



Adapting Pharmacoeconomic Data or Analyses from Overseas for Decision-Making in Middle Income Countries

Taiwan Experience

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New Drug Listing Decision

- New drugs listing decision is made according to the following factors:
 - Relative effectiveness/Safety
 - Budget impact
 - Cost-effectiveness
 - It is not mandatory for manufacturers to submit CEA evidence
 - Ethical/Law/Social/Political Impact



Incentive for Local CEA Evidence

To encourage the manufacturers to provide local CEA evidence in the dossier

An incentive of a maximum **10%** mark-up for conducting local CEA for category 2 new drugs has been announced since 2010

Mark-up is recommended by Expert Committee, and then approved by PBRS Joint Committee



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Assessment for Local PE Study

NHIA

How to assess the **strength** of evidence of local CEA analysis?

A tool for local CEA Quality Assessment was proposed by NIHTA in Taiwan

- to ensure the consistency
- to improve the transparency



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What is a good PE study?

- What is a good PE study for listing decision?
 - Providing **valid** economic evaluation
 - Reflecting **local** scenario
 - **Regardless of the ICER value**



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What is a good PE Quality Assessment Tool?

- What is a good Quality Assessment Tool for listing & mark-up decision?
 - Discriminability
 - Consistency
 - Transparency
 - Grading?
 - ➔ **A checklist was proposed**



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Four review dimensions

- PIC
- CEA design
- Parameters
- Overall quality



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If the analysis relevant to the application?

- (Yes, Acceptable, No)
 - 1.1 Population
 - 1.2 Intervention
 - 1.3 Comparator



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The appropriateness of the study design

- (Yes, No)
 - 2.1 Method
 - 2.2 Perspective
 - 2.3 Analytic horizon
 - 2.4 Discounting
 - 2.5 Effectiveness indicators
 - 2.6 Economic indicators
 - 2.7 Sensitivity analysis
 - 2.8 Sponsorship disclosure



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Quality of Parameters and the level of local adaptation

- (Good, Acceptable, Flawed)
 - 3.1 Comparative effectiveness
 - 3.2 Safety/AE
 - 3.3 Baseline event rate
 - 3.4 Epidemiology
 - 3.5 Medication costs
 - 3.6 Other medical costs
 - 3.7 Other non-medical costs
 - 3.8 Utility weight



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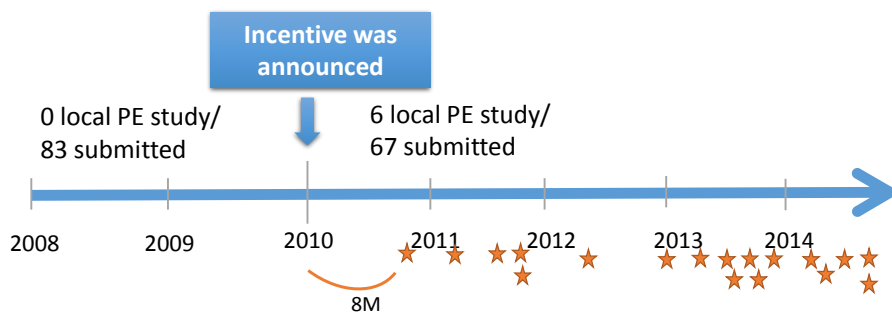
Overall Quality

- (Good, Acceptable, Flawed)
 - 4.1 Study model and the clinical pathway
 - 4.2 Assumptions
 - 4.3 Include all important costs?
 - 4.4 Include all important health outcomes?
 - 4.5 Sensitivity analysis
 - 4.6 Value of parameters
 - 4.7 Calculation
 - 4.8 Completeness of results
 - 4.9 Reporting



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The Impact of Local PE Incentive

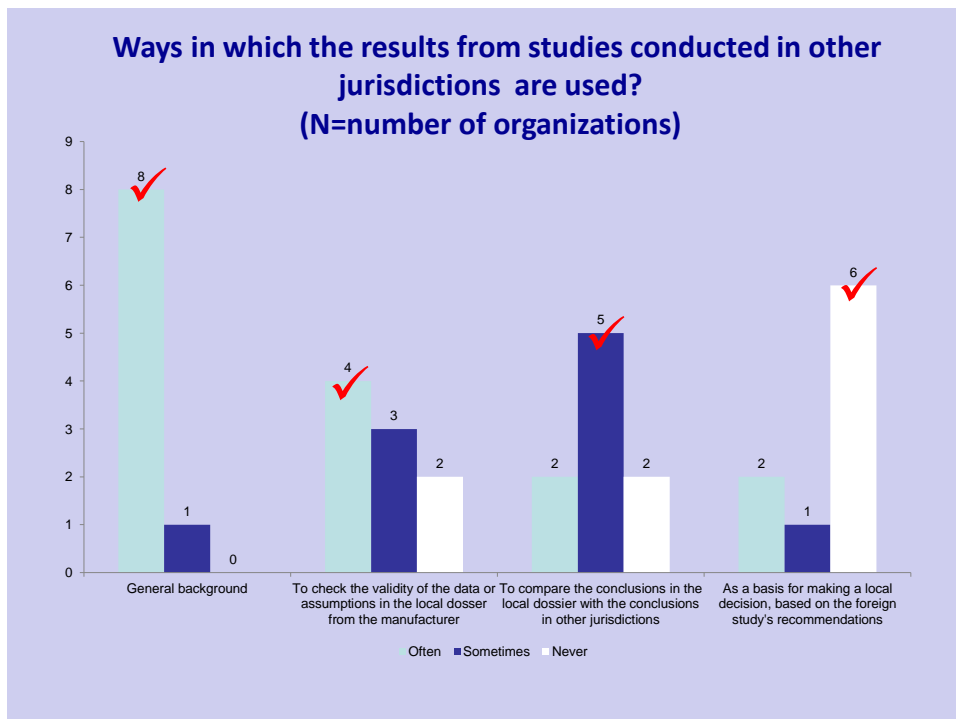


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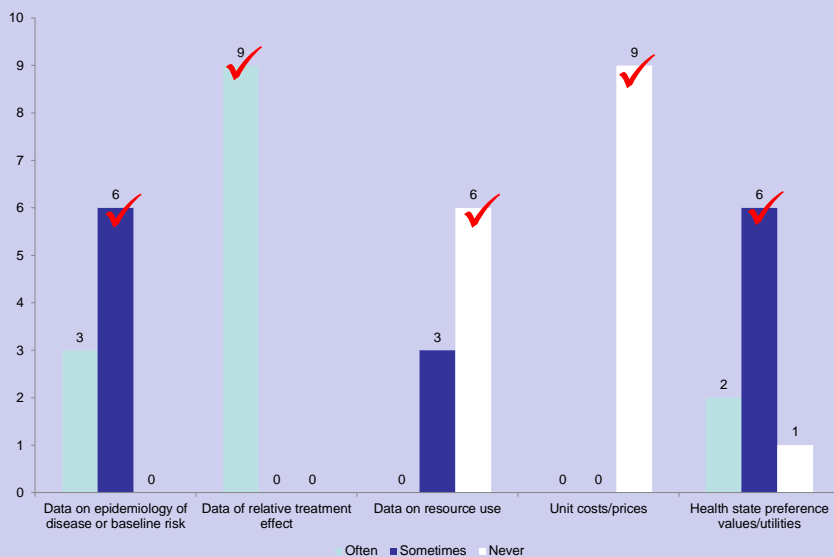
Comparing to the survey results



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Categories of foreign data used when conducting local studies (N=number of responses)



OBSTACLES TO TRANSFERRING ECONOMIC EVALUATIONS FROM OTHER JURISDICTIONS	Number of times mentioned
Other practice patterns, or the availability of facilities, are often different in my jurisdiction	10
The current standard of care/ relevant comparator is often different in my jurisdiction	9
Studies are often conducted in countries with a higher GDP, so the results do not apply in my jurisdiction	8
Studies are often badly reported, or not enough details are given	8
It is often difficult or impossible to obtain an electronic copy of the model	7
The patient population is often different in my jurisdiction	6
Often, it is not possible to find local data to re-populate the model	6
Studies often have methodological deficiencies	5
Decision-makers in my jurisdiction much prefer a locally designed study	5
Studies often use methods that are too advanced for decision-makers in my jurisdiction	4
Other obstacles (please list and rank)	3
Lack of local technical capability	1
Decision-makers in my jurisdiction much prefer non-data driven arguments	1
Different resources & costs used in other jurisdictions	1

Comparisons...

- Are there any examples in your country of using data or analyses from overseas in local decisions?
 - No (because the pricing rule...)
- What do you see as the major challenges and how are they resolved in your country?
 - Lack of capacity in the beginning
 - Change of decision-making system
 - Need to reform!

Thank you!

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