KEY FUTURE CAREERS FOR HEALTH TECHNOLOGY INNOVATION

The activities of clinical engineers for health technology management in the lifecycle of health technologies

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1 / Clinical engineer: a definition (AIIC)

The clinical engineer participates in the health care ensuring a safe, appropriate and economical use of the biomedical equipment and medical-IT used in healthcare facilities, guarantying the following activities:

• evaluation of health technologies and health systems with the "Health Technology Assessment" methods;
• planning and evaluation of technology purchases;
• technology management and functional design;
• acceptance tests;
• management of maintenance and consequent activities;
• risk management;
• safety management and functional checks;
• training and education on the use of technologies;
Clinical engineering: strategic role

- integration of technologies in the hospital environment;
- clinical informatics and "Information Technology";
- technical-scientific and economic management research;
- research and development of software, procedures and medical devices

The multidisciplinary activities related to the management of biomedical technologies by the Clinical Engineering Services, for their role as an interface between technology and health care justify an organizational peculiarity and autonomy with respect to other technical specialties present in the healthcare facilities.
Clinical engineering: strategic role

As part of the technology management activities, the Clinical Engineering Service constantly interacts with the other professionals present in the healthcare facilities normally located in the Technical Service (building and plant service), in the Prevention & Protection Service (corporate safety), in the Information Technology Service (SW, HW, networks, TLC) and in the Medical Physics Service (radioprotection).

The organization of Clinical Engineering for health facilities becomes, therefore, a strategic factor, both for the management and control of costs, and, at the same time, to ensure the highest quality of services provided in a frame of appropriateness and safety.
3 / Characteristics of Clinical Engineering: what do we do?

- Clinical Engineering does not just fix medical devices and equipment
- Provide comprehensive support
- Interact with entire hospital/health stakeholders

*reference - Clinical Engineering Handbook - Joseph F. Dyro*
4 / Characteristics of Clinical Engineering: who are we?

- “…trained professionals who support and advance patient care by applying engineering skills to healthcare technology…”
- Our mission: to ensure the safety and performance of medical devices and equipment
- To provide a broad based engineering program that addresses all aspects of medical instrumentation and systems support*

*reference - Clinical Engineering Handbook - Joseph F. Dyro
Characteristics of Clinical Engineering: what do we do? 9 disciplines

- Health Technology Management
  - Technology assessment, evaluation, strategic planning, acquisition, license, lifecycle cost analysis, upgrades & national health technology policy, program & personnel administration

- Safety
  - Systems analysis, hospital safety programs, incident investigation, root cause analysis, user error, risk analysis & management, hazard & recall reporting systems, post-market device surveillance, device-device interactions, electromagnetic compatibility, disaster preparedness

- Medical Device Service
  - Equipment control, computerized assets & maintenance management systems, inspection, maintenance, repair, in-house and outsourced programs, independent service organizations, vendor & service management, spare parts management

- Technology Application
  - Engineering at the bed side, specialization in clinical areas, quality assurance & improvement, clinical application support, home care support, help desk, installation & integration

- Information Technology
  - Information system integration and management, patient data management, artificial intelligence, telemedicine, picture archiving and communication systems, wireless networks (telemetry), Health Insurance Portability and Accountability Act

- Education & Training
  - Credentialing, healthcare provider technology training, distance education, in-service education, training schools, academic programs, international training, professional development, volunteer work

- Research & Development
  - Medical device design & manufacturing, evaluations, modeling & simulation, human factors, failure mode and effect analysis, clinical trials & institutional review board support

- Clinical Facilities
  - Clinical space design, electrical power, medical gases, water, HVAC (heating, ventilation, air conditioning), sanitation, construction, renovation, communications infrastructure

- Standards & Regulations
  - Compliance insurance, medical device and facilities standards, quality standards, regulations, consensus, standards and guidelines, accreditation, expert witness, certification

*reference - Clinical Engineering Handbook
Joseph F. Dyro
7 / Role of Clinical Engineering: **Health Technologies**

**Life Cycle Management**

- **Purchase**
- **Investment planning**
- **Life Cycle Management**
- **Installation and acceptance activities**
- **End of service/life**
- **Maintenance and Safety**
Total Life Cycle Cost of Ownership

- Purchasing costs
- Maintenance costs
- Operating costs
- Transport and installation costs
- Staff costs
- Training costs
- Costs of removal from service
- Administration and supply costs
- Cost of recording and evaluating data
9 / Investment planning

Investment plan

Identification of replacement priorities

Evaluation of clinical and technical appropriateness

Technological renewal

Technological Innovation
10 / Tool to govern technological innovation: HTA

Health technology assessment (HTA) refers to the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision making.
10 / Hospital Based HTA

- Planning
  - Clinical function

- Technical specifications for tender

- Installation and acceptance activities
  - Training and educate

- Needs Assessment

- Clinical applicability analysis

- System Assessment

- Approvement

- Implementation

- Follow up

- Analysis of technological alternatives
  - Integration with environment and procedures

- Purchase

- Maintenance
  - Monitoring
  - Safety check
  - End of life

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- Responsible for Life Cycle Management for thousands of medical devices within healthcare facilities
- Perform continual risk analyses:
  - Pre-Procurement planning
  - System quality/efficiency
  - Safe and effective for patient care
  - Serviceable/Upgradable
  - Reliable
  - Device Integration
  - System Integration/Interoperability
Characteristics of Clinical Engineering:
what do we do? Health Technology & Risk Management

Perform continual risk analyses:

- Equipment Installation and implementation:
  - Assess and minimize clinical and physical risks
  - Establish policy and criteria for routine maintenance
  - Ensure functionality
  - Ensure used in a safe and effective manner
  - Establish emergency procedures
  - Educate clinical staff
- Requires substantial coordination with multiple departments
- Systematically review system performance, safety and effectiveness throughout the medical device’s entire life cycle

Equipment service stakeholders:

In-house clinical engineering +

OEM (Original Equipment Manufacturer)
3rd Party Service Organizations
3rd Party Parts Suppliers/Distributors
Independent Service Organizations
12/ Characteristics of Clinical Engineering: how do we do? Partnership

- Organizational flexibility
- High technological specialization (independent service organization for medium-low complexity technology maintenance and OEM for the maintenance of highly complex technologies)
- Internal control: Ensure Quality of Services from Independent Service Organizations and OEMs

Successful In-House Clinical Engineering, Independent Service Organization, 3rd party Clinical Engineering service and OEM partnerships are essential.
**12/ Characteristics of Clinical Engineering:**

**how do we do? Activities in outsourcing**

- Equipment inventory assets
- Acceptance activities
- Effective documentation system
- Inspection, testing, safety,
- maintenance, preventive
  maintenance, repairs

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- Technology assessment
- Investment planning
- Risk analysis
- Management control
- ICT
- Research
- Education and training
Thank you for your attention

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