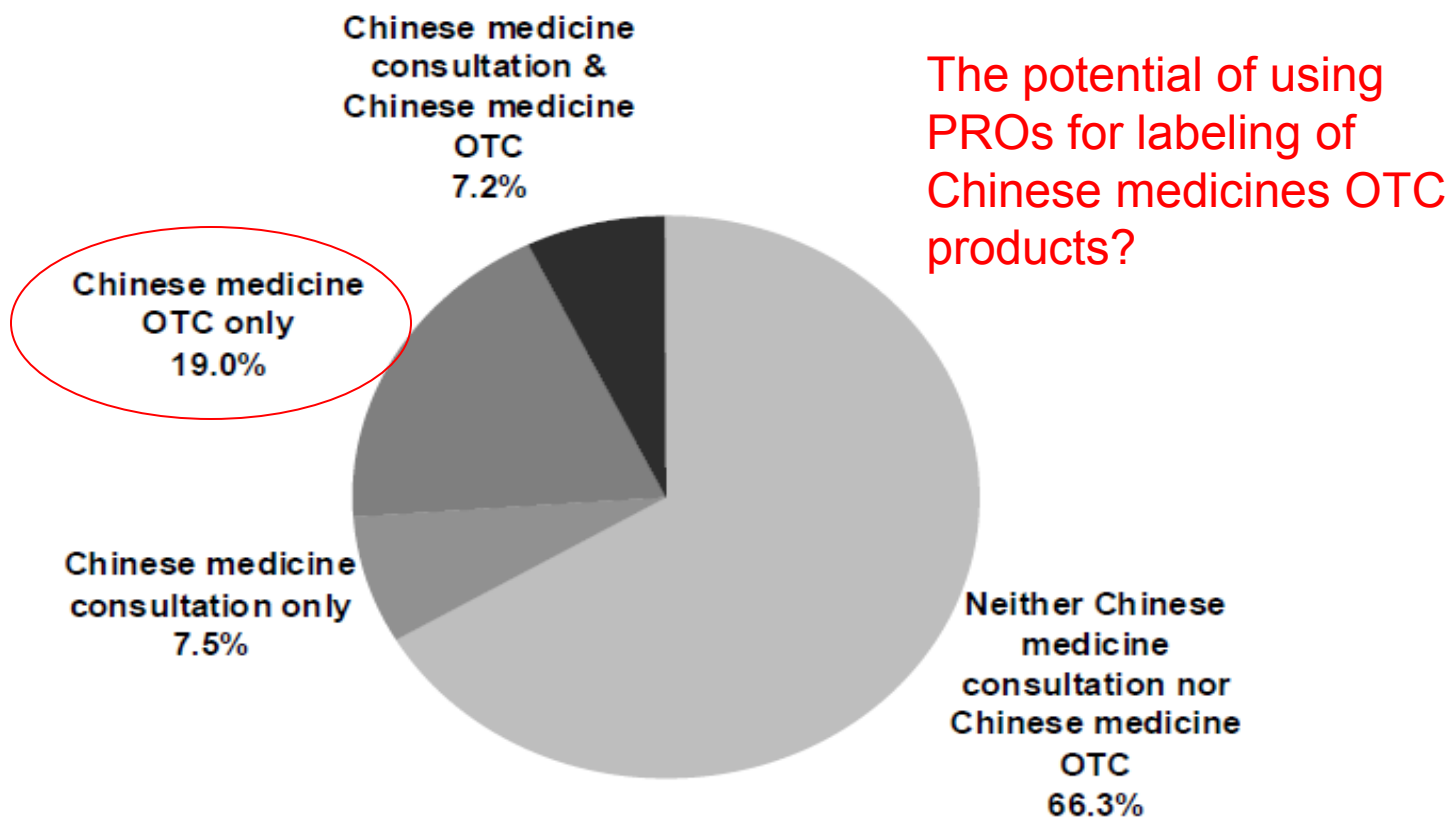


COMMENTARY

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# Use of chinese and western over-the-counter medications in Hong Kong

Vincent Chi Ho Chung<sup>1\*</sup>, Chun Hong Lau<sup>1</sup>, Frank Wan Kin Chan<sup>1</sup>, Joyce Hoi Sze You<sup>2</sup>, Eliza Lai Yi Wong<sup>1</sup>, Eng Kiong Yeoh<sup>1</sup>, Sian Meryl Griffiths<sup>1</sup>



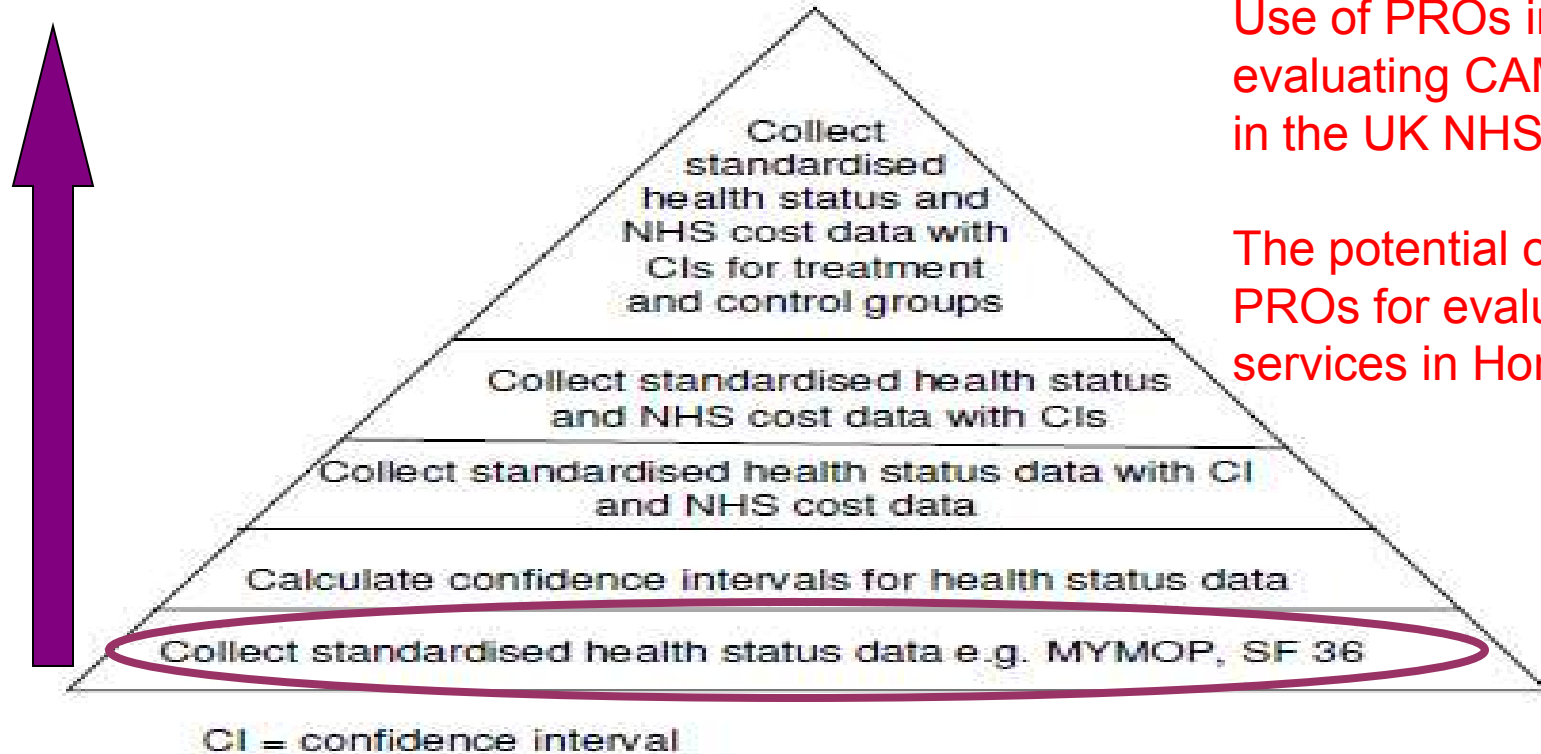
The potential of using PROs for labeling of Chinese medicines OTC products?

Figure 3 Healthcare choices (Chinese medicine) made by respondents in the previous year (n = 33,263).

Research article

Open Access

## The impact of NHS based primary care complementary therapy services on health outcomes and NHS costs: a review of service audits and evaluations



Use of PROs in evaluating CAM services in the UK NHS:

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

**Figure 1**  
Quality markers for evaluations of NHS primary care complementary therapy services.



# 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.

C Paterson, N Britten. In pursuit of patient-centred outcomes: a qualitative evaluation of the 'Measure Yourself Medical Outcome Profile'. *J Health Serv Res Policy* 2000; 5(1):27-36





# MYMOP: Measure Yourself Medical Outcome Profile

## 醫療成效自測簡表



PLEASE FILL THIS IN ON ..... MYMOP. Follow up

Name ..... Date completed .....

Please circle the number to show how severe your problem has been IN THE LAST WEEK.  
 – this should be YOUR opinion, no-one else's!

SYMPTOM 1: ..... as good as it could be | 1 2 3 4 5 6 7 | as bad as it could be  
 .....  
 .....

SYMPTOM 2: ..... as good as it could be | 1 2 3 4 5 6 7 | as bad as it could be  
 .....  
 .....

ACTIVITY: I cannot ..... able to do it normally | 1 2 3 4 5 6 7 | not able to do it at all  
 .....  
 .....

WELLBEING: How would you rate your general feeling of wellbeing as good as it could be | 1 2 3 4 5 6 7 | as bad as it could be

**Profile score = Total score / 4**



Chung *et al.* *Health and Quality of Life Outcomes* 2010, **8**:111  
<http://www.hqlo.com/content/8/1/111>



HEALTH AND QUALITY  
OF LIFE OUTCOMES

**RESEARCH**

**Open Access**

# Using Chinese Version of MYMOP in Chinese Medicine Evaluation: Validity, Responsiveness and Minimally Important Change

Vincent CH Chung<sup>1\*</sup>, Vivian CW Wong<sup>2</sup>, Chun Hong Lau<sup>1</sup>, Henny Hui<sup>2</sup>, Tat Hing Lam<sup>3</sup>, Lin Xiao Zhong<sup>3</sup>, Samuel YS Wong<sup>1</sup>, Sian M Griffiths<sup>1</sup>



# CMYMOP: Translation Process

Forward-backward-forward translation

Step 1  
English to Chinese

MYMOP Forward 1

MYMOP Forward 2

MYMOP Forward 3

Step 2  
Chinese to English

MYMOP Backward 1

MYMOP Backward 2

Step 3  
English to Chinese

MYMOP Backward 3

MYMOP Forward 4

MYMOP Forward 5

CMYMOP

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, including 116 phone interview. Response rate: 63.6%)



Follow up **at 4 weeks**: CMYMOP, SF36 and self perceived health status change

(n=272, 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**



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

\*All  $p < 0.001$

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



## 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 4<sup>th</sup> 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*

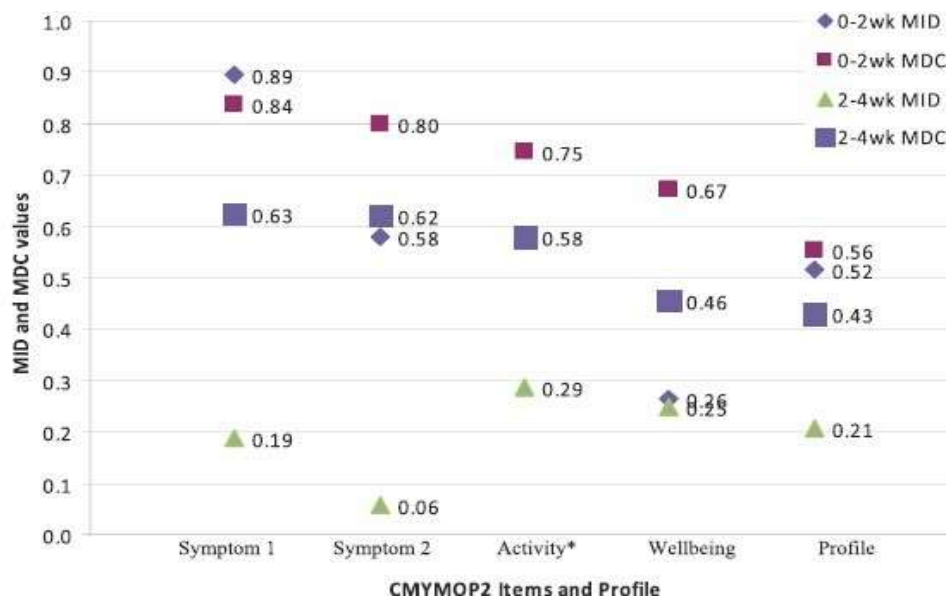




# Interpretation of CMYMOP scoring change



- 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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