

Three topics today

RWD usage in HTA

Possibilities, a view from Industry

Comprehensive Support Project
Health Outcomes Research Project
9th Annual Meeting - Tokyo, June 27, 2015

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1. Bayer HTA readiness
2. Feedback from HTAi 2015, Oslo
3. A gift for researchers

医薬品企業の取り組み

- "HTA Readiness"
- Organisation, Skills, Support
- Alone / Industry together
- Projects and examples

A limited point of view

- Pharmaceutical
- Medical Device
- Diagnostic
- Consultant
- Japanese multinational
- Affiliate of foreign multinational
- Domestic pharmaceutical company
- Biotech venture company
- "Individual company" vs. Industry Association"

Our HTA readiness

- Learning from meaningful examples overseas
 - Relevant for Japan - Understand the context
 - Company drive + own research and contacts
- Recruit, guide and develop staff
 - Present, publish, engage stakeholders
- A real opportunity to learn, by doing
 - Joining international projects, international staff exchange and rotations
 - Our own, stand-alone studies and projects in Japan
 - Studies and publications from Japan, to be used outside of Japan
- Improve ourselves continuously, attend courses
- Join professional societies: ISPOR, DIA, JSPE, HTAi

← Mix of recruit overseas and in Japan

← DIA-Japan October 2

Economic considerations are only one small part of HTA

The nine domains of HTA
Health problem and current use of technology
Description and technical characteristics
Safety
Clinical Effectiveness
Cost and Economic Evaluation
Ethical analysis
Organisational aspects
Social aspects
Legal aspects

Different healthcare systems, values and practices require different HTA archetypes

What do we want learn, from Japan?

What do we to transpose and adopt in Japan?

<ul style="list-style-type: none"> • National Health Insurance <ul style="list-style-type: none"> • Single Payer • Multiple Payers • Mix of Public + Private health care providers • Scope of patient co-pay, Complementary health insurance • Tax-based <ul style="list-style-type: none"> • Single payer • Often Public providers • Parallel systems <ul style="list-style-type: none"> • Private or Integrated healthcare (Managed Care) • Public (US Veterans, Medicare, etc.) • Emerging Universal Health Care Coverage 	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> Access Rationing Prevention funded, or not? </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> Society Age Gender Caregivers </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> Outcomes tracked? Guidelines updated and implemented? Costs comparable? </div> <div style="border: 1px solid black; padding: 5px;"> Data Available? Accessible? Consistent? </div>
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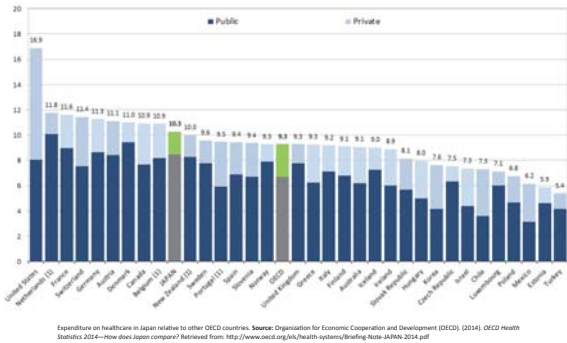
Different healthcare systems, values and practices require different HTA archetypes

What do we want learn, which is useful for us in Japan?

What could we to transpose and adopt [adapt] in Japan?



Health spending in OECD in % of GDP



Learn and practice

- Global Value Dossier
- Net Clinical Benefits
- Economic Models (CE or rather BI)
- Price Strategy
- Price Submission & Negotiation
- Continuous Data Generation
- Access Channels
 - Medical Education (Doctors, Nurses, Pharmacists, Technicians)
 - Patient Education (esp. if devices, AE)
- Societal needs
- Disease burden
- Unmet needs
- Medical Practice
- Comparators
- Funding
- Rx decision (Drs)
- Patient insights
- Caregiver
- Product specifics, e.g. CDx, drug-device combination
- Distribution: HP, pharmacy, physical access (cold chain, RI)
- Clinical Development
- Post-Marketing Surveillance
- Study end-points
- PRO tools (usage, validation of new tools)
- Epidemiology
- Treatment patterns
- Cost of therapy, Medical fees, Healthcare Resource Utilisation
- Database studies
- Patient profiles
- Patient surveys, Patient preference studies
- Caregiver surveys

A particular challenge: A study comparing Physician and Patient Preferences

- Title: Comparing Patient and Physician Risk Tolerance for Bleeding Events Associated with Anticoagulants in Atrial Fibrillation - Evidence from the United States and Japan
- Citation: Okumura K, Inoue H, Yasaka M, et al. Comparing Patient and Physician Risk Tolerance for Bleeding Events Associated with Anticoagulants in Atrial Fibrillation - Evidence from the United States and Japan. Value Health Regional 2015; 6: 65-72.
- Synopsis Author: Ken Okumura
- Anticoagulants are crucial in preventing stroke among patients with atrial fibrillation (AF) but are associated with bleeding risks. Recent studies have shown that a substantial proportion of AF patients receive subtherapeutic levels of anticoagulation because of concerns about bleeding. Using a discrete-choice experiment, we evaluated how the relative importance of treatment-related benefits and risks are perceived and vary between patients and physicians in the U.S. and Japan. U.S. patients and physicians were willing to accept similar levels of non-major clinically relevant bleeding risks when they were consequences of preventing disabling strokes. In contrast, Japanese patients were willing to accept four times the level of such risk than Japanese physicians as a consequence of preventing disabling strokes.



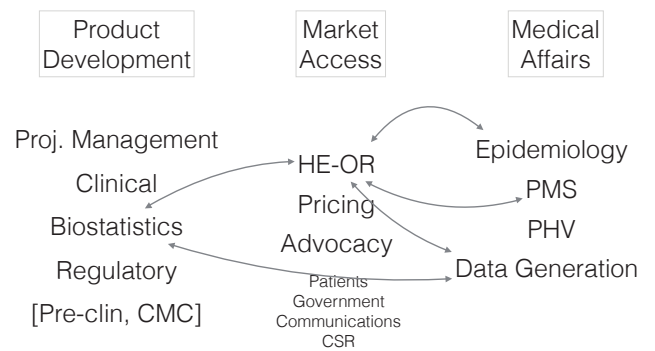
Areas for improvement: Working as an integrated team, in a new environment, with new regulators and stakeholders



External requirements, internal challenges, resources and complexity vary by company

- Japanese multinational
 - Affiliate of foreign multinational
 - Domestic pharmaceutical company
 - Biotech venture company
 - "Individual company" vs. Industry Association"
- Higher opportunity to exchange best internal practices

Organisation models



Thank you.
Questions during the panel