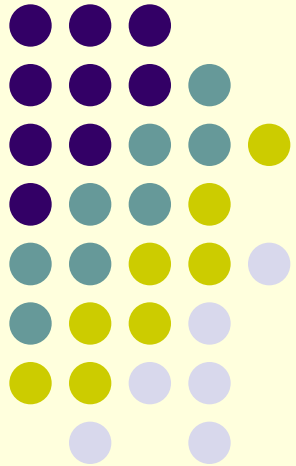
The Challenge of the Next Generation of Medical Equipment from the CE's Perspective

June 27, 2010



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Ⅰ. Enhancing the Role of the CE in Japan

June 27, 2010

Topics

1. History & Current Status of CE in Japan

2. Definition & Duties of CE

3. Situation of CE

4. Issues & Challenges of CE's Activities in 2005 ～ 2008

5. Current Situation of CE

6. Future of CE

7. Conceptual Scheme of "JACET Academy" and "JACET Seminar Center"

1. History & Current Status of CE in Japan

- Improvement of Medical & Engineering Technologies(Technology)
  (ex. Rapid growing of medical support by artificial organs)
- Substantial increase of ESRD patients in hemodialysis (HD) field

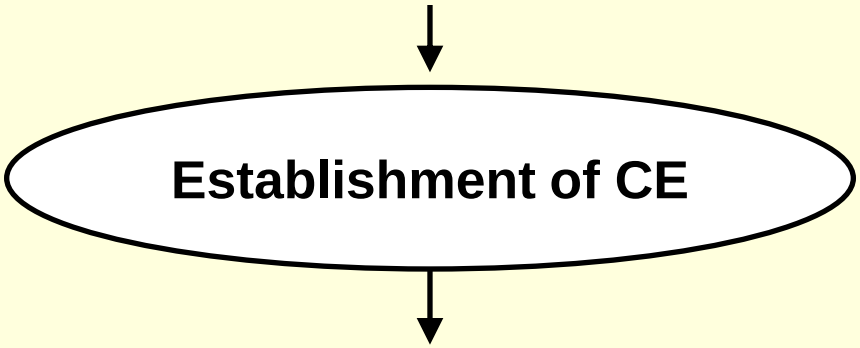
→ Safe and appropriate operation/application of HD machine

→ Need of more HD specialists and CEs operating artificial heart & lung

- Strict requirements for safe & appropriate operation of all medical equipments

→ Need of more specialists

- Requests for specialists from medical field



Growing need & number of CE

Administrative Milestone of CE

1987 **"Clinical Engineers Law"** was promulgated by MHLW
(Ministry of Health, Labour and Welfare)

1990 Professional organization **JACET** was founded
(Japan Association of Clinical Engineering Technologists)

2002 JACET was **certified by MHLW as** a public utilities corporation

2008

"JACET Academy" and "JACET Seminar Center" were founded

2010 20th Anniversary of " JACET "
CE's business expansion
Additional service fee for CE

2. Definition & Duties of CE in Japan

in 2008

1) Qualification of Clinical Engineer :

- **Licensed by the Government (MHLW)**
- **Under " the Clinical Engineering Law"**

2) Main Duties :

- Operation of **life-support medical equipments**
  - **Check & maintenance work**
  - **Direct medical actions to patients**
    - Blood & drug injection to patients
    - Blood sampling of patients
    - Electronic care to patients
    - Others
  - **Care to patients**
- Training of Other medical staff
- Cooperation with doctors, nurses and other medical staff to take **team approach**

3) Applicable Medical Equipment

Life-Support Equipments:

Biogenic functional support of respiratory, circulation and metabolism with life-support equipments

2009 ～ 2010

Blood drawing

Sputum suction etc.

3. Situation of CE in Japan

No. of Licensed CE:

27,699 as of March 2010

1,555 were newly licensed in March 2010

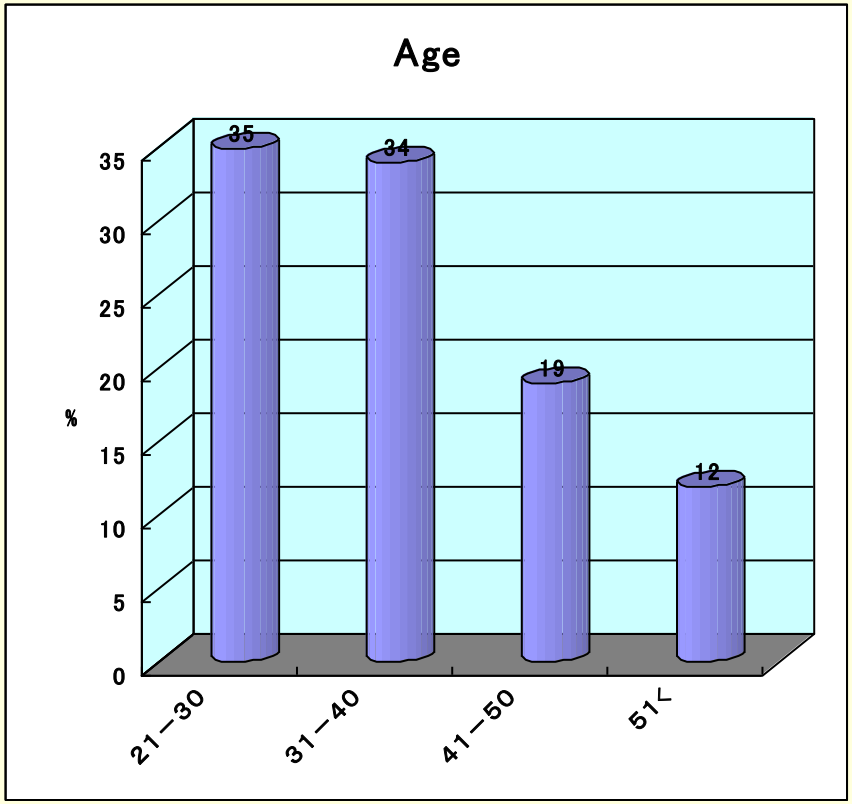
Actually working CE:

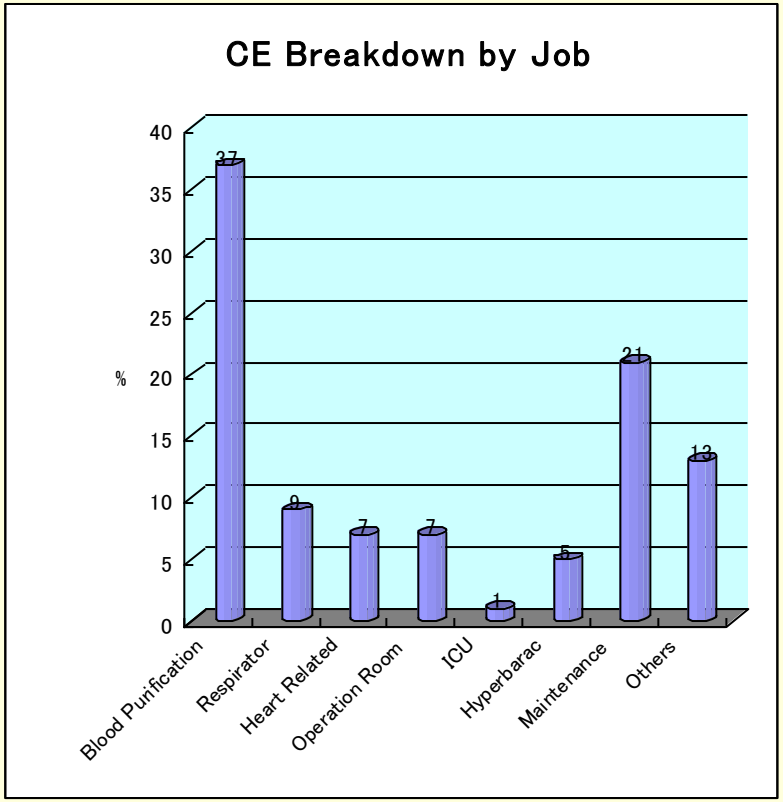
approximately 18,000

Member of JACET:

approximately 10,900 as of May 2010

CE at Work


Age
%
35
30
25
20
15
10
5
0
35
34
19
12
21−30
31−40
41−50
51ｲ


CE Breakdown by Job
%
40
35
30
25
20
15
10
5
0
37
9
7
7
1
5
21
13
Blood Purification
Respirator
Heart Related
Operation Room
ICU
Hyperbarac
Maintenance
Others

4. Issues & Challenges of CE Activities in Japan

1) Issues of CE in 2005 ～ 2008

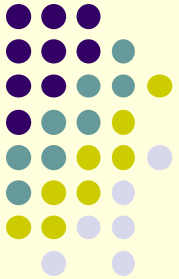
- **Jobs not clearly defined by Law**
- **No public remuneration guaranteed**
- **Duties** including sanction of phlegm and blood drawing **are not legally admitted**
- **Insufficient education period**
- **Lack of understanding of CE' jobs in medical institutions**

2) Challenges of CE in Japan in 2005 ～ 2008

－For Safer Medical Equipments Operation－

- **Longer & continuous education/training**
- **Clear legal definitions**
- **Enhance CE's position in LSS at medical institutions**
- **Improve skill by Certification System**
- **More central ME control centers at medical institutions**
- **Cooperation with industries in the development of safer & advanced LSS**

5. Current situation of CE (in 2007～2010)



Some examples are as follows:

1. Revision of Medical Law was enforced in April 2007, and staffing of a person in charge of medical equipment management became mandatory for the safety purpose.

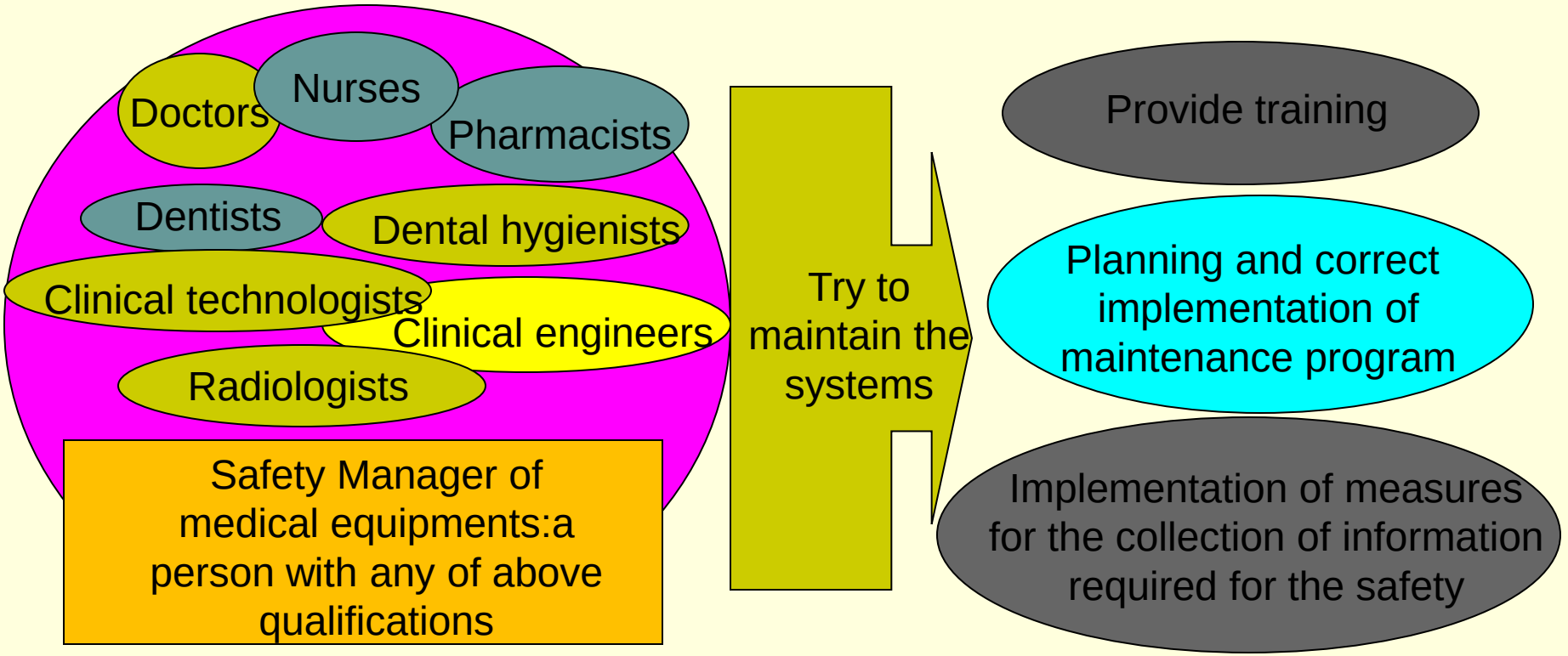
2. MHLW issued a notification in December 2007 urging positive utilization of CE.

3. A law enforced in April 2008 restricts the attendance of medical equipment manufacturer representatives to clinical site, and original role of CE is highly recognized again.

4. Public remuneration for one of CE's jobs became payable in April 2008.

Appointment of Safety Manager of Medical Equipments

- Allocation of a person in charge of maintenance and safe use of medical equipments



Involvement of manufacturer's reps at clinical sites

- Eliminate unfair actions of soliciting purchase of equipments
- Prohibit manufacturer's rep's involvement in team medical care at clinical site
- Prohibited by Fair Trade Agreement as of April 2008

Issues caused by the Involvement of reps

Services in question	Conflicting law
Involvement of unqualified rep in team medical care	Medical Law
Qualified rep's paid or unpaid involvement in team medical care	Manpower Dispatching Law
Providing free of charge services by qualified or unqualified reps	Fair trade Agreement

6. Future of CE in Japan

- Continuous efforts towards safe operation of LSS
- Legal enhancement of CE's duties
- Authoritative specialists to LSS at medical institutions
- Improvement & Expand of Education system & Certification system
- Improvement & Expand of"JACET Academy" & "JACET Seminar center"

7.Objectives of “JACET Academy” & “JACET Seminar center”

founded in 2008

“JACET Academy”

- Sharing of know-how and technologies
- Contribution to future development

.Certificate system

- Award system

“JSC”

Planning and running of educational programs

Ⅱ. The Challenge of the Next Generation of Medical Equipment from the CE's Perspective

Kiyoshi Matsusaka

Vice Chairman

Japan Incorporated Association for Clinical Engineering Technologists

TOPICS

1. JACET's achievements in 2008 - 2010
   - *JACET*
   - *JACET Academy Fellows*
2. How should CEs be involved in future medical equipment

1.JACET 's Achievements in 2008-2010

- Active in professional and academic activities
- Stressed the need of medical equipment safety management at clinical site to MHLW *
- Held workshops and seminars

*MHLW * : Ministry of Health, Labor and Welfare*

CE's Additional Medical Service Fee

☆Medical equipment safety management fee

2008

Safety Management Fee:50 points (1/month)

Two years later

X 2

2010

100 points (1/month)

1 point = ¥ 10

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☆ Dialysate quality control fee

Dialysate quality control fee (10 points) was added if the following requirements are met:

- Setting of Dialysis Machine Safety Management Committee
- Regular checking of water quality
- Assignment of 1 doctor or more than 1 CE exclusively responsible for the dialysate quality control

☆Additional Service Fee for Respiratory Care Team

Requirements

- Setting up of a team exclusively responsible for the removal of respirators
- CE should be included in the team in addition to a doctor and nurses
- This service fee is applicable for the removal after 2 – 30 days of its putting.

150 points / week

Additional Medical Service Fee under Health Insurance

☆Medical equipment safety management fee

☆Dialysate quality control fee

☆ Respiratory　Care Team fee

Above fees will be paid when CEs are acutually involved in providing the services on site

2. How should CEs be involved in future medical equipment

JACET & Academy organizational chart

MHLW → JACET

Academic

Academy

- Education
- Certification
- Collaboration with Academic Medical Societies
- Award

specialized field
- The breathing
- The circulation
- The metabolism
- The high atmospheric pressure oxygen medical treatment
- The medical equipment administration
- Emergency care & Intensive care

Professional

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Current activities of JACET

JACET

Academic

Professional

MHLW

Joint Committee

Collaborative Joint Works

Medical Societies

18 groups

Doctors

Nurses

etc.

New Basic Roles of CE's Jobs

The Business expansion of the CE's Jobs

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The next development step of medical equipment

Academy

Medical Societies

Manufactures

Collaborative joint Works

Accelerate the search and development of Future Medical Equipment

Educators

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Academy's future responsibilities

Qualified medical equipment can be secured by manufacturers effort

Then, the safety of patients can be secured!!

Positive propose for the Development

precision, quality, economical efficiency, validation and a quality management

Fair Evaluation from neutral Viewpoints

Academy

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Summary

- 22 years since the birth of CEs in Japan
- 8 years since incorporation of JACET as a public service corporation
- CEs are indispensable at the clinical site. Their comments based on the expertise in medical equipments are brought to MHLW through JACET.

Summary

- JACET Academy fellows are top class CEs representing each field
- They work together with academic societies of their fields to make recommendation and develop next generation medical equipment