

# **Outsourcing Implementation of Cost-**Effectiveness Evaluation by the Japanese Ministry of Health, Labour and Welfare

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## Background & Objectives

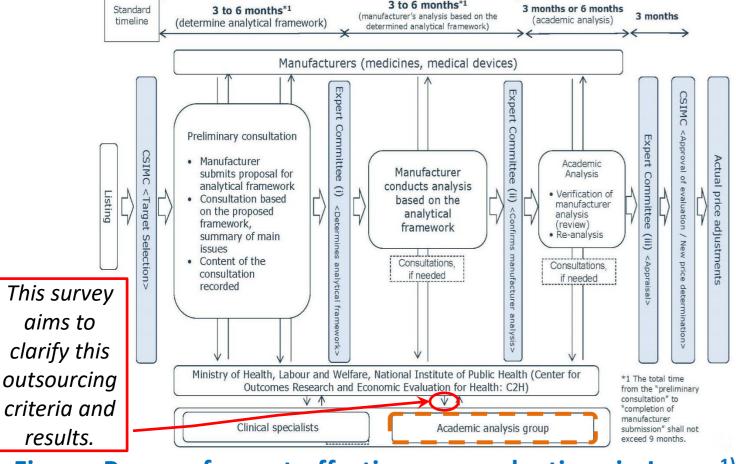
The Japanese national medical care expenditure is increasing, and it exceeded 43 trillion yen in 2017. In FY 2016/2017, a pilot implementation for the economic evaluation of pharmaceuticals and medical devices was conducted to provide efficient health care and pricing of health technology. Then, a new full-scale process was implemented in FY 2019 (Figure). However, the selections of executing academic agency of costeffectiveness evaluation for these pilot and new full-scale implementations remain obscure. A survey for the outsourcing of these pilot and full-scale implementations was conducted to clarify the executing institutions, participation requirements, and costs.

#### Methods

- Disclosure of administrative documents related to outsourcing contracts for public cost-effectiveness analysis was requested from the Japanese National Institute of Public Health (NIPH).
- ◆ The requested documents' period was from the beginning of the pilot phase to the end of June 2019. Relevant information about each item was summarized in tables.

### Results

- > Outsourcing contracts were signed with seven universities, one national institute for pilot implementation (16 items), and with two universities for full-scale implementation (50 items).
- > The unit costs for the pilot and full-scale implementation were approximately **US\$55,000 to \$124,000** and approximately \$226,000, per item, respectively.
- > Contracts were not awarded through competitive bidding, but they were discretionary.
- > Participation requirements for competitive bidding were stipulated (Table): a university or a national research and development agency that has experience in public cost-effectiveness analysis, no conflict of interest (COI) in the analysis target, and researchers participating in these analyses are approved by the Center for Outcomes Research and Economic Evaluation for Health, NIPH.



9 months (manufacturer's analysis)\*1

Figure. Process for cost-effectiveness evaluations in Japan 1)

#### Table. Requirements for full-scale implementation of economic evaluations Excessive restriction?

Item Be a university or national research organization with practical experience in pilot evaluation

- Establish a group that involves four or more faculty members (for five items per year, with at least one member at professor level or equivalent) and which occupies at least half of the members' effort
  - The appointment of full time members of the group in item 2 should be discussed in advance with the center. Accordingly, please submit a list of the full-time faculty members and off-campus personnel involved to C2H.
- Select the group leader (professor equivalent) from the list of full time staff submitted in item 2. Anyone who is not named in the list from item 3 must not be permitted to work on the project, even if they are a member of the institution
- The group of personnel selected in item 3 should be given an organizational name that makes it clear that it is affiliated with the full scale implementation of economic evaluations during this period.
- The personnel listed in item 3 must not receive donations, research funds, personal remuneration or goods of any value, regardless of the amounts involved.
- The personnel listed in item 3 must not come into contact with any representative or related staff of a manufacturer or retailer whose product is the subject of the full scale implementation of economic evaluations being conducted, except with the express permission of C2H.
- Any violation of items 6 or 7 will result in the immediate dismissal of the relevant personnel and may lead to contract
- All personnel selected in item 3 must report any conflicts of interest for a period of three years after commissioning. Any false statements with regards to the above will result in contract cancellation.

Note: These points have been reprinted by the author from the disclosed commission specifications.

"C2H" refers to the Center for Outcomes Research and Economic Evaluation for Health, National Institute of Public Health.

#### Conclusions

The implementation of a cost-effectiveness evaluation is cost-incurring. To implement it smoothly and sustainably, it is necessary to ensure the validity, accountability, and competitiveness of the outsourcing costs. It is important to act and/or re-consider the participation requirements for competitive bidding as soon as possible, to increase the number of universities and institutions that have experience in public cost-effectiveness analysis in Japanese settings.

Reference

1) Medical Economics Division, Health Insurance Bureau, Ministry of Health, Labour and Welfare (MHLW), and Full Scale Introduction of Cost-Effectiveness **Evaluations** Japan. Japan. 2019. https://c2h.niph.go.jp/tools/system/overview en.pdf

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**COI Disclosure Information MURASAWA Hideki** I have no financial relationship to disclose.