GLOBAL CLINICAL ENGINEERING ALLIANCE™

TECHNOLOGY SNAPSHOTS

CE-HTM Indicators: The Reality Today

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globalcea.org

Why Indicators?

- You can't manage what you do not measure."
  - Attributed to USA management expert Peter Drucker
  - Discussed widely in CE-BME Community prior to 2000 by **CE Robert (Bob) Morris**
- "Where are the Ventilators? The Oxygen equipment?
  - The World Health Organization (WHO) World Health Assembly 2020 & 2021
  - This is the group of Ministers of Health (MOH) from WHO's 194 Member States
  - WHO as a result expanded the scope of the CE-BME profession to lifecycle management of traditional medical devices, PPE, oxygen sources and delivery devices, and digital health tools during the pandemic
- My Own Clinical Engineering Journey https://www.youtube.com/watch?v=VClAgQXw1Uw

So Many Perspectives: What's Most Important?
Impact on Clinical Outcomes!

- 30 years of CE-HTM Indicator History
  - Grounded through our profession's World Health Organization (WHO) partnership
  - Gaining wider Healthcare System views and impacts from quality, safety, & benchmarks
  - One of several key Elements: our CE-HTM Capacity Building Framework
- Asset Management
- Nomenclature
- Digital Health
- Case Studies
- Next Steps – including AI, IoT and more

Our Indicator History & Current Perspective

- **2025 IADB Measures of Hospital Efficiency and Quality**
  - **Covers LA&C perspectives. "**Hospital performance is influenced not only by internal processes but also by the overall health system. Therefore, considering the environment and context is critical to interpreting any performance indicator at the hospital level. For example, context will be relevant to fully understand whether extended lengths of stay result from poor hospital performance or from a broader health system issue, such as lack of medical equipment or services, or human resources." **Typical documents such as this for the most part completely ignore management of Health Technologies as envisioned by the World Health Organization**.
- **2024 GCEA-AAMI HTM Benchmarking Guide (USA 2021)**
  - Over 100 CE-HTM Indicators used in the USA & globally with definitions provided; translated into 5 other global languages so far, 5 others pending
- **2023 Global CE Community, *CE-BME Capacity Building Framework*** (GCEA & IFMBE CE Division combined efforts), next page
  - Outlines key CE-BME key Capacity Indicators across countries
- **2020 CE-HTM Indicators CED Webinar**, Luis Fernandez, Jennifer DeFrancesco
  - Hospital & Department Profiles; Safety;
  - Program & Financial Performance; Program Maturity;
  - Interoperability & Cybersecurity; Inventory Management; Other
- **2019 Global Clinical Engineerng Handbook** *Indicators* chapter, Antonio Hernandez, Tom Judd
  - Showed Indicators from the 2009 Study, below
- **2018 Global CE Journal** Making a Difference: Global Health Technology Success Stories: Overview of over 400 submissions from 125 Countries, Yadin David, Tom Judd
  - The stories were aggregated across 6 themes that demonstrated improved clinical outcomes: **Innovation**; **Access**; **Health Systems**; **Safety & Quality**; **Healthcare Technology Management**; (HTM) and **e-Technology (**Digital Health)
- **2009 WHO-Luxembourg Project** *Strengthening Healthcare Infrastructure and HTM for Optimized Health Service Delivery,* Joachim Nagel, Adriana Velazquez, Antonio Hernandez, Tom Judd
  - Groups of Indicators: **Implementation of HTM** (national, centrally, & local levels)**;**
  - **Quality of HTM; Impact of HTM on the investment / use of resources;**
  - **Impact of HTM on the quality of care and patient safety**
- **1989 WHO Manpower Development for a Health Care Technical Service,** With global group developed *Equipment Maintenance requirements across Health Care Technical Services***,** Yadin David, Tom Judd, Frank Painter, Robert Morris

CE-BME *Capacity Building* Framework

Clinical Engineers:

- **Manage** *Health Technologies (HT)* through their lifecycle, according to World Health Organization methodologies
- **Innovate** to create new models and tools for healthcare delivery including Digital Health approaches
- Ensure ***Appropriate*** HT selection and deployment initially & ***Sustainability*** during use
- Work through ***National CE-BME Societies*** to assist ***Capacity Building*** at country and regional levels
- Have measurably improved healthcare ***Safety, Quality*** **and** ***Clinical Outcomes***
- **Addresses all Asset Management boxes / categories noted next**

Status	Low	Middle	High
KNOWLEDGE			
Education (Academia)	2-4 year Academia	Academia: 4 year undergraduate & graduate	Graduate CE
Training (Academia - CPD, CEU & Industry)	Limited	Ongoing	Ongoing for typical devices plus more for high tech devices
Internships (part of Academic studies or independently in hospitals)	Absent	Limited	Available through different sources
Credentialing (Certification & Registration)	Absent	Limited	<50% Certified
Digital Health & Innovation (Knowledge used to improve devices and clinical & business workflows, etc.)	Absent	Limited	Beginning involvement
INVESTMENT			
Investment Drivers Externally (NGOs, Industry) versus internally (MOH, Universities)	Externally driven	Ministry of Health (MOH) directed	MOH driven, aligned well with University & Industry partners
Device Sources Majority Donations versus Majority Central Health Leader-driven	Majority Donations	MOH-led device planning, selection, & management	Extensive central planning, selection, & management through MOH
CE Department **Staffing**, Facilities & Test Equipment	Limited	Full range for typical devices & growing staff to meet needs	Extensive facilities & wide range of test systems with mature staff size matching needs
Inventory Management Manual versus CMMS	Manual	CMMS	CMMS includes Digital Health & Cybersecurity information, with ability to share data with decision makers & colleagues across hospitals
Added Value: Quality & Safety Measurement, monitoring, improvement, and risk management	Absent	Limited	Extensive
COMPETENCIES			
Scope of CE-HT Management Activities	Minimal set of devices	Full range of typical devices	Typical plus high-tech devices + Digital Health tools & Cyber
Device Preventive Maintenance & Repair	Limited PM & Repair of typical devices	Full range for typical devices	Full range PM & repair typical + high tech specialty devices
Clinician & Healthcare Team Relationships	Absent	Limited	Strong partnerships
National CE / BME Society (Bringing HT colleagues together to share best practices and training)	Absent	Beginning	Mature and able to assist other nearby countries
Leadership Development (Developing & Mentoring CE practitioners/Influencers)	Absent	Limited	Key country CE leaders mentored externally, They train & mentor others; become Influencers
Policy, Regulation, Legislation (Raising HT issues to national level in Political context)	Absent	Limited	Extensive

CE-BME & WHO:

- The World Health Organization (WHO) Medical Device Unit created the **STAG MEDEV** in 2022 to lead global HT improvement efforts, with many CE-BME on the team
- WHO measured 800K+ existing CE practitioners in 2018 from 130+ countries; the Global CE community efforts now show **over 1M colleagues in 200+ countries**
- The Global CE Community 50+ best practice webinars with WHO **were attended by 160 countries** 2020-2023 during COVID-19
- The Global CE Community joined WHO evaluations team in 2020-2024 to create ***WHO's Compendia of innovative health technologies for low-resource settings***

CE-HTM Indicators: Important but not Enough

- *Asset Management Perspective – an anatomy*, July 2024, Version 4 www.theIAM.org

CE-HTM in Context of Asset Management

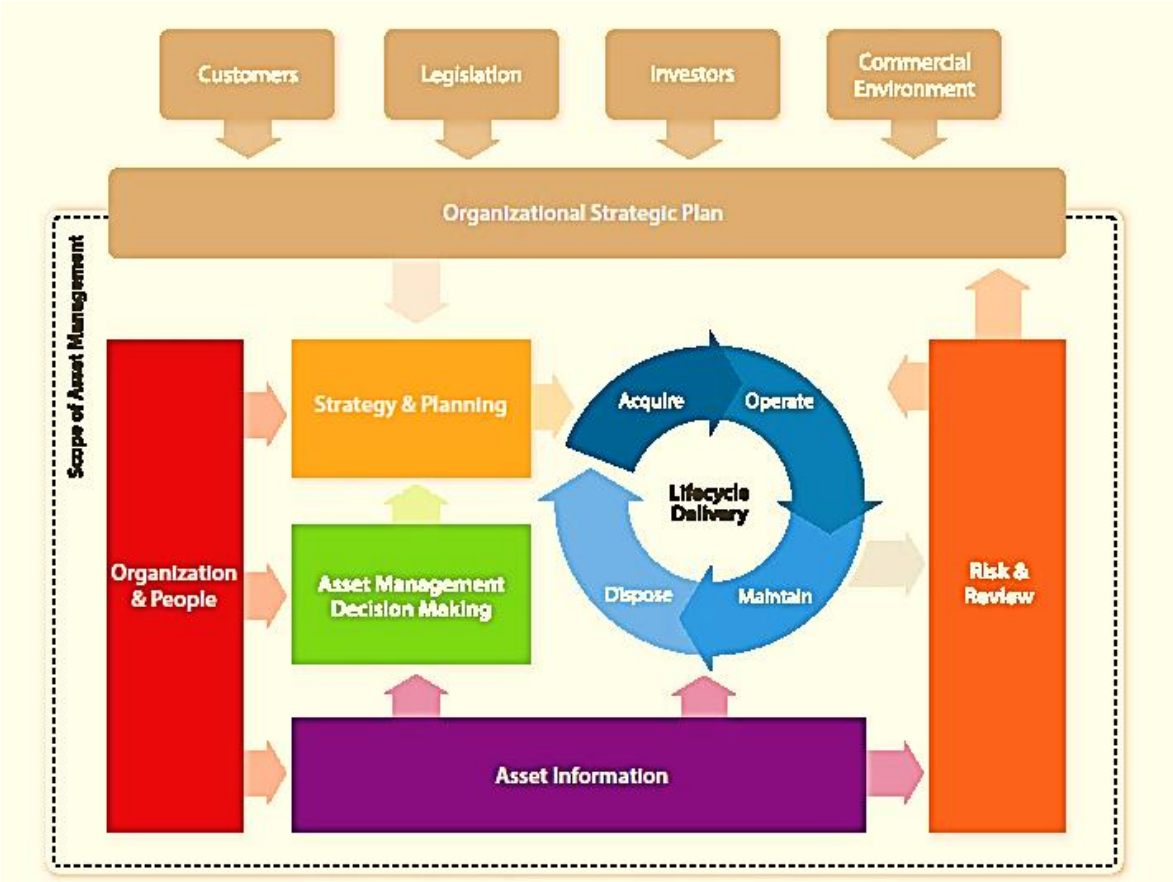
Purpose & Context
- Organizational Purpose and Context
- Stakeholder Management

Leadership & Governance
- Asset Management Leadership
- Asset Management Policy
- Asset Management System
- Asset Management Assurance and Audit
- Technical Standards and Legislation

Organization & People
- Organizational Arrangements
- Organizational Culture
- Competence Management
- Organizational Change Management

Strategy & Planning
- Demand Analysis
- Sustainable Development
- Asset Management Strategy and Objectives
- Planning
- Shutdown & Outage Strategy & Planning
- Contingency Planning & Resilience Analysis
- Resource Strategy and Management
- Supply Chain Management
- Life Cycle Value Realization
- Asset Costing and Valuation

Asset Management Decision-Making
- Decision-Making



Life Cycle Delivery
- Asset Creation and Acquisition
- Systems Engineering
- Integrated Reliability
- Asset Operations
- Maintenance Delivery
- Incident Management & Response
- Asset Repurposing & Disposal

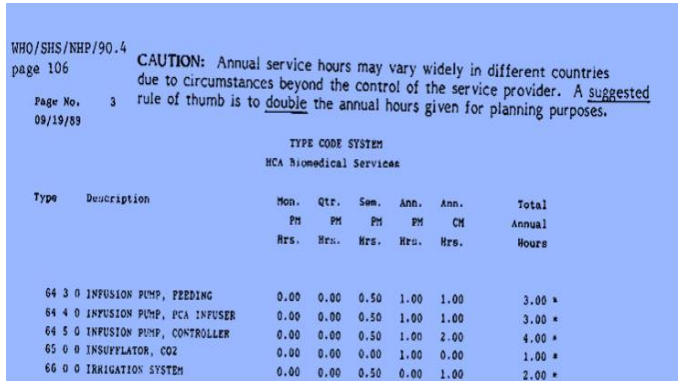
Risk
- Risk Management

Review & Continual Improvement
- Monitoring
- Continuous Improvement
- Management of Change

Information Management
- Asset Management Data and Information Strategy
- Knowledge Management
- Asset Management Data and Information Standards
- Asset Management Data and Information Management
- Asset Management Data and Information Systems
- Configuration Management

Value & Outcomes
- Outcomes and Impacts

1989 WHO: Focused on projected Annual Hours for Preventive (PM) & Corrective Maintenance (CM)



WHO/SHS/NHP/90.4
page 106

CAUTION: Annual service hours may vary widely in different countries due to circumstances beyond the control of the service provider. A suggested rule of thumb is to double the annual hours given for planning purposes.

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09/19/89

TYPE CODE SYSTEM
HCA Biomedical Services

Type	Description	Mon. PM Hrs.	Qtr. PM Hrs.	Sem. PM Hrs.	Ann. PM Hrs.	Ann. CM Hrs.	Total Annual Hours
64 3 0	INFUSION PUMP, FEEDING	0.00	0.00	0.50	1.00	1.00	3.00 *
64 4 0	INFUSION PUMP, PCA INFUSER	0.00	0.00	0.50	1.00	1.00	3.00 *
64 5 0	INFUSION PUMP, CONTROLLER	0.00	0.00	0.50	1.00	2.00	4.00 *
65 0 0	INSUFFLATOR, CO2	0.00	0.00	0.00	1.00	0.00	1.00 *
66 0 0	IRRIGATION SYSTEM	0.00	0.00	0.50	0.00	1.00	2.00 *

2009 WHO: Focused on Impact of HTM on Quality of Care

Indicators for the impact of Health Technology Management on the Quality of Health Care

1. Wait time for specific clinical procedures due to equipment issues
2. Percentage of scheduled surgical procedures cancelled due to problems with equipment and devices
3. Rate of equipment incidents/events during surgery
4. Rate of fatal events during surgery due to equipment problems
5. Rate of fatal events during surgery due to operator errors, e.g. HTM user training
6. How many equipment problems during surgery not resolved due to lack of HTM personnel (e.g. CEs, BMETs) on duty
7. Infection rate due to reprocessing of multiple-use devices
8. Infection rate due to reuse of single use devices
9. How many adverse events due to malfunctioning equipment reported
10. Number/% of referrals to higher level facility due to equipment problems
11. Accident Trauma survival rates – equipment in place for rapid response

... 20 indicators

GlobalCE

Global Clinical Engineering Journal

ISSN: 2578-2762

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2018 Global CE Journal: Showed 6 themes demonstrating improved clinical outcomes

Success Story HTM Global Examples→→→

- **Innovation**
- **Access**
- **Health System**
- **Safety & Quality**
- **Healthcare Technology Management** (HTM)
- **e-Technology** (Digital Health)

Global Clinical Engineering Journal

GlobalCE

Received September 10, 2018, accepted October 9, 2018, date of publication October 13, 2018

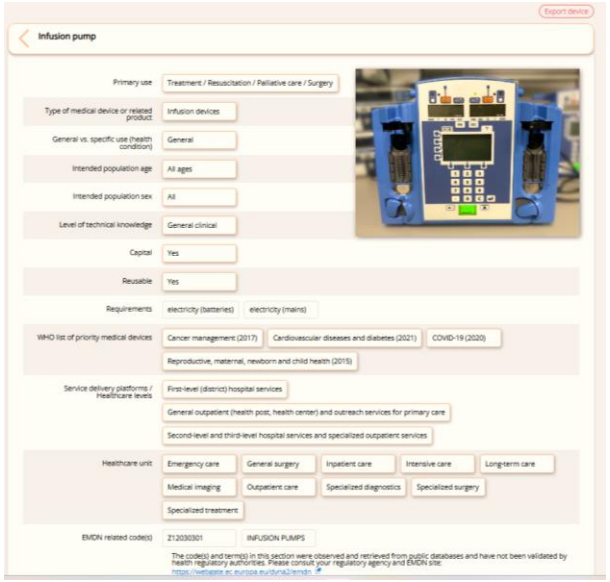
Making a Difference – Global Health Technology Success Stories: Overview of over 400 submissions from 125 Countries

Judd and David: **Global Health Technology Success Stories:** Management

Focus Area	***Title,*** authors, with active links
Italy	***Launch of the new WHO Collaborating Centre for Research and Training in CE and HTM,*** Paolo Lago
Italy	***A Novel Approach to Improve the Technical Maintenance of Biomedical Equipment,*** Daniele Bibbo et al
Jamaica	***Health Technology Management in Jamaica,*** 2010, Keith Richards
Kenya	***MoH ophthalmic equipment support,*** Philip Anyango, Mary Nguri & Joseph Rugut
Kenya	***MoH Device HydroCarbon Refrigeration Training BMETs,*** J. Rugut
Kosovo	***HTM in Kosovo,*** 2010, Agron Boshnjaku S. Ramiqi S, K. Hashani, (***part2***)
Kyrgyzstan	***HTM in Kyrgyzstan,*** 2010, Kazbek Agibetov, (***part2***)
Laos	***HTM in Laos,*** 2GFMD 2013, Thanom Insal
Lebanon	***HTM Implementation at Saint George Hospital – Lebanon,*** Riad Farah
Lebanon	***Medical Devices Repair/Replacement Algorithm Model,*** Riah Farah
Mexico	***Decodifying HTM in Mexican Private Hospitals,*** Luis Fernandez
Nigeria	***Key areas of challenge and progress of CE-HTM in Nigeria,*** Bukola Esan
Paraguay	***Health Technology Management in Paraguay,*** Pedro Galvan, (***part2***)
Peru	***Fostering Clinical Engineering & HTM in Developing Countries: Alignment and Effectiveness in Peruvian Health Sector,*** Rossana Rivas
Puerto Rico	***Health Technology Management update in Puerto Rico,*** Oscar Misla, (***part2***)
Romania	***Prioritization of Medical Devices for Maintenance Decisions,*** S. Taghjpour et al
Rwanda	***Medical device technician training,*** A. Worm, Mpamije Tonkin, Mol, Kasaro
Saudi Arabia	***Creation of Health Technology Technical E-Library,*** Salah Alkhallagi
Senegal	***Maintenance of medical devices and quality management in Senegal,*** Dr. Mamadou Sow, Senegal, WHO 2GFMD
Sierra Leone	***Immediate impacts of inventory on procurement,donations,maintenance and use of medical equipment,*** Kabia, Johnson, Ministry of Health, WHO 2GFMD, 2013
South Africa	***Math Model for Reliable Maintenance of Medical Equipment,*** Baset Khalaf, 2015, (***part2***)
Sub-Sharan Africa	***The status of medical equipment in Sub-Sahara Africa,*** Anna Worm, Theogene Nama-hungu, Harold Chimphepo, Charles P. Soroheye

2020 CED: Indicators in Context of Whole Hospital Performance

2025 WHO Nomenclature MeDevIS



2025: WHO Nomenclature: Example of Priority Infusion Devices for Cancer Management

ICHI codes [clickable]	Clinical interventions	Level of care 1	2	3
Hospitalization				
	Inpatient admission		X	X
	Clinical and paraclinical monitoring (scheduled tests)		X	X
	Medical treatment and wound care	X	X	X
	Administration of medication (administration of oral and parenteral treatment)	X	X	X
Intensive care unit				
JTB.DE.AC	Mechanical ventilation		X	X
PZA.DD.AC	Oxygen therapy	X	X	X
HT2.AA.ZZ; ITA.AI.AF	Continuous multiparametric cardiac monitoring with non-invasive/invasive blood pressure monitoring and ambulatory blood pressure monitoring		X	X
JTB.AI.ZZ	Monitoring of oxygen saturation	X	X	X
HTB.SC.AH	Defibrillation and external pacemaker/resuscitation	X	X	X
PAK.BA.BJ; IZZ.BA.BJ; KMA.BA.BJ	Ultrasound scan		X	X
JZZ.DL.AC	Intubation		X	X
PZX.DB.AE PZX.DB.AF	Continuous infusion and application of supportive drugs		X	X
PZX.AH.XA	Blood gas analysis		X	X
JCH.BA.BA	Imaging of the chest	X	X	X
PZX.AH.XA	Point-of-care glucose test	X	X	X

III. Priority medical devices by clinical area

EMDN related code(s) Z12030301 INFUSION PUMPS

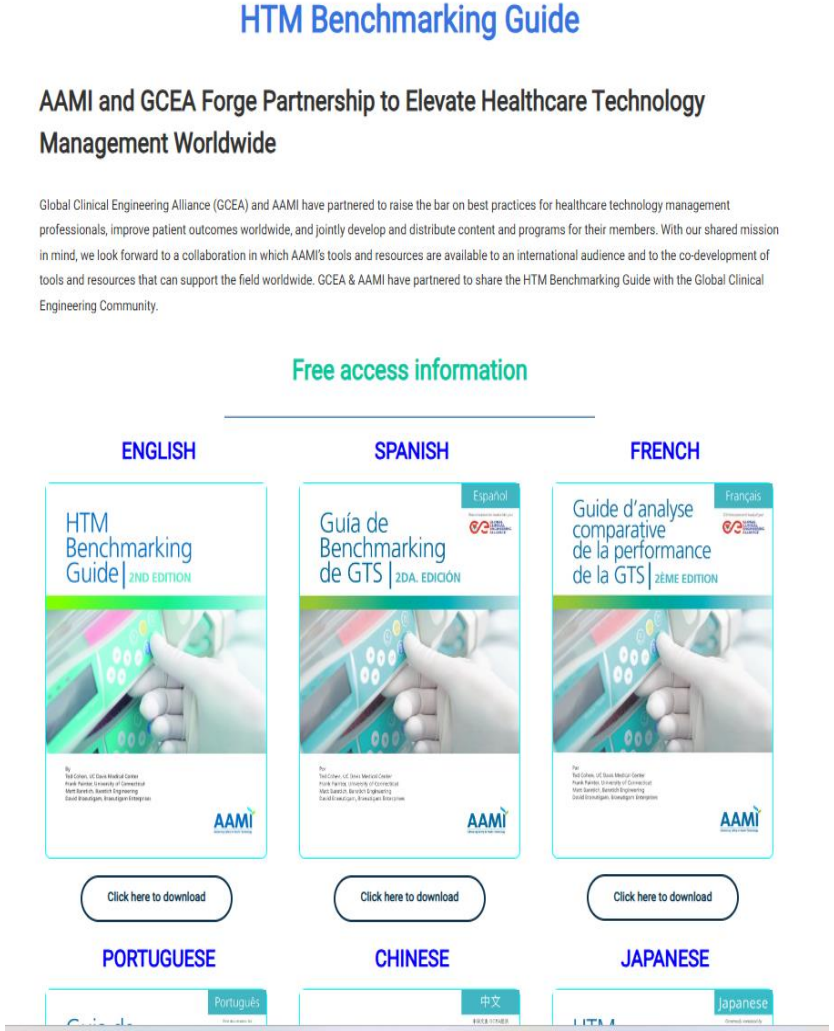
The code(s) and term(s) in this section were observed and retrieved from public databases and have not been validated by health regulatory authorities. Please consult your regulatory agency and EMDN site:
https://webgate.ec.europa.eu/dyna2/emdn

GMDN related code(s) 13215

Bedside infusion pump, single-channel (An electrically-powered, non-ambulatory (bedside) device designed to facilitate the accurate and consistent administration of a single drug/solution which can be delivered via intravenous, subcutaneous, arterial, epidural, and intracavital routes using a dedicated infusion set; it is not dedicated to a specific treatment type. It is used to supply higher pressures than those provided by gravity infusion sets or infusion controllers (e.g., typical flow range of 1 to 999 ml/hour) and delivers solutions from a standard infusion bag or bottle of fluid. It is intended primarily for use at the bedside but typically has internal batteries that enable operation, e.g., during transportation.)

The medical device term(s), code(s) and definition(s) in this section were retrieved from databases external to WHO. As there might be more than one name, definition and "Nomenclature Code" related to the specific medical device, please consult https://gmdnagency.org GMDN ®. © GMDN Agency 2005-2025

2024: GCEA-AAMI Translation of *CE-HTM Benchmarking* Guide – 9 languages completed so far



Nomenclature, WHO DG EB156/13 report v1, January 2025

https://apps.who.int/gb/ebwha/pdf_files/EB156/B156_13-en.pdf **Required Asset Standardization**

- **The WHO Medical Devices Unit is described here:** https://www.who.int/health-topics/medical-devices
- **Medical devices** are health products that are required for protection, prevention, diagnosis, treatment, rehabilitation and palliation, and that do not have a pharmacological function.
- **Through an evidence-based assessment** process, WHO publishes lists of priority medical devices for the following conditions: reproductive, maternal, newborn and child health; cancer management; COVID-19; cardiovascular diseases and diabetes.
- **The lists of priority medical devices** are continuously expanding to include other health conditions.
- To facilitate dissemination and data management, **the publications are hosted in the WHO medical devices clearinghouse**, the Medical Devices Information System (MeDevIS) https://medevis.who-healthtechnologies.org/.

The nomenclature for medical devices supports:

- patient safety;
- access to medical devices for universal health coverage;
- emergency preparedness and response;
- efforts to increase quality of healthcare;
- better supply systems;
- regulatory and post-market information;

towards the achievement of **Sustainable Development Goal 3**. The availability of standardized nomenclature will avoid the development and use of separate naming systems by each organization.

Under the terms of a March 2024 agreement, the contents of the WHO databases, including EMDN and GMDN nomenclatures, may be copied, redistributed and adapted for non-commercial purposes, provided that it is appropriately cited. See this 2024 webinar for further description: https://www.who.int/news-room/events/detail/2024/07/08/default-calendar/webinar--nomenclature-of-medical-devices--emdn---gmnd

Digital Health CE-HTM Tools

ITIL internal "configuration items“

Necessary Asset Management Inventory Fields

- software versions
- firmware updates
- security management (cybersecurity)
- provenance of components
- network permission standards
- chip performance data
- memory
- capitalized upgrades
- manufacturing batches of the components
- Release management (patches)
- **Software as Medical Device (SW MD)**
- **Internet of Things (IoT)**
- And more …

- **ITIL** = IT Infrastructure Library
- **Continuing to emerge** new set of Asset Fields, software-based devices needing CE-BME standardization
- **ITIL Configuration Management** is a process that manages and controls an organization's IT assets. It includes identifying, controlling, and documenting the configuration of IT services and their components.

Case Study 1: *Kaiser Permanente (KP) Digital Operating Rooms (DOR)**

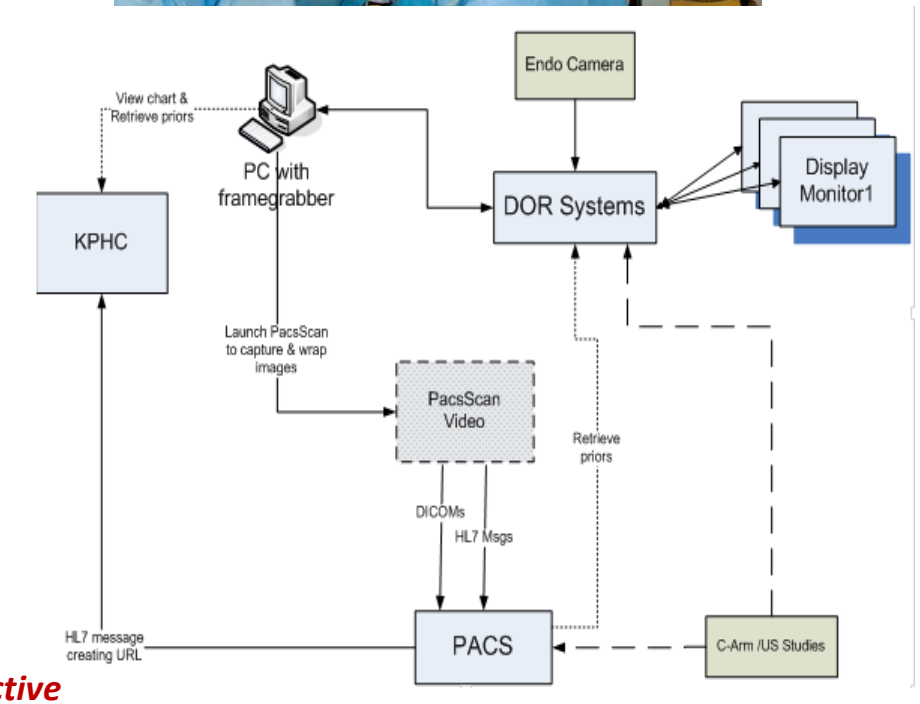
Multiple Manufacturers, Devices Integrated into EHRs, Improved Quality

1. ***DOR:*** KP began deploying Integrated or Digital OR (DOR) systems along with its High-Definition (HD) Rigid Endoscopes via its national Surgeon & Perioperative Nursing leaders purchasing group in 2006. By 2015, there were over 200 DOR systems in place whose images were able to be integrated with PACS and EHR (called KP HealthConnect-KPHC), allowing OR scheduling via the EHR and later image retrieval from PACS for diagnoses.

2. ***Clinical Requirements met include***: (1) Superior image quality of surgical video (HD), with easy-to-use system features for staff, and supportable by KP ***Clinical Engineering*** and KP IT. (2) Surgical images and video are able to be seamlessly integrated with PACS systems and EHRs. (3) DOR functionality is able to keep pace with latest computer/tele-communication technologies, eg, streaming video, e-consult Interfacing / interoperability of various image sources with DOR systems, e.g., C- Arms, ultrasound, and digital microscopes.

3. ***Quality Challenges include*****: (1)** Device interoperability ensuring image quality when using different DOR and Rigid Endoscopy suppliers; (2) Storage and retrieval of surgical images with appropriate privacy and security compliance; and (3) Reliability, reprocessing, and durability of surgical video Endoscopy.

4. ***Other Digital Health Challenges included*****: (1)** Different image capture and management strategies for different surgical sub- specialties; (2) Sending images to mHealth platforms, eg, SmartPhones, Tablets while meeting needed privacy and security; (3) Wireless image transfer and fidelity; and (4) Ongoing testing of image quality.



*Judd, 2023 ***Post-Market Surveillance (PMS) for Medical Devices: A Clinical Engineering (CE) Perspective***

Case Study 2: USA, *KP Infusion Pump Systems*

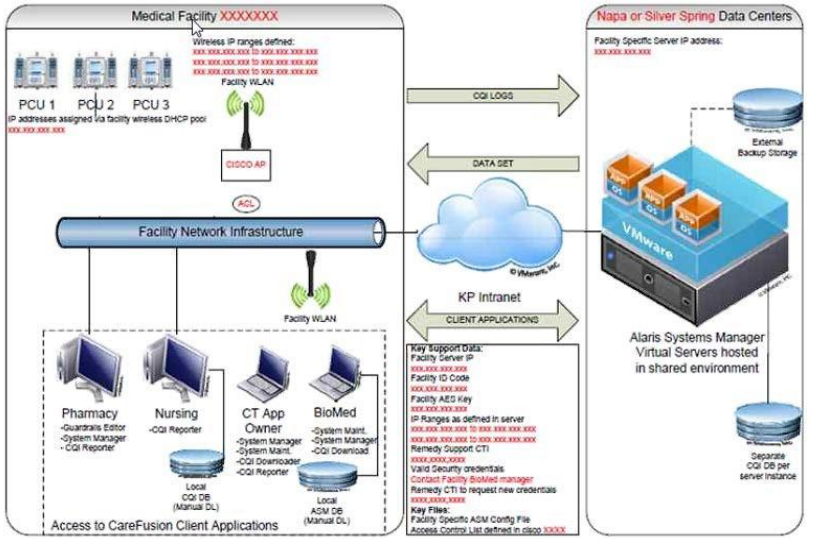
Single Manufacturer, Digital Health tools, Quality, Cybersecurity

1. ***Overview***: Kaiser Permanente (KP) replaced *Vendor X* with 17,000 *Vendor Y* ***large volume infusion pumps (LVP)*** used for inpatient and clinic care across KP Regions. KP had on average an LVP 'Brain' (PC Unit) and 1.5 Modules for each patient care set-up. See ***Figure below*** for KP LVP IT Infrastructure.

2. ***Clinical Requirements were met by***: utilizing *Guardrails* Drug Error Reduction System (DERS) with downloadable clinical quality information (CQI) per pump and programmable profiles per use area to monitor quality of use, and Drug Library data sets with 2500 programmable drugs across all settings. A supporting ***Clinical Engineering*** (called ***Clinical Technology-CT***) / IT infrastructure was developed, with the ability to later integrate LVP into KP's EHR.

3. ***Quality Challenges***: Several USA FDA alerts re design, software (SW)/firmware, cleaning and infection control, equipment preventive maintenance, and other issues; over-infusion Incidents supplier follow-up; warranty and post-warranty support concerns; and alarms, e.g., such as tubing setup and artifact interference in certain clinical settings.

4. ***Other Digital Health Challenges included***: wireless challenges for CQI downloads and SW change management - took the manufacturer two years to re-design and correct the wireless card; eventually hit limit and need to exceed 2500 programmable drugs for all clinical use cases; and security protocols for all device use cases **(Cybersecurity).**

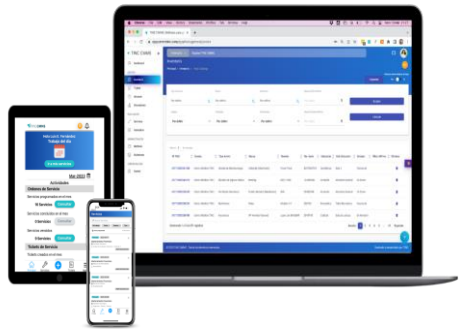


KP LVP Photo and KP IT Infrastructure

Case Study 3: TINC Mexico: *IoT Applied to Hospital Infrastructure Projects***

2025: Interaction of Asset Management, CE and Enterprise Digital Health Tools

- ***TINC:*** Develop and implement software for asset management and maintenance exclusively for health. Offer telemetry and RTLS services for healthcare infrastructure optimization along with our partners. https://cmmstinc.com/
- **Digital Transformation Hospital infrastructure** is critical to healthcare. Digitalization and connectivity allow for more efficient management. The **Internet of Things (IoT)** is key to this transformation. Connected sensors collect data in real time, allowing continuous monitoring and automatic alerts. Health applications: medical equipment, infrastructure, security, reducing manual measurements.



Interoperability of CE-BME, Business & Clinical IT systems

CMMS — ERP — HIS

ICU IT Support

- Costs of staff
- Patient-connected to EHR
- Medications used
- Materials & Services used
- Medical equipment usage
- Equipment Maintenance

** TINC Mexico, Luis Fernandez, January 2025, Health Data Webinar

What's Next in 2025?

- ***Call for Action for all CE-BME-HTM worldwide!*** **Join GCEA as we build on the following!**
  - **Artificial Intelligence (AI);** see Dr. Ricardo Silva's February 2025 GCEA Tech Snapshot
  - **Internet of Things (IoT);** see Luis Fernandez, TINC Mexico January 2025 Health Data Webinar
  - **Impact on CMMS from Digital Health, Quality and Safety,** eg, Cybersecurity
  - **Hospital and Health System Performance,** perhaps through International Hospital Fed. recognition
  - ***Clinical Engineering Department*** **& Independent Service Organization (ISO) Accreditation**
    - **More and more countries defining their Standards of Practice using CE-HTM Indicators**
    - **CMBES Canada does CE Department Accreditation/Peer Review & ABEClin Brazil assists ISO Accred.**
    - **GCEA with CMBES is developing Global CE Program Accreditation as well as collaborating with ISQua for this approach**

GLOBAL CLINICAL ENGINEERING ALLIANCE™

Thank you!

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