

Challenges in HTA of medical devices in countries with limited experience: situations in Japan

Rei Goto, MD, PhD(Econ) Graduate School of Business Administration, Keio University, Japan
reigoto@kbs.keio.ac.jp

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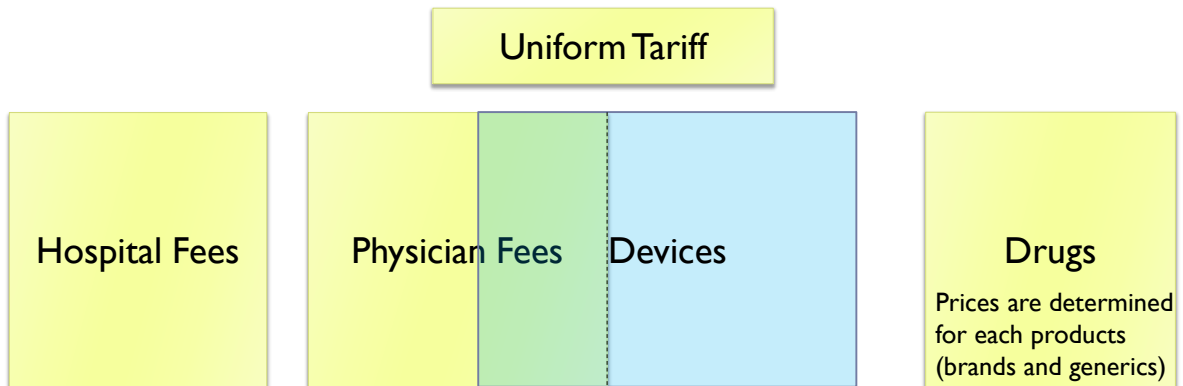
Japanese HTA on trial

- ▶ Almost all approved drugs and devices are automatically reimbursed without referring to cost-effectiveness analysis
- ▶ Their prices are determined by the Central Social Insurance Medical Council of Ministry of Health, Labour and Welfare
- ▶ So far, prices are depreciated based on the official survey of wholesale prices every two years
- ▶ From 2016, cost-effectiveness evaluation is considered for **their re-pricing** (on trial)
- ▶ An official methodological guidelines for the EE published (Shiroiwa et al., 2017)



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Device prices in Japan



1. Cost of devices (fixed and variable cost) is included in physician fee (e.g., suture threads, needles and syringes, CT, MRI, robot-assisted surgery system)
2. Devices are priced according to their "functional classification"
Not for each products

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Device prices in Japan

- ▶ Price list updated every two years according to 1200 functional classifications
- ▶ Low price (several pence) to High price (>150K\$)
- ▶ The lower committee of the Central Social Insurance Medical Council examine the novelty of products
 - ▶ Novel ones produce new functional category
 - ▶ Products lacking novelty classified with existing categories
- ▶ Whole market size (per year) is approx. 1 bil. \$

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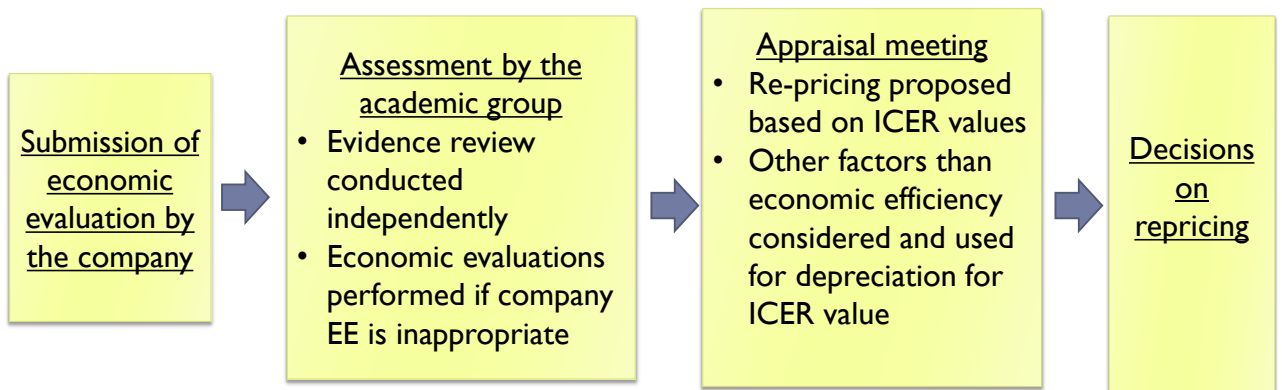
7 drugs and 5 devices are under trial HTA

- ▶ **7 drugs**
 - ▶ 5 anti-HCV and 2 anti-cancer drugs
 - ▶ **5 devices**
 - ▶ A graft system for thoracic artery
 - ▶ Three digital brain stimulating systems for tremors
 - ▶ A regenerated cartilage for traumatic cartilage defect
 - ▶ A transcatheter aortic valve
- No diagnostic technology

Evaluations of devices has the same positions as drugs in HTA

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The flows of HTA on trial



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Economic evaluations of devices in Japan

- ▶ **Companies are required to submit an original economic evaluation**
 - ▶ Evaluations methodology needs approval from the authority beforehand
- ▶ **Drugs and devices are applied to the same methodological guideline**
 - ▶ Perspective: public healthcare
 - ▶ Outcome: QALY
 - ▶ Comparator: Technology, reimbursed by public health insurance, widely used in clinical practice before the introduction of the technology
 - ▶ Evidence with higher internal and external validity is preferred as the sources of clinical evidence
 - ▶ Uniform fee schedule used for calculations of costs

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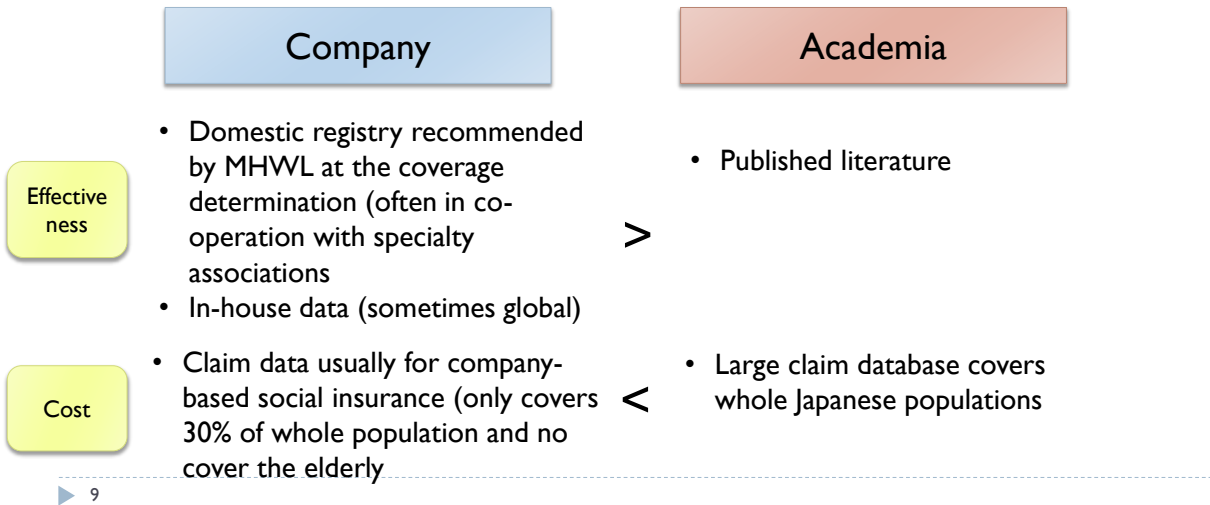
Challenges in assessing medical devices in Japan

- I. **Devices are assessed under the same methodology used for pharmaceuticals**
 - ▶ Evidence level tend to be lower
 - ▶ Some data are not existed (e.g., QOL data for Japanese people, clinical data for sub-population)
- Real-world data (RWD) becomes more important in this field

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Challenges in assessing medical devices in Japan(cont.)

2. “Asymmetric information” for RWD b/w the company and the academia



Challenges in assessing medical devices in Japan (cont.)

3. Low experience of economic evaluations particularly for domestic companies which farm size is relatively small

Company name	Company	Sales (approx.)
Kawasumi Laboratories	Domestic	0.2 bil. \$
Medtronic Japan	Global	30 bil. \$
Boston Scientific Japan	Global	9 bil. \$
St. Jude Medical Japan	Global	6 bil. \$
Japan Tissue Engineering	Domestic	2 mil. \$
Edwards Lifesciences	Global	3.5 bil \$

4. However, ICER number is directly connected to the price (and then to the sales)

- ▶ Small ICER difference counts (particularly for small companies), but ICER in EE of devices bears uncertainty (e.g., evidence consistency, learning curve)

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Challenges in assessing medical devices in Japan (cont.)

5. Difficulty in assessing broader value of devices

- Real option values and technological spillovers
- Equity (regional difference during early adoption phase)

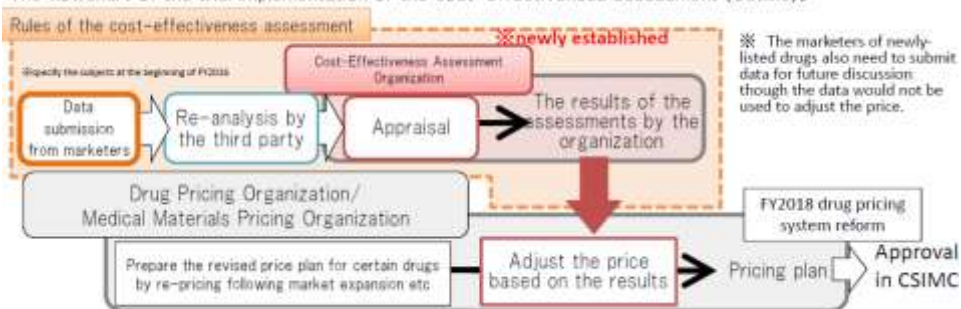
6. Patient involvement is minor

- ▶ The roles of patient may be important when quantitative evidence is limited

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Patient roles is now minor

The flowchart of the trial implementation of the cost-effectiveness assessment (Outline)>



- ▶ The member of two organization (lower organizations of CSIMC) is unstated
- ▶ Meetings closed
- ▶ The role of patients has not been enlarged after official HTA

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<https://www.mhlw.go.jp/file/04-Houdouhappyou-11123000-lyakushokuhinkyoku-Shinsakanrika/price.pdf>

HTA for medical devices in Japan: in the future

- ▶ **The same guideline for drugs and devices**
 - ▶ different guideline?
 - ▶ educational program focusing on EE for devices?
- ▶ **Economic evaluations conducted independently b/w company and academia**
- ▶ **Access to RWD is varied between two sides**
- ▶ **Low experience of EE**
 - ▶ Frequent meeting during evaluations process?
 - ▶ Joint projects of evaluations sharing RWD?
 - ▶ Registry including comparator?

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HTA for medical devices in Japan: in the future (cont.)

- ▶ **ICER value directly change the price**
 - ▶ Pricing decision mechanism updated?
 - ▶ Updating HTA result using RWD more frequently?
- ▶ **Assessment of broader values**
- ▶ **Low patient involvement**
 - ▶ Different appraisal rules for devices?
 - ▶ Participation of patients officially in appraisal phase?

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Thank you for your attention!