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Development Environment for medical devices in Japan and the United States: Impact on current activities and the roles of clinical engineering (CE)

June 11 | 8:00-9:00

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Agenda

- Introduction of clinical engineer system in Japan
- Recent movement of medical device development in Japan
- Intellectual properties and medical professions
- JACE Medical-Academia-Industrial Collaboration Committee

The author has no conflict of interest to disclose concerning the presentation.

Introduction of Clinical Engineer System in Japan

Clinical Engineers : Japan

- Clinical Engineer License System

  Established in 1987
  National License

- Education

  4 years education in university
  or
  3 years education at a polytechnic college

The Facts

Operating Equipment in the Clinical Environment 40%

- Respiratory therapy
- Perfusion (HEART-LUNG machine)
- Dialysis (Dialysis equipment)
- Operative treatment (Surgical equipment)
- Intensive care units
- Cardiac catheterization
- Hyperbaric oxygen therapy
- Other treatment (defibrillators)
- Pacemakers
- Implantable cardioverter defibrillators (including CRT-D)

Service Delivery Management 20%

Patient Safety 20%

Healthcare Technology Management (HTM) 20%

Our Clinical Fields *(a case of Aso Iizuka Hospital)*

HTM

Haemodialysis

Operation Room

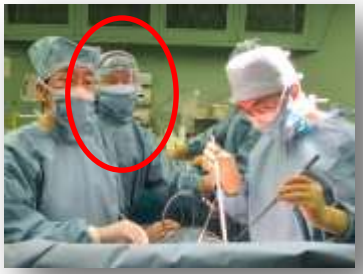
Perfusion

Intensive Care

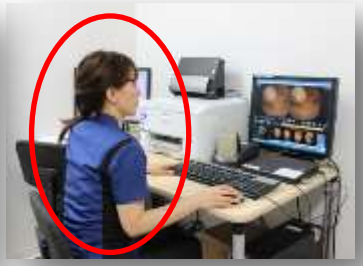
Endoscopy

Cardiac Catheter (intervention)

Hyperbaric Oxygen Therapy



Operation Assistance



Capsule Endoscopy (Interpretation)

Pacemaker Clinic

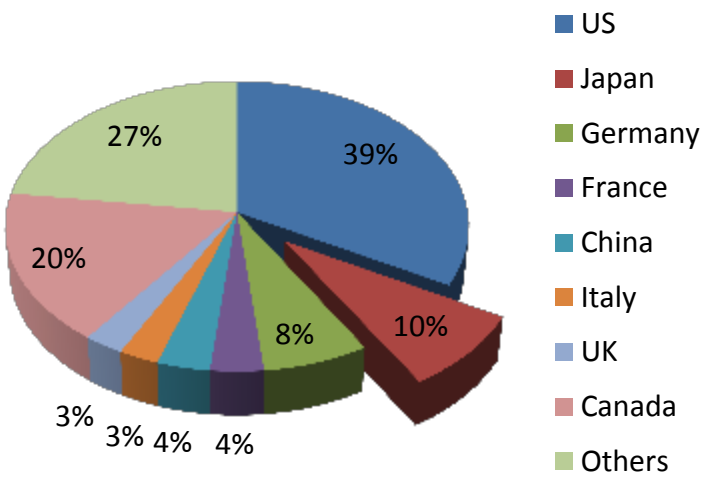
Staff Education

Recent Movement of Medical Device Development in Japan

Japan Association for Clinical Engineers (JACE)

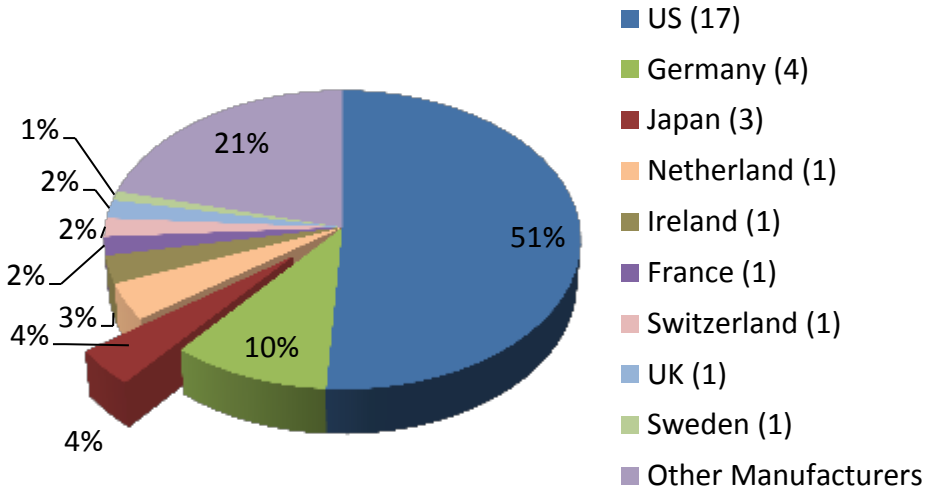
ASO IIZUKA HOSPITAL

Japanese Medical Device Market



Market Size of Medical Device

espicom "Medistat Worldwide Medical Market Forecasts to 2017"



Market Share of Top 30 Device Manufacturers

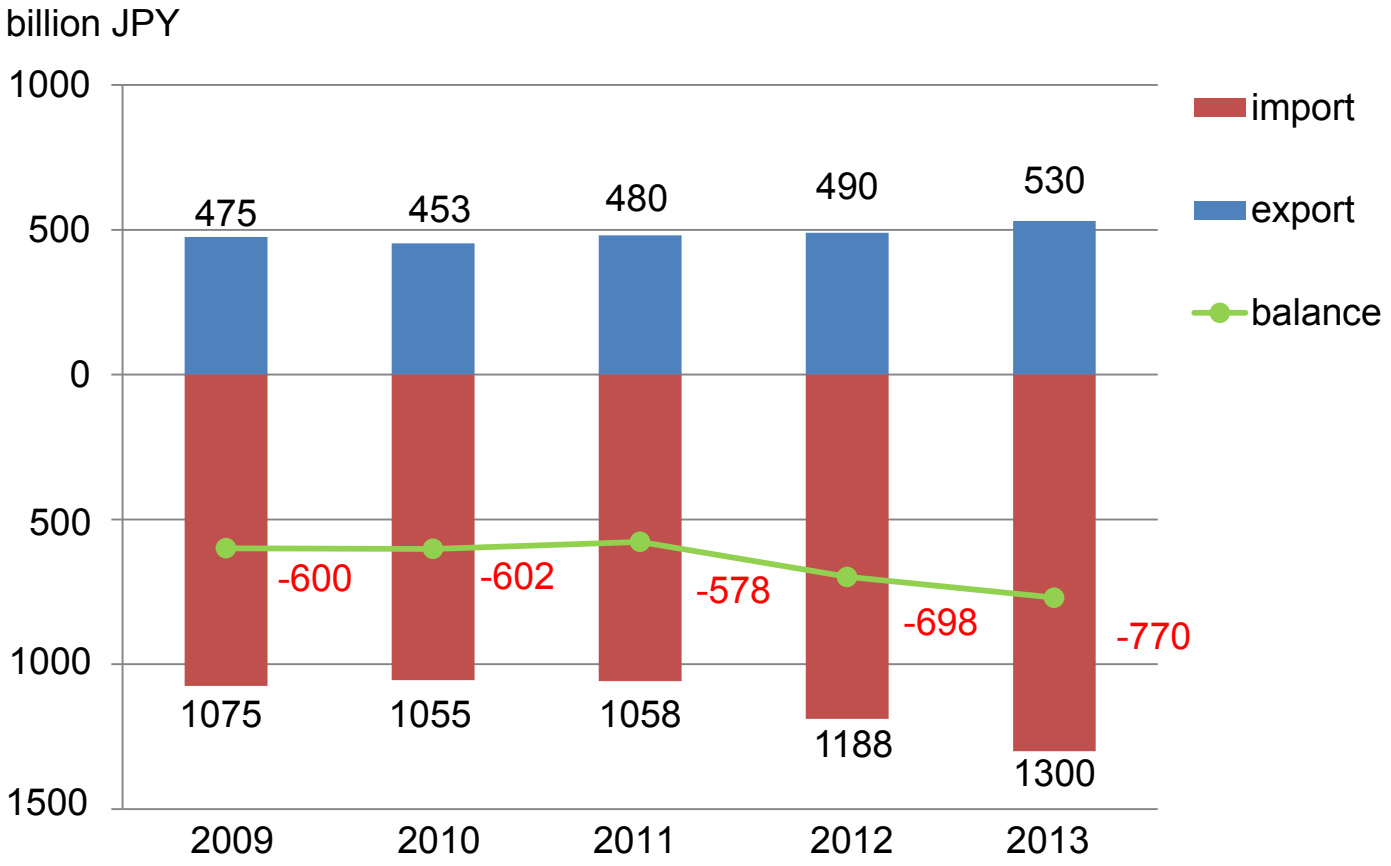
Rodman Media "TOP 30 MEDICAL DEVICE MANUFACTURERS (by FY12 revenue)"

Japanese Market Size of Medical Device and the Import Rate

	Domestic Market (billion JPY)	Import Rate (%)
Therapeutic	1256.4	51
Diagnostic	612.6	28
Total	**2386.0**	**44**

MHLW "Annual Report on Statistic of Pharmaceutical Industry"

Japanese Trade Balance of Medical Devices



Japanese Trade Balance of Medical Devices

Data from: MHLW "Annual Report on Statistic of Pharmaceutical Industry"

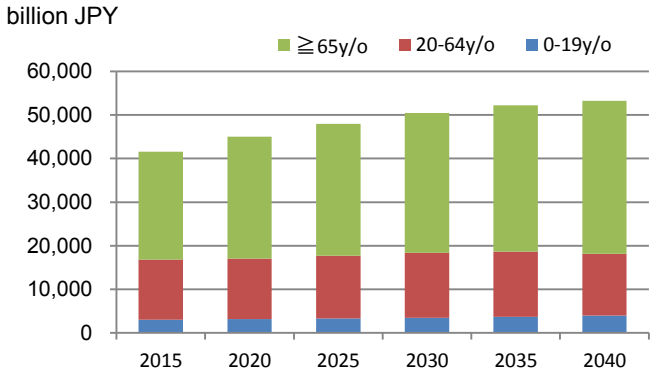
Recent Movement

Japanese government issued New Growth Strategy "Japan Revitalization Strategy - Japan is Back -"

The policy is a mix of the "three arrows" for reviving the Japanese economy:

(1) Aggressive monetary policy
(2) Flexible fiscal policy
(3) A growth strategy that encourages private sector investment

From: The office of the Prime Minister of Japan



Estimating Future Medical Expense in Japan

Data from "Japan Medical Association Research Institute"

Barriers of Device Development

Strict regulatory and time consuming approval process

Difficulty of fundraising

Seeds or academic oriented development

Lack of human resources in project management

The Situation is Changing

Strict regulatory and time consuming approval process

Central and local governments are implementing variety of aggressive measures and taking strong actions

Difficulty of fundraising

Variety of public subsidies
Increasing public and private financing institutions

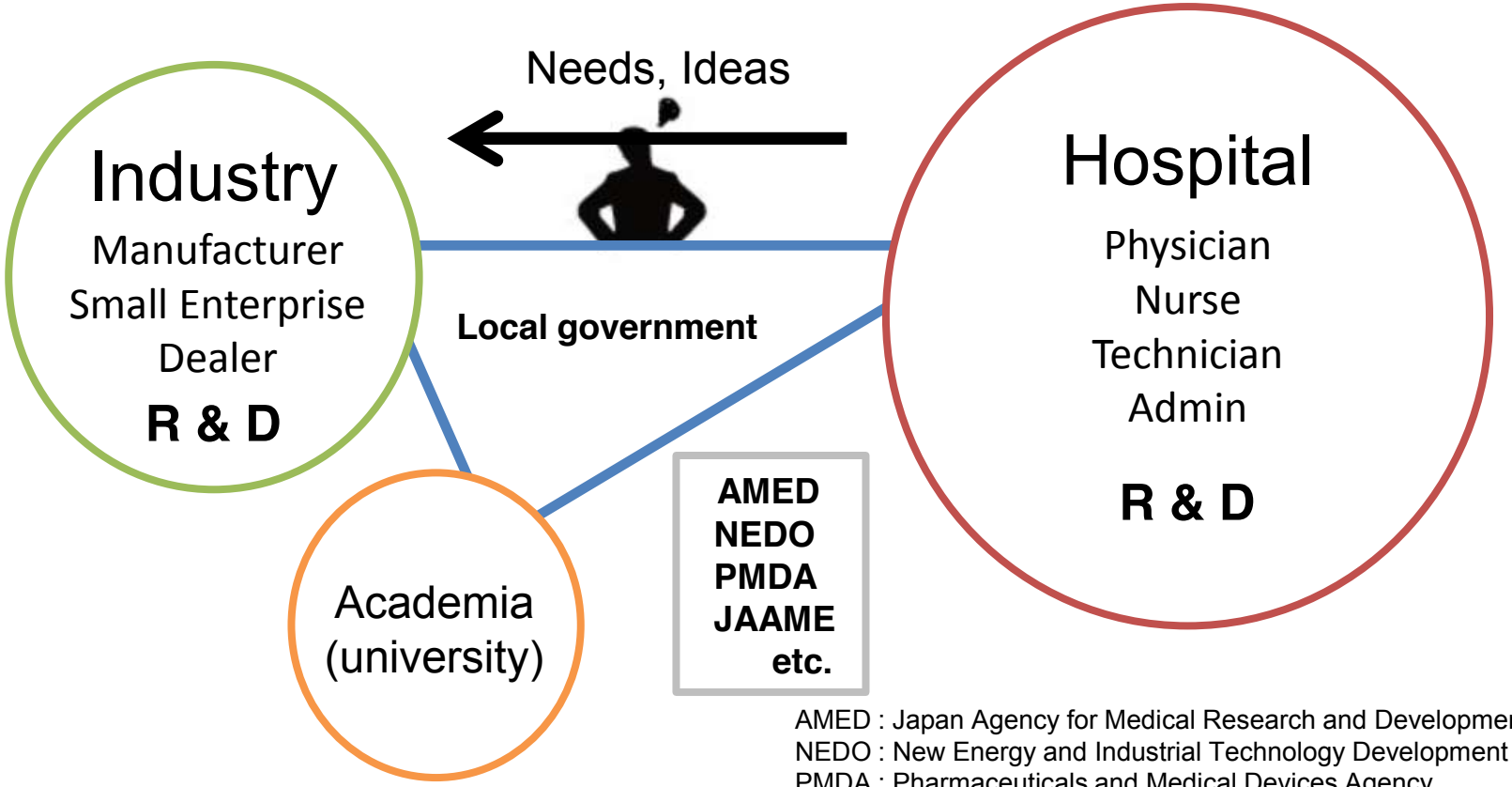
Seeds or academic oriented development

Some movement of shifting to needs oriented development

Lack of human resources in project management

Education courses in some universities
e.g. Biodesign course in three universities

Medical-Engineering Collaboration



AMED : Japan Agency for Medical Research and Development
NEDO : New Energy and Industrial Technology Development Organization
PMDA : Pharmaceuticals and Medical Devices Agency
JAAME: Japan Association for the Advancement of Medical Equipment

- Poor evaluation of needs and ideas (clinical perspective)
- Lost in translation between the industry and clinical field

Expected Roles of Clinical Engineers in Device Development

- Evaluation of needs and ideas
- Translation between industry and the medical field
- Promotion of the activities
- Gathering information and summarization

Intellectual Properties and Medical Professions

Intellectual Properties

- **Patent** (Patented invention)
- **Utility Model**
- Design
- Trademark

Not many medical professions including physicians and CEs are involved in medical device development especially with IP strategies.

Cultural Background

- 医は仁術 i-wa-jinjyutsu

  Medicine is benevolent act or humanitarian profession.

- Japanese Medical Law

  Notwithstanding the provisions of the preceding paragraph, the permission set forth in paragraph (1) may **be refused to a person who wishes to establish a hospital, clinic or birthing center for profit**.

  Article 7-4 of the Medical Care Act (Act No. 205 of 1948)

Medicine  Money

Other Factors

- Most of hospitals, clinics don't have any rules, regulations or policies concerning IP.
  (except university hospitals, national centres, etc.)

- Medical professions serving for public institutes may not be allowed to receive extra income
  (side job prohibition rule)

Article 103 of the National Public Service Act (Act No. 120 of 1947)
Article 38 of the Local Public Service Act (Act No. 261 of 1950) etc.

Need to establish rules or policies concerning IP

Other Factors

- Medical staff are busy especially physicians.
  (The average Japanese physician's work week : 63.3-70.6 hours)

	No. of Dr/1000	No. of Ns/1000	No. of beds/1000	length of hospital Stay (days)	No. of Dr/100beds (estimated)	No. of Ns/100beds (estimated)
Japan	2.3	10.5	13.3	17.2 *1	17.3	78.9
US	2.5	11.2	2.9	6.1	86.2	386.2

(2012)

*1 general ward only
Data from: OECD "Health-Statistics 2015"

- Poor environment of medical device development for medical professions. (e.g. consultation, agent)

JACE supports to improve the environment

JACE Medical-Academia-Industrial Collaboration Committee

(established in 2016)

Roles of the Committee

1) To promote medical device development based on clinical needs

2) To support our members in device development

3) To expand CEs' fields and opportunities

Activities of the Committee

1) To promote medical device development based on clinical needs

- Idea posting system on the web site of JACE

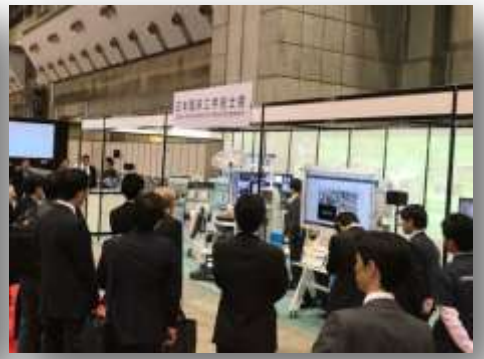
- Needs/idea evaluation service by committee members and observers.

Activities of the Committee

2) To support our members in device development

- Introducing CEs' needs and ideas at medical-industrial matching events.
- Introducing needs and ideas by CEs at exhibitions, expos, trade shows

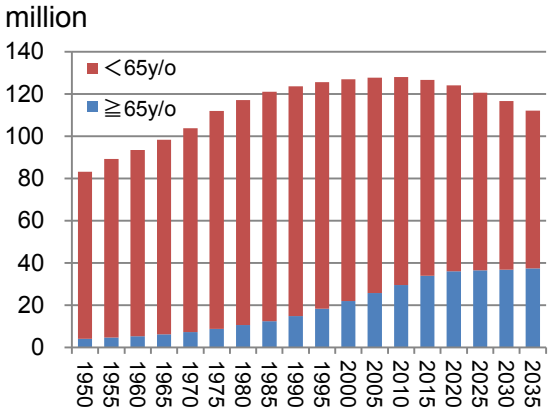




Activities of the Committee

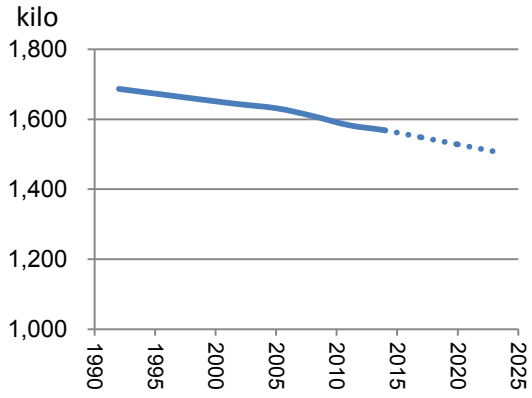
3) To expand CEs' fields and opportunities

- Medical device development could be a new field to use CEs' engineering skills and their medical knowledge.

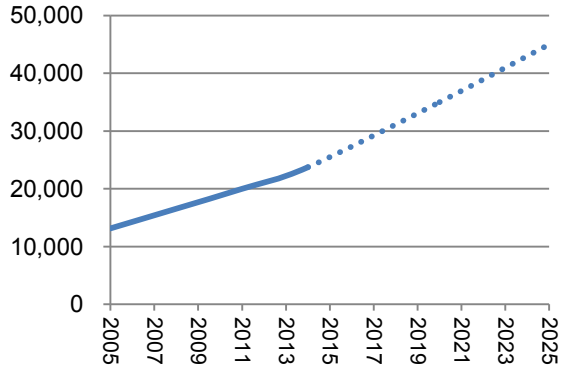


Population Trends of Japan

Data from "Bureau of Statistics of the Ministry of Internal Affairs and Communications"



Number of Beds



Number of Clinical Engineers

Data from the Ministry of Health, Labour and Welfare

Conclusion

Majority of Japanese clinical engineers work in active medical fields

Japanese government encourages and promotes medical device development under the new growth strategy.

Not many medical professions are involved in medical device development especially with IP strategies.

Clinical engineers are expected to play their roles in medical device development especially in medical-engineering collaboration.

JACE established the “Medical-Academic-Industrial Collaboration Committee” to support the members in medical device development.

Thank you for your attention

Sheep-Rin

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