AAMI2016
Conference & Expo
June 3–6, Tampa, FL

The premier industry event for healthcare technology management professionals

Roles of Clinical Engineers in Medical Device Development

June 5 | 10:00-11:00

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Agenda

- Clinical engineer system in Japan
- Recent movement of medical device development in Japan
- Expected roles of CEs in medical device development
- Introduction of a case of ASO Iizuka Hospital as an example

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%

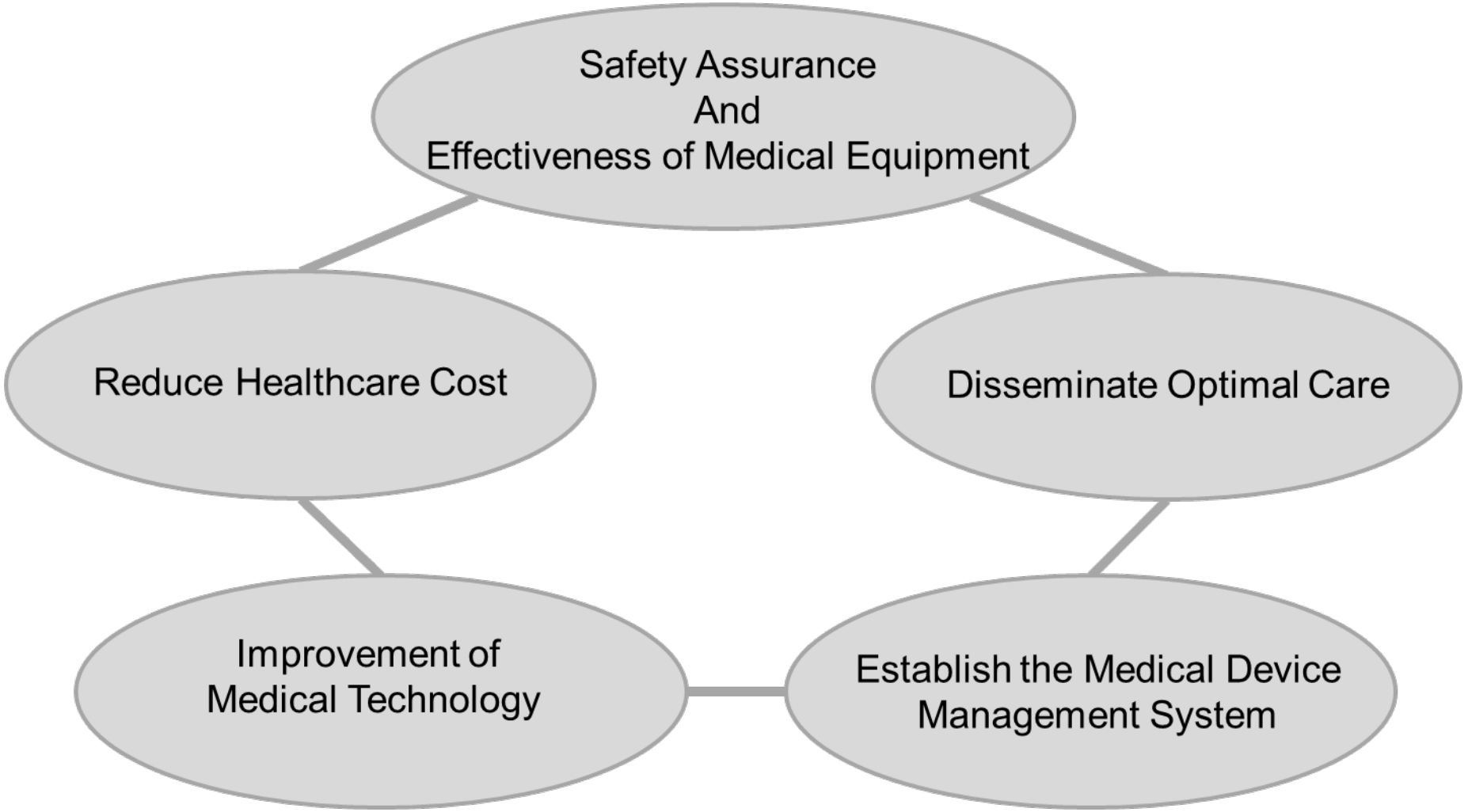
Japan Association for Clinical Engineers (JACE)

JACE was established under the approval of the Ministry of Health, Labor, and Welfare (MHLW) in March 2002.

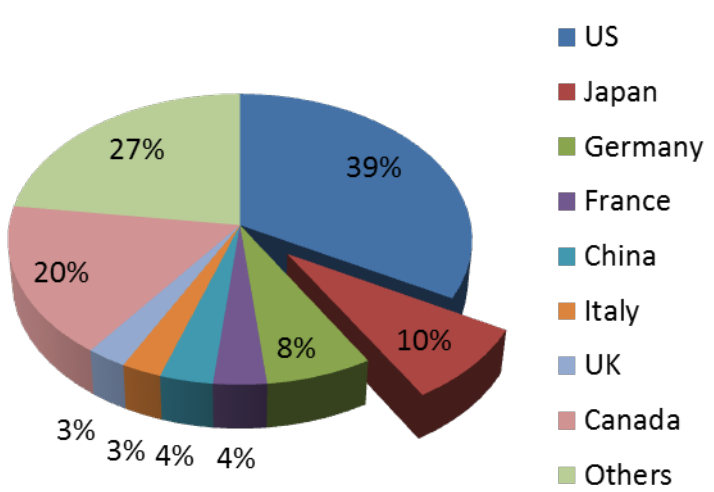
The objective of JACE is to contribute to the promotion and development of the nation's medical care and welfare through the raise of professional ethics of CEs, enhancement of their professional knowledge and skills, and improvement of reliability of equipment-based medical care and welfare, including life-support systems.

35,000 licensed Clinical Engineers in Japan
15,000 of them are the members of JACE

Social Mission of CE

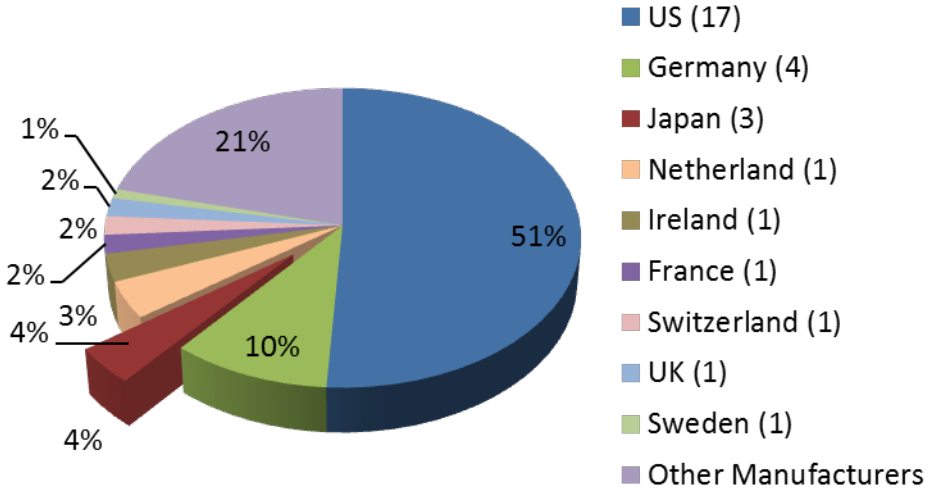


Japanese Medical Device Market



Market Size of Medical Device

espicom "Medistat Worldwide Medical Market Forecasts to 2017"



Market Share of Top 30 Device Manufacturers

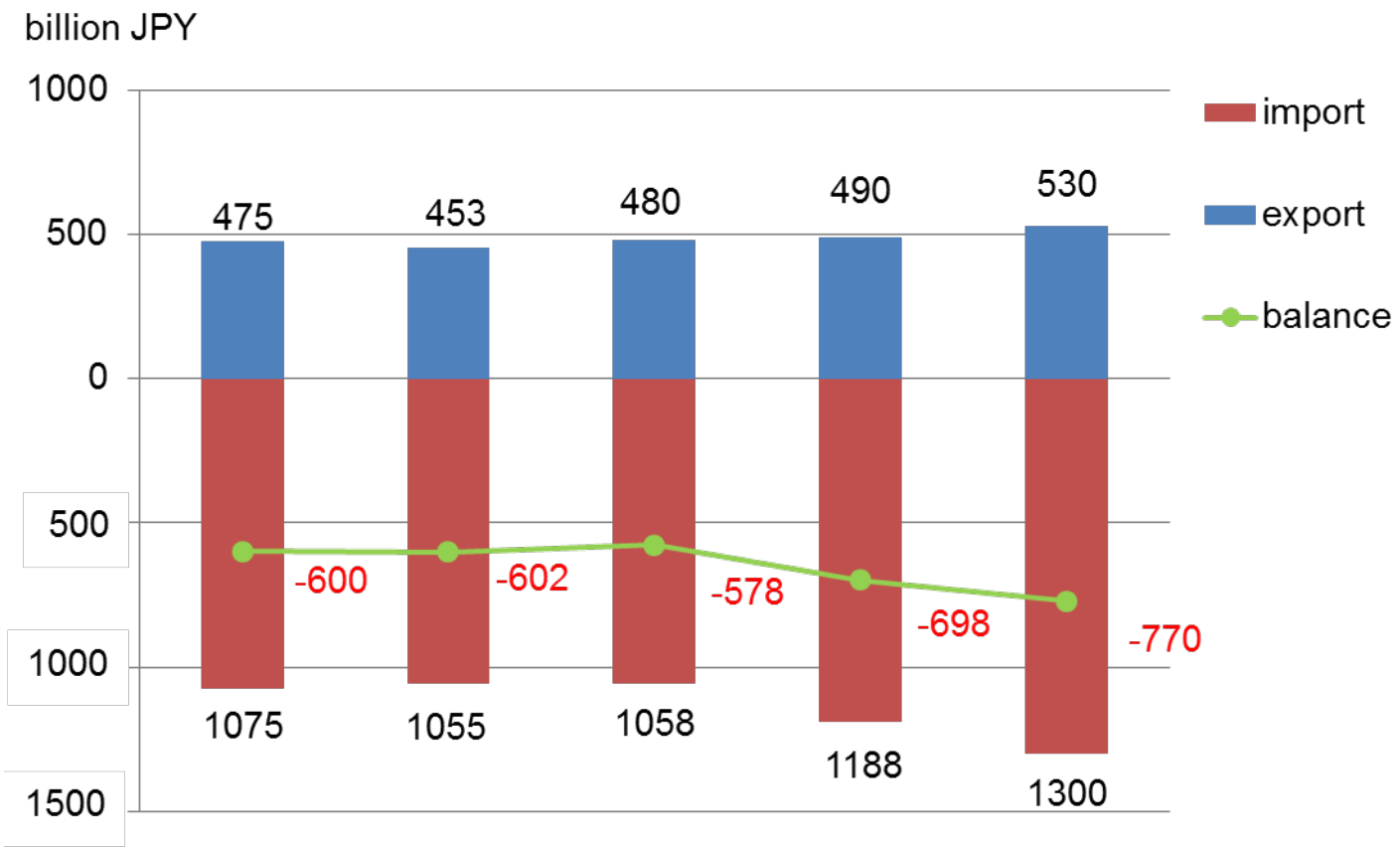
Rodman Media "TOP 30 MEDICAL DEVICE MANUFACTURERS (by FY12 revenue)"

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 -" in 2013

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

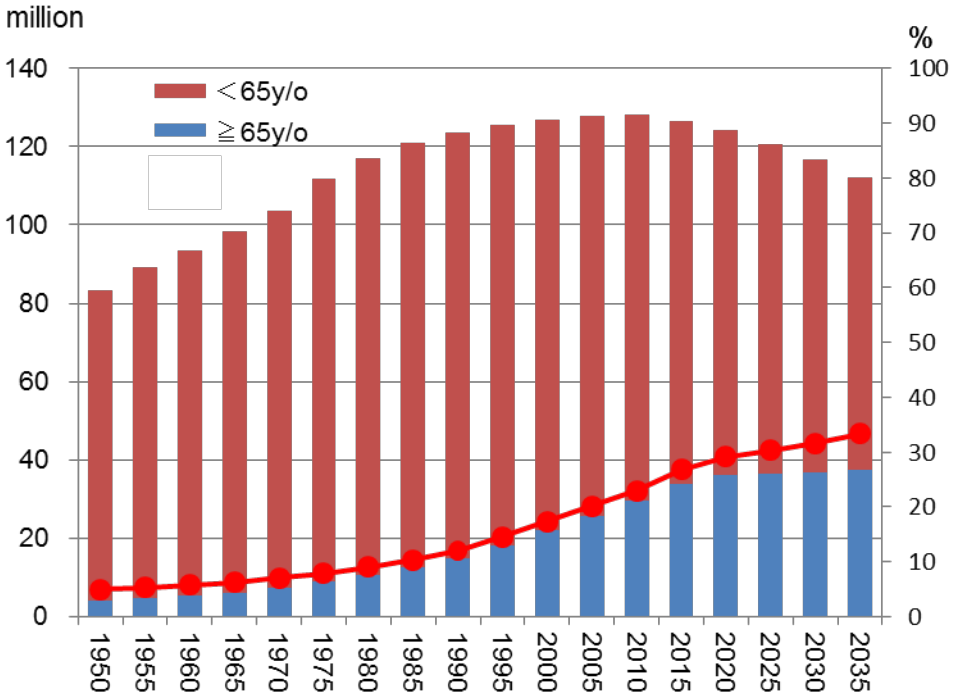
From: The office of the Prime Minister of Japan

Three Action Plans of "Japan Revitalization Strategy"

"Japan Revitalization Strategy" sets three action plans detailing concrete initiatives for the realization of growth:

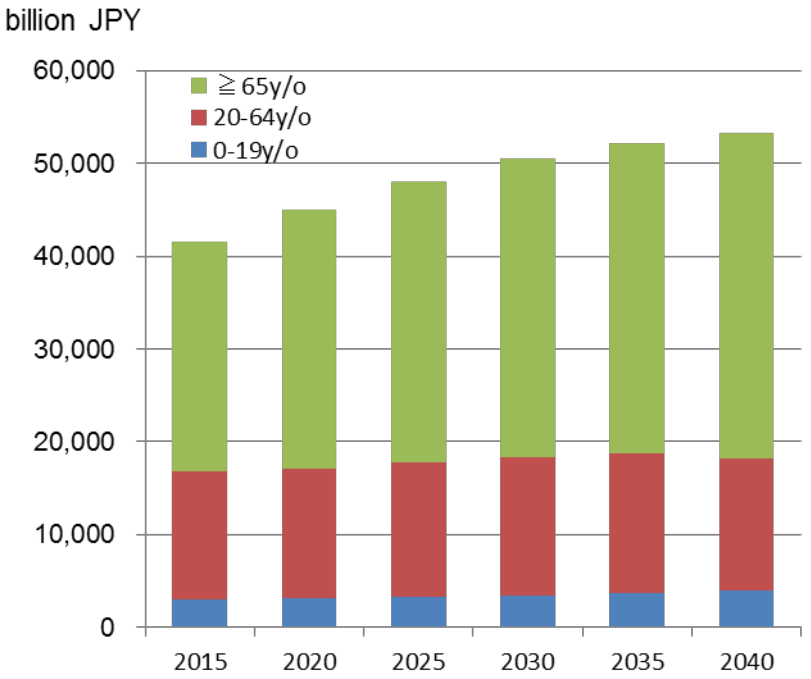
From: The office of the Prime Minister of Japan
(http://japan.kantei.go.jp/96_abe/documents/2013/1200485_7321.html)

Market Size



Population Trends of Japan

Data from “Bureau of Statistics of the Ministry of Internal Affairs and Communications”



Estimating Future Medical Expense in Japan

Data from “Japan Medical Association Research Institute”

Japan Association for Clinical Engineers (JACE)

ASO IIZUKA HOSPITAL

Government Policies in Medical Device Industry

(Ministry of Economy, Trade and Industry)

Device development through medical-engineering collaboration

Promoting new entrants from outside industry or start-up companies
Promoting device development based on clinical needs

Most advanced medical device development

Promoting advanced medical technologies by “industry-government-academia” collaboration

Business environment improvement to meet regulatory system

Capturing medical device market abroad

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

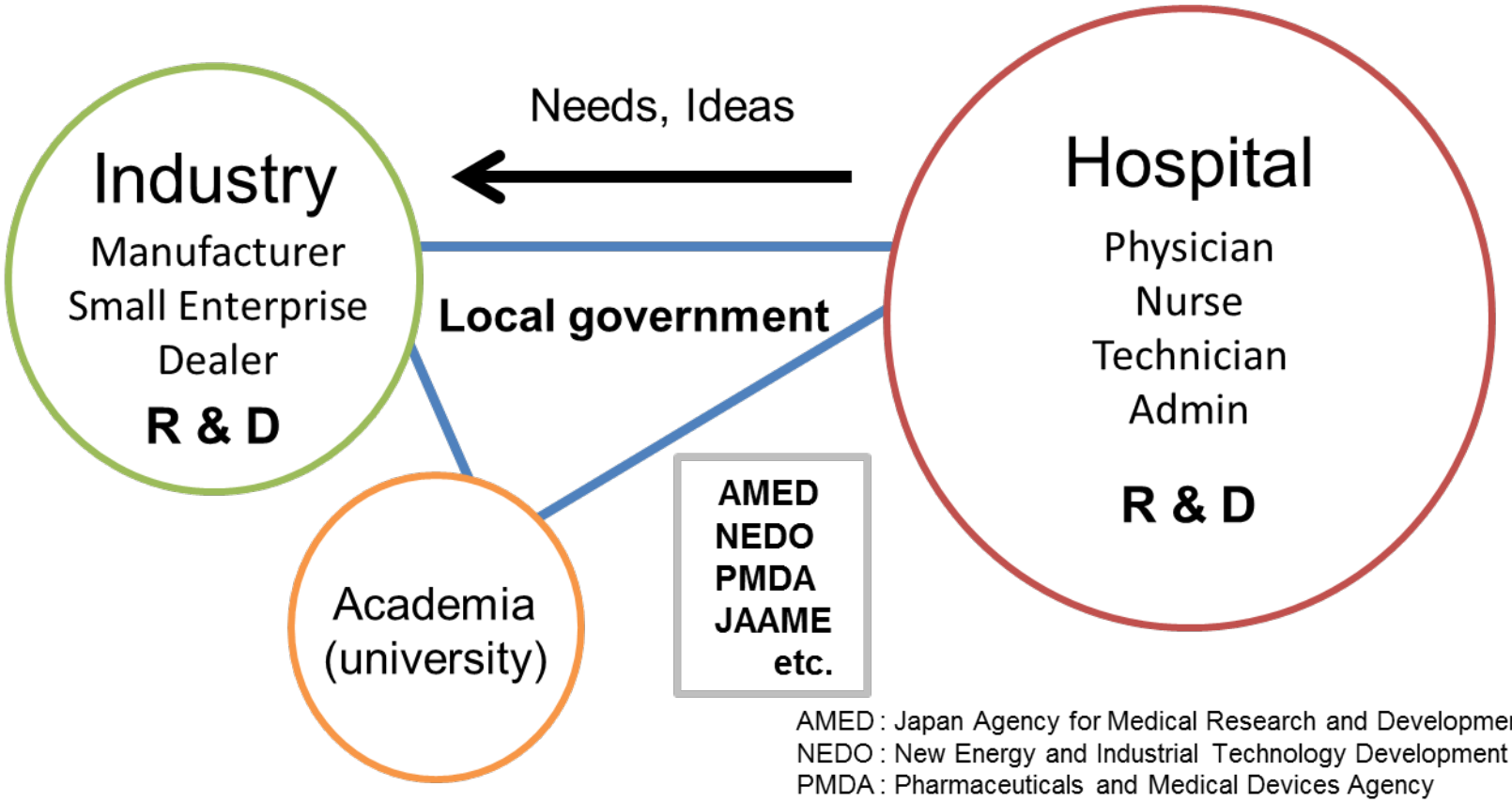
Seeds or academic oriented development

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

Why Clinical Engineer?

- Specialized in medical devices
  - HTM
  - Safety Education for staff and patients

Engineering knowledge

- Working in the clinical field
  - 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)

Medical knowledge

Close relationship with physicians, nurses, other medical professions.

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

JACE and Prefectural Association for CE

Introducing needs and ideas by clinical engineers at exhibitions, expos, trade shows

Introducing needs and ideas at medical-engineering collaboration matching events

http://www.hospital-expo.jp/

http://www.medtecjapan.com/

Japan Association for Clinical Engineers (JACE)

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JACE and Prefectural Association for CE

What are the advantages for hospitals? CE?

IP?

Need to establish a continuing mechanism.

JACE is considering to establish a new board or commission for medical innovation and medical-industrial collaboration.

Case of ASO Iizuka Hospital

Establishment :	August 1918	
Hospital Division :	Community Health Care Support Center	
Beds :	1116 beds	
Wards :	32 wards	
Staff:	Physician	298
	Nurse	1103
	Technician	533
	(Clinical Engineer	65)
	Administrator, etc.	517
	Total	2451

Clinical Department: 39

Internal Medicine, Hepatic Medicine, Gastrointestinal Medicine, Respiratory Medicine, Endocrine & Diabetic Medicine, Blood Medicine, Primary Care Medicine, Psychosomatic Internal Medicine, Collagen Diseases &Rheumatism Medicine, Radiology, Psychiatry, Pediatrics, Nephrology, Cardiology, Surgery, Digestive Organ Surgery, Respiratory Organ Surgery, Pediatric Surgery, Orthopedics, Dermatology, Plastic Surgery, Urology, Obstetrics & Gynecology, Ophthalmology, Otorhinolaryngology, Neurosurgery, Neurology, Cardiovascular Surgery, Dentistry & Oral Surgery, KANPO medicine, Anesthesia, Rehabilitation, Pathology, Emergency Section, etc.

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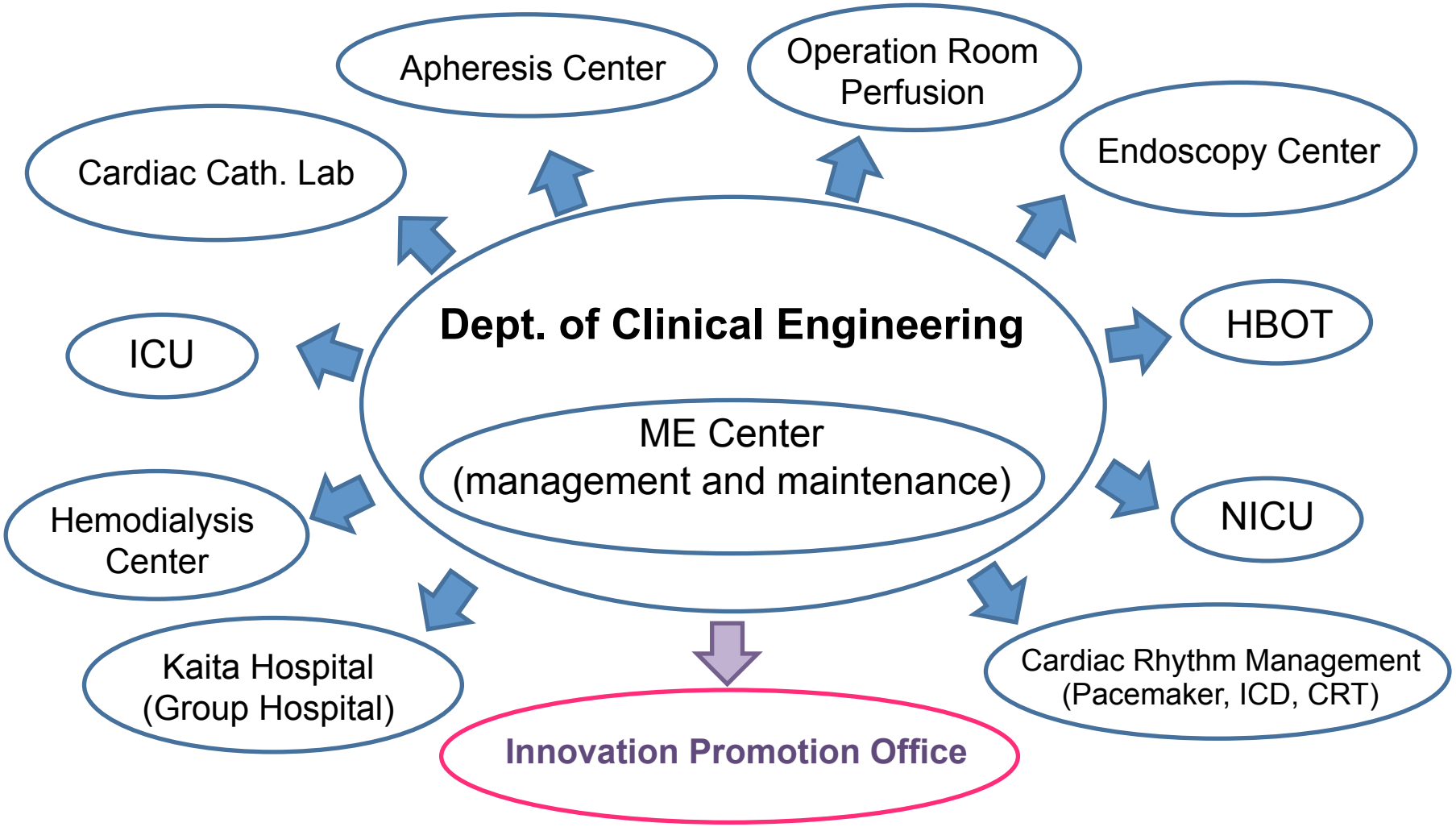
Roles of Clinical Engineers in AIH



Innovation Promotion Office

- Needs and Ideas Management
- Intellectual Property Management
- Education
- Medical Engineering Partnership
  (Local government, university and AIH)
- Coordination with Partner Institutes

Staff

Physician	1
Clinical Engineer	**3**
Administrator	3

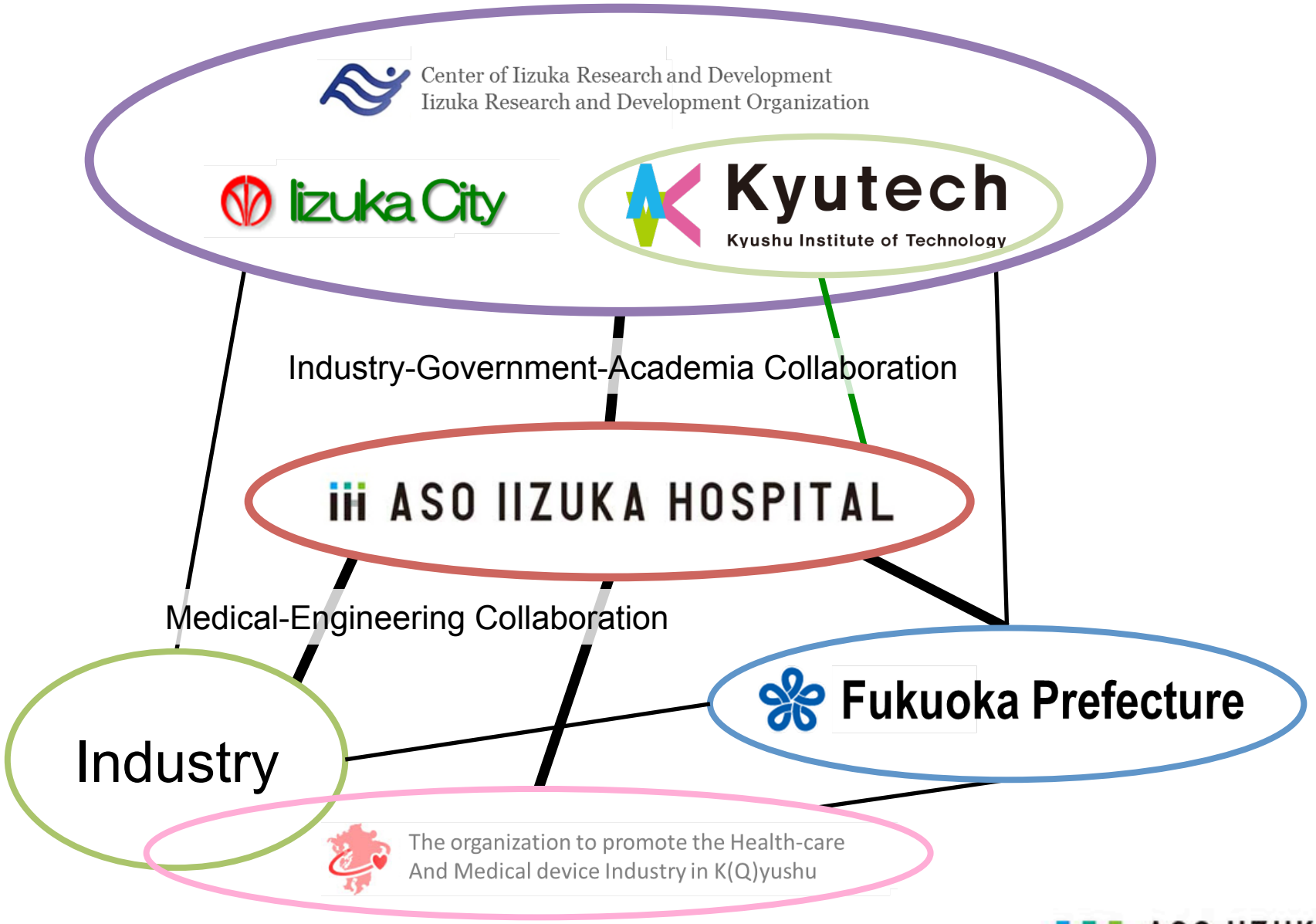
What can we do as a hospital?

Advantages as a hospital

Could be possible as a hospital

Needs Finding	Idea
Needs Evaluation	Prototyping
Idea Generation	Animal Test
Idea Assessment	Preclinical Test
IP Survey	Clinical Trial
Patenting	Regulatory
Idea Identifying	Into the Market

a case of ASO Iizuka Hospital



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Conclusion

Majority of Japanese clinical engineers work in active medical fields

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

Industry-government-academia collaboration and medical-engineering collaboration are promoted and are now practiced in many areas.

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

- Needs and ideas collection and evaluation
- Interpreter between the industry and clinical field
- Promotion using the networks though the organizations

Thank you for your attention

Sheep-Rin

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