IP2 Opportunities and Challenges in International Harmonization of HTA of Medical Devices – Gaps Between European and Asian Countries.. From Japanese view

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HTA (narrower definition) in Medical devices in Japan

- Approved by PMDA, reimbursed via MHLW, Chu-i-Kyo
- Dossiers for reimbursement contains;
  - Possible numbers of patients and sales amount
  - documents for “Health economic usefulness” (Legacy HTA)
- Several products (not new but current existing) are nominated as candidates for the Newly-developed HTA program since Apr. 2016

State-of-the-art HTA vs Legacy HTA

- **A few devices are nominated for pure HTA submission as the "Pilot HTA introduction" in Japan**

- **For a long time, the dossier already contains "usefulness from the Health-Economic perspective"**

Requirement for "usefulness from HE"	
A	Additional medical cost with introduction of new devices
B	Medical cost saved with introduction of new devices
C	Overall impact for medical costs (A minus B)

Device vs Drug??

- Device HTAs is more likely to be bothered with..

Lack of data	No (Scarce) RCT is available, while there are some observational studies
"Value" of data	"New" device, which was nominated for HTA submission, will no longer be "New" one as next-generation ones will soon become available
Lack of capacity	Some device is suitable for CUA, while others not

Uniform guidelines both applicable for drugs and devices

- Issues around data sources
  - Data prioritization (Scarce RCT vs. Sufficient Obs. Study)
  - Capability of CUA (QALY preferred)
- Scarce availability for DIRECT comparison
  - Devices MOSTLY REPLACED one should be the comparator
  - Rapid replacement (comp. drugs)

Assessment results of MSAC australia (devices for treatment)

- 101 Results are available for 1999-2017

	Methods	Number
Economic Evaluation Performed 55 (54%)	CUA (with QALY)	22
	CEA（without QALY)	14
	CMA	12
	CUA and CEA	6
	CUA and CMA	1
Not performed 46 (46%)	cost comparison/cost analysis	19
	nothing	26
	PBAC did	1

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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)

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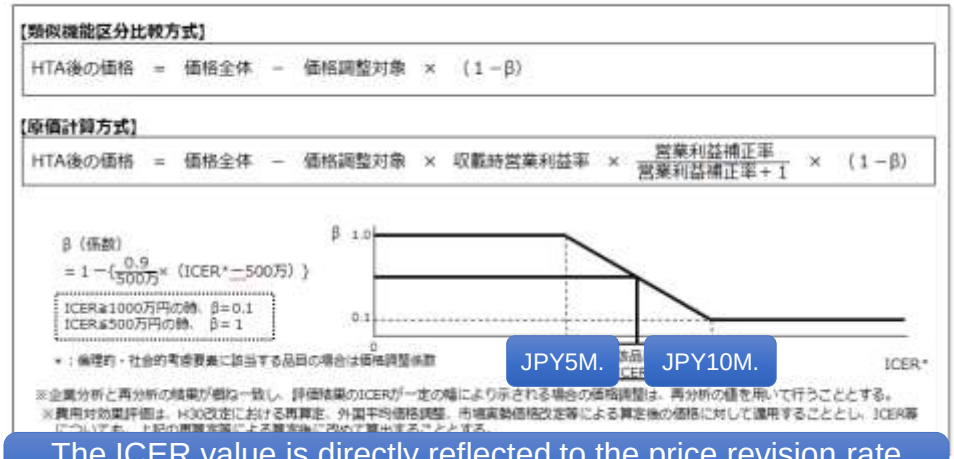
Japan-specific way how to reflect results into price revision rate

（図4）価格調整方法



The ICER value is directly reflected to the price revision rate
->Then, LITTLE opportunity to consider uncertainty

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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

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

Component	Description
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
Innovation	To enhance the development of innovative/novel medications
Pediatric disease	To hold the marketability of pediatric medications

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

No additional factor needs to be considered in the appraisal process???

- **What is the key role of the appraisal?**

Viewpoint	Role	Importance
Practical	Simply minimize price reduction rate	Less important Additional factor should only be considered if HTA is used to coverage decision
Conceptual	To compensate the limitation of CEA/ICER	More important Other factors should be seriously considered, as no flexibility is allowed for CEA/ICER part

“Extra value” other than CEA/ICER is difficult to be incorporated to one-dimensional scale

Issues around traditional “evidence level”

- Which one should be preferred?
  - Scarce direct comparison data (RCT)
  - Indirect comparison data
  - Meta-analysis of observational data

NO clear-cut criteria for prioritization

Several challenges around Japanese HTA

Challenges and Best Practices for the Japan Health Technology Assessment Pilot Program

KEY POINTS

When not executed according to sound principles, HTA could be viewed skeptically as an attempt to limit patient access to contain costs or a lever for government price negotiation.

DEFINING A COST-EFFECTIVENESS THRESHOLD

BUILDING CAPACITY

STAKEHOLDER BUY-IN

TRANSPARENT PROCESSES AND DECISION MAKING

REAL-WORLD DATA INCORPORATION

MULTISTAKEHOLDER ENGAGEMENT

Kristensen KB, Igarashi A, Neumann PJ, Goldman DP. Challenges and Best Practices for the Japan Health Technology Assessment Pilot Program. ISPOR Value & Outcomes Spotlight 2018: 4 (4): 40-1.

My personal view for HTA

It should be “SUICIDE OF ACADEMICIAN”, if I say
Japanese HTA is fairly good system, as EXPERTS says that “it is fairly good system”.
Should there be any issues, we have only to say “further discussion will be very important”, regardless of the actual capability of discussion
PRE-HTA ERA is more favorable. Then, we need to go back to that ERA. We can deceive the publics, only arguing that “ACCESS LIMITATION”!