How do Culture, Values and Institutional Context Shape the Methods and Use of Economic Evaluation?

-- Taiwan Scenario

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- Land Size: 36,190 km$^2$
- Population: 23.5 million
- GDP per capita: US$22,469 (2015, nominal)
- NHE as 6.19% GDP (2014)
  - NHIA account for 52.5%
  - Out-of-pocket: 35.8%
- Elderly (> 65 y) : 12.2% (2015)
- Private hospitals : 85% (total: 540)
- Private clinics: 98%
- National Health Insurance Scheme (since 1995, 99.5% pop)
- Pay monthly premium
- Comprehensive coverage: ER, hospital inpatient and ambulatory care, primary care, Chinese Medicine, Dental
- Using global budget, FFS and partial DRG on reimbursement
Introducing a new drug to the health care system in Taiwan

- **Step 1:** Marketing approval
  - Appraisal: DAC (Drug Advisory Committee, TFDA)
  - Decision: Taiwan Food and Drug Administration, Ministry of Health and Welfare (MHW, 2013)

- **Step 2:** Reimbursed by the National Health Insurance program (start 1995)
  - Assessment: HTA/CDE (start 2008)
  - Appraisal: PBRS Committee Meeting (2013, since 2nd gen. NHI)
  - Decision: National Health Insurance Administration, MHW

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**HTA Process in Taiwan**
(starting 2013)

1. **Dossier submissions by Manufacturers**
2. **NHIA**
   - Initial Recommendation for listing & pricing
   - Expert Consultation Meeting
     - Make coverage decision:
       - Covered / Not covered
       - Range of coverage
       - Set the price
3. **National Institute of HTA (NIHTA)**
   - Drug assessment report in 42 days
   - New drugs
   - Medical devices
   - Diagnostics
   - Procedures

NHIA: National Health Insurance Administration
PBRS: Pharmaceutical Benefit and Reimbursement Scheme
Payers Considerations

Clinical Consideration

Pharmaco-Economic Consideration

Budget Consideration

Scientific Judgment

Preference Judgment

Public/Patient Involvement

Healthcare Resources Allocation Decision

1. Is it safe?
2. Does it work?
3. Comparative Eff

4. Is it worth the cost?

5. Can we afford it?

6. Is it medically necessary?

7. Does it support our policy position?

Political, Necessity, Cost-effective Consideration

Meet the pt. unmet need?
How do we control its use?
Social/Ethical Consideration

Pricing and Reimbursement Guideline (1)

- **Category 1 new drug**: (Breakthrough innovative product)

- **Must meet one of the following criteria**:
  - Have new mechanism of action
  - The first drug for a specific disease shown to have good effectiveness
  - Via head-to-head comparison or indirect comparison indicates substantial improvement of the therapeutic value than the current listed comparator
  - Shown to be cost-effectiveness

- **Pricing principle**
  - Set at median price of international ten ref. C
  - Have efficacy and safety clinical trial in Taiwan with a reasonable scale, add 10%.

* UK, Germany, Japan, Swiss, US, Belgian, Australia, France, Sweden and Canada
Pricing and Reimbursement Guideline (2)

- **Category 2 new drug**:  
  - Category 2A:  
    - Compare to the current best comparator shown to have *moderate improvement* of the therapeutic value  
  - Category 2B:  
    - Compare to the current best comparator shown to have *similar* therapeutic value

Pricing principle for Category 2 new drugs

- **Pricing principle**:  
  - median of International ten is the ceiling price
- **methods**:  
  - The lowest of the international ten  
  - Prices at the original country  
  - International price ratio  
  - Dosage regimen ratio  
  - Combination product: sum of single drug price times 70% or one single drug price
Bonus principle for Category 2A new drugs

- Have efficacy and safety clinical trial in Taiwan with a reasonable scale, **add 10%**.
- Have pharmacoeconomic study in Taiwan, **add the maximum of 10%**.

No ICER threshold established yet
**Recommended 1.4~2.1 GDP/QALY**
around **US$30,000~US$47,000/QALY**

<table>
<thead>
<tr>
<th>Equality</th>
<th>Equity</th>
<th>Liberation</th>
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<tbody>
<tr>
<td>Sameness</td>
<td>Fairness</td>
<td>Liberation</td>
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DAA for hepatitis C reimbursement decision in Taiwan (Four brands on the market)

<table>
<thead>
<tr>
<th></th>
<th>Harvoni® Tab (90mg ledipasvir, 400mg sofosbuvir)</th>
<th>Viekirax® Tab (12.5mg ombitasvir, 75mg paritaprevir, 50mg ritonavir)</th>
<th>Daklinza® 60mg Daclatasvir</th>
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<tbody>
<tr>
<td>Daily dose</td>
<td>#1 QD</td>
<td>#2 QD + #1 BID</td>
<td>#1 QD + #1 BID</td>
</tr>
<tr>
<td>Duration</td>
<td>3 months</td>
<td>3 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Cure rate</td>
<td>94–99%</td>
<td>91%–100%</td>
<td>82–92%</td>
</tr>
<tr>
<td>Self pay cost/course</td>
<td>~NT$1,250,000 (~US$39,062)</td>
<td>~NT$1,490,000 (+Exviera: Dasabuvir)</td>
<td>~NT$330,000 (+Sunvepra) (~US$10,000)</td>
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NHIA will negotiate drug cost/course, plans to have an independent budget for this category of drug treatment for ten years (Aug. 2016). Treat 10,000 patients/year, budget: US$ 80 million. (1US$=32NT$)

Drug Treatment for Patients with Rare Diseases

- **Rare Disease and Orphan Drugs Act** since the year 2000 advocated by Taiwan Foundation for Rare Diseases
- **Rare Diseases and Drugs Council** decided 210 rare diseases, 92 drugs and 40 nutritional foods
- NHIA created special fund to cover all, free of copayment **(2013 annual budget US$ 93 million)**
- The diagnosis, treatment, drugs, nutritional foods to sustain life, and medical devices for daily living, if not covered yet, can be subsidized (80~100%) by the National Health Promotion Administration

Conclusions

- Economic evaluation is not fully utilized to make reimbursement decision
- However, the culture is to fully support those in need
- The value of drugs and therefore the reimbursement price is still based on the comparative effectiveness and confounded by budget impact to the payer.