Pharmacoeconomic Guidelines in Asia: Focus on China guidelines for Pharmacoeconomic evaluations

Introduction

Shanlian Hu, MD. MSc. Professor
School of Public Health, Fudan University
ISPOR Consortium Forum at ISPOR 16th International Meeting
ISPOR Forum Session I, May 23, 2011
Hilton Baltimore, Baltimore, MD, USA

Objectives of the Session

- The China Guidelines for Pharmacoeconomic Evaluations were recently updated
- The forum will introduce the development of the China PE guidelines and will discuss the course of future actions
- The forum will share experiences and lessons of the implementation of pharmacoeconomic guidelines in other Asian

Presented by the

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Agenda

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<th>Title</th>
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<td>Overview of Pharmacoeconomic Guidelines in Asia</td>
<td>Bong-Min Yang PhD, Professor</td>
<td>2010-2012 Chair, ISPOR Asia Consortium Executive Committee and Professor of Economics, School of Public Health, Seoul National University, Seoul, South Korea</td>
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<td>China Guidelines Current States and Future Actions</td>
<td>Gordon G. Liu PhD, Professor</td>
<td>ISPOR Beijing Chapter, Professor and Executive Director, Health Economics and Management Institute, Guanghua School of Management, Peking University, Beijing, China</td>
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<td>Comments on China Guidelines: Clinician Perspective</td>
<td>Juhong Wu PhD</td>
<td>Vice President, ISPOR Beijing Chapter and Director, Department of Pharmacy, 306 Hospital of PLA, Beijing, China</td>
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<td>Comments on China Guidelines: Industry Perspective</td>
<td>Jianwei Xuan PhD</td>
<td>2010-2012 Chair, ISPOR Asia Consortium Health Technology Producers (Industry) Committee and Senior Director, Asia Lead, Pfizer Emerging Market, USA</td>
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<td>Comments on China Guidelines: Sharing Experiences/Lessons (Q/A)</td>
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CHINA PE GUIDELINES
BACKGROUND AND IMPLICATIONS

Gordon G Liu, PhD
Peking University
Guanghua School of Management

Email: ggliu@unc.edu

Presentations at the 2011 ISPOR Conference, Baltimore
2011-5-23
China’s GDP and Health Spending

China’s Problems in Health Care

Five Core Tasks (2009-2011)

- The Healthcare Financing
  - Universal basic medical insurance system (excellent)
  - Equal public health system (good)

- Healthcare Delivery
  - Sound public community facilities (fair)
  - Essential drug policy system (poor)
  - Public hospital reform (very challenging)

More on Essential Drug Policy

- What we know well: the fact
  - Overall prescribing: Rx as 50% of THE; over 25-30% growth rate;
  - Potential population health hazard and medical cost driver

- What we know somewhat: possible causes
  - Medical service hugely underpaid
  - Pricing regulation: 15+30% mark-up

- What we intend to do next
  - EDP (307 medicines, 2009 edition), coupled with policy of “0 mark-up” for sales and public subsidy for losses, aiming to control over-prescribing in community and rural public facilities
  - The State Reform Policy Calls: economic evaluation of new medications

China’s Problems in Health Care

- Exceedingly High Prescribing

China PE Guidelines Advisory Board

《中国药物经济学评价指南》
China Guidelines for Pharmacoeconomic Evaluations

Mr. Li, Keqiang
Deputy Prime Minister

Mr. Sang, Guowei
Vice Chairman
People’s Congress of China

China PE Guidelines Taskforce
- Chief Advisor: Guowei SANG (桑国卫), China’s PCC Vice Chairman
- Executive Committee
  - Chair: Gordon G LIU (刘国恩), PKU
  - Vice Chair: Shanlian HU (胡善联), Fudan U
  - Members: Jing WU (吴晶), Li YANG (杨莉), Zhaohui DONG (董朝晖), Hongchao LI (李洪超), Minghui LI (李明晖), Ning SHI (史宁), Jinghua CHANG (常精华)

Mr. Sang, Guowei
Vice Chairman
People’s Congress of China
### PE Guideline Released on 4-9-2011

- Guideline 1: Study Question
- Guideline 2: Study Design
- Guideline 3: Cost
- Guideline 4: Health Outcomes
- Guideline 5: Evaluation Techniques
- Guideline 6: Modeling Analysis
- Guideline 7: Variability and Uncertainty
- Guideline 8: Equity
- Guideline 9: Generalizability
- Guideline 10: Budget Impact Analysis

**Key Features**

<table>
<thead>
<tr>
<th>Module</th>
<th>Feature</th>
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<tbody>
<tr>
<td><strong>Guideline 1: Study Question</strong></td>
<td>Yes, review, design and economic framework.</td>
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<tr>
<td><strong>Guideline 2: Study Design</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Guideline 3: Cost</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Guideline 4: Health Outcomes</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Guideline 6: Modeling Analysis</strong></td>
<td>Model should address the extent to which both the input data and the results can be applied from one setting to another, both domestically and internationally if cross-country data is involved.</td>
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<td><strong>Guideline 7: Variability and Uncertainty</strong></td>
<td>Yes</td>
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<td><strong>Guideline 8: Equity</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Guideline 9: Generalizability</strong></td>
<td>Yes</td>
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<tr>
<td><strong>Guideline 10: Budget Impact Analysis</strong></td>
<td>Yes</td>
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**Modeling**

- Yes, both deterministic and economic framework.
- Yes, yes.
- Yes. Sensitivity analysis is recommended if data available.
- One-way, multi-way, threshold analysis, analysis of extremes, scenario analysis.
- Risk factors, QALY, WTP.
- Yes.
- Yes.
- Sensitivity analysis methods.
- Yes.
- Yes.
- Yes.
- Yes.
- Yes.

**Costs to be included**

- Primarily direct medical costs, followed by direct non-medical costs and indirect costs.
- Primarily cost-utility analysis.
- Primarily CUA.
- Yes.
- Yes.
- Yes.
- Yes.
- Yes.

**Assumptions required**

- Yes.
- Yes.
- Yes.
- Yes.
- Yes.

**Cohort**

- Primarily society, followed by payers, employers, health care providers, patients.
- Yes.
- No.
- Yes.
- Yes.
- Yes.

**Perspective**

- Primarily societal, followed by payers, employers, health care providers, patients.
- Yes.
- Yes.
- Yes.
- Yes.
- Yes.

**Presentation**

- Reports both in disaggregated and aggregated form.
- Sensitivity analysis: 1-way, multi-way, threshold analysis, analysis of extremes, scenario analysis.
- Needs to reflect the outcomes and stakeholders.
- Voluntary for now to start, expecting to be recommended in a few years.

### China PE Guidelines Dissemination

- Chinese Version: contact PKU China Center for Health Economic Research (CCHER), China.PEG@gmail.com
- English Version: contact R&D-based Pharmaceutical Association of China (RDPAC), available soon

Comments and suggestions are welcome: China.PEG@gmail.com

### Pharmacoeconomics and Resource Utilization

**Increasing aging in the sixth national census**

- Total national population is 1,339,724,852. Comparing to the fifth census in 2000, population increased 7390 million in the past 10 years accounting for 5.84%.
- Population aged 0-14 was 222.5 million, accounting for 16.60%; 15-59 was 939.6 million, accounting for 70.14%; 60 and above was 177.6 million, accounting for 13.26%, of which 65 and above is 118.8 million, accounting for 8.87%.
- Compared with the fifth national census, population aged 0-14 has dropped 6.29 %, 15-59 increased by 3.36 %, 60 and above increased by 2.93 %, 65 and above increased by 1.91 %.

### COMMENTS ON CHINA GUIDELINES: CLINICIAN PERSPECTIVE

Jiuhong Wu Ph.D.
ISPOR Beijing Chapter Vice President and Director of Department of Pharmacy, 306 Hospital of Beijing, China

2011.09.23, Award-winning, BCD
Pharmacoeconomics & Value-based Medicine

- Health Economic
- Pharmacoeconomics (PE)
- Health Technology Assessment (HTA)
- Evidence-based Medicine (EBM)
- Value-based Medicine (VBM)

Different study methods have the same objective and are interoperable methodologically, all of them are dependent on the clinical evidence and policy support is needed for all.

Outcomes Research In China

- Clinical View (China)
- Humanistic View
- Intermediary Study (China)
- Treatment Outcomes (end results)

Concept rather than Assessment in China

- Lack of qualified assessment organization
- Lack of experienced professional assessment personnel and team
- Lack of concepts of pharmacoeconomics and value-based medicine
- Long-term large amount investment is needed for the aspects as capacity building and data demands (Information Platform Construction)

Problems of Medicines Used in China

- Various dose forms and doses (More than 180 thousand Registered drugs in SFDA)
- 4 thousand pharmaceutical companies
- Different Medicine Quality
- Complex circulation and distribution (personal agent and outsourcing)
- Various drug prices (Pharmaceutical company's pricing and Government's pricing; different prices in the same city and region)
- Complicated medical insurance system (Urban employee, resident, new rural medical insurance)
- Drug safety issues (more ADR and ADE)
- Irrational medicine use (large dose and overdose of prescription)
- Abuse of injection dosage form of Traditional Chinese Medicine
PE Assessment & Rational Medicine Use

- Medicines supplied in Hospital need the guidance of Pharmacoeconomics
- Hospital Formulary need PE assessment
- Take medicine based on Treatment Guidelines

Selection Principle of the Hospital Formulary

- Prefer the innovative drug with important clinical significance
- Keep reasonable amount for the similar drugs and the new products should have significant advantages over the old products
- Generic Drugs: Choose one brand name drug and one generic drug under the condition that the quality is reliable and the price is reasonable

Industry Perspective:

- Jianwei Xuan, MD, PhD
  Chair, ISPOR Asia Consortium Health Technology Producers (Industry) Committee
  Senior Director, Asia Lead, Pfizer Emerging Market
  Adjunct Professor, Fudan University, Shanghai, China
  Clinical Associate Professor, University of Florida

Acknowledgement

- Hong Li, Ph.D. BMS
- Jennifer Sung, Pharm. D, MS, Novartis
- Mingliang Zhang, Ph.D. J&J
- ShiQing Liu, J&J China
- Boxiong Tang, MD, PhD. Pfizer
- Peng Dong, PhD. Pfizer China

Ideas expressed in this presentation are individual’s professional opinions and does not reflect affiliated company’s official position.
Industry Perspective

- We support the establishment/update of PE guidelines so the research standard can be aligned.
- We are more “concerned/interested” on issues and challenges we are facing on the implementation of the guidelines.

Issues And Challenges On The Implementation

- Capacity Development:
  - Lack of right/well trained personnel at all levels (Government, Academic, and Industry).
- Knowledge Development:
  - Lack of systematic knowledge accumulations on success and failure of past evaluation.
- Data:
  - Lack of good data source
  - Lack of access when database available.

Without above building blocks, successful implementation of PE Guideline might be difficult.

Potential Solutions

- Capacity Development:
  - Government, academia, and industry work together to build research capacity, develops training opportunities, university programs, workshops, seminars, course etc.
- Knowledge Development:
  - Establish consortium to systematically cumulate knowledge and evaluate success and failure of past experience.
- Data:
  - Start work together to build and identify good data source.
  - Closer collaborations allow industry to access the available database.

Objective

- HTA policy/PE evaluation will be employed to use evidence of comparative/cost-effectiveness analysis to define “value for money” for innovative drugs to facilitate optimum reimbursement decision with the purpose to best optimize a country's population drug utilization level.