# How can we incentivize medical technology innovation through premium reimbursement in Asia Pacific: A case study discussion?

ISPOR APAC 2022 Issue Panel

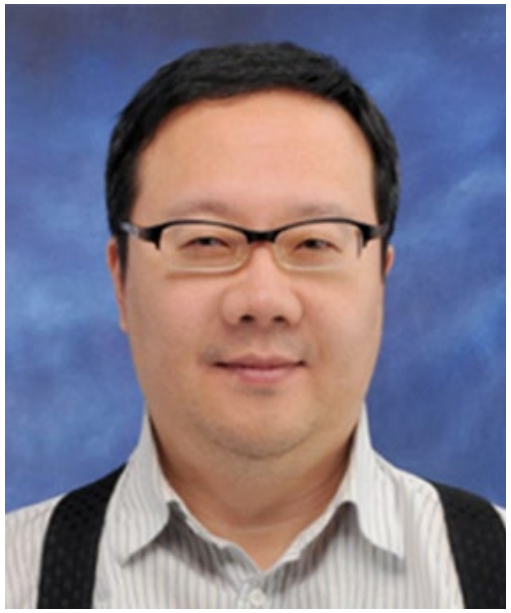
Sep 20th, 2022

Moderated by: Dr Viva Ma
Director, Strategic Access, Greater Asia, BD

# DISTINGUISHED SPEAKERS

Dr Yue XIAO
Department of Health Technology Assessment,
China National Health Development Research Center

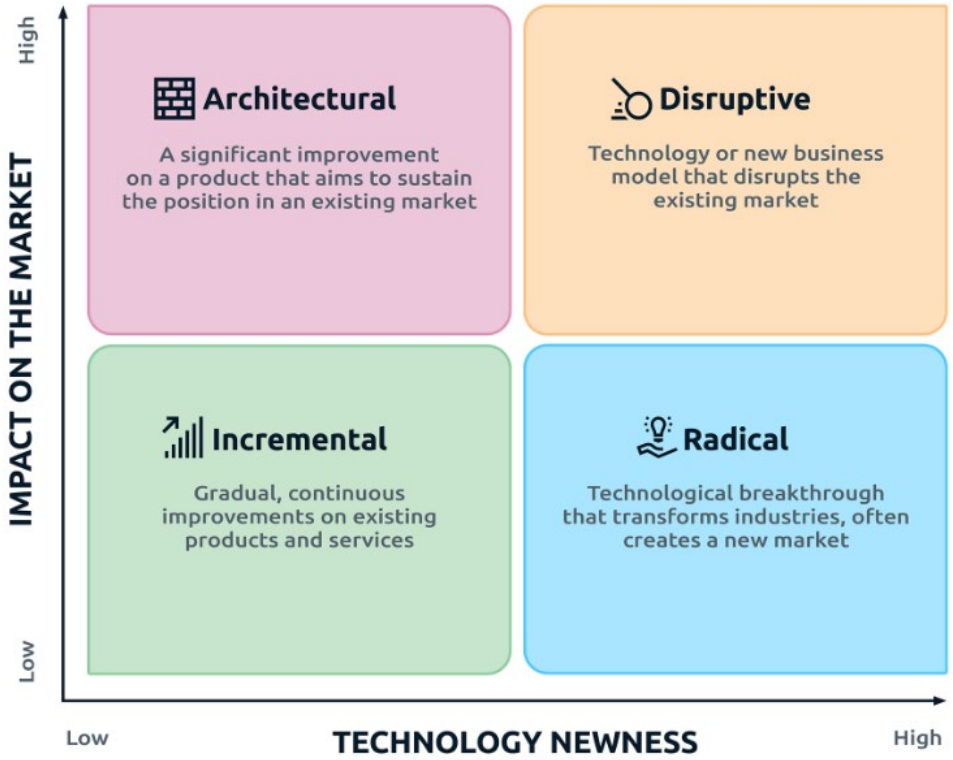
A/Prof Ataru IGARASHI
Graduate School of Pharmaceutical Sciences
The University of Tokyo



Prof Jeonghoon AHN
Department of Health Convergence
Ewha Womans University

# MEDICAL DEVICE INNOVATION

**Types of Innovation**[1]

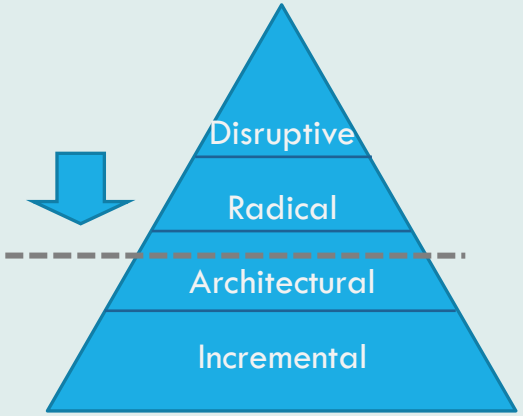



The Center for Device and Radiological Health (CRDH) proposed criteria for the FDA Innovation Pathway (to meet ≥1 below):[2]

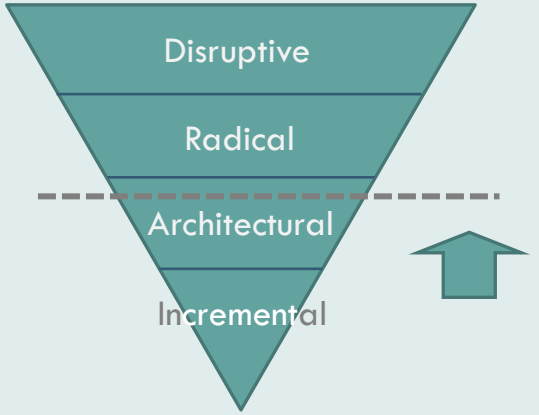
1. **significantly improve** upon currently available treatments or diagnostics for life-threatening or irreversibly debilitating diseases or conditions;
2. treat or diagnose a life-threatening or irreversibly debilitating disease or condition for which **no approved or cleared alternative** treatment or means of diagnosis exists;
3. address an **unmet public health need** as identified by the Council on Medical Device Innovation; or
4. address an issue relevant to **national security** such as vaccine development and medical counter measures.

Innovative medical devices can help to improve patient outcome, quality of services, and/or cost saving.[3] To improve health care results, we can:

**1. Lower the waterline for innovation eligibility**




**2. Incentivize more game changing innovations**



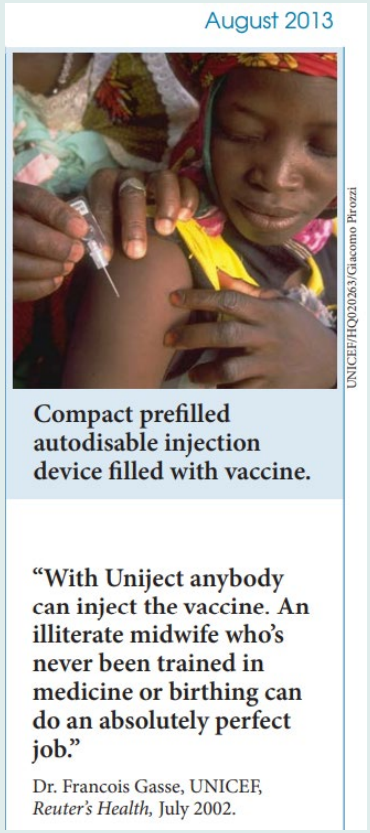


1. Dieffenbacher S.F. Digital Leadership. June 7th, 2022.
2. CDRH, U.S. FDA, CDRH Innovation Initiative, February 2011.
3. Campbell et al. Int J Technol Assess Health Care. 2018; 34(4): 419–424.

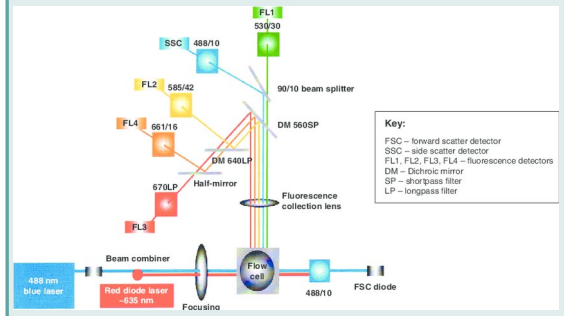
# CONCEPTS TO ALIGN

## Innovative Medical Device does not need to break the bank


According to WHO, the percentage of injections given with syringes or **needles reused** without sterilization is as high as 70% in some countries. At the same time, the use of multidose vials often leads to 50% of **vaccine being wasted or children being turned away** because health workers are reluctant to open a vial for just one child.




## Innovative Technologies will not be effective if patient cannot access




# Key considerations and challenges in evaluating innovative health technologies in China

**Yue XIAO, PhD, Research Fellow**

**China National Health Development Research Center**

**National Center for Medicine and Health Technology Assessment**

# Outline

01 Innovative health technologies in China

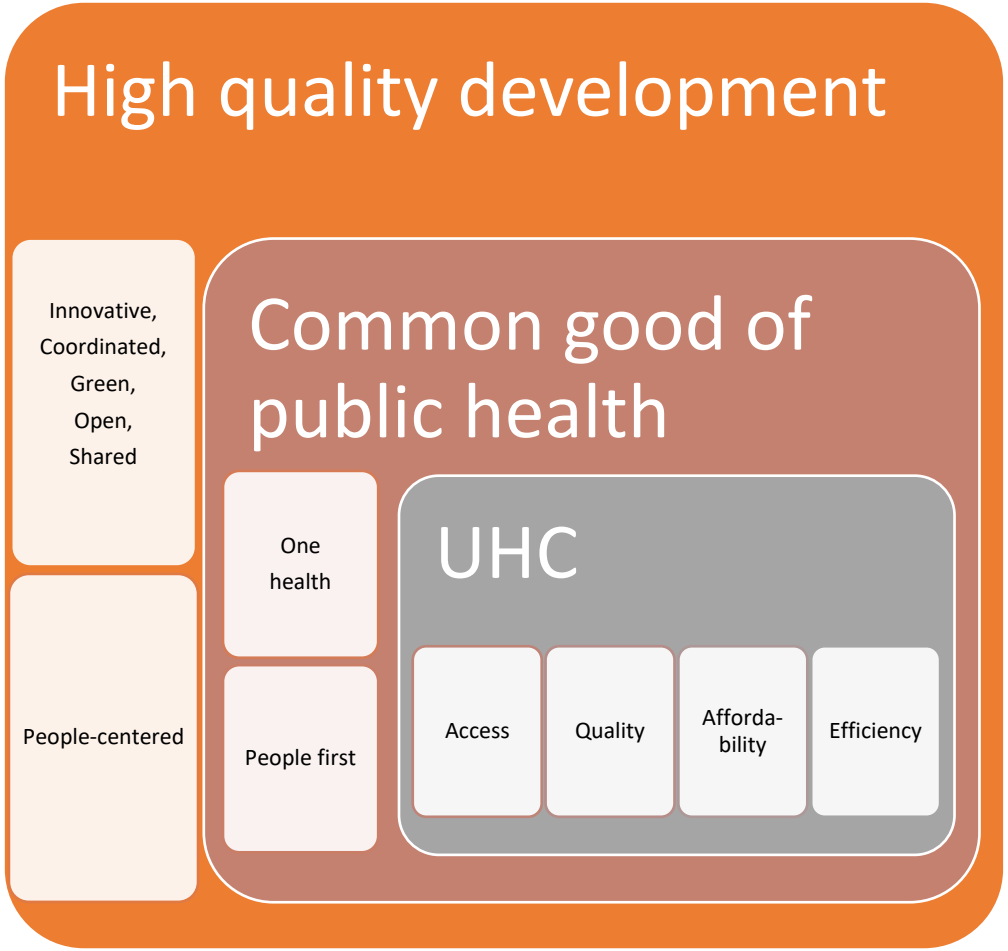
02 Key considerations and challenges

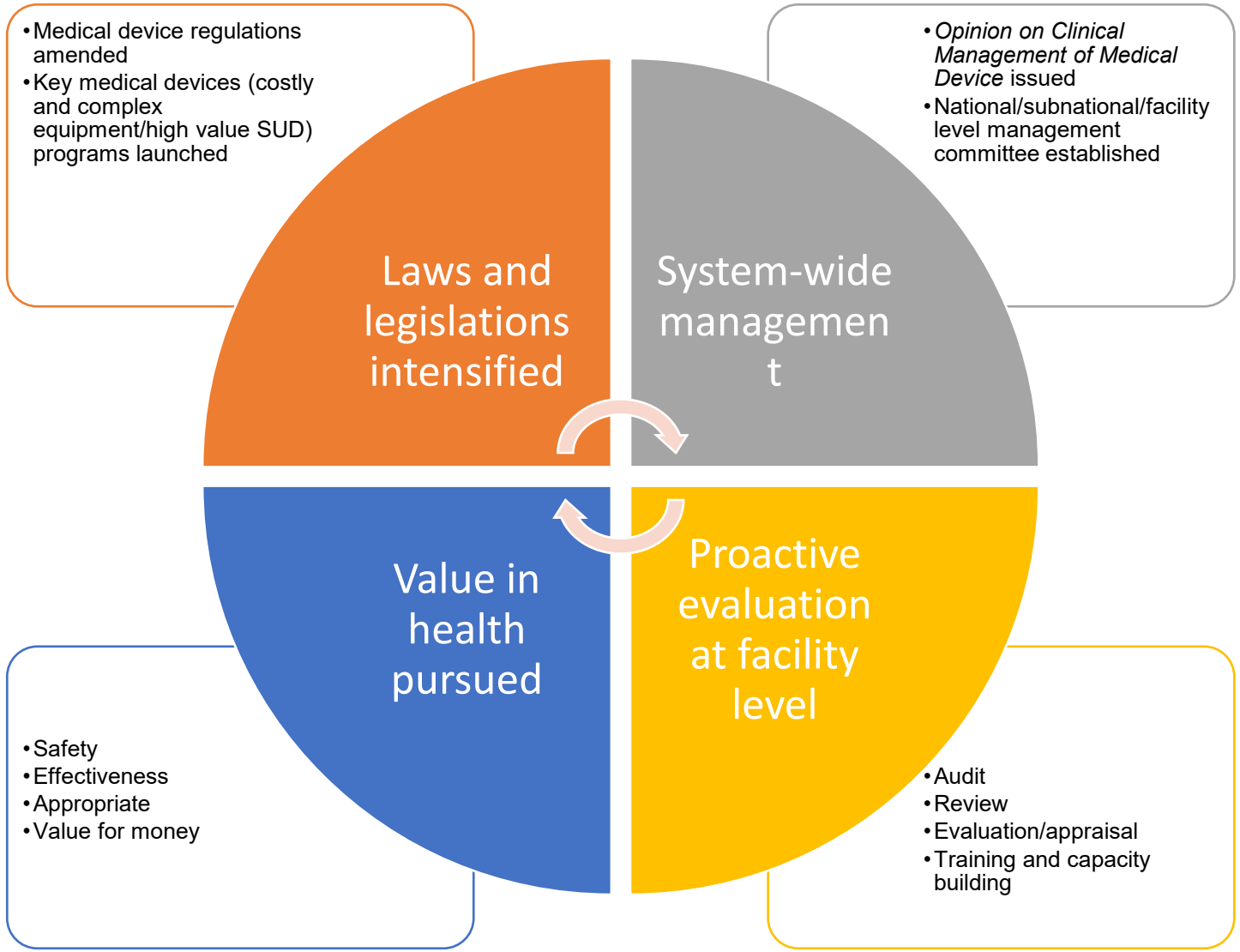
03 Forward looking

PART 1

# Innovative health technology in China

# Innovative health technologies in China



# Policy stance in the country

## S & T innovation emphasized

- Important role of science and technology in powering China's development;
- Institutional arrangement for R&D and rapid diffusion of innovative tech;

## Health technology innovation encouraged

- **Market access:** green light for innovative devices (-83 days/over 90 medical device products approved);
- **Pricing & payment policy:** special arrangement for innovative tech;
- **Procurement:** exemption from centralized procurement;

PART 2

# Key considerations and challenges

# Key considerations and challenges

## Access management

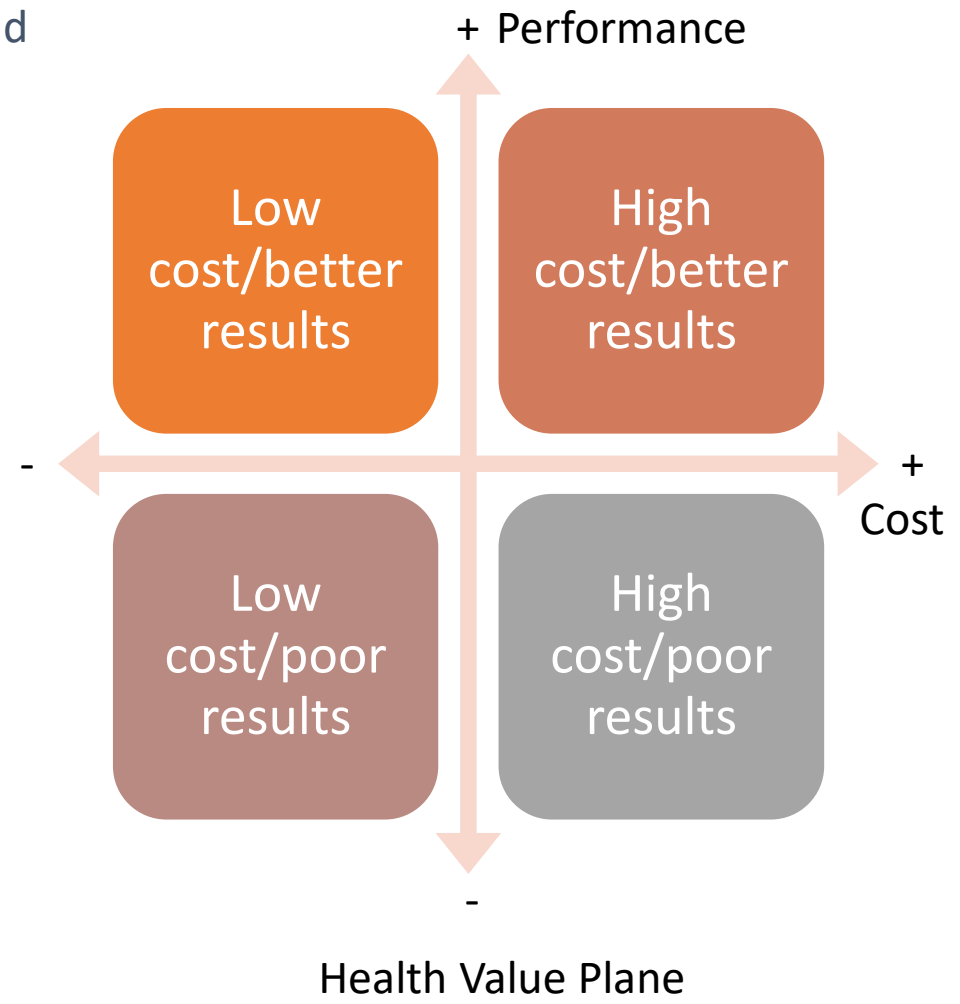
- **Institutional arrangement:** coordination of fragmented regulation and management policies;
- **Management tool:** Liaising market, clinical, and insurance access;

## Value definition

- **System-wide:** political commitment; socio-economic development; population health and demand;
- **Organizational value:** sustainable operation, quality development;
- **Individual values:** safety/effectiveness/value for money/appropriate

## Health financing issues

- **Who pay:** public finance; national payer, out-of-pocket, commercial insurer, charity;
- **How much to pay:** health fee schedule (cost and fee), listing and payment policy, negotiation and procurement;




Health Value Plane

# Case study

## Ultrasound-guided vacuum-assisted breast biopsy(VABB) in the diagnosis and treatment of breast masses in China

## Design and method

- RWS-based approach
- Systematic review + hospital survey+ patient survey +modeling + interviews/consultancy

## Deliverables

- produced policy report and technical report in 10 months

## Outcomes/impact

- Contributed to local knowledge on pricing and paying VABB
- Introduced patient's choice and willingness in judging value of innovative technologies

| | Hospital A | Hospital B | Hospital C |
|---|---|---|---|
| **Patients number** | 198 | 128 | 2717 |
| **Average age** | 51.05 | 37.86 | 38.78 |
| **Gender** | | | |
| **Male** | 1 | - | 2 |
| **Female** | 197 | 128 | 2715 |
| **Types of medical insurance（proportion）** | | | |
| New Cooperative Medical Scheme(NCMS) | 84（42.42%） | - | - |
| basic medical security for urban residents | 78（39.40%） | - | 9（0.33%） |
| basic medical security for urban employees | - | - | 2082（76.63%） |
| Free medical service | - | - | 55（2.02%） |
| At your own expense | 36（18.18%） | - | 571（21.02%） |

# Patients' preference and willingness to pay

| Changes | Willingness to pay（yuan）[a] | |
|---|---|---|
| **Operating time** | | |
| Be shortened to 20 minutes | 1275.9 | (-1278.0, 3829.9) |
| **Incision length** | | |
| Be shortened to about 3mm | 3866.0 * | (375.9, 7356.1) |
| **Incision number** | | |
| decrease to 1 incision | 9766.6 ** | (2907.0, 16626.2) |
| **Postoperative scar** | | |
| be improved to not obvious | 5137.4 * | (1022.0, 9252.9) |
| **Postoperative hematoma** | | |
| none | 8764.8 ** | (2526.5, 15003.1) |

Attribute importance (in order of importance)

- Number of incisions
- Postoperative hematoma
- Postoperative scar
- Incision length
- Out of pocket expenses

Optimal selection (in line with the characteristics of VABB surgery)

- 1 incision
- no hematoma
- The scar is not obvious and the incision length is about 3 mm

With the increase of out of pocket costs, the patients are less likely to choose the new procedure

[a]：95% confidence interval.

*：P<0.05；**：P<0.01；***：P<0.001

PART 3

# Forward looking

# Future HTA development in China

## Embracing complexity

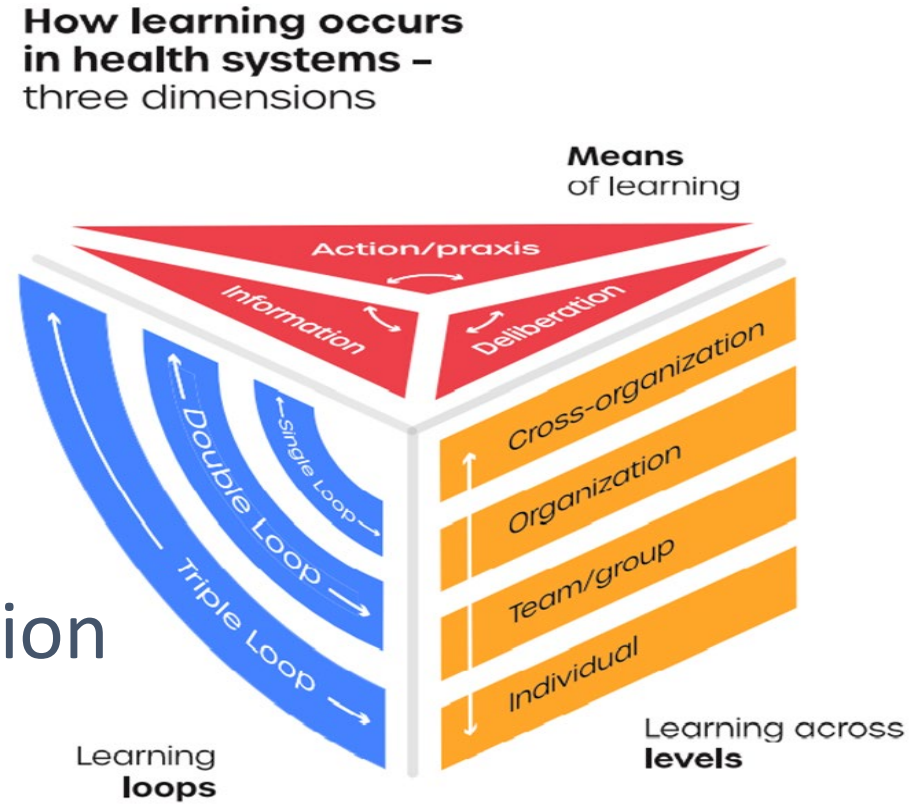
- Multiple dimensions and values
- System learning

## Taking a realist view

- RWD/RWE/RWS
- Conscious of limit of evidence and human knowledge

## Improving stakeholder communication

- Bridging gaps in knowledge




Sheikh K, Abimbola S, editors. Learning health systems: pathways to progress. Flagship report of the Alliance for Health Policy and Systems Research. Geneva: World Health Organization; 2021.


THANKS
谢谢

# The Value of innovation: Insight from Japan

**Ataru IGARASHI, PhD.**

**Unit of public health and preventive medicine, Yokohama City University**

**Dept. of Health Economics and Outcomes Research, Graduate School of Pharmaceutical Sciences, The University of Tokyo**

**atarui1@mac.com**

**20 Sep. 2020  ISPOR AP Summit**

# Overview of Japanese Healthcare system

- All people are covered by Public Health Insurance (HI) System since 1961

| Name | # of Insurers | # of Insured | characteristic | Co-payment |
|---|---|---|---|---|
| Employees' HI | 1,400 | 65Mil. | Employees under 74y | 30% for ordinal 20% for 70-74y |
| National HI | 1,900 (each city/town) | 38Mil. | Others under 74y | |
| Mutual aid association | 90 | 9Mil. | Civil servants under 74y | |
| HI for Aged population | 47 (each pref.) | 15Mil. | All persons >=75y | 10% |

**Basic package are almost the same throughout every insurers**

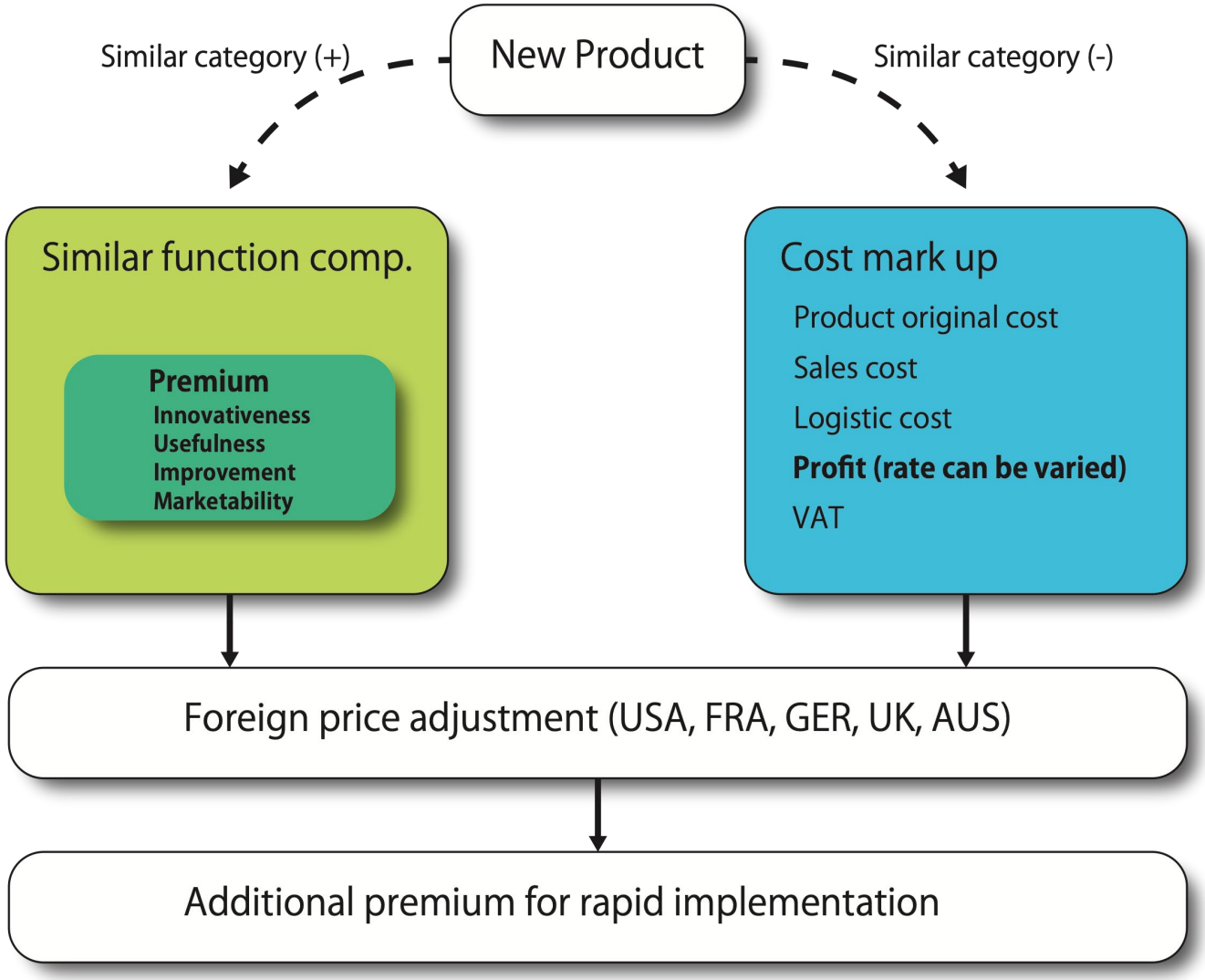
# Current system for giving premium for “innovative” product

| Category | Name | concept | example |
|---|---|---|---|
| C1 | New function | ”New subcategory” will be added | Artificial joint with special Processing |
| C2 | New function/technology | Entirely new category will be established | Capsule Endoscope |

# New system for giving premium for moderately “innovative” product from Apr. 2018

| Category | Name | concept | example |
|---|---|---|---|
| C1 | New function | ”New subcategory” will be added | Artificial joint with special Processing |
| C2 | New function/technology | Entirely new category will be established | Capsule Endoscope |
| B3 | Time-limited premium for improvement | Current subcategory plus “time-limited” premium | INSPIRIS RESILIA Aortic Valve |

# Pricing System for New devices (C1,C2,B3)



# Condition for Innovativeness, Usefulness and Improvement

## Premium for Innovativeness / Usefulness

A: Devices with new mechanisms which clinically useful

B: Devices which are superior to those within same category classification in terms of efficacy/safety with objective evidence

C: Devices which can upgrade the treatment strategy for targeted disease with objective evidence

## Premium for Improvement

A: Upgraded safety for healthcare providers

B: Less environmental impact of disposed products

C: Structural improvement (less invasive, fewer complications, etc)

D: Expansion of indication towards pediatric area

E: Structural improvement for more comprehensive (easier) intervention

F: Structural improvement for longevity

G: Structural improvement for in-home care

H: Similar function without bio-origin products

# Additional rule for enhansing innovation (since Apr. 2022)

- Two additional premium system

| | |
|---|---|
| **Premium for "First-in-Japan" Devices (SAKIGAKE)** | **Special premium (10%) for innovative product approved in Japan (no later than in US/EU)** |
| **Premium for specialized devices** | **Special premium (10%) for;**<br>**A) Pediatric area**<br>**B) Areas with huge unmet needs**<br>**C) Extremely valuable** |
| **"Mild" criteria will be applied for foreign price adjustment system** | |

# New rules starting from April 2018 (Challenge Application (Shinsei))

- It may took TOO LONG time for certain products to prove usefulness in particular with TRUE endpoint
  - Implantable product (Bioabsorbable stent)
    - At least 3y will be needed to prove superiority
  - Highly innovative product
- Conflict between ”rapid access” and “proving true usefulness”

# New rules starting from April 2018 (Challenge Application (Shinsei))

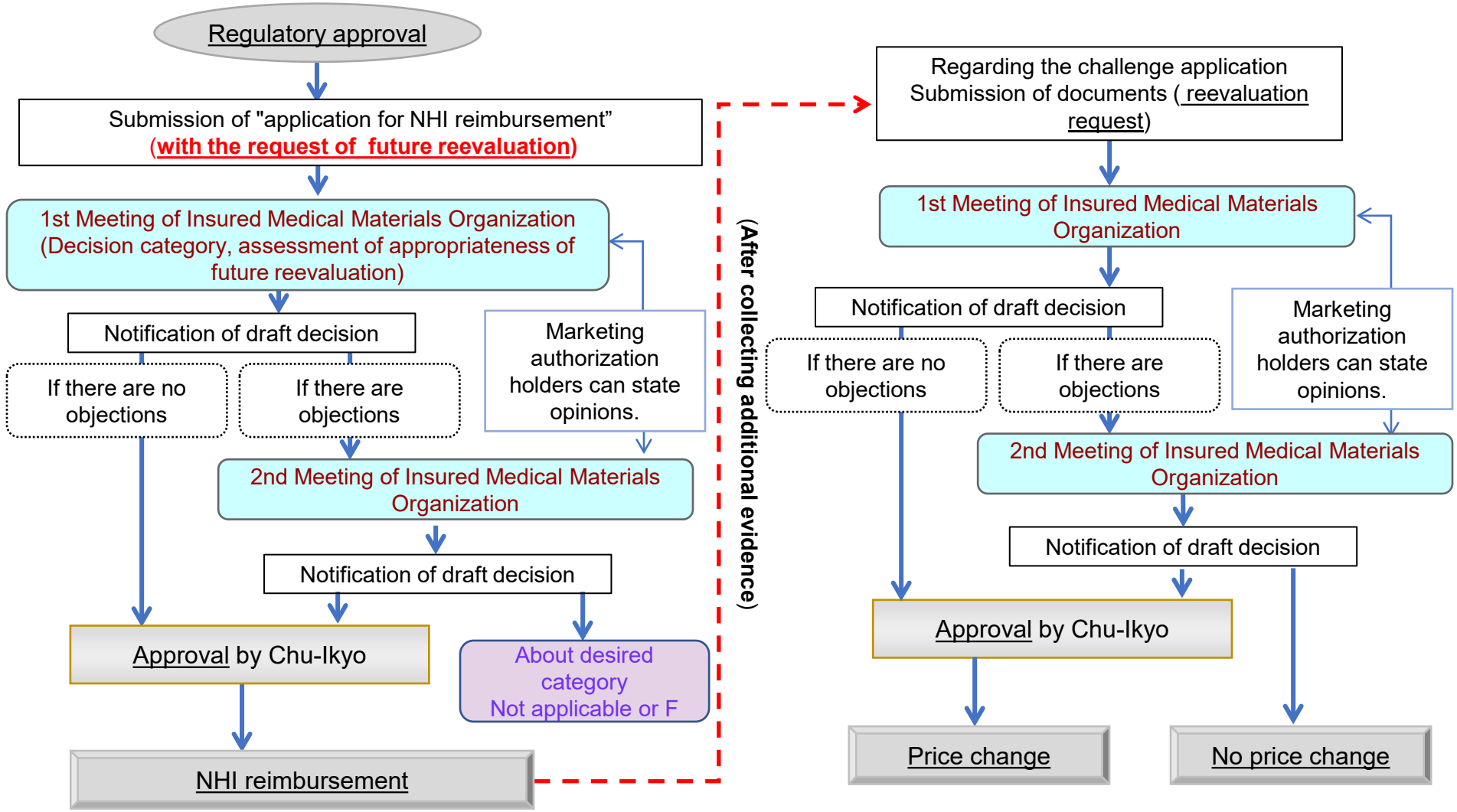
- Under Challenge Application system, Manufacture can request “C1 reclassification” after new evidence is sufficiently proved
- Manufactures have to declare that they shall use this system in future at the beginning of first negotiation process

**CED (Coverage with Evidence Development)-like system for long-term and unproven benefits**

# Rough (but complicated) sketch of whole process

[Normal scheme + scheme for assessment of appropriateness of challenge application]

[Challenge application scheme]

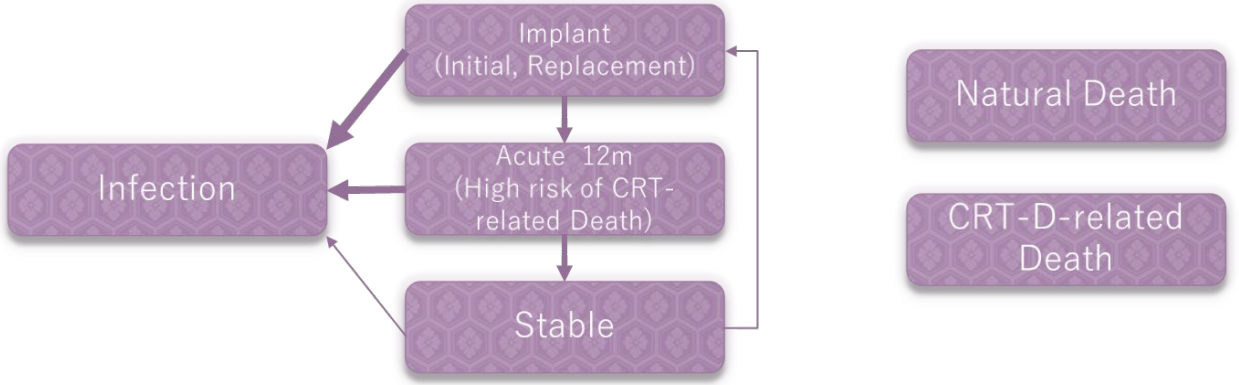


# Product got premium with “Challenge Application” system (as of Apr.2022)

| Product | | Function for challenge application | |
|---|---|---|---|
| Advisa MRI | Pacemaker | Reactive ATP | Improvement (3%) |
| Claria MRI CRT-D | Pacemaker (CRT-D) | Reactive ATP | Usefulness (3%) |
| Viva CRT-D | | | |
| RESONATE CRT-D | Pacemaker (CRT-D) | Longer Battery Life | Improvement (5%) |
| Aquala liner | Prosthetic liner | Longer product life (with polymer surface treatment) | Improvement (3%) |
| Expedium Verse Fenestrated Screw system | Spinal Fixation system | Lower rate for reoperation (for osteoporosis patients) | Improvement (5%) |

# Case for RESONATE system

- Simple cost-minimization analysis was conducted




**RESONATE system would save JPY700Million and avoid 6.0 CRT-death (per 1,000 patients)**

# When can new products get new sub-categories?

- “Device-Oriented” ERA to “Patient-Oriented” one

| | Hidden Concept | Premium will be given for… |
|---|---|---|
| **Past** | **Device (Technology)-Oriented** | **Products come with new Technology, System** |
| **Recent** | **Patient-Oriented** | **Products come with new (additional) clinical benefit for patients** |

# Robot-assisted laparoscopic surgery (da Vinci surgical system)

| Code | Name | Fee |
|---|---|---|
| K843 | Prostatectomy | 410,800 |
| K843-2 | Prostatectomy (Laparoscopic) | 774,300 |
| K843-3 | Prostatectomy (Laparo, small incision) | 597,800 |
| K843-4 | Prostatectomy (Robot-assist. Laparo) | 952,800 |

| Code | Name | Fee |
|---|---|---|
| K773 | Nephrectomy | 427,700 |
| K773-2 | Nephrectomy (Laparoscopic) | 647,200 |
| K773-3 | Nephrectomy (Laparo, small incision) | 498,700 |
| K773-5 | Nephrectomy (Robot-assist. Laparo) | 707,300 |

**Narrower indication but with additional premium against Laparoscopic Pros/Neph without robot**

# Broad expansion, but..,

| | Reimbursement status | | |
|---|---|---|---|
| Apr. 2018 | Mediastinum tumor | Mediastinum benign tumor | Lung cancer |
| | Esophagus cancer | Valvular heart disease | Rectal resection |
| | Gastrectomy | Proximal gastrectomy | Total gastrectomy |
| | Bladder cancer | Uterine body cancer | Total hystrectomy |

**Broader indication but WITHOUT additional premium against Laparoscopic surgery**

# Additional data collection for Gastrectomy

- Matched cohort study was conducted to evaluate mid-term efficacy of da vinci system

| Intervention (da vinci) | Patient treated in 2015-2017 with “advanced medical treatment” system |
|---|---|
| **Comparator (Laparoscopic)** | **Patient treated in 2009-2012 with ordinal health insurance system (Matched)** |

- Cost-effectiveness analysis data was attached to dossier for requesting premium, with better ICER/QALY

**Robotic Gastrectomy got premium since Apr.2022 against Laparoscopic Gastrectomy**

INNOVATION EWHA

# How innovative medical devices are evaluated under the nHTA and medical device reimbursement process in Korea?

ISPOR AP September 20, 2022

Jeonghoon Ahn
Department of Health Convergence

이화여자대학교
EWHA WOMANS UNIVERSITY

# Korean System: Institutions

| | Drugs | Medical Devices | Diagnostics and Procedures |
|---|---|---|---|
| HTA research (reports published) | National Evidence-based healthcare Collaborating Agency (NECA) | National Evidence-based healthcare Collaborating Agency (NECA) | National Evidence-based healthcare Collaborating Agency (NECA) |
| Approval | Korean Food and Drug Administration (KFDA) | Korean Food and Drug Administration (KFDA) | Committee for New Health Technology Assessment (CNHTA) |
| Review and Recommendation | Health Insurance Review and Assessment Services (HIRA) | Health Insurance Review and Assessment Services (HIRA) | Health Insurance Review and Assessment Services (HIRA) |
| | National Health Insurance Corporation (NHIS)* | | |
| Decision Making | Ministry Of Health and Welfare (MOHW) | Ministry Of Health and Welfare (MOHW) | Ministry Of Health and Welfare (MOHW) |

HTA report linked to CnHTA decisions

*For drugs, HIRA does dossier review and NHIS does price negotiation

From Ahn et al. 2012. Social Values and Healthcare Priority Setting in Korea. *Journal of Health Organization and Management* **26**(3):343-350

# Value based Assessment for Innovative Health Technology

- Overview

- Some high technologies based treatment or diagnosis (ex, 3D printing, Robot, AI, VR, AR …) **have difficulties in accumulating evidence, but social needs and values are high**
- **MOHW decided to approve innovative health technologies** by value based assessment (safety must be ensured in advance)
- Pilot project was conducted (from Sep 23rd, 2018)
- Regulations were revised (March 15th, 2019)
- By July, 2022 **30 applications ->10 assessment targets -> 7 cases were approved**

# Value based Assessment for Innovative Health Technology

- Criteria Determining Target to Assess

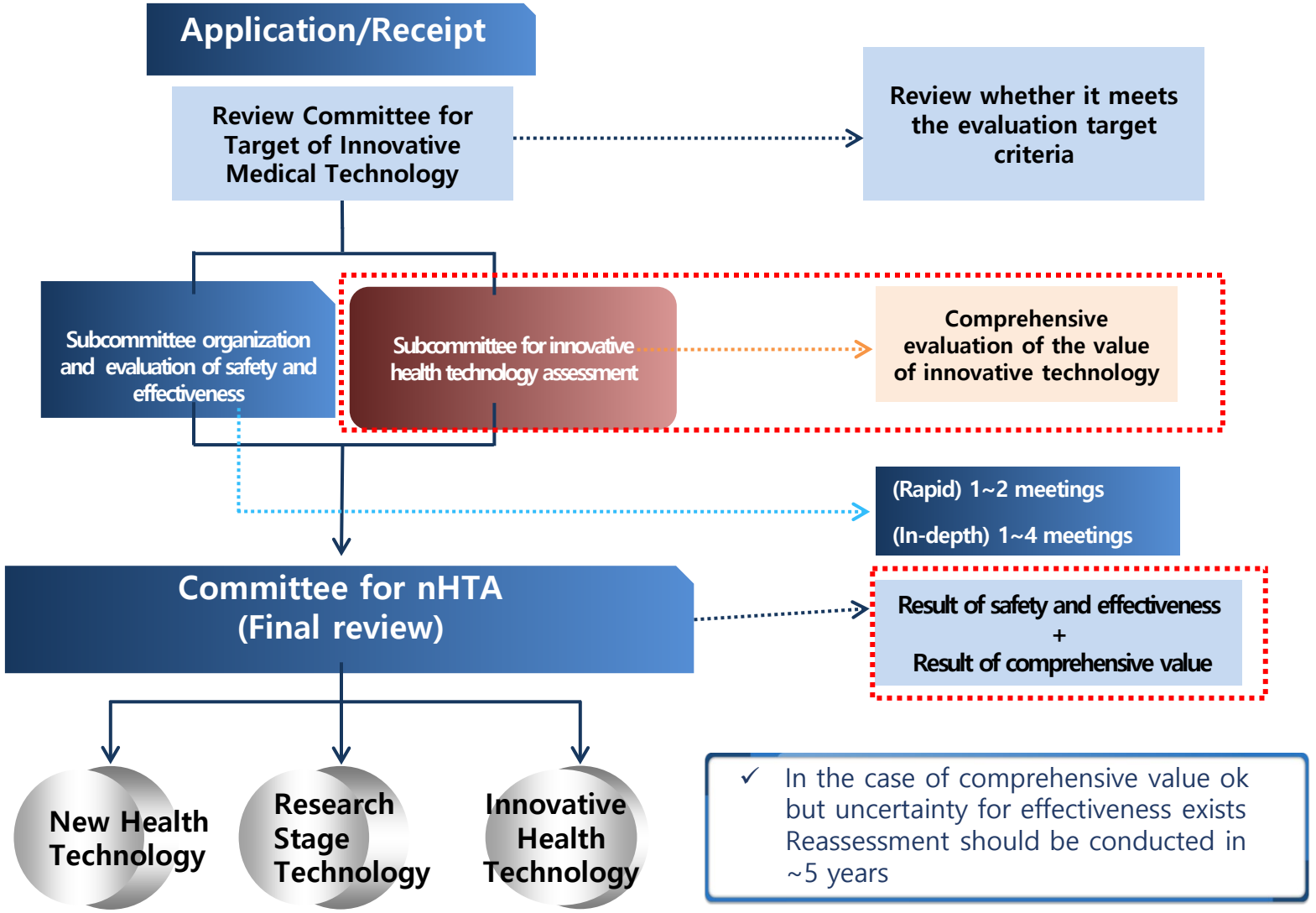
| | Criteria |
|---|---|
| **Technical Property** | Customized health technologies |
| | Using innovative devices and/or technologies |
| **Social Property** | Diseases with high social needs |
| | Absence of alternative technology |
| **Medical Property** | Patient centered technologies |
| | Medical outcomes improvement |

# Value based Assessment for Innovative Health Technology

- Assessment Criteria

- **Importance of the disease**
- **Rarity of the disease**
- **Physical burden of patient**
- **Quality of life**
- **Economic burden of the patient**
- **Possibility of abuse**
- **Presence of alternative technology**

# Value based Assessment for Innovative Health Technology



# Value based Assessment for Innovative Health Technology

- Application and Assessment Result (2018.9.14.~2022.7.31.)

| | Total Number of Application | Non Target | Assessment Target | | | |
|---|---|---|---|---|---|---|
| | | | Total | New Health Technology | Innovative Health Technology | Research Stage Technology |
| year | 30 | 20 | 10 | 2 | 5 | 3 |
| 2019 | 10 | 8 | 2 | 1 | 1 | 0 |
| 2020 | 12 | 7 | 5 | 0 | 3 | 2 |
| 2021 | 6 | 3 | 3 | 1 | 1 | 1 |
| 2022 2nd Quarter | 2 | 2 | 0 | 0 | 0 | 0 |

- 16 out of 30 cases were reapplications after failing nHTA
- Advanced medical technologies are 40% (12/30)
  - 3D Printing (7), Robot (1), AI (1), Precision Medicine (2), Regenerative Medicine (1)
- Application to Target Ratio = 33% (10/30)
- Target to Approval Ratio = 70% (7/10)

# Value based Assessment for Innovative Health Technology

- Approved Cases (2018.9.14.~2022.7.31.)

| No. | Technology | Approved Period |
|---|---|---|
| 1 | Genetic Diagnosis for Gastric Cancer Prognosis Prediction [Real-time PCR] | '19.11.1.~'24.10.31. |
| 2 | Electromyography-driven hand robot assisted rehabilitation therapy* | - |
| 3 | Prognostic Test for Early Breast Cancer Patient based on the Gene Expression Signature through the Alogrithm | '20.12.1.~'25.11.30. |
| 4 | Autologous Peripheral Blood Stem Cell Treatment for Myocardial Regeneration in Acute Myocardial Infarction | '20.12.1~'25.11.30. |
| 5 | Customized 3D printed Breast Cancer Surgery Guide in Breast Conserving Surgery | '21.9.1.~'26.8.31. |
| 6 | Application of 3D CT based Patient Customized Surgical Guide in Artificial Shoulder Joint Replacement Surgery* | - |
| 7 | Application of Patient Customized Guide for the Manufacture of Prostheses in Orbital Wall Fracture Repair | '22.4.1.~'27.3.31. |

* Approved both innovative health technology and new health technology

# Value based Assessment for Innovative Health Technology

## ▪ Approved Cases

### 1. Stomach cancer prognosis prediction algorithm

(safe and has possibility to provide customized prognosis information to stomach cancer patients)

### 2. Robot assisted orthopedic exercise device

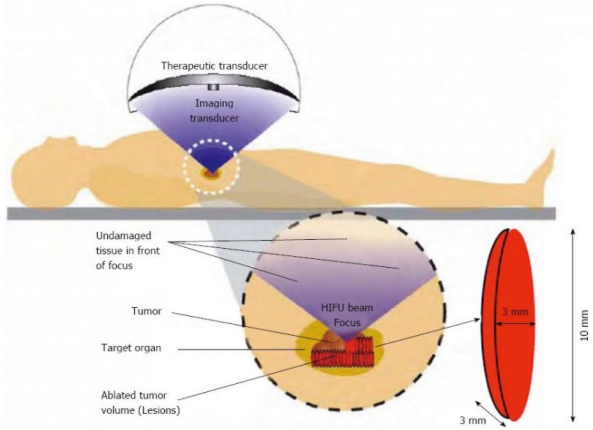
(safe and could be same or more effective than a rehabilitation therapist does)

**[Improve timely access to new safe technologies and the patient's quality of life]**

# Value based Assessment for Innovative Health Technology

- Rejected Case due to safety issue

## 1. Ultrasound guided high intensity focused ultrasound for pancreatic cancer


Target : end-stage pancreatic cancer patient

Safety may vary depending on the treatment range – large distribution of nerves and blood vessels around pancreas

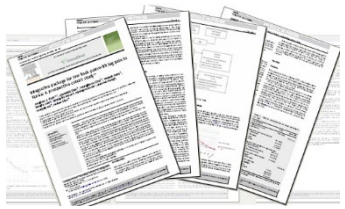
∴ Insufficient evidence for safety

# Value based Assessment for Innovative Health Technology

- Related Regulation
  - **[ Regulations on The Assessment and Implementation of Innovative Health Technologies]**

- After approval

1. **Real World Data (RWD) accumulation for 5 years**
2. **New Health Technology Assessment with (RWD, Literature evidence)**
3. **Formal health insurance registration (HIRA)**



# Thank you!

E-mail: ahnjeonghoon@ewha.ac.kr