



從病人角度評價中醫療效
Evaluating effectiveness of Chinese medicine
treatment from patients' perspective

Seminar on Chinese Medicines
14 Sep 2012

鍾志豪博士
助理教授
註冊中醫
香港中文大學賽馬會公共衛生及基層醫療學院

Dr. Vincent CH CHUNG
Assistant Professor
Registered Chinese Medicine Practitioner
Jockey Club School of Public Health and Primary Care, CUHK



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



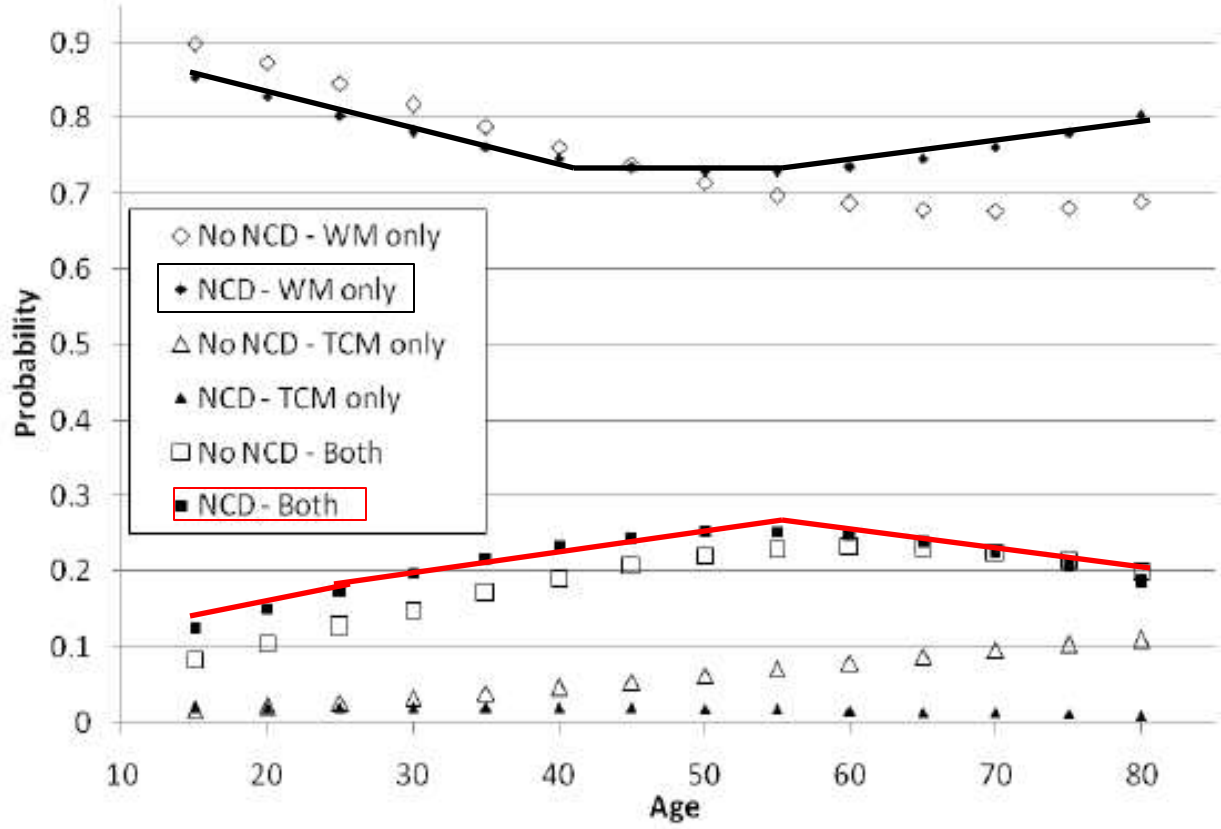
Research article

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

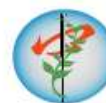
HRQOL = Health related quality of life

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

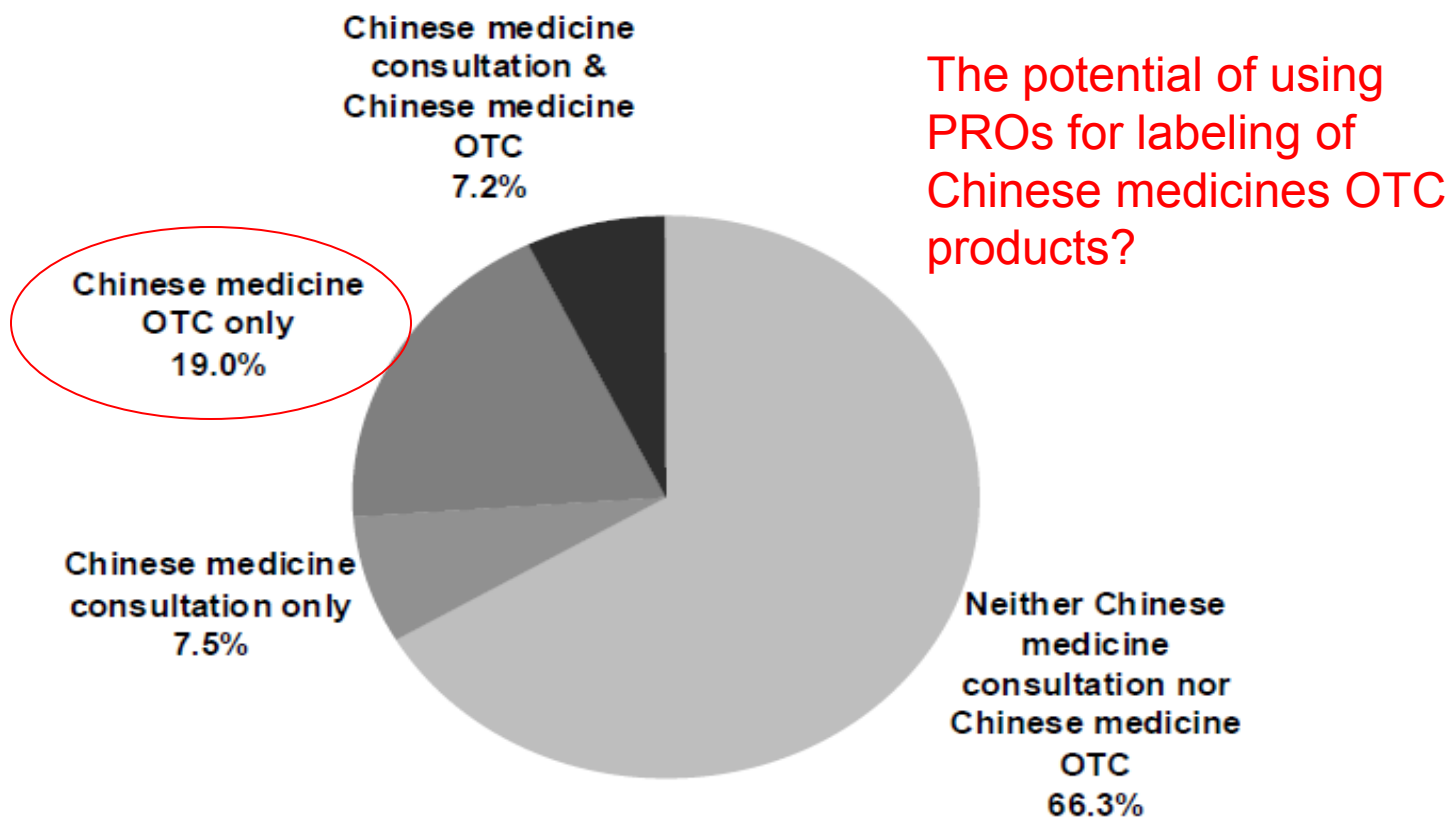


COMMENTARY

Open Access

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

Vincent Chi Ho Chung^{1*}, Chun Hong Lau¹, Frank Wan Kin Chan¹, Joyce Hoi Sze You², Eliza Lai Yi Wong¹, Eng Kiong Yeoh¹, Sian Meryl Griffiths¹



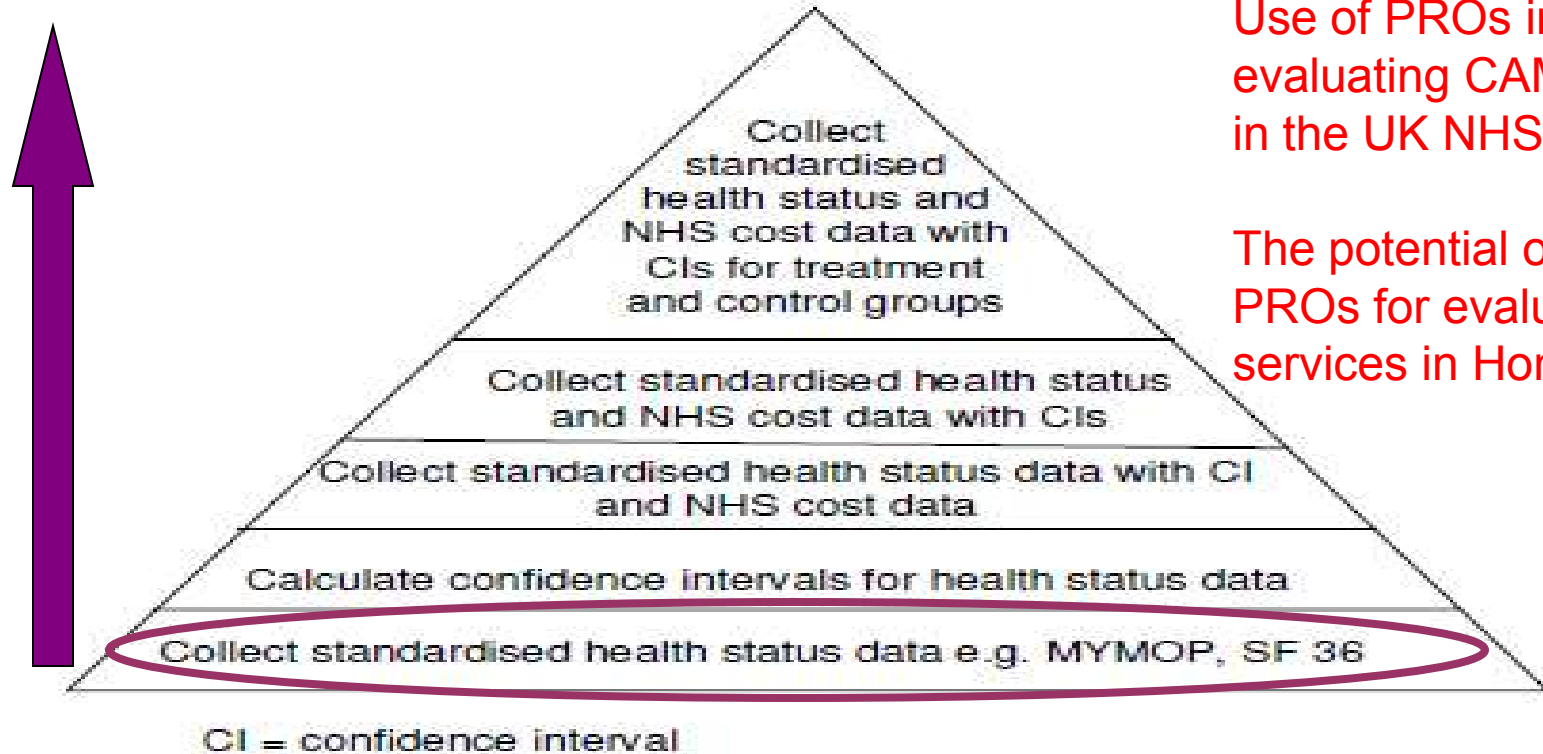
The potential of using PROs for labeling of Chinese medicines OTC products?

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^{1*}, Vivian CW Wong², Chun Hong Lau¹, Henny Hui², Tat Hing Lam³, Lin Xiao Zhong³, Samuel YS Wong¹, Sian M Griffiths¹



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 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**

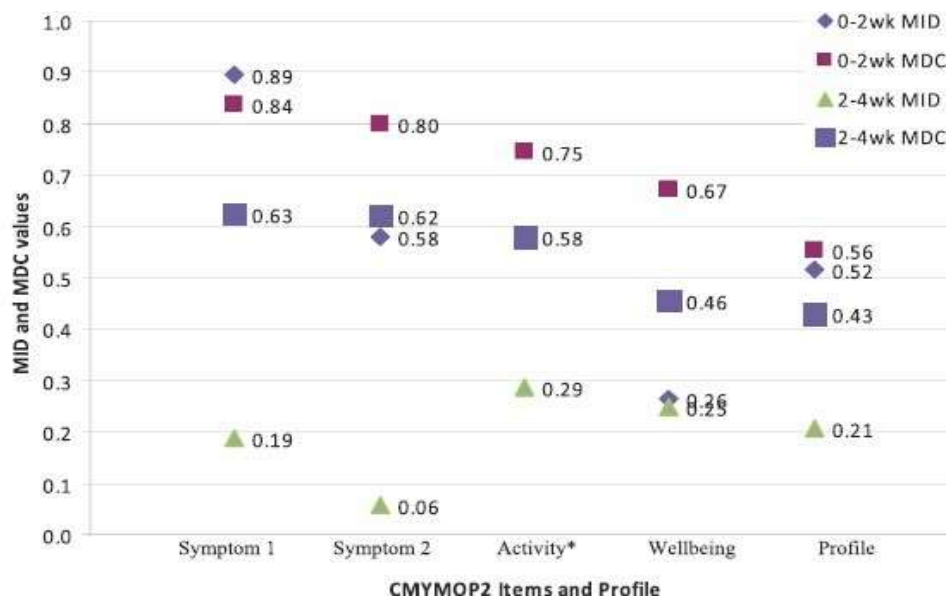
- **MID**: *the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management*



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

Vincent Chung, Johnson Lau, Samuel Wong, Sian Griffiths
Jockey Club School of Public Health and Primary Care, CUHK

Vivian Wong, Henny Hui,
Chinese Medicine Department, Hospital Authority

Lam Tat Hing, Lin X Zhong
Yan Chai Chinese Medicine Centre

