

# AAMI2016

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## Environment for Medical Device Development in Japan and the USA: Current Activities & Roles of Clinical Engineers June 5 | 10:00 AM

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# Overview

- Japan & USA Clinical Engineering Comparison
- Medical Device Development Environment
  - USA Health Needs, Regulatory, Industry, & Innovation
  - Japan Health Needs, Regulatory, Industry, & Innovation
- How the Environment Impacts CE Roles
  - USA
  - Japan
- Conclusions

# Comparison of Japan and USA Clinical Engineering (CE) Practice

## Japan

- Operate high technology medical equipment such as life support systems, with specialty-specific certifications.
- Conduct other HTM activities, and oversee technicians who maintain equipment.
- Conduct patient safety activities, not including device alarm systems.
- Not yet
- Facilitate different certifications related to equipment operation.

## USA

- Manage a wide variety of medical equipment through its life cycle, including life support, imaging and laboratory.
- Conduct other HTM activities, and oversee technicians who maintain equipment.
- Conduct patient safety of medical devices and associated systems, such as alarm management
- Conduct CE-IT, device integration with electronic medical records and other Health IT activities.
- Facilitate a CE Body of Knowledge certification.

# USA Healthcare in 2016

## USA: Chronic Disease Management (CDM) – medical devices needed!

- USA Centers for Disease Control: 75% of healthcare expenses devoted to CDM, particularly for the ageing
- Need for national legislation to align incentives between providers, payers, patients

## Can innovative technology help?

### Precision Medicine Initiative<sup>1</sup>

- An emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.

### Google X Moonshots<sup>2</sup>

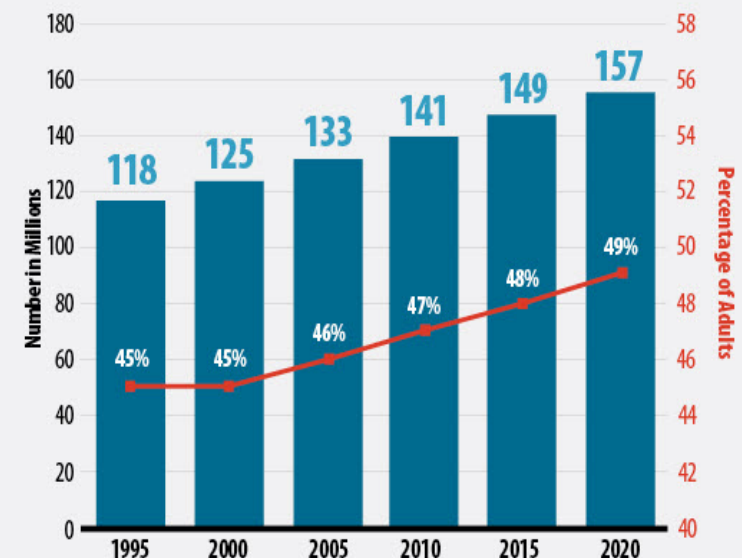
- A variety of approaches for CDM, cancer, and healthcare resource management

### National Moonshot<sup>3</sup>: Cancer

- Marshalling national resources for early detection and best treatment, and data sharing among experts

## The prevalence of chronic disease is extraordinarily high and growing

Proportion of Americans with at least one chronic condition



Source: Chronic Care: Making the Case for Ongoing Care, Robert Wood Johnson Foundation (2010)

<sup>1</sup><https://www.nih.gov/precision-medicine-initiative-cohort-program>

<sup>2</sup><http://www.techinsider.io/20-moonshot-projects-by-google-turned-alphabet-2016-2>

<sup>3</sup><http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>

# USA Industry & Medical Devices

## CEs managed rising complexity of devices & users

- **Interoperability**
  - Between devices and the Electronic Health Record (EHR)
- **Wireless**
  - Particularly for SmartPhones & mobile medical devices
- **mHealth**
  - Care driven by SmartPhone use & as platform for device functions
- **Device Security**
  - Medical device cybersecurity a growing concern
- **Human Factors**
  - As device complexity grows, clarity for & ease of use major challenges

# USA Medical Device Regulation

- FDA & HTM Issues (2016)

- ACCE giving feedback to FDA on proposed new directive<sup>1</sup>: *Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third- Party Entities and Original Equipment Manufacturers*

- FDA & Health IT Issues (2012-present)

- ACCE helps address FDA's Safety & Innovation Act (FDASIA)<sup>2</sup>
  - A nationwide health IT (HIT) infrastructure
  - Risk-based framework for HIT
  - FDA to focus its attention/oversight on device health IT functionality

- How devices are used in EMR/EHR Workflows

- |                      |                             |
|----------------------|-----------------------------|
| ▶ Patient Management | ▶ Clinical documentation    |
| ▶ Patient Context    | ▶ Surveillance              |
| ▶ Scheduling         | ▶ Messaging                 |
| ▶ Order Workflow     | ▶ Data management           |
| ▶ Data acquisition   | ▶ Report generation         |
| ▶ Data analysis      | ▶ Device specific workflows |



<sup>1</sup><https://www.regulations.gov/#!documentDetail;D=FDA-2016-N-0436-0039>

<sup>2</sup><http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentsToTheFDCAAct/FDASIA/ucm20027187.htm>

# Japanese Healthcare in 2016

- Ageing population; a major MHLW (Ministry of Health, Labor, and Welfare) focus on care delivery innovation to create sustainable health cost
- Moving to evidence-based medical practice, with focus on preventive care, with improved governance
- Health leaders propose a move from healthcare government regulation to professional self-regulation

# Japan's Medical Device Industry

- Market remains the 2<sup>nd</sup> largest in the world, behind only USA
  - \$27B USD in 2016; or 3.2T Yen
  - Strained government health expenditure due to a rapidly ageing population will hinder market growth; like the USA resulting in Chronic Disease Management
  - Market to grow at 3.6% in USD in 2016, a faster pace than the economy
- World's 3<sup>rd</sup> largest device importer, behind USA & Germany
  - AMDD (see Appendix) facilitates the work of 62 USA companies in Japan
- Among the world's top 10 device largest exporters
  - Imaging powerhouse Toshiba was acquired by Canon in March 2016



# Japan's Medical Device Regulations

- Japan's Pharmaceutical and Medical Devices Agency (PMDA) changed in 2014 via *The Pharmaceutical and Medical Device Law (PMDL)*<sup>1</sup>
  - Previously the law had greater focus on Pharmaceuticals than Devices
  - PMDL directed improved ... Medical device industry in-country representation; Industry quality system compliance; Third party certifications, and Regulation of medical software
  - EHR development lags behind the USA
    - Protection of personal data is not defined in law; see recent development since 2011 in Appendix
- Device Reimbursement in Japan<sup>2</sup>
  - All residents are mandated to have healthcare insurance under the country's universal health insurance system. The health plan is strictly regulated by the government to keep the monthly premium affordable, via the MHLW. Device use as part of recognized medical practice is a component of prospective payment/reimbursement.
  - A medical device recognized by the universal health insurance system means that the availability of the device must be ensured immediately after the enlistment in the system. Also, the law mandates that a sufficient supply of devices be available until replacement by a successive device.

<sup>1</sup><http://www.meddeviceonline.com/doc/what-the-new-japanese-medical-device-regulations-mean-for-you-0001>

<sup>2</sup><http://www.mddionline.com/blog/devicetalk/demystifying-device-reimbursement-japan-03-21-16>

# USA Clinical Engineering

## ACCE's CE-HTM National and Global Focus

- **Government/Advocacy:** address HTM & CE-IT concerns
  - e.g., Regulatory (FDA) and Accreditation (The Joint Commission) HTM issues
- **Patient Safety:** Partner with other health leaders/stakeholders to improve
- **Influence:** over 800 individual leaders, 20 key hospital systems in USA, as well as over 150 international CE leaders from 40 countries
- **Certification:** oversee professional body of knowledge certification
- **Youth:** 60% of ACCE membership is 40 years old and younger as we continue to grow and to attract younger members
- **Education:** Historical strong USA role; often for leading edge topics and key professional conference venues.
  - Provide monthly educational on-line training as well as at major conferences
  - 25 years of global HTM seminars to 80 countries

# Japan Clinical Engineering

## JACE's national / global focus

- **Certification:** Facilitate for life support equipment
- **Education:** Internally through annual Congress (800+ in 2016); externally through Japan Overseas Cooperation Volunteer Program, Japan-based Kids Programs, etc.
- **Membership/Promotion:** estimated 20K+ JACE members and ongoing growth of profession
- **Advocacy:** Tsunami and Earthquake response efforts
- **Innovation:** VOLT BANK (battery charge management system); IPDC tester, Automatic Surgery Shoe Cover quick release box,...etc.

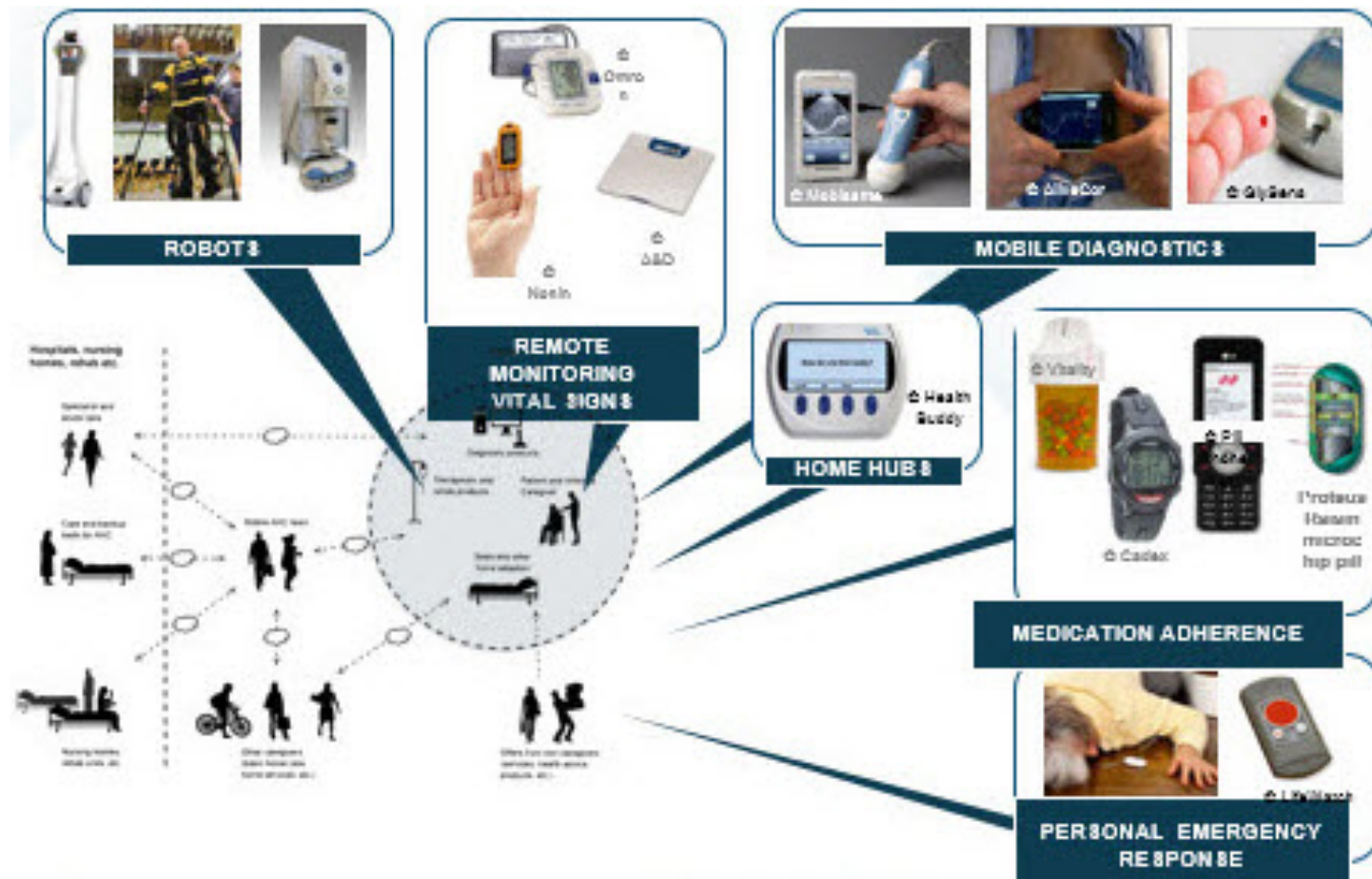
# Conclusions

- **External to CE** (at society & organizations level)
  - Gain visibility/influence
    - Get involved in government innovation, mHealth initiatives, and JACE advocacy activities.
    - Communicate your value to health leaders
      - Through demonstrating impact on country health priorities
- **Internal to CE** (at individual & departmental level)
  - Practice of Clinical Engineering
    - Recognize CE activities that contribute to priority health issues and address health leader concerns
      - Quality of care, outcomes-based care
      - Emerging e-Health (Health IT or CE-IT) opportunities
  - Continuing Education
    - Prepare for addressing HTM gaps
      - Both individually and at the society level

# Appendix

- USA Examples
  - Kaiser Permanente (KP) Clinical Engineering
    - Medical Device & Care Delivery via Health IT
    - KP-Industry Quality & Health IT Case Studies/Challenges
      - Infusion Devices
      - Alarm Management
      - Integrated Digital Operating Room
  - USA Regulatory-Industry Medical Device Example
- Japan Examples
  - AMDD in Japan: American Medical Devices and Diagnostics Manufacturers' Association
  - Japan's Healthcare Environment and EHR Status

# KP Care Delivery in All Environments



# KP Case Study 1: Infusion Pump Systems



# Case Study 1: Infusion Pump Systems

## Quality Challenges

- Several FDA alerts re design, SW/ firmware, cleaning/infection control, equipment PM, & other issues
- Over-infusion Incidents supplier follow-up
- Warranty & Post-warranty support concerns
- Add additional alarms, eg tubing setup
- Artifact interference in certain clinical settings

## Requirements Challenges

- Wireless challenges for CQI downloads and SW change management ; took 2 years to re-design and correct wireless card
- Eventually hit limit and needed to exceed 2500 programmable drugs for all use cases
- Security protocols for all device use cases



# KP Case Study 2: Alarm Management Systems (AMS)



# Case Study 2: Alarm Management Systems (AMS)

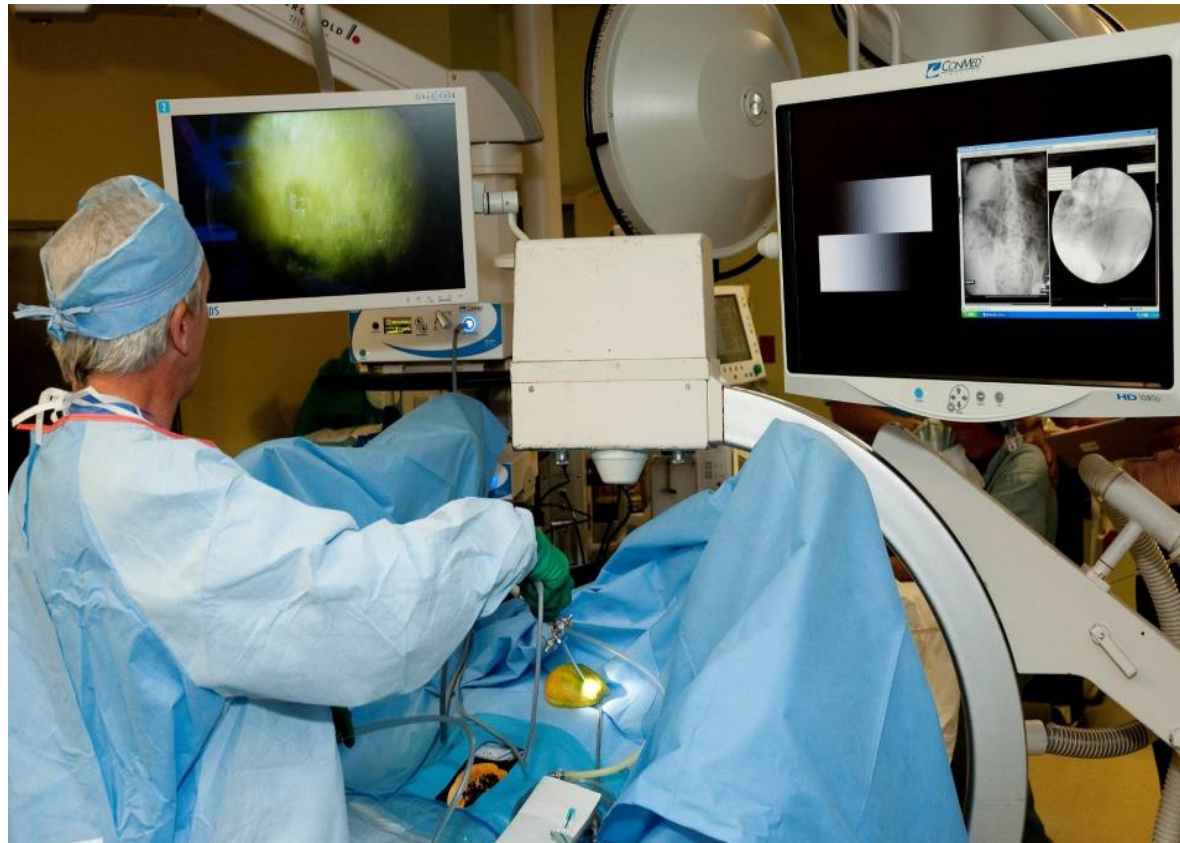
## Quality Challenges

- Scalable solutions not fully developed so initially server overloads & intermittent system shutdowns; supplier purchased smaller company but had not fully assessed current product and its then current capabilities
- Reduction of monitoring techs by Customer before Alarm response protocols worked out became a patient safety issue
- Different subsystems gaining significant national scrutiny as The Joint Commission National Patient Safety Goal emerged

## Requirements Challenges

- A secondary alarm notification tool; not optimized for primary notification
- KP conducted end-to-end testing and invested significantly to build up IT infrastructure to support enterprise-wide approach
- More readily monitor and adjust individual device AMS configurations

# KP Case Study 3: Integrated OR Systems



# Case Study 3: Integrated OR Systems

## Quality Challenges

- Device interoperability ensuring image quality when using different DOR and Rigid Endoscopy suppliers
- Storage and retrieval of surgical images with appropriate privacy and security compliance
- Reliability, reprocessing, and durability of surgical video Endoscopy

## Requirements Challenges

- Different image capture / management strategies for different surgical sub-specialties
- Sending images to mHealth platforms, eg, SmartPhones, Tablets while meeting needed privacy and security
- Wireless image transfer and fidelity
- Ongoing testing of image quality

# USA Medical Device Quality Example

## Baxter Recall 2010

- Numerous design flaws
- USA Food & Drug Administration-FDA Total Product Life Cycle



## FDA 7 opportunities, 2011

1. Design & reliability
2. *Monitoring & feedback*
3. Supplier management
4. *Quality metrics & systems*
5. Quality organization
6. *Performance management*
7. Quality culture



## Industry response 2013

- Challenges
  - a) quality costs
  - b) problem prevention
  - c) low-quality supplier performance
- Transformation
  - a) reduce quality-related costs while increasing capacity
  - b) reorganization of the quality function
  - c) Introduce proactive quality, system for tracking, dialogues around key indicators, and root-cause problem solving
- Results
  - a) Reduction in cost of Q by 35%
  - b) improved profit by 2.5% revenues

## Pew Charitable Trust to FDA, 2014

- New approach to device development
  - a) ensure timely pre-market studies
  - b) robust post-market surveillance infrastructure
  - c) unique device identifier (UDI) capture in EHRs
  - d) and use of clinical registries



# Japan's AMDD: American Medical Devices and Diagnostics Manufacturers' Association

## Purpose

- AMDD represents<sup>1</sup>: 62 companies that provide medical devices and in-vitro diagnostics (IVD) and other advanced medical technology in Japan.
- AMDD addresses<sup>2</sup>: **Device Lag** (leading edge products getting to Japan later); **Device Gap** (products not yet introduced because of price restrictions) & the **Japan Reimbursement rule-FAP**<sup>3</sup> (not consistent with market reality); see next slide

## Goals

1. Implement appropriate evaluation of innovation to limit medical costs
  - For better value to the patient, and
  - policy recommendations
2. Activities to accelerate the Pharmaceuticals and Medical Devices Act (PMDA) with the global medical device industry
3. Promotion of Japan medical device industry in the USA
4. Partnership with the USA Advanced Medical Technology Association (AdvaMed)

<sup>1</sup><https://amdd.jp/en/>

<sup>2</sup>AMDD Comparison of market environment for medical devices in Japan, China, and Korea, 2011

<sup>3</sup><http://www.mddionline.com/blog/devicetalk/demystifying-device-reimbursement-japan-03-21-16>

# Japan's Healthcare Environment

## OECD 2015<sup>1</sup>

- One of Japan's foremost policy challenges is to create an economically-active ageing society.
- Japan needs to shift to a more structured health system, separating out more clearly different health care functions (primary care, acute care and long-term care, for example) to ensure that peoples' needs can be met by the most appropriate service, in a coordinated manner if needed.
- As this differentiation occurs, the infrastructure to monitor and improve the quality of care must simultaneously deepen and become embedded at every level of governance –institutionally, regionally and nationally.

## EHR/EMRs Japan

- Despite a number of initiatives over the past decade, EHR networks have developed only as experiments in selected areas. Interoperability between providers has not been generally established.<sup>2</sup>
  - In 2013, almost all hospitals used electronic billing, compared with 85.6 percent of medical clinics, 47.2 percent of dental clinics, and 94.8 percent of pharmacies. The government has made electronic billing obligatory in the public health insurance system for all providers except those without the necessary staffing and instruments. Protection of personal data is not defined in law
- Example: University hospitals (2014)<sup>3</sup>
  - Bioinformatics studies are started for genome cohort and EMR data combination analysis.
  - Kyoto university BIC (Biobank & Informatics for Cancer) project
- Japanese government<sup>3</sup> [http://www.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-care-quality-japan-2015\\_9789264225817-en](http://www.oecd-ilibrary.org/social-issues-migration-health/oecd-reviews-of-health-care-quality-japan-2015_9789264225817-en)
  - The 2011 earthquake changed the atmosphere; “Japanese-NIH” under preparation
  - “Next generation medical ICT” working group tends to connect “pencil building” services with fully support of fund, legal force, and authority establishment of personal information management.
  - Principle of national healthcare insurance shifts the coverage from acute care hospital to home care

<sup>2</sup>Commonwealth 2014: [http://www.commonwealthfund.org/~media/files/publications/fund-report/2015/jan/1802\\_mossialos\\_intl\\_profiles\\_2014\\_v7.pdf](http://www.commonwealthfund.org/~media/files/publications/fund-report/2015/jan/1802_mossialos_intl_profiles_2014_v7.pdf)

<sup>3</sup>ISPOR 2014, Naoto Kume, PhD, Kyoto Prefecture