Safety and Quality of Medical Equipment

Global Clinical Engineering Perspectives

Wednesday, May 11

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2 PM NEW YORK TIME (ET)

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Safety and Quality

Health Technology Management in the Northwest Territories, Canada

Kevin Taylor
Territorial Manager of Biomedical Engineering for the Northwest Territories, Canada
Background – Geography and Environment

- Geographic Area of about 1/5 the US.
  - From Yellowknife to Sanikiluaq is > 2000km.
- Remote Communities
- Harsh Environments
- Problematic Utilities
- Limited local remote troubleshooting / support resources
Background – Demographics

• NTHSSA Biomedical Engineering supports health technology in all NWT and 2/3rds of Nunavut.
  • NWT – 33 communities
  • Nunavut (Kivalliq and Kitikmeot Regions) – 12 communities
• Population
  • NWT – 45,000 - 51% Indigenous comprising
  • Kivalliq and Kitikmeot Regions of Nunavut – 17,000 - 86% Indigenous
• Access
  • Approximately 40% of NWT communities are fly in or winter ice road only
  • All Nunavut communities are fly in only.
NWT Health Technology Management

- Northwest Territories Health and Social Services Authority
  - Biomedical Engineering
    - Part of Informatics and Health Technology Division
    - 1 Territorial Manager – Professional Engineer
    - 7 Biomedical Engineering Technologists
    - Manage service on health technology – in-house service on vital signs through to dialysis, anaesthesia, community x-ray in-house
    - Manage all Territories health technology service contracts

- Department of Health and Social Services
  - Health Technology Planning
    - Part of Infrastructure Planning Division
    - 1 Manager – Professional Engineer
    - 3 Health Technology Planners
    - Manage all NWT health technology evergreening
Quality and Safety Challenges

• Prior to 2018
  • NWT had a solid Health Technology Management foundation
    • Territorial In-house Biomedical Engineering program (1 Engineer and 4 Technologists)
    • Evergreening Planning Team at DHSS (1 Engineer and 2 to 3 Planners)

• Core Quality and Safety Challenges Identified in 2018
  • In-house Biomedical Engineering resources hadn’t changed since 2005
    • Complexity and quantity increased substantially
  • Service contracts not managed and divided between regions
  • Information, communication and collaboration challenges between NTHSSA and DHSS
  • Increasing number of vendors not providing manuals or parts
  • Nunavut and NWT separate systems each with limited resources
    • Nunavut had recruitment challenges
    • One region had no community service for two years
Quality and Safety Initiatives

• DHSS and NTHSSA Collaboration
  • Created Territorial Health Technology Management Committee
  • Full inventory and assessment of all health technology
    • Shared full access to Territorial Health Technology Database
  • Collaborated on re-creating health technology management tools
    • Medical Equipment Replacement Score System
  • Loaned resources and support to each other to maximize system needs
    • COVID – purchased 1 years capital equipment in 1 month
    • Resource gaps – loaned and shared resources

• Right to Repair
  • Set Requirement in Territorial level Health Technology Policy
  • DHSS and NTHSSA created and refining mandatory procurement clauses to align with Territorial policy.
  • Work started to implement Right to Repair as a standard Nationally
Quality and Safety Initiatives

• Consolidated all Service Contracts
  • Ensured service contract compliance
    • Repatriated community x-ray gaining additional staff
  • Ensure standardized Terms and Conditions
    • DHSS supporting contract terms during procurement process

• Partnered with Nunavut
  • All policies and procedures were aligned
    • Developed collaboratively
  • Share health technology database
  • Formed partnership agreement to support all Kivalliq and Kitikmeot combined
    • Staffed resource to support Nunavut regions
    • Shared access to Nunavut and NWT resources
Thank you!

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Medical Equipment QA and Safety
With a Clinical Perspective

Dr. Niranjan D. Khambete
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Outline of the talk

• Medical Equipment QA and Safety – The need

• Medical Equipment Safety Demystified

• Electrical Safety – Getting the basics right

• Performance Evaluation – The ‘Glucometer Story’

• Training – Empowering the frontline clinical staff
Not a very happy scenario
Medical Equipment in Clinical Use !!!
Electrical Extensions – a Hazard !!!
National initiatives for awareness creation
Surgical Scalpel

Functional Requirement
- Sharpness

Safety Requirement
- Sterility
(An independent requirement)

Clinical professionals will NOT use this device in this condition

Functional and Safe

Functional BUT Unsafe !!!
Equipment QA and Safety Extrapolated

Patient Monitor

Functional Requirement
- Monitor patient parameters

Safety Requirement
- **Electrical Safety**
- Calibration and QA
  *(An independent requirement)*

Are clinical professionals **aware** of these requirements?
Electrical Safety Testing
Electrical Safety Testing - IEC 62353(2014)

Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

• Periodicity – 6 months / 12 months

• Earth bonding – an essential first !!!

• What is the situation in clinical use?
Sub-optimal earth bonding in clinical use

Lack of reliable Earth Bonding - a chronic problem !!!
Poor Earth Bonding – investigating the root cause

European pin top in an Indian socket
- No earth connection possible

Disconnected Earth
Weak Retainer clip

European pin top in an Indian socket
- No earth connection possible
Solution - securing the cable and earth connection

A simple and cost-effective solution

- Interlocking with cable tie
- SS Ny-lock nuts and bolts
- Strong nylon retainer clip
The ‘Glucometer Story’
The ‘Glucometer Story’

• A call from Obstetrics ward at **8 p.m.** to Clin. Engg. Dept.
  • Neonate having **low blood glucose** as shown by **Glucometer-1**
  • Shifted to Neonatal IC (NICU)
  • **Glucometer-2** in NICU showed **normal blood glucose**
  • **Was there a real need to shift the neonate to NICU?**

• Which of the two **Glucometers** was correct?

• **Can the field Clinical Engineer** find an immediate answer?
Isolating the source(s) of the error

• Medical Device
  • The Glucometer and the strips?

• In-correct use
  • Untrained user?

Clinical Engineer needs to isolate the source?
In-house generation of ‘Reference data’

Reference Dextrose solutions with 3 different concentrations:

- 35 mg/dl
- 125 mg/dl
- 225 mg/dl

Dextrose concentration

Glucometer output

GLUCOMETER REFERENCE DATA

Acceptance zone

\[ y = 1.4465x + 17.033 \]
Empowering the clinical staff through training
Training of clinical staff – an essential step
Medical Equipment Literature – a key resource
E-learning – an effective tool
In Summary .....
The take home message

- Engage
  - with the clinical staff
- Observe
  - with a keen eye
- Investigate
  - with a scientific mind
- Innovate
  - with simplicity
- Implement
  - a cost-effective solution
- Follow-up
  - on its effectiveness
A BIG thank you to ..........

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• Deenanath Mangeshkar Hospital and Research Centre

All my colleagues and friends who continue to encourage us as well as contribute in these efforts to offer Safe and Quality care to patients
Thank you!

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A list of additional topics and dates for next webinars will be soon announced on our website www.GlobalCEA.org

THANK YOU for your participation