How do I think, what should I say about the Japanese HTA?

Educational symposium: Evaluations on the health technology assessment era in Japan – from governmental, academic, and pharmaceutical perspectives

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Characteristics of JP-HTA (pilot)

1	Eligible products are chosen from drugs ALREADY REIMBURSED
2	Results are used for PRICE REVISION, not for COVERAGE DECISION (French HAS – like system)
3	HTA result will be applied only to PREMIUM portion
4	ICER values are compared with the threshold value to determine if it is cost-effective (UK NICE – like system)
5	The threshold value will be defined via several survey, including WTP (What is often referred to in basic textbook)
6	Things other than Cost-Effecitiveness will be taken into account at the appraisal process (UK NICE – like system)
7	Drugs with multiple indications are evaluated via merging multiple ICER value (ORIGINAL system)

What are important differences between JP-HTA and Other HTA's?

vs. UK-NICE	Opportunity to pushback for results from ERG is only at ONCE
vs. UK-NICE	Minimum impact on final results of OTHER issue than ICER
vs. FRA-HAS	ICER values would directly be reflected to price revision rate
vs. all HTA agency	The appraisal body do not have enough experience for conducting true APPRAISAL
vs. all HTA agency	Very scarce capacity for taking UNCERTAINTY into account

Japan-specific way how to reflect results into price revision rate

The ICER value is directly reflected to the price revision rate

How can we justify JPY5M. and JPY10M?

* The function of Multiple threshold values

	How multiple threshold values are used?
Foreign country (UK, Netherands)	Threshold value is chosen among multiple ones, according to the characteristic of diseases/drugs Values would be varied one intervention to another
Japan	Two "Threshold values", JPY5M and 10M will be applied to ALL candidates

Entirely different definition for "MULTIPLE" threshold

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THE INFLUENCE OF COST-EFFECTIVENESS AND OTHER FACTORS ON NICE DECISIONS

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ABSTRACT

The National Institute for Health and Care Excellence (NICE) emphasises that cost-effectiveness is not the only consideration in health technology appraisal and is increasingly explicit about other factors considered relevant but not the weight attached to each.

The objective of this study is to investigate the influence of cost-effectiveness and other factors on NICE decisions and whether NICE's decision-making has changed over time.

We model NICE's decisions as binary choices for or against a health care technology in a specific patient group. Independent variables comprised of the following: clinical and economic evidence; characteristics of patients, disease or treatment; and contextual factors potentially affecting decision-making. Data on all NICE decisions published by December 2011 were obtained from HTAinSite [www.htainsite.com].

Cost-effectiveness alone correctly predicted 82% of decisions; few other variables were significant and alternative model specifications had similar performance. There was no evidence that the threshold has changed significantly over time. The model with highest prediction accuracy suggested that technologies costing £40 000 per quality-adjusted life-year (QALY) have a 50% chance of NICE rejection (75% at £52 000/QALY; 25% at £27 000/QALY).

Past NICE decisions appear to have been based on a higher threshold than £20 000–£30 000/QALY. However, this may reflect consideration of other factors that cannot be easily quantified. © 2014 The Authors. *Health Economics* published by John Wiley & Sons Ltd.

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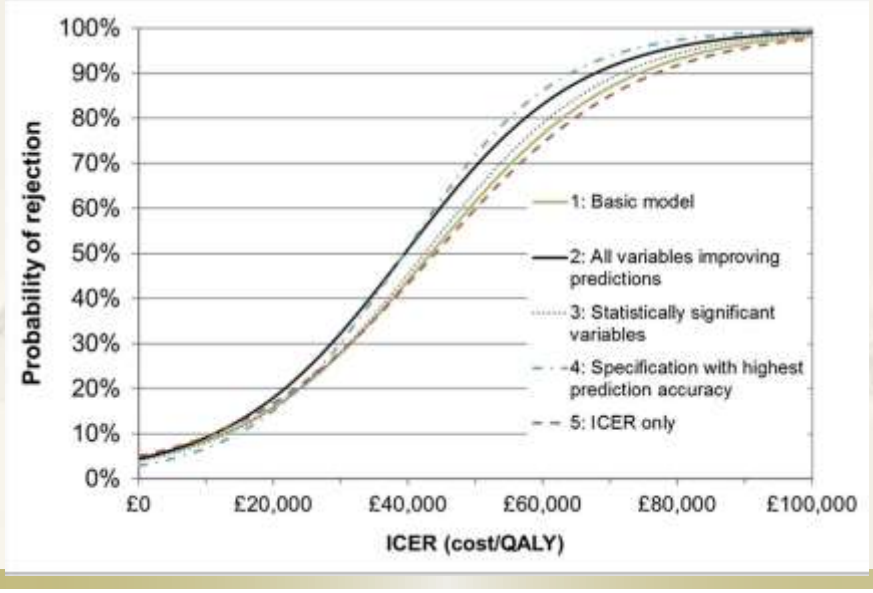
KEY WORDS: health technology assessment; implicit weights; cost-effectiveness; National Institute for Health and Care Excellence (NICE); logistic regression

Much higher than so-called threshold value



ICER values with 50% possibility for rejection

Area	ICER for 50% rejection
Respiratory	£20,356
Cardiovascular	£37,950
Cancer	£46,082
Infection	£49,292
Musclo-Skeltal	£55,512
Others	£32,263

How the“other factors” could be taken into account at Appraisal phase?

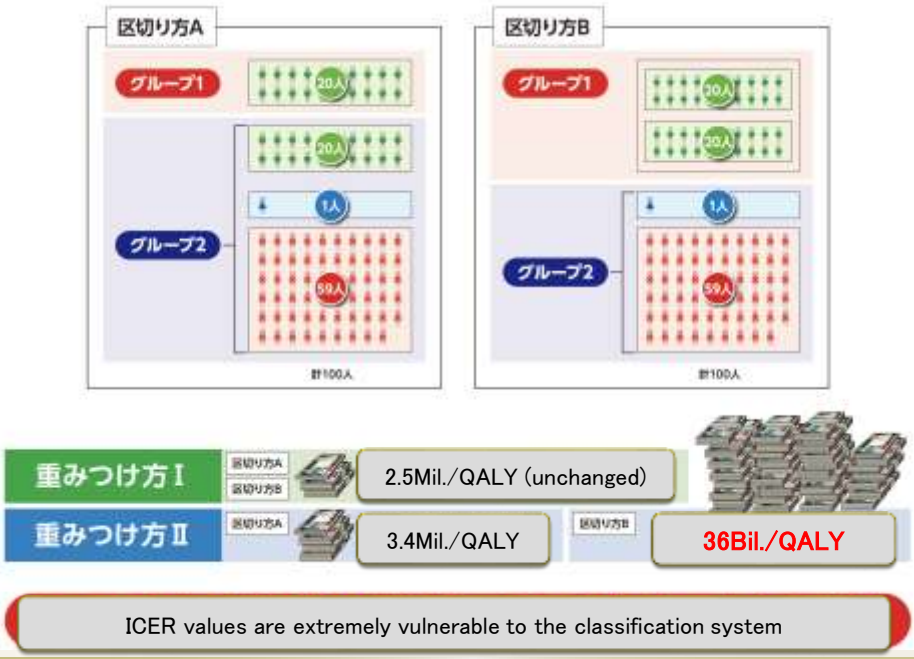
Component	Descripition
Public health matter	”External usefulness” like herd effects for communicable diseases
Costs other than HC payers’ perspective	Caregiving costs and productivity losses should be taken into account in some particular cases
Disease severity	“End-of-Life” like issues?
Availability of alternative treatment	In order not to prevent the development of treatment for diseases which no alternatives are available

ICERs will be discounted for 5% per 1 criteria met..
(cf. End-of-Life in UK: 20K-30K to 50K)

HOW can we calculate WEIGHTED-ICER?

METHOD 1 (ordinal)	METHOD 2 (governmental)
1 Calculate overall costs for all indication	1 Calculate ICER for each indication
2 Calc. overall outcomes for all indication	2 Multiply prop. of patient
3 Calc. ICER via 1÷2	3 Summing up “weighted” ICER
Summing and divide	Divide and summing

Which method is more closer to the definition of ICER?



My definition of “HEOR” in Pharma

- ANY researches to upgrade the value of products could be HEOR
- Data could be used to PURSUADE somebody, not only to the Gov.
- HEOR data would not be restricted to HE data
- QOL /Disease burden/Relative Effectiveness
- Never to exaggerate data, nor hide unfavourable data
  - sooner or later, it would be accused of by criticians!

Do we need to do HTA even without governmental request?

Till now (PAX Japana)	Nobody curious about HTA data (Then, let sleeping dogs lie!)
From now	Every stakeholders may curious about HTA data

Industries can stay without HTA.
However, YOU must be tried with ABSENCE

We may ”lose“ if we do CEA. Then, we would not do that

What’s happened if we ESCAPE from conducting CEA?	
Till now (PAX Japana)	Nothing would be happened
From now	All other stakeholders will simply accept data from OTHERS

Role of HEOR section to be..

- To facilitate, occasionally fight with…
  - Internal sectors
  - External sectors
- Not short-time win, but intermediate-long term win
  - Couple of quick ones would be needed to secure the Gas

Future desirable role of HTA

- HTA is introduced to maintain (upgrade) the transparency, while it contains so many uncertainty
- So many un-resolved issues when tried to connect with the ICER value to the price revision rate
- Possible solution?
  - Give up HTA? (I do not think so)
  - Introduce it to coverage decision with some aids?