Clinical Engineering Support toward Optimum Quality and Safety in Hospitals

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ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

Join ACCE and the world as we celebrate the 2nd Global Clinical Engineering Day

10/21/2017
2nd Global Clinical Engineering Day

GLOBAL
CE
DAY 10.21

Happy Global CE Day to all Clinical Engineers, and thank you for your continued support of the field!

Neonatal Intensive Care Unit (NICU)

"Only three things in life are certain, birth, Death and Change"   **Arabic Proverb**

" To improve is to change, to be the best is to change often "   **Winston Churchill**

Overview

- Biomedical Engineering
  - Solving problems in biology and medicine using engineering methods and technology (e.g., <u>research, design and development</u> of biomedical instrumentation.)
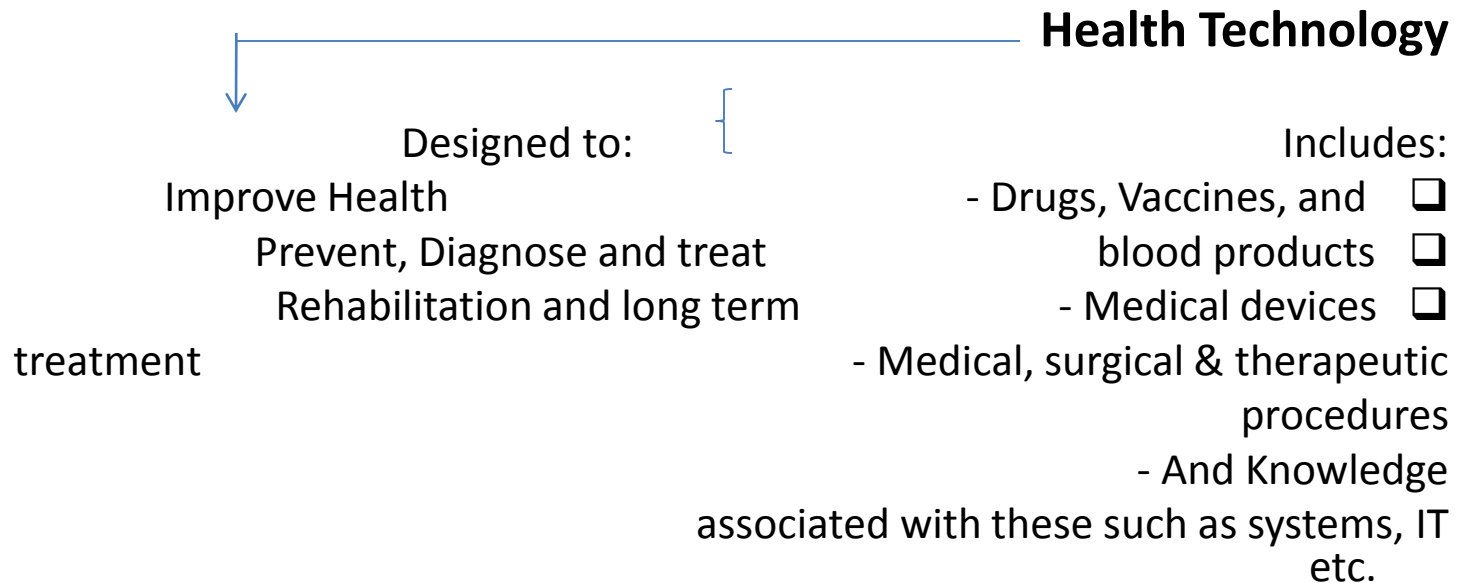
Clinical Engineering

A clinical Engineer according to American College of Clinical Engineering definition, 1992; is " a professional who supports and advances patient care by applying engineering and management skills to healthcare technology"

Clinical Engineering is the application of Engineering and Technology to Analyze and provide solutions for the clinical needs of Patients, it's an application of Biomedical Engineering to **Health Technology**

Health Technology

Health Technology

Designed to:
Improve Health
Prevent, Diagnose and treat
Rehabilitation and long term treatment

Includes:
- Drugs, Vaccines, and ❏
blood products ❏
- Medical devices ❏
- Medical, surgical & therapeutic procedures
- And Knowledge associated with these such as systems, IT etc.

''It's the application of Organized knowledge and skills in the form of devices, medicines, vaccines , procedures and systems developed to solve a health problem and improve quality of life'' WHO

History and trending of Clinical Engineering

- 1970-1978;
  - Associated with Physical Plant
  - Electrical safety
  - Corrective maintenance of basic electromedical equipment
  - Technicians oriented
  - Mechanical oriented
  - Initiation of PM program
  - Equipment Control Program initiated

History ....CE

- 1978-1984;
  - Maintenance oriented
  - Center for hazard and recall network
  - Incident investigation
  - Significant involvement in acquisition process
  - Initial involvement in outside service contracts
  - Initial involvement in equipment acquisition process
  - Heavy on PM and electrical safety

History ….. CE ….

- 1984-1989;

  - Many report directly to administration
  - Computerized equipment control program with productivity and cost analysis capability
  - Maintenance of more sophisticated technology including medical imaging and clinical lab.
  - Initial involvement with service contract management

History….CE ….

- 1996- 2017;
  - Medical Technology networking
  - CMMS Comprehensive maintenance management
  - Accreditation and QMS
  - Active participation in equipment planning and facilities development till commissioning and up keeping
  - Initial involvement in HTA

Evolution of Clinical Engineering

- 2017 + Future Projection)

    – Health Technology Assessment
    – Device risk assessment analyisis
    – Strategic Technology Planning
    – Integration of Clinical and Information Technologies
    – Increasing clinical involvement
    – Quality project management
    – RFID application, real time tracking system
    – IT Networking
    – VPN Networks for Troubleshooting
    – Smart Technology Convergence
    – IoT application
    – Little of no traditional services
    – Clinical Knowledge
    – Cybersecurity
    – Chief Technology Officer
    – Complete IT convergence

Clinical Engineering in Action

- Mission:

  - Ensure the safe and effective application of Health technology to patient care.

- Customers:

Dual Role: 1. Provide the highest level of technology patient care to customers in hospitals and 2. Maximum utilization of the asset or device with no interruption of patient care from patient entry till exit- 95% is not enough! ----Cost savings

- Nurses, Physicians, patients, allied health professionals
- Management, hospital environment, finance
- Venders, manufacturers, third parties
- Regulators, FDA
- Clinical research
- Quality and accreditation

Functions of Clinical Engineering

- Health Technology Planning
- Health Technology Assessment
- Acquisition and Application of Health Technology
- Health Technology Management and Service
- Equipment Control
- Preventive and Corrective Maintenance
- Service Contract Management
- Standards and regulations
- Technology Application
- Technology Consultant

Functions of Clinical Engineering

- Development of New Technology
- Facility Planning and Development
- Safety and Risk Management
- Continuous Quality Improvement
- Education and training
- Clinical Equipment Application
- Research and development
- Information Technology

Technology Planning

- What types of technology are best suited to satisfy the program needs of this facility?

- What are the future technology requirements?

- What technologies are under development? How will they impact patient care?

- Going beyond repair history and end of life cycle

- How can technology be better utilized to improve patient outcome, control costs and improve productivity?

Technology Planning….

- Awareness of Program Needs
  - Frequent communication with users
  - Involvement with technology related committees
- Awareness of Technology Resources
  - Equipment Control Program
- Technology Budget planning
- Continuing Education
  - Professional Journals and Newsletters
  - Professional Societies
  - Internet
  - Seminars and Conferences

Health Technology Assessment (HTA)

Definition:

- Assessment of medical technology (devices, drugs, procedures, devices & systems)
  - Safety
  - Clinical effectiveness
  - Cost effectiveness
  - Ethical (e.g., reproductive technologies)
  - Legal

CE role in HTA

- Information gathering
- Information dissemination
- Facilitation
- Research
- Networking
- Recommendations
- Follow up and consultation

Involvement in HTA

- HTA for Medical devices
- Evidence based
- Effectively, performance and cost for current technologies
- Benchmark with other local and International organizations
- Networking with other HTA organizations
- Establish HTA units in hospitals

Acquisition and Application of Technology ….

- Needs Assessment
- Environmental Assessment
- Translation of Clinical Requirements into Technical Specifications
- Research
- Technical & Functional Evaluations

Acquisition and Application of Technology ….

- Recommendation and Purchase

- Incoming Inspection

- Add to Equipment Control Program

- Installation

- User Education

Equipment Control ….

- User application
- Utilization
- Replacement requirements
- Service history, parts' usage, and monitoring cost
- Frequency of PM and performance assurance. What P.M. procedures are performed?

Technology management and Service

- Life cycle management and cost of ownership
- In-house or external service?
- System integration
- Warranty management
- Level of in-house service
- Corrective-maintenance service process
- Service facility (size, location, etc.)
- Size of technical staff

Technology management and Service ….

- Sustainability of operation
- Staff training
- Staff organization
- Parts inventory
- Test equipment
- Equipment manuals & documentation
- Diagnostic software

Technology management and Service ….

- Vendor support
- Frequency of PMs
- Scheduling
- PM procedures
- Service reports
- Billing rate

Service Contract Management

- In-house, vendor, third-party, maintenance insurance?
- Provisions of service contracts
- Service contract negotiation
- Monitoring and documentation service contracts
- Cost analysis

Development of New Technology

- Needs assessment

- Safety assessment

- Research

- Design and specification

- Prototype construction, testing and evaluation

Development of New Technology….

- Construction, testing and documentation of final assembly

- Regulatory approvals

- User education

- Modification, documentation and reporting

- Add to equipment control program

- Others ……

Projects involvement

- Real time tracking system/ RFID
- Cybersecurity initiatives
- Risk assessment analysis
- Utilization/RCA
- EMR device integration
- FPDCA
- Six sigma projects
- EMR device integration
- Alarm fatigue analysis for meaningful alarms
- Others ……….

Facility Planning and Development

- Specifying equipment requirements
- Liaison between contractor and hospital
- Project planning and management
- Ensure conformance to relevant to standards, codes & regulations

Safety and Risk Management

- Remain current on all pertinent codes & regulations
- Interpretation of codes & regulations
- Implementation and enforcement of codes & regulations
- Maintain system for responding to published equipment hazard reports

Safety and Risk Management

- Reviewing requests for new technology as to safety and effectiveness
- Identification of potential hazards
- Assessing degree of hazard protection required in relation to size of risk
- Preventing technological change when risk unwarranted or effectiveness not demonstrated
- Users errors

Safety and Risk Management….

- Incident investigation and reporting
- Maintain incident database.
- Safety policy development
- Development of safety education programs
- Representation on hospital safety committee
- Liaison with manufacturers
- Liaison with hazard reporting agencies (ECRI, Government)

Continuous Quality Improvement

- Identify customers
- Identify and <u>measure</u> improvement needs (KPIs)
  - Identify critical processes
  - Identify quality indicators
- Examine problems and analyze the causes
- Auditing processes
- Decide on solutions and action plans to achieve them
- Implement proposed solutions, measure and evaluate
- Adopt and standardize improved processes
- Users questionnaires and complaints analysis

Training

- Clinical Engineering staff
- Clinical Staff
- Patients
- Partnership with local Clinical Engineering Technology Programs

Training of CE staff

- Attend relevant conferences and seminars
- Attend vendor service courses
- Participate in Clinical Engineering professional associations
- Available clinical engineering magazines and journals
- Remain current on developments in medical technology (vendor contacts)
- Participate in quality seminars
- Online training
- Participate and become certified surveyor

Training of Clinical Staff

- Development of in-service education programs
- User training on new equipment and problematic equipment
- Annual refresher courses for clinical staff
- Informal user assistance and training
- Documentation of user training
- Education of clinical staff on new developments in medical technology

Training Partnerships

- Advise local Clinical Engineering Technology programs on curriculum content
- Assist with training
- Provide hospital internship program
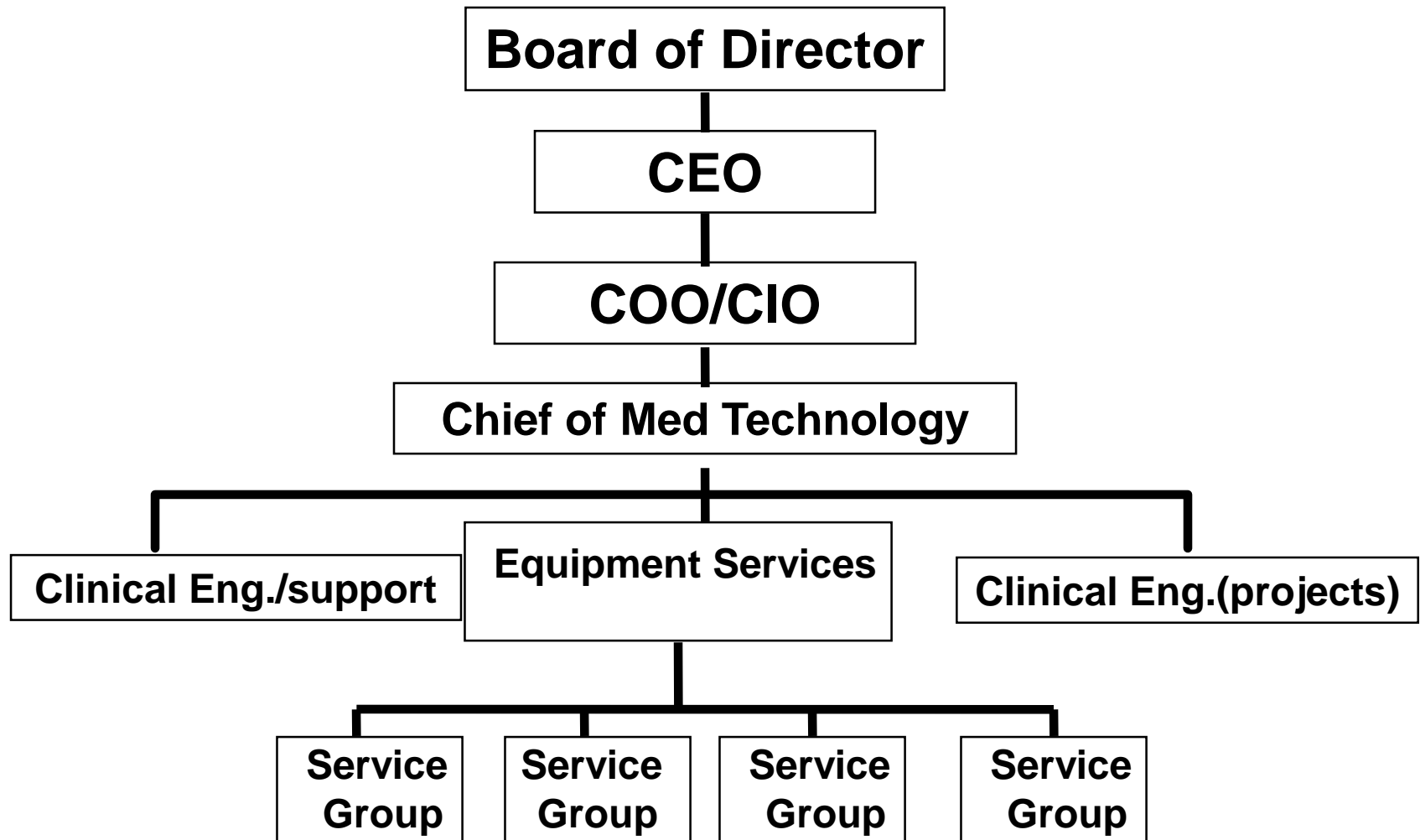
Clinical Equipment Application

- Provide assistance with set-up and operation of technically complex medical devices
- Assist clinicians with application of medical technology in tertiary care areas (ICUs, Diagnostic areas, and ORs)
  - Dialysis
  - Intraaortic Balloon Pump
  - Lasers & Electrosurgery

Clinical Engineering Department Sections an option

- Risk management/CQI, Quality; Projects
- Technology Planning and Assessment; Support
- Technology Development, training; Support
- Equipment Services
  - Clinical Laboratory
  - Diagnostic Imaging
  - Medical Instrumentation Group 1
  - Medical Instrumentation Group 2
  - etc.

Modern Clinical Engineering Organizational Structure

Board of Director

CEO

COO/CIO

Chief of Med Technology

Clinical Eng./support

Equipment Services

Clinical Eng.(projects)

Service Group

Service Group

Service Group

Service Group

CE JCI Standards

❑ 1. Medical equipment is managed throughout the
     Organization according to a plan.

❑ 2. There is an inventory of all medical equipment.

❑ 3. Medical Equipment is regularly inspected.

❑ 4. Medical Equipment is tested when new for
     incoming inspection.

❑ 5. There is a preventive maintenance program.

❑ 6. Qualified individuals provide these services.

CE JCI Standards…

❑ 7. Monitoring data are collected and
    documented

❑ 8 . Documentation is used for purposes of
    Planning and improvements.

❑ 9 . There is a product / equipment recall system
    in place.

❑10 . Policies and procedures addresses any use of
    devices under recall.

❑11. The policies and procedures are
    implemented.

CE Temos Standards

❑ 1. Inventory of all medical equipment is available

❑ 2. Equipment is checked and inspected and users are trained before operation

❑ 3. Medical Equipment is regularly inspected, tagged with valid dates.

❑ 4. Repair services are documented and monitored..

❑ 5. There is a preventive maintenance program.

❑ 6. Adequate number of staff members, qualified and trained

CE Temos Standards …

❐ 7. Data is collected and monitored through KPIs

❐ 8. Documentations is collected for the purpose of
planning and improvement.

❐ 9. There is a product recall system in place and policy
dealing with any recall.

❐ 10. Policies and procedures are available and cover
all services of a CE department.

❐ 11. Availability of needed medical devices in critical
areas

❐ 12. Critical equipment: Defibrillators, ventilators, anesthesia
equipment etc. have implemented users inspection and
cleaning procedures.

CE Temos Standards …

❐ 13. Service contract management and follow up including remote services for major digital systems are in place.

❐ 14. Safety inspection and QC protocols are available and implemented in Radiology and nuclear services.

❐ 15. Test equipment management certification protocols are available and implemented

❐ 16. Disposal evaluation and equipment retirement protocols are available and implemented.

❐ 17. Sterilization of medical devices protocols and on processing of single use devices are available.

❐ 18. Protocol is available for Technical terms and conditions

What others CE standards?

Clinical Engineering auditing

- Tracing Methodology
- Key performance Indicators
- Quality improvement projects
- Customer surveys
- External audits
- Dash boards
- Others?

Tracing Methodology for CE

- Tracking equipment from floor and tracing it back
- Identifying the needs, Budgeting and purchasing process
- How the equipment entered the hospital, incoming inspection, documentations, .. Is it according to the purchasing process?
- Trace training to users, check records and training orientation to CE staff, records …
- Checking Medical Equipment plans and IPPs
- Checking maintenance history, PM, repair, up time etc.
- Documentations, service manuals and operating manuals access to engineers and technicians
- Quality improvement statistics and general progress reports
- Evidence of team work with users and other departments

What are the top problems with equipment in your hospital?

- ?????????

Findings from actual surveys

Hygiene and cleaning	35
Maintenance of equipment	33
Infection prevention and control	28
Staff training (different areas)	22
Security and evacuation system	21
Medication handling incl. narcotics, HAM, LASAD	17
Fire and smoke detection	16
Emergency exit signs	15
Defibrillators	14

*Data from 38 hospital's onsite surveys/reports from Europe, Middle East and Far East from 2012-2016

Temos
Trust · effective medicine · optimized services

CE Challenges
in Arab countries

- Utilization of equipment

- HTA non exixtant

- Resources /support/appropriation

- Healthcare Technology Management process ?

- Awareness of clinicians

- Others ….

Discussion

1. What specific challenges you have in
your hospital? Select top 3
2. What specific strengths of your department?
Select top 3
3. What KPIs you are using or suggest to use?
What do you think should be the solution to your
challenges?
5. Select best 3 recommendations

Conclusion

- Clinical Engineering optimum services and activities are essential to the safety and efficacy of medical devices and towards improving healthcare services for optimum quality and safety.

- Successful In-House Clinical Engineering, 3rd party Clinical Engineering service must keep up with trends and to partner with all stakeholders.

شكرا جزيلا
Thank you

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