Global Clinical Engineering Journal

Special Issue 1

ISSN: 2578-2762

GlobalCE

Publisher Longhorn Surgical Consulting, LLC

open access

www.GlobalCE.org

Editor's Corner

Over the past three-plus decades, my work as a clinical engineer has brought me to close to 50 countries where I have had the good fortune to meet and collaborate with many dedicated practitioners in our field. The professionals I have had an opportunity to work with are passionate about our shared endeavor--sometimes in the face of adversity, minimal institutional support, or an outright lack of resources. But the universal concern of the clinical engineer remains laser-like focus on making sure that patients are cared for with safe, appropriate and effective technology. Over the years, many have told me that while their passion and efforts have never diminished, the recognition of their contributions has yet to be expressed. Some have argued that this is at least partially the result of insufficiently publicity about the good work performed by clinical engineers, that we do not publish enough, and that we do not participate in the exchange of evidence-based publications that promote awareness of our many achievements in the field. Therefore, the argument continues, our profession's critical contributions to the improvement of world population health, wellness, and rehabilitation for the most part goes unrecognized.

At the same time, the healthcare system has never been more dependent on technology than today. That may seem axiomatic. But the integration of technology into patient care has become routinized, accepted by, and more visible to patients than even before. In a **study published in 2016** the estimated volume of medical devices sale for 2015 was 371$ US billion and projected to reach 530$ billion US in 2022. So, it seems only appropriate that the management of healthcare technology will increasingly be led by the professionals who create, curate, and manage this critical tool. However, academic opportunities to enter the field as well as to sustain life-long professional development seem to fall short compared with other professions in healthcare. If clinical engineering is to have a future, it must capture and retain the imaginations of educating the talent pool. The projected need of educated manpower capacity is growing while level of competent clinical engineers' stays leveled around the world.

For these reasons, I am very enthusiastic about the creation of this new on-line, open-access free journal. The Global Clinical Engineering Journal (GlobalCE) is intended to focus on the intersection of technology and patient care and to promote the exchange of scientific knowledge to better patients' care outcomes and promote safe, appropriate and effective instrumentation as well as optimally trained users. GlobalCE will promote and publicize innovative work while encouraging new practitioners to research and publish. Our objective for this publication is to create a public forum to share observations and insights about technological tools improving healthcare delivery outcomes. Our hope is that this interaction will create a forum for our community of professionals. GlobalCE is your publication and will reflect your efforts.

We issue a Call for Papers and encourage you to consider publishing your work with us and ask you to share this Call for Papers with colleagues even if they have never previously published.

We are proud of the Editorial Board we have assembled for our publication. The team represents the best and brightest in our profession across multiple disciplines. Their acceptance of the editorials duties is evidence of their commitment to the journal mission. We are looking to add quality reviewers. Please visit our website and register as reviewer if you have expertise in subject of the field that is identified in the Call for Papers.

Our aspiration for this unique journal is to rapidly connect the far corners of the globe and bring clinical engineers from every laboratory, university, and industry closer together than ever before. Please join me in celebrating this long-awaited new beginning.

Together we can make it better!

Dr. Yadin David

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Received February 2, 2018, accepted March 14, 2018, date of publication March 25, 2018.

Clinical Engineering/Health Technology Management 2015 Global Update

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ABSTRACT

Medical device systems Clinical Engineering (CE)/Health Technology Management (HTM) strategies and best practices are now well established in most first world and many developing countries (DC).

Progress is being made to address identified gaps in DC CE/HTM, such as appropriate equipment selection and lifecycle management. One contributor to this progress is the 25 years of CE/HTM Seminars provided by WHO-PAHO, ACCE, and more recently, IFMBE CED, to 80 countries. There is also a new emerging challenge; the requirement for medical device (clinical data) integration (MDI) into electronic health records (EHRs) to improve care quality and safety (aka CE-IT).

This study will review CE/HTM progress, gaps, and new challenges since the last study in 2011. It will provide a framework to direct the global CE/HTM movement forward in collaborative fashion, alongside other initiatives in 2015, such as the 1st International CE-HTM Congress and the Global CE Summit held in Hanzhou, China, in October, 2015.

Keywords: *Clinical Engineering, Health Technology Management, CE, HTM, CE/HTM seminars, medical device lifecycle management, CE education, CE-Information Technology (CE-IT), medical device integration, IFMBE CE Division.*

INTRODUCTION

"In the 1980s, it became clear to the World Health Organization (WHO), academia, and various global non-government organizations (NGOs) that there were many failed medical device technology transfer projects in the previous 2 decades, resulting in a large amount of inoperable sophisticated equipment and unmet healthcare needs in spite of significant financial investment."[1]

"In 1988, WHO organized a virtual international roundtable with input from experts around the world and published the discussion in World Health Forum.[2] The roundtable not only confirmed the 2 challenges identified earlier – acquisition planning and maintenance, but also pointed out fundamental underlying issues. First and foremost is the fact that unlike drugs and vaccines, medical equipment requires continual outlay of funds, on order of 6–15% of original acquisition price, for the life of equipment, often up to 10–20 years after acquisition.[1] Thus, it is useless for NGOs and financing organizations to provide equipment donations or investment loans if the recipient countries cannot pay for recurrent expenses,

even if adequate planning and maintenance are available. Another serious deficiency is the lack of a framework for proper HTM in most developing countries. Without a framework defined and supported by policies, procedures, defined responsibilities, and earmarked resources for HTM, it is difficult to perform technology planning in harmony with the country's health policies and priorities, ensure appropriate human and material resources necessary to operate the equipment, and maintain it in safe and operational conditions."[1]

DEFINITIONS AND CONTEXT

Definitions

Health Technologies (HT): The term refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures & systems developed to solve a health problem and improve quality of lives.[3]

Clinical Engineer: A Clinical Engineer (CE) is a professional who supports and advances patient care applying engineering and managerial skills to health care technology. (Sometimes also referred to as a Biomedical Engineer [BME].)[4]

Health Technology Management (HTM): For USA CE certification, defined by the ACCE Body of Knowledge survey of CE practitioners, HTM is broadly defined as "lifecycle management of medical devices and systems."[5]

Context and Key Acronyms

The main elements of developing country HTM and its key health system relationships are outlined in Figure 1.[1]

The 60th World Health Assembly, convened by WHO in 2007, passed the Resolution WHA60.29 relating to Health Technologies.[6] This resolution urges Member States:

1. "to collect, verify, update and exchange information on ***health technologies*** **(HT);** in particular medical devices as an aid to prioritization of needs and allocation of resources";
2. "to formulate as appropriate national, strategies and plans for the establishment of systems for the assessment, planning, procurement and HT management in particular medical devices, in collaboration with

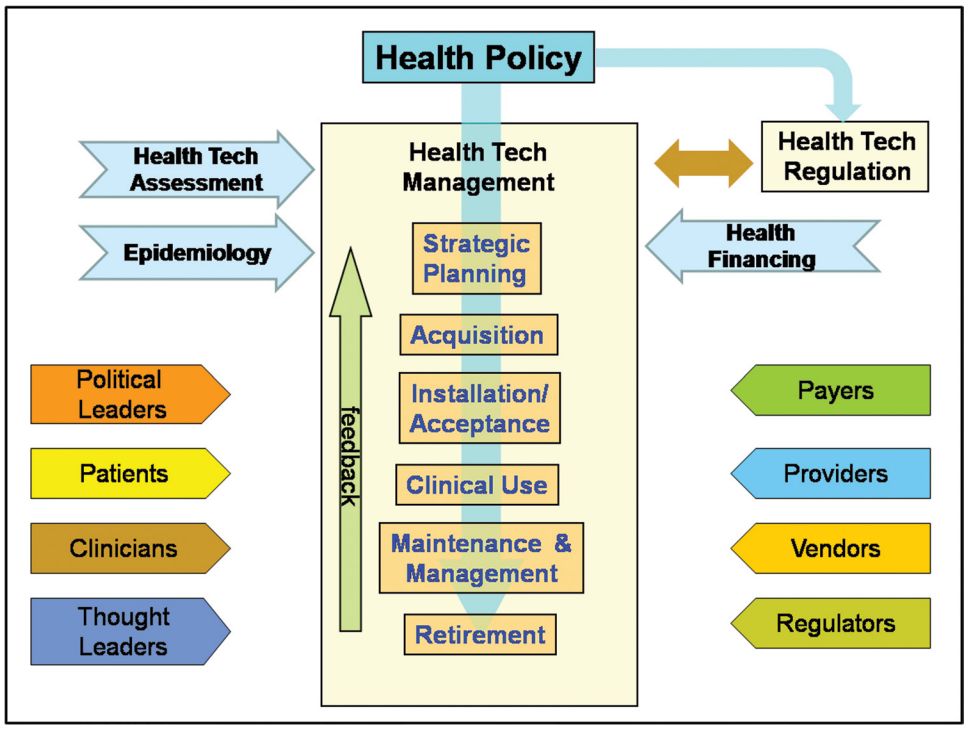

FIGURE 1. The main elements of developing country HTM and its key health system relationships.

personnel involved in ***health technology assessment*** **(HTA)** and ***biomedical engineering"*** (**BME);**

3. "to draw up national or regional guidelines for ***good manufacturing and regulatory practices***, to establish surveillance systems and other measures to ensure the ***quality, (risk,) safety and efficacy*** of devices and where appropriate participate in international harmonization" **(HTR, Risk & Safety or R&S);**
4. "to establish where necessary ***national and regional*** institutions of health technology, and to collaborate and build partnerships with health care providers, industry, patients' associations and professional, scientific and technical organizations;" **(e.g., MOH HT units**); and
5. "to collect information that interrelates medical devices which deal with priority public health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;" (to improve Maternal Child Health (**MCH)**, such as **HT improving MCH care outcomes**).

To illustrate these points, we include a figure from our previous article, which is a graphical representation of the main elements of Health Technology Management, and how it relates to other areas of the health system (see Figure 1).

As a capital investment, equipment needs to be managed from deployment (strategic planning, acquisition, installation / acceptance) until retirement, guided by a country's ***health technology policy*** (**HTP**).

During its useful life, proper maintenance and management are essential to ensure safe, efficient, and cost-effective patient care. Often neglected, feedback provided by users and maintainers is essential to continually improve **HTM** within the country or system, and avoid mistakes made previously.

HTM is intimately related to but distinct ***from health technology regulation*** (**HTR,** and **Risk & Safety**), as the latter is focused on safety and efficacy, with little concern on costs and management challenges.

Health Technology Assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.[5–7] **HTA** provides the foundation for successful planning and subsequent use of health technologies.

HTM GAPS AND PROGRESS

Earlier HTM Study: Our prior article[1] described progress in HTM *in 51 countries, including Africa (11 countries) Asia (11 countries), Latin America & the Caribbean (19 countries), and other (10 countries).* In that article, the following gaps in HTM were identified:

- A lack of competent staff (*Human Resource development* - **HR**)
- Limited access to technical documentation & spare parts **(HTM)**
- Poor planning and lack of commitment **(HTM)**
- Irrational HT incorporation and deployment **(HTM)**
- Limited influence with decision makers (e.g., <10 countries then had designated Ministry of Health, Health Technology-**HT** Units)
- Donations provided that do not align with Ministry of Health **(MOH**) priorities

In addition, the article identified the following root causes of HTM challenges:

- Lack of: training to develop human resources-HR; experience; awareness; and influence with decision makers regarding HTM
- Equipment is often considered a status symbol instead of a service production tool
- Greed and short-sightedness of manufacturers and distributors
- Selfishness of some "aid," "cooperation," and "donation" programs that are actual sales-promoting schemes or publicity stunts
- Lack of vision and courage among HTM professionals

Global HTM Seminars: Further progress in HTM has been documented in a series of Seminars presented from 1991-2015 by ACCE and WHO-PAHO.[8]

As a result of these seminars, progress was seen in the following areas *(with aggregate evidence noted below summarized):*

- HT Policy (**HTP**) developed, *e.g., in 27 of 51 countries (>50%)*
- HTM training provided (**HR**), *e.g., 40+ of 51 countries (>80%)*
- National professional societies created; *e.g., in 20 of 51 (~40%)*

WHO Global Forums: Further progress in HTM was documented in the WHO 2nd Global Forum on Medical Devices, 2013 (2GFMD).[9] This progress was documented in a series of country reports presented at the Forum, and is summarized in the following tables (Tables 1A-D).

The 2013 WHO 2nd Global Forum provided an important update on the information presented in our prior paper.[1] We now see indications of further progress.

Africa (20 countries)

- HTM programs have doubled in the region.
  - Increased NGO HTM involvement has helped, such as, THET-Zambia, MRC-Gambia, and CMBES-Ghana.
- Increasing HT involvement with MOH decision makers.
  - Growing HTA and HTR initiatives.
- Earlier HTM programs now aggressively pursuing MCH.
  - Limited CE-IT initiatives.

Asia (13 countries)

- Big 3: strong national programs in China, Japan, and India.
  - MOH Unit in India comprehensively addressing HT.
  - Continued growth of Japan and its national CE society.
  - Rapid growth of China CEs, societies, & certification.
- Countries with prior HTM (2011) pursuing HTA and HTR.
  - Increasing involvement with MOH decision makers. Limited CE-IT initiatives other than Big 3.

Latin & Central America (12 countries)

- PAHO investment in HTM and HR training anchored in academia.
  - Freeing MOHs to work on HTA and HTR.
- Big 4: historical HT strength of Brazil & *Mexico* + Colombia & Peru.

  Brazil largest CE base; very multidisciplinary approach.
  - *Mexico MOH Unit; wide-ranging with decision makers.*
  - Colombia (strong HT history; introduced IHE to Region); & Peru (developed MOH Unit, key academia partnerships).

Others (26 countries)

- Group with extensive capabilities along HT continuum.
  - Most have mature HTM & are pursuing HTA & HTR.
  - Several key HTM contributors in region and or globally.
  - Also among global leaders for CE-IT and MCH.

2015 HTM Seminar: In June 2015 another major HTM Seminar was organized by ACCE in collaboration with WHO-PAHO, with 32 HTM leaders from 22 countries represented, and one USA NGO.[10] Table 2 lists the participants in this seminar, and their affiliations.

This table illustrates the following indications of progress: HT units now more frequently created at MOH level (15/22 countries) and HTM leaders are emerging with increasing influence at the MOH level.

Table 3 summarizes the gains and challenges in HTM, HTA, HTP, HTR, and CE-IT that were reported at the seminar.

The following detail the gains and challenges identified at the 2015 HTM seminar:

Africa (5 countries reporting)

- Tend to have established HTM, but need HR, HTP, and HTR

Asia (3 countries reporting)

- Rapid growth HT capabilities for 2 high population countries
  - India MOH HT Unit leading country-wide initiatives
  - Bangladesh increasing scope of HT work

Latin & Central America (8 countries reporting)

- Two in early stages of HTM; most mature pursuing CE-IT
  - Mexico MOH HT Unit (CENETEC) a global best practice
  - Most countries also need MOH HTP and HTR

TABLE 1A. Africa – 20 Countries/Entities Presented at 2GFMD

Country	Major Accomplishments	References
AFRO-WHO	HTM	Ndihokubwayo (AFRO), 2013
Benin	HTM	Adjaratou et al (MOH), 2013
Burkina Faso	HTM	Emmanuel et al (MOH), 2013
Cameroon	HTM, CE-IT	Ngaleu-Toko et al, 2013
Cote D'Ivoire	HTM	YriéUDenis (MOH), 2013
Ethiopia	HTM, MCH	Mulegeta et al (MOH), 2013
The Gambia	HTM, MCH	Nyassi et al, Faye et al, 2013
Ghana	HTM, HR, HTA, MCH	Adjabu, THET & MOH, 2013
Kenya	HTM, HR, HTA, HTR, MCH	Owino, Anyango, Mwaru et al (MOH), 2013
Malawi	MCH	Mwanza et al (MOH), 2013
Nigeria	HTM, HTR, MCH	Ilonze et al (MOH), Fatunde, 2013
RSA	HTM, HTA, HTR	Poluta, Khalaf et al, Mueller, 2013
Rwanda	HTM	Mukama et al (MOH), 2013
Senegal	HTM	Sow et al (MOH), 2013
Sierra Leone	HTM	Kabia (MOH), 2013
South Sudan	HTA	Lilford et al, 2013
Tanzania	HTR, MCH	Kijo et al (MOH), 2013
Togo	HTM, MCH	Tsolenyanu et al (NGO), 2013
Uganda	HTM, HR, HTA, MCH	Wanda et al (MOH), Ssekitoleko et al, 2013
Zambia	HTM, MCH	Mullally, Machbani, Musiwa (MOH), 2013

Other (2 countries reporting)

- Albania HT Unit a global best practice for small countries

WHO

- WHO desires the following global Surveys in 2016:
  - Value of Donations, e.g., percent implemented and in use
  - Number BMETs needed at country level, for MOH plans
  - HTM outcome measures; influence MOH decision makers
- WHO facilitating BME/CE global recognition in 2018 by ILO
  - Causing WHO to annually track key CE/HTM measures

The 2015 Seminar Participant Recommendations were:

1. *Increase Awareness of CE/HTM Influence on HT Policy*
   - WHO can assist countries to develop/implement HT policies
2. *Communicate global HTM point of view to help countries*
   - How to address when government not involved in HTM

TABLE 1B. Asia - 13

Bangladesh	HTM, HTA, HTR	Hasan, Rabbani et al (MOH), 2013
China	HTM, HTA, HTR, CE-IT	Zhong et al, 2013
India	HTM, HTA, HTR, CE-IT, MCH	Sharma et al (MOH), Khambete et al, 2013
Japan	HTM, HR, HTA, HTR, HTP, CE-IT	Fukuta (MOH), Nakazaki, Sugiura, 2013
Korea	HTA	Hwang et al, 2013
Laos	HTM	Insal (MOH), 2013
Malaysia	HTR	Rahman (MOH), 2013
Myanmar	HTM	Lin (MOH), 2013
Philippines	CE-IT	Mojica et al, 2013
Singapore	HR, HTR, HTA	Goh et al (MOH), 2013
Sri Lanka	HTA	Galappatthy et al (MOH), 2013
Thailand	HTA	Tantivess, Wibulpolprasert (MOH), 2013
Vietnam	HTM, MCH	Dajer, 2013

TABLE 1C. Latin & Central America - 12

Argentina	HTM	Giles et al, 2013
Bolivia	HTM	Urioste (MOH), 2013
Brazil	HTM, HR, HTA, HTR, HTP, R&S	Garcia, Calil, Conto (MOH), 2013
Colombia	HTM, CE-IT	Quintero, Hernandez, Castaneda, 2013
Chile	HTA	Duarte et al, 2013
Cuba	HTR	Pereira et al (MOH), 2011
Ecuador	CE-IT	Silva et al, 2013
Haiti	HTM	Judd et al, 2013
Mexico	HTM, HTA, HTR, HTP	Cardenas, Moreno (CENETEC) 2013
PAHO-WHO	HTM, HTA	Lemgruber, Jimenez, 2013
Peru	HTM, HTA, HTR	Rivas et al, Pinedo, 2013
Uruguay	HTP, HTA	Galan et al (MOH), 2013

TABLE 1D. Australia, Europe, Middle East, NGOs - 26

Australia	HTA, HTR, CE-IT	Babige, Kearney, Tang, Mcewan 2013
Belgium	HTM, HTR	Demade, Bogg, Merlevede 2013
Bulgaria	HTA	Dimitrova (MOH), 2013
Croatia	HR	Magjarevic, 2013
Egypt	HTA	Salem, ElSaadany (MOH), 2013
EWH	HTM	Malkin, 2013
EURO-WHO	HTA, CE-IT	Pedersen et al (EURO), Kulkarni, 2013
Greece	HTM, HTP, R&S	Pallikarakis, Stavrianou, 2013
Hungary	HTA	Szacsky, 2013
Israel	MCH	Mayaan, 2013
Italy	HTM, HTA, CE-IT	Iadanza, Pecchia, Musi, 2013
Jordan	HTM	Rahim, Dalou, 2013
Kuwait	HR, HTR	Alzawadhi, 2013
KSA	HTA, HTR, CE-IT	Hassanain, Al Tayyar, 2013
Laerdal	MCH	Laerdal et al, 2013
Lebanon	HTA	Rihana, 2013
Netherlands	HR, HTA	Hurts/Hansen (MOH), Linnenbank, 2013
Norway	HTA	Lauvrak et al, 2013
Portugal	HR, HTA, HTR	Secca, Da Silva, Madureira et al, 2013
Slovakia	HTA	Jadud (MOH), 2013
Spain	HTA, CE-IT	Falcon et al, 2013
Switzerland	HTM, HTR	Zaugg, Werlein, Voelksen, 2013
Tunisia	CE-IT	Ouhichi, 2013
Turkey	HTM, HTA, HTR, R&S	Copur, Demirbas, Turgut/Kuru, Ozdemir, 2013
UK	HTM, HTR, R&S	Murray/Gammie/Wasmuth/McNerney 2013
Yemen	HTA	Mujamal (MOH) et al, 2013

TABLE 2. 2015 HTM Seminar Participants

Albania	MOH Health Technology (HT) Director
Argentina	MOH HT Coordinator
Argentina	Private Hospital CE Director
Australia / Egypt	WHO BME Intern
Bangladesh	University BME Professor
Bangladesh	University BME graduate student
Bhutan	MOH Director HT Unit
Botswana	MOH Regional HT Director
Brazil	MOH HT Manager
Brazil	Private CE Company COO
Canada	WHO BME Intern
Colombia	MOH Director HT Unit
Colombia	MOH Laboratory CE Director
Colombia	University BME Professor
Cuba	MOH Hospital CE
Ethiopia	MOH BME Advisor
Haiti	National Hospital CE Director
Haiti / USA	Medical Device Consultant
India	MOH WHO HT Center Director
India	MOH Consultant
Kenya	MOH Hospital CE
Kosovo	Telecommunications Engineer
Mexico	MOH Hospital Coordinator
Mexico	University CE Professor
Mexico	University CE Professor
Nigeria	MOH Director HT Unit
Peru	MOH Consultant, University CE Professor
Sierra Leone/USA	University CE Professor
Suriname	MOH Hospital CE Director
Uganda	MOH Director HT Unit
Uganda	MOH Senior BME
USA	NGO BME Leader

- How to enable, using resources & influence to help drive HTM
- WHO needs data from specific case studies to better assist

3. *Develop Regional Training Centers (RTC) – Improves HR & HTM*
   - Need *Key* HTM *Process Standardization*
   - Lessons learned to be applied: (1) create RTC for maintenance; (2) Training that is university-based is more sustainable
   - Incorporate CE/HTM in health care clinical & business courses, such as for physicians and health administrators
   - Share different methods of risk management across countries
4. *Develop standard medical equipment procurement documents*
   - Incorporate Life Cycle Cost (LCC) Analysis, as World Bank has done for Information and Communication Technologies
   - Make use of WHO resources on Device Specifications
   - Consider central/national Public-Private-Partnership (PPP)
5. *Consider how to best facilitate "our group" ongoing communications and networking* – e.g., INFRATECH and WHO Listservs
6. *Maintenance Management*
   - Need inventory management system on line with history (CMMS); such as, basic inventory, then layers
   - India is working on a national CMMS that can be made available on line for free
7. *WHO & Medical Equipment Manufacturers*
   - How to improve interactions?
   - WHO: Has created a Forum for manufacturers
8. *Improve Domestic production of Medical Devices*
   - Affects HTM, making best use of Technology Transfer
9. *Organize professional societies to extend influence*
   - Many benefits to join locally, nationally, regionally, globally

TABLE 3. Summary of Participant Gains/Challenges [A-Y]

Country (Pop. in M)	Key Gains	Key Challenges
Albania (2.9)	HTM, HTP, HTR	HR, CE-IT
Argentina (43)	HTM, CE-IT	
Bangladesh (157)	HTM, HTA, HTP, CE-IT	HR
Bhutan (0.74)	HTM, HTA	HR, HTP, HTR
Botswana (2.2)	HTM	HR, HTP, HTR
Brazil (202)	HTM, CE-IT	
Colombia (48)	HTM, CE-IT	HTP, HTR
Cuba (11)	HTM, HR	CE-IT
Ethiopia (92)	HTM, HTP	Wider HTP, HTR
Haiti (10)	HTM	HR, HTP, HTR
India (1,250)	HTM, HTA, HTP, HTR, CE-IT	Wider CE-IT
Kenya (44)	HTM, HR	HTP, HTR
Kosovo (1.9)	HTM, CE-IT	HR, HTP, HTR
Mexico (122)	HTM, HR, HTP, HTA, HTR, CE-IT	Wider CE-IT
Nigeria (140)	HTM	HR, HTP, HTR
Peru (30)	HTM, HR, CE-IT	HTP, HTR
Suriname (0.57)	HTM	HR, HTP, HTR
Uganda (40)	HTM	HR, HTP, HTR

CASE STUDIES / SUCCESS STORIES

Ghana

Improved HTM and HR: In 2009, 2 HTM Seminars were organized by ACCE in collaboration with WHO, International Aid, and the Ghana Health Service. Essential HTM topics were covered. The curriculum for the HTM workshop was based on the WHO-adopted "*How to Manage*" series for HT.[11] The seminars were well attended, with 135 at the first and 83 at the second. Participants identified a number of HTM challenges including: (1) A lack of training on HTM topics. (2) Inadequate tools and test equipment. (3) Poor availability of spare parts. (4) A lack of communication between government policy makers and HT stakeholders affected by policies (HTP). This indicates a need for future seminars to include more content for government policy makers.

Results

Professional Society: At the conclusion of the second seminar, the attendees initiated the Ghana Biomedical Engineering Society (GBES). An email listserv was set up to facilitate communication among workshop attendees.

Global Partnerships: In addition, the faculty members from Canada initiated a formal partnership between the Canadian Medical and Biological Engineering Society (CMBES) and GBES. There is also opportunity for CMBES and GBES to partner more closely with WHO via regional African societies under development and through joint WHO and IFMBE CED global initiatives.

The CMBES-GBES partnership has resulted in the successful application for a research grant to examine medical equipment donation practices in Canada, and the experiences of recipients of such donations in Ghana. Members of the 2 societies are in frequent communication. Such ongoing partnerships are considered an important factor in the strengthening of HTM programs.

ALBANIA

Improved Access and HTM: Before September 2014, MOH Albania had no maintenance strategy for its hospitals' highest technology diagnostic equipment – linear accelerators, magnetic resonance imaging, computed tomography scanners and angiography – resulting in higher costs, significant downtime, and poor vendor relationships. They then implemented a new approach based on global best practices: full risk, 2-year service contracts via negotiation; vendor meetings to present our new approach and for authorized distributor confirmation; then open tender procedures for international participation, to avoid speculation of monopoly.

MEXICO

Role Model: Established MOH Unit in 2004, CENETEC; has become a global CE-HTM role model with country-wide HTP, HTM, HTA, HTR, HR, and Practice Guideline development.

BRAZIL

First MOH Unit – established at *São* Paolo state level in 1980s. Key leader in global HTP, HTM, HR, and CE-IT.

FUTURE: 2015–2020

What is needed for CE/HTM profession?[10]

- *CE-IT:* need education for MDI seamlessly into EHRs[7]
  - Technical, Management, Leadership, Health IT (CE-IT) Standards, and Regulatory (HTR) framework
  - Global Drivers: eHealth, Patient Safety & Risk Management, Medical Device Cybersecurity, Patient & Population Health Outcomes
  - *Clinical workflows*: CE/HTM leaders provide improved design
  - *Leading edge initiatives*: CE/HTM leading telehealth, smartphone/mHealth, in their countries and regions to improve quality, safety, access and affordability.
  - Maternal and Child Health (MCH), e.g., Neonatal and Newborn Care, using WHO-vetted Evidence-Based Interventions & Practice Guidelines
  - *Influence*: Stronger leaders, with wider impact on decision makers

CONCLUSIONS

This study showed steady improvements globally in most indicators for Health Technology. Health Technologies will play an increasing role in global health care delivery with the emerging spread of CE-IT (EHR-enabled care) to improve quality and continue to make care affordable.

ACKNOWLEDGMENT

The authors wish to acknowledge the invaluable contribution made by dozens of volunteers from less-developed countries who provided information and suggestions in various means. They also want to apologize to countries from which no information was obtained, mostly due to their limited knowledge of those countries and their key stakeholders.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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APPENDIX

The following listing is the country-level presentations made during the 2015 HTM Seminar in Denver, CO USA, and Toronto, Canada. They can be obtained from the authors and or the presenters.

A. Picari L, *Albania HTM Seminar Country Update*, & *MOH HT Unit Maintenance of Medical Devices* (high technology systems), 2015
B. Giles G, Lencina M, *Argentina HTM Country Update*, 2015
C. Abir AR, Rabbani KS, *Bangladesh HTM Seminar Update*, 2015
D. Penjore T, *Bhutan HTM Seminar Country Update*, 2015
E. Tlhomelang B, *Botswana HTM Seminar Country Update*, 2015
F. Contó M, Katz Z, *Brazil HTM Seminar Country Update*, 2015
G. García Ibarra AR, Rojas Morales JM, *Colombia HTM Seminar Country Update*, 2015
H. Castro Medina J, *Cuba HTM Seminar Country Update*, 2015
I. Mideksa M, E*thiopia HTM Seminar Country Update*, 2015
J. Valliere M, Chery J, *Haiti HTM Seminar Country Update*, 2015
K. Sharma Dr. JK, Arora P, *India HTM Seminar Country Update*, 2015
L. Anyango Amoko P, *Kenya HTM Seminar Country Update*, 2015
M. Abazi N, *Kosovo HTM Seminar Country Update*, 2015
N. Cardenas Alanis C, Leon de Alba F, Orencio E, Moreno ME, *Mexico HTM Seminar Country Update,* 2015
O. Bukola E, *Nigeria HTM Seminar Country Update,* 2015
P. Rivas R, *Peru HTM Seminar Country Update*, 2015
Q. Jie G, *Suriname HTM Seminar Country Update*, 2015
R. Mulepo S, Edward K, *Uganda HTM Seminar Country Update*, 2015
S. Castañeda M, *Business Opportunities in Health Technology Projects*, 2015 (outcomes of August 2013 ACCE HT Seminar, Barranquilla, Colombia)
T. Clark T, Lemgruber A & Caccavo F (PAHO), Molina Velasquez T (Universidad CES Colombia), Graciá F (Universidad National Tech. Argentina), Rivas R & Vilcahuaman L, (Universidad PUCP Peru), *Biomedical Technology Online Courses for the Americas*, 2015
U. Hernandez A, *Trends on IT and Health Technology* (CE-IT), 2015
V. Painter F, *Risk Management,* 2015 (outline of device Risk & Safety issues)
W. Quintero Dr. V, *IHE Colombia Crash Course on Interoperability* (CE-IT), from Universidad Simón Bolívar, Barranquilla, Colombia, 2015
X. Sloane Dr. E, *Medical Device and ICT Convergence (*CE-IT), 2015
Y. European Network for Health Technology Assessment. Common Questions. What is Health Technology Assessment (HTA)? Accessed Dec. 1, 2015 at: http://www.eunethta.eu/about-us/faq#t287n73

Received February 15, 2018, accepted March 8, 2018, date of publication March 25, 2018.

Certification in the United States, Canada and Asia

By James O. Wear

CERTIFIED BIOMEDICAL EQUIPMENT TECHNICIANS

The first certification in the US in the clinical engineering field was for biomedical equipment technicians (BMETs).[1–4] As biomedical equipment maintenance was developing in US hospitals in the late 1960s, there were no training programs for BMETs. A few 2-year technical schools initiated training programs based on their electronics curriculum, but there was no standardized curriculum. Even the electronic programs in these schools were not accredited nor had a standard electronic curriculum. There were also BMETs that had been trained in the military.

The Association for the Advancement of Medical Instrumentation (AAMI) had a task force to look at the BMET field and the maintenance of medical equipment in hospitals. The task force decided that something needed to be done to allow BMETs to demonstrate that they had a minimum level of expertise. Certification of BMETs became the tool to demonstrate this minimum level of expertise. A Board of Examiners was established by AAMI and the first exam was given in 1970. Individuals who passed the written exam became Certified Biomedical Equipment Technicians (CBETs).

Certification was not readily accepted by BMETs or by the institutions hiring them. There also was an issue of testing sites and dates to allow BMETs to readily be tested without considerable travel expenses.

The Department of Veterans Affairs (VA) wanted to have its BMETs certified, but funds were not available to provide travel for them to go to the AAMI meeting for testing. In 1973, the VA developed its own BMET certification program from its Engineering Training Center.[5] The requirements to take the exam were the same as the AAMI and the exam was similar since the director of the VA Training Center was on the AAMI Board of Examiners. The VA used the Human Resources Department at each hospital as a testing site since they were approved for giving other exams. The VA exam was developed by the VA Training Center faculty. In the VA, the technicians are called biomedical engineering technicians which is still BMET.

AAMI found a need to develop specialist exams for BMETs who worked on laboratory and radiological equipment. These BMETs might not be able to pass the general exam since they only worked on special equipment, but they need certification to demonstrate a minimum level of expertise in their specialty. AAMI developed specialty exams in these two areas and individuals that passed these exams became Certified Radiological Equipment Specialists (CRESs) and Clinical Laboratory Equipment Specialists (CLESs). These three certification programs still exist today.

The VA also found the need to establish the radiological specialty certification program and CRES. In 1984-5, the VA merged its certification program with the AAMI program. All VA certifications were accepted by the AAMI program and the VA allowed its Human Resources Offices to be used to give AAMI certification exams.

Individuals must meet the following qualifications to take the AAMI BMET certification exam:

- Associate's degree in biomedical equipment technology program and two years' full-time
- BMET work experience; OR
- Completion of a U.S. military biomedical equipment technology program and two years' full-time BMET work experience; OR

- Associate's degree in electronics technology and three years' full-time BMET work experience; OR
- Four years' full-time BMET work experience

The exam can be taken if a person has an associate degree in BMET or two-years' experience full time as a BMET. If they pass the exam, they have five years to complete the additional 2 years of full-time experience as a BMET to be certified. To take the CRES or CLES exam, a person must have worked at least 40% of the time in the past two years or 25% of the time in the past five years in the designated specialty area.

Each of the AAMI exams is 165 multiple-choice questions and is administered by a professional testing organization. The Board of Examiners creates questions for the exam bank and reviews new exams before they are used. The professional testing organization has responsibility for the exam security.

In the AAMI certification program over 3000 are CBETs, about 600 CRESs and around 100 CLESs. Every three years, individuals must renew their certification by demonstrating a certain amount of continuing education to be maintained as a CBET, CRES or CLES. Most of the CBETs are in the United States, but BMETs in several other countries have taken the exam and become CBETs.

AAMI has placed all of their certification programs in their AAMI Credentials Institute (ACI). In 2016 the CBET, CLES and CRES became ANSI accredited under ISO/IEC 17024 Personnel Certification.

Electronics Technicians Association International (ETA) also certifies BMET as both general medical equipment and radiological equipment technicians. They must be certified as Certified Electronics Technicians (CET) before they can take the journeyman certification exams. With six or more years of training and work experience in the field, the CET can take the journeyman exam. They must score 85% on the journeyman exam to be certified.[6] If they pass the journeyman certification exam for medical equipment, they become CET-BMD. By passing the journeyman certification exam for radiological equipment, they become CET-BIET.[7] Their programs are aligned with the ISO/IEC 17024 standards "*Conformity assessment – General requirements for bodies operating certification of persons*"

CERTIFIED HEALTHCARE TECHNOLOGY MANAGER (CHTM)

In 2015, the AAMI Credentials Institute (ACI) initiated the Certified Healthcare Technology Manager (CHTM) program.[8] ACI defines a CHTM as

> "The healthcare technology manager is a person responsible for planning and directing activities of other healthcare technology management professionals, monitoring their work, and taking corrective actions when necessary. This HTM certification covers two major areas in healthcare technology management: the management of healthcare technology operations; and, the management of personnel. The functions of the manager are to include the participation in the "leadership" of the business enterprise. The manager is also expected to have the skills and understanding needed to perform strategic, business, and change management as well as employee relation."

This certification is not currently ANSI accredited.

Individuals interested in pursuing the CHTM designation must meet one of the following paths to be eligible for the program.

Path 1: A current certification as a clinical engineer (CCE), biomedical equipment technician (CBET), radiology equipment specialist (CRES), or a laboratory equipment specialist (CLES) with at least three (3) years of work experience as a supervisor or manager in the last five (5) years.

Path 2: Successful completion of the Department of Defense's biomedical equipment maintenance technician (DOD BMET) training program with at least three years of work experience, military or civilian, as an HTM supervisor or manager in the last five years

Path 3: An Associate degree in biomedical technology, related health care discipline, information technology or business with at least three years of work experience as an HTM supervisor or manager in the last five years.

Path 4: A Bachelor's degree or higher in biomedical technology, engineering, related health care discipline, information technology or business with at least two years as a manager within the last five years.

Path 5: Work experience with or without a degree not related to biomedical technology, related health care discipline,

information technology, or business management. Seven years of work experience in the HTM field with three years of management experience in the last five years

In any of the paths, if the individual does not have the title of supervisor or manager, he/she would have to confirm that he/she performs management duties either through self or third-party attestation.

Recertification requirements for this certification are a combination of work experience and continuing education to demonstrate sustained competency and knowledge in the healthcare technology management field.

CERTIFIED IN CLINICAL ENGINEERING (CCE)

Dr. Caesar Caceres, MD coined the term "Clinical Engineer" in 1967 for engineers working with physicians in the clinical setting. At that time, various types of engineers, physical scientists, and physiologists were performing engineering type work in the clinical setting in hospitals. As more medical instrumentation came into the hospital, more of this type of personnel came into the field as well. Also, as BMETs were hired to maintain the medical instrumentation, engineers and physical scientists were hired to manage clinical/biomedical engineering departments in hospitals.

AAMI thought that engineers should be certified in clinical engineering since there were no academic programs that trained clinical engineers. Some of the major people working in the field of clinical engineering were not engineers but held degrees in some other scientific field. It was decided that a program should be developed to certify people in the clinical engineering field and not as clinical engineers. An initial Board of Examiners was established with prominent people in the clinical engineering field. It was decided that for one year, individuals working in clinical engineering could be certified based on credentials. They had to have at least a BS degree in engineering or a physical science and at least three years experience working in the field of clinical engineering. These credentials were evaluated by the Board of Examiners. The AAMI certification program for clinical engineering was established in 1975 and within a year about 200 individuals were certified in clinical engineering (CCE). After this first group of CCEs, the Board of Examiner developed a written exam and an oral exam to test future individuals for certification.

At this same time, another group of prominent individuals in the field decided that certification on credentials was the wrong approach to certifying people. They decided that people should take an exam to become certified in clinical engineering. As a result, five people self-certified themselves and developed an exam for certification in clinical engineering. This group became the American Board of Clinical Engineering (ABCE) and also started their certification program in 1975. Most of the initial individuals in this program were academic clinical engineers.

AAMI and the ABCE continued to certify individuals in clinical engineering until 1984. In 1983 the two groups began discussions on a possible merger of their programs. The merger was finalized in 1984 with all the ABCE CCEs being accepted into the AAMI certification program. As part of the merger the International Certification Commission for Clinical Engineering and Biomedical Technology (ICC) was established. Fifty individuals had been certified by the ABCE.

In 1979, AAMI started requiring CCEs to renew their certification every three years by demonstrating continuing education. In 1992, the renewal policy was that anyone certified after 1992 and not renewed would have their certification revoked. Anyone certified before 1992 that did not renew would become delisted. As of 2002, there were about 100 listed CCEs on the AAMI website. In 1999 AAMI discontinued accepting applications for certification because there were not enough applicants to support the program financially. However, they did continue to accept renewals. At the time AAMI discontinued accepting applications for certification, 474 had become a CCE by credentials or exam including 50 certified by the Canadian Board of Examiners for Clinical Engineering. This also included several individuals in other countries certified by the US Board of Examiners. However only about 200 had kept their renewal up-to-date.

In 2002, the Healthcare Technology Certification Commission (HTCC) was created under the Healthcare Technology Foundation (HTF) to reestablish a CCE program. A US Board of Examiners was created to develop a written and oral exam. The written exam was based on

the American College of Clinical Engineering (ACCE) Body of Knowledge (BOK) determined by an ACCE survey of practicing clinical engineers. This survey asked the clinical engineers about the work that they were doing and the knowledge requirements. The new certification program accepted anyone from a previous certification program who demonstrated that they were current in the field by continuing education for a one-year period. There were 112 individuals that were accepted in the new program from the previous program. The first exam was given in 2004 with three individuals taking the exam.

In 2013 the HTCC begin looking for a new sponsoring body since new US tax policies were such that a non-profit foundation such as HTF could not have an income producing unit like the HTCC. They looked at various organizations as sponsors as well as considering becoming a stand-alone organization without a sponsor. Finally, AAMI and ACCE indicated an interest in becoming a sponsor and each presented their proposal. The ACCE was accepted as a sponsor since they guaranteed the exam process could continue to have the oral exam. AAMI was not sure they could continue to sponsor with the oral exam since they were trying to obtain ANSI recognition of their exam program. Thus, ACCE became the administrative sponsor for HTCC in 2014. At that time there were a little over 200 individuals certified by the HTCC from the US and the Canadian Board of Examiners.

Individuals must meet the following qualifications to take the CCE exam:

- Three years of clinical engineering experience plus
- Profession Engineer License or
- MS Eng or
- BS Eng plus 4 years total engineering experience or
- BSET in engineering technology plus 8 years total engineering experience.

They also must provide three professional references. The written exam is 150 multiple choice questions administered by a professional testing company. The questions are developed by the Board of Examiners and are based on the BOK developed by the ACCE. The oral exam is about 2 hours and given by two members of the Board of Examiners and is based on practical knowledge needed to function on the job.

CANADA CERTIFICATION

Canada uses the ICC for certifying BMETs and they add the requirement that an individual must have a BS in biomedical technology to take the exam.[9] The exam is developed by the Canadian Board of Examiners under the ICC

Under the laws of the Canadian provinces and territories, the use of the title "engineer" in a job description requires that the incumbent be licensed as a professional engineer in that jurisdiction. Canada has always taken the position that to be eligible to seek certification in clinical engineering; an applicant must first obtain licensure as a professional engineer. Once a person is licensed as a professional engineer and is working in the field of clinical engineering, then he or she can apply to the Canadian Board of Examiners for Clinical Engineering Certification.

By 1980, it was recognized that engineers working in the clinical engineering role required a distinct but unrecognized BOK to perform their tasks competently. Since there was no licensing process in place specifically for clinical engineering, leaders in Canada decided to establish a certification process that would be administered by competent members of the profession. In order to begin such an effort, discussions were held with colleagues in the United States who had undertaken a similar approach under the leadership of the (AAMI). Canadians with established track records working in the profession were grandfathered as certified and established the first Canadian Board of Examiners for Clinical Engineering Certification. They developed a written exam and an oral exam.

This process of certification continued for several years. However, the initial rush of applicants dwindled, and it remained a voluntary activity with limited visibility amongst the health care community. By the late 1990s, the work of the Board had effectively ceased with very few applicants coming forward.

Around 2008, there was a growing interest in certification in Canada as younger engineers entered the profession and the need for skilled staff continued to grow.

Members of the former Canadian Board were asked by the Canadian Medical and Biological Engineering Society (CMBES) to restart a Canadian certification process and bring it up-to-date. It was apparent that with the small number of certification applicants, it would be difficult to launch and sustain a self-supporting certification process. Since there are many similarities in the practice of clinical engineering between Canada and the United States, they decided to approach the US Board about the possibility of sharing aspects of the enhanced US exam process.

Adding further credibility to the process, The US Board of Examiners is accountable to the Health Technology Certification Commission, which oversees the work of the Board and ultimately decides on recommendations from the Board to certify individuals.

Discussions between the Canadian and US Boards went well with good support and encouragement from US colleagues. The main issue of divergence of practice between Canadian and US clinical engineers relates to the country specific codes, regulations and standards, an important but relatively small part of the written exam. In discussion, it was agreed that members of the Canadian Board would review the US written exam, to identify those questions requiring specific knowledge of US codes, standards and regulations. Out of a full exam of 150 multiple-choice questions, the total number of exempted questions is typically no more than 30. These questions are not counted for Canadian examinees and the same percentage pass mark is used. To compensate for the lack of written exam questions on Canadian codes, standards and regulations, it was decided to put an additional (fourth) question into the Canadian oral exam process, specifically on these topics. The Canadian Board agreed to develop such a question using the same process as the US Board. In this way, Canadian candidates are examined through a slightly different but parallel process to their US counterparts.

It was agreed that Canadian applicants would register and be administered by the Secretariat to the US Board, to avoid setting up a parallel office in Canada. Sites are available in Canada to sit for the written exam, which is made available in both countries on a single date and time each year, early in November. All policies and procedures are harmonized, and the Canadian Board assists the US Board in the generation of new written and oral exam questions. Members of the two Boards discuss their work on a regular basis, and the Chairs of each Board sit on the HTCC.

The harmonized process was established in 2010 and remains in place. There has been good communication between each Board, and a generally high level of support for this harmonized process.

COMMISSION FOR THE ADVANCEMENT OF HEALTHCARE TECHNOLOGY MANAGEMENT IN ASIA (CAHTMA)

CAHTMA was initiated in 2005 with the endorsement of the Asian Hospital Federation.[10] The Asian Hospital Federation (AHF) is an international non-governmental organization, supported by members from 14 countries in the Asia Pacific Region. CAHTMA is a member of the International Federation of Medical and Biological Engineering (IFMBE) and initially had WHO advisers. It was established to provide a platform for health care professionals to discuss and exchange ideas on health care technologies and practices. Central to these objectives are the promotion of best technology management practices, the certification of clinical engineering practitioners and healthcare professionals and the dissemination of appropriate management tools through seminars and workshops.

CAHTMA has certified a few clinical practitioners, but there has been no major need for certification in Malaysia since it has not been required. When CAHTMA started certification, the government was planning legislation to require certification for maintenance of medical equipment. Technicians are certified as a level one clinical practitioner with a written exam and experience which is like the ICC BMET. Engineers are certified as level two clinical practitioners with a written exam and an oral exam and experience which is similar to the HTCC CCE. In order to encourage more engineers to become certified, CAHTMA is going to use the process of certifying individuals based on credentials similar to what has been with the initial program in the US and Taiwan.

CAHTMA is also certifying faculty for biomedical engineering technology programs which are developing with the increased need for technologist to maintain the medical equipment. The government is looking at requiring

these technologists to be certified for certain work. In 2012, lecturers at one school were tested as assessors and certified by CATHMA with Certification for Clinical Engineering Assessors. Lecturers who completed five weeks of training and passed the exams were certified by CATHMA with Certification for Clinical Engineering Trainers.

CERTIFICATION IN TAIWAN

Certification in clinical engineering in Taiwan is performed by the Taiwan Society for Biomedical Engineering (TSBME).[11] In 2000, TSBME established the Certification Executive Committee for CE certification. During 2001, they certified clinical engineers by application. In 2003, they initiated a recertification program for CCE. The first testing for certification of clinical engineering and technologists of medical equipment was in 2007.

The TSBME provides certification for clinical engineers, medical equipment technicians and biomedical engineers. In 2010 they had certified 93 clinical engineers, 132 medical equipment technicians and 224 biomedical engineers. The clinical engineers and medical equipment technicians are for working in the hospitals and the biomedical engineers are for working in the medical device industry. This is the only certification that has separate certification for hospital and industry engineers.

To become certified an individual must be a member of TSBME. The requirements to take the certification exam are as follows:

- **Clinical Engineer**: MS degree in biomedical or related field plus at least one year of CE experience plus working in a hospital for more than 10 years.
- **Medical Equipment Technician**: BS degree in biomedical or related field plus at least one year of CE experience plus working in a hospital for more than 4 years.
- **Biomedical Engineer**: BS degree in Engineering plus at least two years of BME experience plus working in BME field for more than 4 years.

The content of the assessment exams by the TSBME for each of their certifications is as follows:

Clinical Engineer (core exam plus oral exam)

- Anatomy (24%)
- Medical Instrumentation (16%)
- Clinical Engineering (16%)
- Medical Imaging System (16%)
- Major Area: (Biomechanical or Biomaterial or Medical Electronics or Medical Information (28%)

Medical Equipment Technician (core exam)

- Anatomy (20%)
- Electronics & Electrical Safety (40%)
- Medical Instrumentation (40%)

Biomedical Engineer (core exam)

- Anatomy (20%)
- Medical Devices, Safety Regulation & GMP (10%)
- Major/Minor (Biomechanics plus Biomaterial or Medical Electronics plus Medical Instrumentation) Major 45% and Minor 25% (70%)

CERTIFICATION IN JAPAN

Clinical engineering in Japan is different from other parts of the world.[12,13] It is the only country that the government certifies clinical engineering technologists (CETs). The CETs must graduate from a clinical engineering training school which can be a university, junior college or training school and pass a national exam to be certified. The CETs are also called clinical engineers. The CETs are paramedical staff and specialize in the medical equipment essentials in medical care. About 35% work in hemodialysis and about 20% in maintenance. Others work in respiratory, operating room, ICU, heart related, hyperbaric and other areas.

The clinical engineer system was established in 1987 by the Clinical Engineers Act. This act created the CET as a professional medical position responsible for the operation and maintenance of life-support systems under the direction of doctors. This act established a national qualification including passage of the 180-question exam in medicine, engineering and medical technology. In 2010 there were about 28,000 certified CETs and about 18,000 current working in the field. The certification of the CETs is most equivalent to the CBET in the ICC system in the US.

In addition to the CET certification by the government, the Japan Society for Medical and Biological Engineering

(JSMBE) has a Biomedical Engineering Certificate program.[14] The JSMBE has two classes of certification for biomedical engineers. The 1st class certification is for experienced clinical engineers and in 2008 the pass rate was 22.2% for 433 applicants. The 1st class exam covers basic aspects on medical engineering and medical device related subjects. The 2nd class exam is for students or recent graduates of clinical engineering and many take it as preparation for the national CET exam. In 2008 the pass rate on the 2nd class exam was 29.3% for 1398 applicants.

CERTIFICATION IN CHINA

In 2005, the international clinical engineer certification was introduced in China.[15] The Medical Engineering Division of the Chinese Medical Association hosted the first international clinical engineering certification training courses and certification examination. From 2005 to 2016, eight sessions of lectures by international senior specialists and exams were done. A written exam based on the ACCE BOK with some adjustment for the practice of clinical engineering in China. The written exam is in English and is prepared by international senior specialists. Individuals that pass this 100-question multiple choice exam have to pass an oral exam in English to become certified. The oral exam is given by the international senior specialists. In the eight training sessions, there have been 700 clinical engineering personnel from hospitals and universities. There have been 219 individuals that have passed the two exams and been certified as international clinical engineers.

In the past 7 years, China has been working to establish its own certification program. In 2012, the Medical Engineering Division of the Chinese Medical Association carried out Chinese Registered Clinical Engineer Certification (RCEC) training and examination. The candidates were junior engineers in large hospitals or new graduates with majors in medical engineering. This exam is the basic admission exam to the occupational qualification of clinical engineering.

The RCEC exam consists of a theoretical exam and practical test. There is a Chinese exam question bank from which the theoretical questions are randomly selected. Candidates then take a practical test including repair, measurement and maintenance of medical devices. A committee of Chinese clinical engineering experts evaluates the ability of the candidates and determines if they are qualified to receive the RCEC. In 2012, there were 176 people who took the exam and 56 passed to become certified as RCEC.

In the future, the candidates for International Clinical Engineering Certification will be mostly senior clinical engineers with more than 10 years experience.

They are establishing a continuing education for both certification to maintain and improve the quality of the clinical engineers. The Medical Engineering Division plans to recommend to the government to officially authorize clinical engineer training and certification.

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Received April 4, 2015, accepted May 8, 2015, date of publication June 1, 2015, revised March 21, 2018.

Planning Medical Technology Management in a Hospital

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ABSTRACT

Appropriate deployment of technological innovation contributes to improvement in the quality of health care delivered, the containment of cost, and access to health care services. Hospitals have been allocating a significant portion of their resources to procuring and managing capital assets; they are continuously faced with demands for newer medical technology and are challenged to interoperate and manage legacy and newer generation of inventory simultaneously. To objectively manage this investment over it life cycle, hospitals are adopting medical technology management programs that need pertinent information and planning methodology for integrating new equipment into existing operations as well as for optimizing costs of ownership of all equipment. Clinical engineers can identify technological solutions based on the matching of new medical equipment with the hospital's objectives. They can review their institution's overall technological position, determine strengths and weaknesses, develop equipment-selection criteria, supervise installations, train users and monitor post procurement performance to assure meeting of goals. This program, together with cost accounting analysis, will objectively guide the capital assets decision-making process. Cost accounting analysis is a multivariate function that includes determining the amount, based upon a strategic plan and financial resources, of funding to be allocated periodically for medical equipment acquisition and replacement. Often this function works closely with clinical engineering to establish equipment's useful lifespan, prioritization of acquisition, upgrade, and replacement of inventory within budget confines and without conducting time-consuming, individual financial capital project evaluations. The clinical engineer's skills and expertise are needed to facilitate the adoption of an objective methodology for implementing the program, thus improving the match between the hospital's needs and budget projections, equipment performance and cost of ownership. Systematic planning and execution will result in a program that assures appropriate inventory level at the lowest life-cycle costs at optimal performance.

Keywords – *clinical engineering, equipment assessment, technology management, equipment planning, technology evaluation, program methodology, cost accounting, life cycle, capital asset, budget.*

INTRODUCTION

The appropriate deployment of technology contributes to improvement in the quality of health care delivered, the containment of cost and to increased access to services offered by the health care system.

Over the past one hundred years, the dependence of the health care system on medical technology for the delivery of its services has continuously grown. In this system, the technology facilitates the delivery of the "human

touch." All medical specialties depend to varying extent on technology for achieving their goals. Some specialties more than others, use medical technology, be it in the fields of preventive medicine, diagnosis, therapeutic care, rehabilitation, administration or health-related education and training. Medical technology enables practitioners to collaboratively and timely intervene together with other caregivers with patients in a cost-effective and efficient manner. Technology also enables integration and continuum care in a way that improves the level of overall health indicators. Hospital and clinical administrators are faced with the expectation for return-on-investment that meets accounting guidelines and financial pressures.

Society's expectations for quality care and for the containment of the cost of care, as expressed in relationship to the Gross National Product brought the need for even better integration and control into the public debate arena. The U.S. government, in 1983, attempted to contain runaway health care costs through Federal regulation. These regulations established a new method of reimbursement, called the prospective payment system, which encouraged hospitals to manage their resources more effectively. Reimbursement methodology continues to influence innovation, development, and adoption of medical technologies.

As a result, routine methods for delivering care are being replaced with alternatives, such as the growth of outpatient clinics, ambulatory surgery and telemedicine. Conventional as well as alternative, sites of health care services are expected to meet a specific set of goals and objectives. These goals and objectives include administrative, clinical, financial, and regulatory parameters that influence how the integration of medical technological tools are planned for, funded, and executed. It also guides how these tools are selected, installed, trained for, integrated, safely operated, serviced, upgraded, and retired or replaced. These are essentially the phases of all technology, including medical technology. The application of knowledge about the optimal management of various life cycle phases of capital assets will maximize system utilization during each one of the phases. Capital assets management, one life cycle phase, the process of selecting and acquiring medical technology, has not been well coordinated in most hospitals until recently.[1] In addition, financial evaluations, which rely upon net present value (NPV) and internal rate of return would consume an enormous amount of a manager's or director's time and may in fact be questionable when put in their proper context.[2] NPV is an important evaluation tool that needs to be integrated with a clinical engineering assessment when evaluating new rather than existing demand-based service lines of business or large program comparisons of alternatives based on cost efficiencies. Examples include, the proposed addition of a diagnostic imaging center or the comparison of major system software packages. Examples of equipment not needing NPV analysis, existing assets include: defibrillators, infusion pumps, and anesthesia machines. In this case, a typical health care organization may have an inventory encompassing thousands of individual pieces of equipment. However, in their attempt to improve allocation of resources to medical equipment, the majority of health care executives have been making significant capital expenditure decisions with growing involvement of clinical engineering expertise and cost-of-ownership information.[3]

The concept of management of capital assets is a far-reaching one that goes beyond merely acquiring or maintaining medical equipment and generally includes market-based demand forecasting as a method of estimating future demand for a health care organization's services.[4] Changing payment methodology and existing inventory operations and maintenance costs are important factors in planning the deployment of new equipment; these are management issues that merge together in the clinical environment.[5] This paper describes the emerging process for managing medical technology in the hospital and the role that clinical engineers are fulfilling.

THE TECHNOLOGY MANAGEMENT PROGRAM – ACHIEVING GOALS

The health care delivery system is going through a transition that is led by three major driving forces: cost, technology, and social expectations. The impact of these forces may change from time to time, as does their relative significance. In addition, the human factor that interacts with these forces is not constant either, thus submitting an important subject for public debate. Nevertheless, the

system is being subjected to mounting pressures from the needs to first identify its goals, secondly select and define priorities, and finally allocate the limited resources.

Hospitals' rising investment demonstrates their belief in the importance of and the benefit from the deployment of technology. Health care organizations have been using a variety of evaluation methodologies to provide alternatives in the delivery of care. They are driven by medical innovation, prospective reimbursement, and societal expectations. In this environment, evaluation methodologies only work if an organization is truly prepared to cancel a project after the initial investment. The flaw in the theory is not its complexity, as some have said, but in the fact that it ignores the psychological and political realities of capital investments.[6] It becomes imperative for providers to make good resource allocations decisions at the outset of their capital budgeting process and often those decisions are biased towards equipment that has a positive impact on reimbursement. Health care providers spent $8.25 billion on capital equipment in 1988, compared with $8.21 billion in 1987.[7] A survey of hospitals' spending plans for capital budgets, one that includes equipment and construction, indicates that spending rose during 1992 by 15%, reaching $23.6 billion.[8]

However, the increasing scarcity of available resources within the hospital community on the one hand and the demand for quality health care on the other, promoted a public debate and awareness of such a paradoxical economic perspective. New tools for cost and outcomes management include disease management and patient safety initiatives.[9] It is in such an environment that hospitals have begun to manage their fixed assets (i.e. capital investments) and equipment-related operation expenditures better than ever before. As the deployment of medical equipment continuously evolves, its impact on the hospital operations and on the consumption rate of its financial resources increases. The ability to forecast and manage this continual evolution and its subsequent implications has become a major component in all health care decisions. In a survey of three large hospitals in Houston, Texas, with a combined licensed capacity of about 1400 beds, the average number of medical devices being used per licensed bed has increased between 1982 and 2002 from four devices per bed to over 17 devices per bed.[10] This illustrates that hospitals are experiencing a continual increase in the number of medical devices used on a per bed basis. It is therefore imperative that in an industry where the only constant is change, there is a program that:

a. provides for a guiding strategy for allocation of limited resources
b. maximizes the value provided by resources invested in medical technology
c. identifies and evaluates technological opportunities or threats
d. optimizes priorities in systems integration, facility preparation and staff planning
e. meets or exceeds standards of care
f. reduces operating costs
g. reduces risk exposurecreates
h. better care environment.

Whereas both knowledge and practice patterns of management in general are well organized in today's literature, the management of the health care delivery system and that of medical technology in the clinical environment is more fragmented and has not yet reached that level of integration. However, we are beginning to understand the relationship between the methods and information that guide the decisions regarding the management of the medical technology that is being deployed in the highly complex environment of the health care delivery system, including the variances among users, applications and cultures from one hospital to another.

The health care delivery system presents a very complex environment where strategy, facilities, equipment, drugs, information and the full range of human interventions are interacting. It is in this clinical environment that patients in various conditions, staff, temporary skilled labor and the wide variety of technology converge. The technology that has been developed for and is deployed in the health care delivery system ranges from the "smart" facilities within which care is being provided to the products that are used around the provision of healthcare services, and to its regulation and management. "Technology means merely the use of tools, that is, the involvement of any agent which assists in the performance of a task."[11] Such tools have been introduced at an increasing rate during the past 100 years and include the use of techniques,

instruments, materials, systems, and facilities. Of all the factors and resources that will shape the future of the health of mankind, the one that most often stretches the imagination is medical technology.[10] But yet, it is also blamed for contributing to the escalation of health care costs without receiving recognition for improving access to and quality and efficiency of the system.

It is, therefore, expected that the only winners are those who use superior strategy and execution. Generally, a superior strategy is the result of the use of market-based demand forecasting. Market-based demand forecasting is a method of estimating future demand for a health care organization's services by using a broad range of data that describe the nature of demand within the organization's service area. This provides a fundamental link between strategic planning and financial planning and thereby provides a rational basis for assessing how many patients may be expected to use services and what level of capital resources is needed to provide those services.[12] This would define the types and volume of equipment needed to meet demand. Equipment is categorized by its function and owner department requirements in an assets list developed by the user and equipment planner as part of Biomedical Engineering validation of meeting appropriate clinical standards and institution integration prior to purchase recommendation. The plan must be layered with present organizational capital asset requirements for replacing and upgrading existing inventory to maximize effective use of the existing capital equipment matrix and for appropriate systemization of medical processes. At this point, it is the managers who have to link technical capabilities to clinical requirements. Too often planning is the result of a crisis, a situation that does not permit thorough analysis and usually it is a time when it is too late to begin a plan. Managers are expected to understand why their institution's values and mission are set as they are, to pursue their institution's strategy and business plan through that knowledge and to act in a way that effectively allocates resources for which they are responsible. One may not necessarily be a part of the organizational level that develops the institution's strategic plan; however, one must be familiar with it, one must understand and believe in it, to be able to develop an action plan at that level that supports the institution's mission.

To implement an effective plan, one will be expected to know how the present state of technological deployment should be assessed, and to have a good rapport with the research and development industry to be able to provide a forecast and review of emerging technological innovations, the impact that they may have on the particular institution, plus have the ability to articulate justifications and provisions for adoption of new technology or of the needs to enhance or replace existing ones. Because tomorrow's clinical devices are in the research laboratories today, a medical equipment manager should be considering visits to such sites as well as to the exhibits areas of the major medical scientific meetings. To facilitate the process, the current state of the health care organization's inventory should be assessed and quantified by the clinical engineer based upon numerous criteria. This process is aided by the existence of both Biomedical Engineering equipment and Finance capital equipment databases. The technology management process would include an assessment using a multi-year template of when and if equipment will need upgrading, replacement, and when new acquisitions are to be added. Clinical engineering should then calculate a life-cycle for each asset. Using cost accounting analysis that includes a review of the impact equipment has on reimbursement methodologies such as cost based or case based, and in conjunction with a market-based forecasting model, each prospective piece of equipment should be priced and an overall annual cost of maintaining the organizational inventory assessed as well as new additions supporting the strategic plan. Given the limits of an organization's resources, an overall prioritization can then be developed so that the most important medical technology related to the strategic plan are procured, thereby enabling the organization to satisfactorily meet its service obligations, maximize financial returns, and attain goals.

The past decade has shown a trend of increased legislation that supports more Federal regulations in health care. These and other pressures will require that deployment of, and justification for, additional or replacement medical technology is well planned. If you subscribe to the saying that you cannot manage what you do not measure, and you cannot measure what you do not define, then the need for the development and the maintenance of a systematic

and comprehensive planning process for the adoption of medical technology in hospitals is obvious. A mixture of literature review and experience demonstrates that the rationale for technology adoption is derived from the following reasons:

Clinical Necessity

- meet or exceed medical standards of care
- impact care quality or level
- effect on life quality
- improve accuracy, specificity, reliability, timing and/or safety of interventions
- change in service volume or focus
- response to community needs
- reduce errors or improve predictability of outcomes

Management Support

- better or more effective decision-making protocol for interventions
- improve operational and maintenance efficiency and effectiveness
- facilitate development of or current offering of service
- reduce liability exposure
- increase compliance with standards or regulations
- decrease dependence on staffing and/or the skill level of personnel, improve staff retention
- effect on supporting departments
- improve return on investment or cash flow
- enhances integration and knowledge sharing
- improve patient throughput

Market Preference

- improve access to quality care
- increase customers' convenience and/or satisfaction
- enhance organization or service image
- improve financial or value impact
- reduce cost of adoption and ownership
- effect on market share
- improves community conditions
- facilitate continuum of care

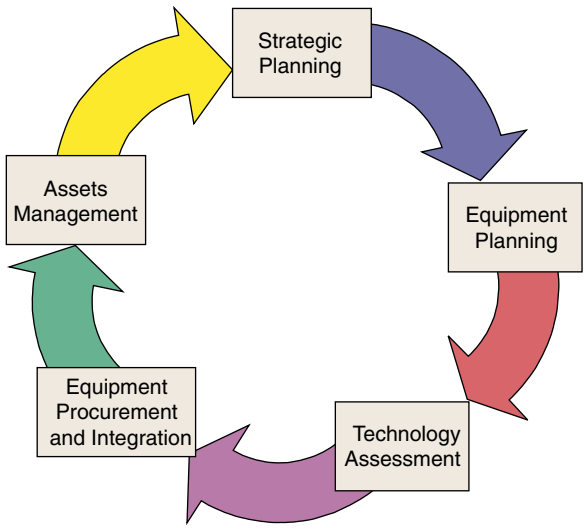

FIGURE 1. The technology management process at the Texas Children's Hospital.

Many hospitals are reformulating their technology management process, which starts with the strategic planning process, thus demonstrating clearer support for the prescribed management of medical technology. It is a process in which the understanding of the key issues and the critical success factors are followed by a more defined task of resource allocation, and assignment of the responsibility for sustained improvement in technology's performance through attainment or progression toward measurable technology utilization rate goals. This is a planned process that may be unique for each organization and is essentially a prescription for the way to look ahead. Although it may be different for every organization, all are faced with the following five similar questions: What are we? What do we want to be? Where are we going? What will be our role? And, how will we do it?

PLANNING AND MONITORING THE DEPLOYMENT OF MEDICAL TECHNOLOGY

As we developed our medical technology management program model (Figure 1), adoption of the strategically prescribed norms took place, as well as the monitoring in accordance with a well-thought-out plan, equipped with know-how from a multidisciplinary team of users, and the implementation of an agreed-upon policy. The

multidisciplinary team has a similar approach toward the creation of definition of needs, scope and objectives for a specific type of technology, such as the equipment.

The question is no longer whether a medical technology management plan is worth the effort, but rather can we afford not to implement it, and do we have the adequate tools to execute it? If we do then the hospital will be able to make informed decisions regarding deployment of new technology as well as monitor its utilization.[3]

The need for clinical engineering involvement in such a team became evident when the following problems were repeatedly encountered:

- recently purchased equipment not sufficiently used
- ongoing user problems with equipment
- excessive downtime and ownership cost
- lack of compliance with accreditation agencies and regulations
- high percentage of equipment failing and awaiting repair
- maintenance costs emerging as a large single expense
- medical equipment upgrading, replacement, and planning are not intertwined
- use errors and near-miss events

A further analysis of these symptoms using a system performance analysis technique would likely reveal.[13]:

- a lack of a central clearing house to collect, index and monitor medical technology performance for resolving current issues and for future planning purposes
- the absence of strategy for identifying emerging technologies for potential integration
- the lack of a systematic plan for conducting technology assessment, thereby not being able to maximize the benefits from prioritization of the deployment of available technology
- an inability to benefit from the organization's experience with a particular type of technology or supplier
- the random replacement of medical technologies, rather than a systematic protocol based on a set of well-developed criteria
- the lack of integration of technology forecasting into the strategic planning of the hospital
- limited opportunities for interdisciplinary exchange between engineering-related and clinically-related professionals

To address these issues a technology assessment plan was initiated with the following six objectives: (1) Accumulate pertinent information regarding decisions about medical equipment. (2) Develop a multi-year plan for technology replacement and associated costs. (3) Communicate replacement selection criteria that is supported by users. (4) Create an ongoing assessment methodology with outcomes measurements. (5) Improve the capital budget process by integrating the status of current technology with long-term needs relative to surgical-medical services goals. (6) Integrate the competency of clinical engineering into patient safety goals.

Because the program provides for both the management of the existing inventory of medical equipment aiming at the lowest reasonable life-cycle cost, and for the recommendations relating to procurement, it is mandatory to integrate trended operational and utilization information with the projected budget strategy into the technology management plan.

At the Texas Children's Hospital, the Biomedical Engineering Department has been accumulating pertinent information and has developed indicators for measuring medical equipment performance.[14] A Medical Technology Evaluation Committee (MTEC), which is chaired by the Director of Biomedical Engineering, began developing analytical selection criteria and life-cycle costs information. The membership of the committee includes representatives of the medical and nursing staff, high-tech users, administration, equipment planning, risk management, safety, and materials management departments. Another clinical engineer from the same department with nursing training experience serves as the committee's designated coordinator for all evaluation tasks. Once the committee accepts a request for review (RR), it identifies other users who may have an interest in it and authorizes the coordinator to assemble a task force of users specified by the committee. This task force then serves as an *ad hoc* committee responsible for the evaluation of the

equipment described on the RR form. During any specific period, there may be multiple task forces, each focusing on a specific equipment protocol.

The task force coordinator cooperates with the Materials Management Department in conducting a market survey, in obtaining equipment for evaluation purposes, and in scheduling of vendor-provided demonstration and in-service training. After establishment of a task force, the coordinator analyses the evaluation objectives and together with input from the task force devises appropriate tests, and the associated evaluation feedback form. There are two stages to this phase: an engineering test to validate safety and performance issues, and a clinical trial to evaluate user interface issues and efficacy. Only equipment that has successfully passed engineering tests may proceed to a clinical trial. A clinical coordinator collects and reports the summary of experiences gained during the clinical trials to the task force. The committee coordinator then combines the results from the engineering tests and the clinical trials into a summary report and prepares recommendations for MTEC approval. In this role, the coordinator serves as a multidisciplinary professional, bridging the gap between the clinical, technical, and administrative needs of the hospital.

The technology assessment process actually begins as soon as a department or individual fills out a budget request and then the RR form already mentioned. The form is submitted to the hospital's Product Utilization and Review Committee, which determines if a previously established standard for this equipment already exists.

On the RR form, the originator delineates the rationale for acquiring the medical device. For example, how the item will improve patient care, generate cost savings, support the quality of service or improve ease of use, and who will be the primary user.

The form is sent to the MTEC if the item requested is not currently used by the hospital, or if it does not conform to previously adopted hospital standards. The committee has the authority to recommend either acceptance or rejection of any request based on a consensus of its members.

If the request is approved by the MTEC, then the requested technology or equipment will be evaluated using technical and performance standards. The role of the medical technology evaluation program in the purchase of medical equipment is threefold: (1) assuring that biomedical equipment facilitates the delivery of quality patient care, (2) assuring that the equipment purchased meets the needs of all users, and (3) establishing hospital standards for biomedical equipment. Medical technology evaluation occurs in two phases. Phase 1 is in the submission of recommendations for the purchase of new equipment. Phase 2 is the technical and clinical evaluation. This allows the hospital to validate equipment specifications, to obtain superior equipment at a competitive price and, in turn, consistently improve the quality of patient care. The evaluation process addresses pertinent issues regarding the medical equipment safety, user friendliness, and equipment performance history. Based on satisfactory evaluation results and feedback from the technical and clinical staff, a recommendation is made to purchase a specific equipment item. Following these product evaluation steps facilitates the standardization of the equipment selection process and, therefore, the standardization of biomedical equipment. This will allow the hospital to obtain superior equipment at a competitive price and, in turn, provide consistent, high-quality patient care.[15] Upon completion of the review, a recommendation is returned to the hospital's Product Standards Committee, which reviews the results of the technology evaluation, determines whether the particular product is suitable as a hospital standard, and decides if it should be purchased. If approved, the request to purchase will be reviewed by the Capital Planning Committee (CPC) to determine if the required expenditure meets with available financial resources of the institution, and if or when it may be feasible to make the purchase. To ensure coordination of the technology evaluation program, the Chairman of the MTEC also serves as a permanent member of the hospital's CPC. In this way, technology evaluation is integrated with and impact budget decisions.

THE ROLE OF A CLINICAL ENGINEER

Advances in technology accelerated multidisciplinary approaches to healthcare management.[16] Clinical engineering, a profession based on both engineering and the life sciences, developed in response. The recently created American College of Clinical Engineering provides a better

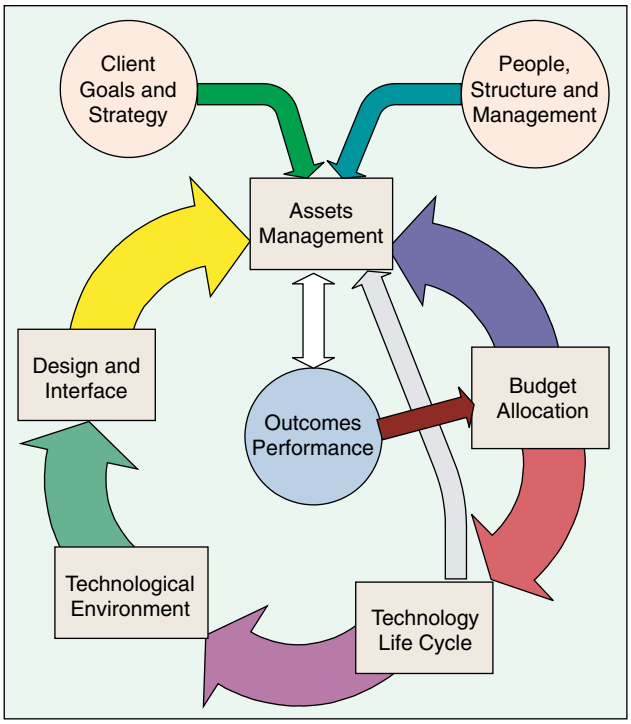

FIGURE 2. Medical technology management environment at Texas Children's Hospital.

understanding of the profession, and defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."[17]

The role of a clinical engineer is shared between planning for new equipment and optimizing the utilization of the existing inventory.[18] The clinical engineer must be completely familiar with the procurement phase of medical equipment and with the synthesizing of clinical needs into a bid request document. This further includes bid specifications, vendor negotiations, installation preparation, acceptance criteria, user training and servicing of the installed base. The clinical engineer is also familiar with methods for assuring that medical equipment performance and risks are monitored, reported and managed. The process includes the assigning of criteria, i.e. values reflecting the evaluator or user preference, and measuring the degree to which those criteria are met in the daily routine of the clinical environment.[19] Criteria could be the format and quality of information displayed at the bedside physiological monitor, the set-up of minimum infused volume of an infusion pump, or the amount of work of breathing associated with one particular brand of mechanical ventilator compared with another.

Medical technology policy supported by an organized program of planning, implementing, monitoring and evaluation results in effective use of resources and reduction in operational risks. Medical Technology Management Environment at Texas Children's Hospital, outlines such a program (Figure 2). Positive outcomes affect allocation of capital and are dependent on the success of the assets management program, the impact of changes in the technology life cycle, the inherent design and quality of the technology as well as the environment within which the assets are deployed and serviced.

The methodology for the development and sustainment of medical technology management program must include properties that demonstrate the impact from each of these parameters on outcomes. Outcomes performance indicators include: cost effectiveness, compliance level, and client satisfaction and service leadership.[20] Performance indicators can include safety-related events such as the elimination or reduction in medical errors. Cost effectiveness can include return-on-investment analysis, reduction in cost per procedure, or improvement in uptime. Other indicators can represent the result of life cycle technology planning and the integration of technologies at the point-of-care measured by utilization rate and the level of satisfaction the caregivers team has with the environment of care.

The program needs to encompass all involved parties. This may at times extend the evaluation and provide for participation of professionals with different interests, which will require mediation between parties. The acceptance of the process is based on respect for their participation and at times will require a sequence of steps taken to pre-empt escalation of antagonistic attitudes among the parties participating in the evaluation. Often, one party seems to prefer an equipment feature that presents unacceptable conditions to another. The clinical engineer should provide the technical and cultural leadership needed to maintain the progress of the evaluation process in a participatory mode. The individuals participating should

be representatives of the user groups, support groups, medical staff, nursing, engineering risk management, finance and administration.

Factors by which the equipment will be evaluated are selected, agreed upon, and a relative importance weight is assigned to them. Devices that pass the engineering bench test are forwarded to the clinical evaluation stage, which must be preceded by user training that is provided to all shifts by the clinical engineering staff and/or the vendor. During the clinical evaluation, the clinical engineer serves as a focal point for collecting users' problems as an indication for a possible mismatch between the equipment's real-life performance and user or system requirements. Following the evaluation, the clinical engineer collects the users' report documenting their experiences and presents it to the committee for a recommendation, while the cost accounting representative reviews the financial alternatives. Generally, to review financial alternatives, information is accumulated and developed into a capital equipment matrix that includes replacement cost, projected retirement, replacement, upgrade, and associated life-cycle dates. Based upon input from clinical engineering, equipment is prioritized regarding their role in the organization. This data is then compiled and provides a useful determination of expected capital costs for future capital budgets and can aid in the development of future strategic planning by providing specific costs by service component. Clinical planning thereby provides options for management in future years despite limited financial resources.

A period of time after equipment has been installed, for example between six and twelve months, a follow-up study of actual operational costs, service problems and utilization indicators relative to projections is performed. This activity supports and becomes part of the equipment planning and continuous quality improvement program. Many good lessons are learned this way. It is also important to review the implementation state and determine if it can be further optimized the next time. The clinical engineer, from that point on, continues with managing the other phases of the equipment life-cycle with proper attention to the planning for equipment upgrades, enhancements and replacement. The skills of the clinical engineer are needed now, more than ever, to manage this new responsibility: a responsibility for managing the medical technology program within guidelines that range from a strategic technology planning phase to the planning for systems replacement.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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Received March 1, 2018, accepted March 19, 2018, date of publication March 25, 2018

Regional Nodes of Colombian Clinical Engineers

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ABSTRACT

The Health Technology Management (HTM) staff in small or remote hospitals can have difficulty accessing good practice information, so we have created a simple, convenient, and accessible networking model for clinical engineers in Colombia, called Regionals Nodes. These Nodes break radically with tradition because they do not have a static structure that limits access to meetings or information. These Nodes are dynamic which allows them to reach more people in less time and at a lower cost. The Nodes use social media to be in contact, coordinate regular meetings with leaders and topics of interest, and disseminate large amounts of information quickly. Thus, new open spaces are created, they are adaptable to each region, and can easily evolve over time. Currently the Ministry of Health and Social Protection (MoHSP), with regional support of engineers from hospitals with national or joint commission accreditation (JCI) lead the Nodes. Today, there are 240 engineers from 140 hospitals and 13 universities and a regulatory agency that recently joined. This initiative began in 2015 with minimal coverage and we have now reached 40% of the country. The members of the Nodes meet every 2 months in order to prepare projects on Medical Equipment Management (MEM) and share information and experiences. Some of the accomplishments and outcomes of these meetings are: continuous training in Colombian regulations, positioning biomedical engineers as key stakeholders in MEM, institutional strengthening of the MoHSP in the health technology field, and HTM regional benchmarking. The interaction among the members of the participant institutions has facilitated a successful knowledge and best practices transfer in MEM from the 8 high-complexity university hospitals to almost 140 regional and local hospitals. These regional and local hospitals have limited access to resources and the operation of the Nodes has contributed in improving the efficiency in the equipment managing process and outcomes that better service the population. One of the priority projects of the Nodes is collaboration with the MoHSP in the validation of the Equipment Maintenance and Obsolescence Assessment Manual. The next steps are strengthening of the Nodes, increasing membership and motivating members and institutions, and interacting with professional engineering societies and health technology organizations worldwide. These steps will involve seeking support and improving communication with health authorities, hospital directors, and administrators looking for the expansion of the Nodes.

Keywords – *Medical Equipment Management, regionals nodes, networking, clinical engineer.*

INTRODUCTION

In the past few years Colombia has made important efforts with legislation development in biomedical equipment. In this context and in terms of formulating public policies that establish goals to strengthen biomedical equipment management practices by the country's health care services providers, the Ministry of Health and Social Protection (MoHSP) has taken the lead, together with hospitals who have national or joint commission accreditation (JCI), and established a working group called the "National Board," with the objective to structure and recommend proposals and guidelines in this field.

With the proposals achieved as a product of a national and international reference process and review and dissemination of successful experiences, the context and the realities analysis of the country in the field of Medical Equipment Management (MEM), we have been seeking to inform health care service providers about their responsibilities and actions in the use, operation, and maintenance of technology. Furthermore, we hope to advance the positioning and empowerment of the leaders of MEM in hospitals and clinics of at all levels.

In order to promote accessibility to information, guidelines, and tools for MEM, the Regional Nodes were established as a result of the work of the central government and the National Board. Thus, a collaborative network of clinical engineering was formed to socialize, disseminate, and validate MEM proposals in a large area of Colombia.

As additional objectives, these Nodes will contribute collectively to the solution of common needs, to generate collaboration and alliances which will materialize in mutual projects, and the exchange of specialized knowledge, initiatives, innovations as well as experiences and best practices among MEM professionals.

This paper presents the set-up and implementation of this work initiative called Regional Nodes, as well as the methodology adopted for its operation, the results obtained, and the next steps.

METHODOLOGY

In order to achieve the proposed objectives from the development and work of clinical engineering Regional Nodes in Colombia, initially the participation of the MoHSP as the project leader was guaranteed. Moreover, the person from MoHSP would represent this institution and be responsible for the coordination of the Nodes, and consequently, the entire network.

RK 16	EMPRESA	PAÍS	CIUDAD
1	Hospital Israelita Albert Einstein	BR	São Paulo
2	Clínica Alemana	CL	Santiago
3	Fundación Valle del Lili	CO	Cali
4	Hospital Samaritano de São Paulo	BR	São Paulo
5	Hospital Italiano de Buenos Aires	AR	Buenos Aires
6	Hospital Clínica Bíblica	CR	San José
7	Fundación Cardioinfantil	CO	Bogotá
8	Fundación Cardiovascular de Colombia	CO	Bucaramanga
9	Hospital Pablo Tobón Uribe	CO	Medellín
10	Hospital Universitario Austral	AR	Buenos Aires
11	Clínica Internacional	PE	Lima
12	Médica Sur	MX	C. de México
13	Centro Médico Imbanaco	CO	Cali
14	Clínica Ricardo Palma	PE	Lima
15	Hospital Alemão Oswaldo Cruz	BR	São Paulo
16	Hospital Universitario de San Vicente Fundación	CO	Medellín

FIGURE 1. Best hospitals and clinics in Latin America. Ranking 2016.

From these providers from different regions of the country, clinical engineers were invited to be part of the National Board together with the MoHSP. This was done to manage and maintain the Regional Nodes of clinical engineering, which are working groups or technical meetings held in the different regions.

The meetings were based on debates and knowledge generated by the National Board. Afterward, the information flowed to the Regional Nodes with support from the MoHSP. After every debate, meetings were held at the Regional Nodes for unification, consolidation, and validation of the MEM information. This was followed by the identification of needs, feedback to the node leaders, and finally feedback to the MoHSP at the meetings of the National Board.

In order to accomplish the described methodology, it was established that there should be a schedule of the regional meetings in which MEM topics were previously defined and discussed. In addition, the results of the work done by the members of the Regional Nodes could be presented.

RESULTS

Currently we have work leaders composed of 12 clinical engineers from 8 high-complexity hospitals, which are recognized because they have national accreditation and JCI accreditation, as well as successful experiences in MEM.

These 12 engineers are leading and maintaining 6 Regional Nodes of Colombian clinical engineering (Figure 2): Center Node: Bogotá, Cundinamarca and departments of the center of the country; South West Node: Valle del Cauca, Cauca, Nariño; Antioquia Node; Santanderes Node: Santander and North of Santander; Caribean Coast Node: Atlántico, Bolívar, Cesar, Córdoba, La Guajira, Magdalena, Sucre; and Coffee Triangle Area Node.

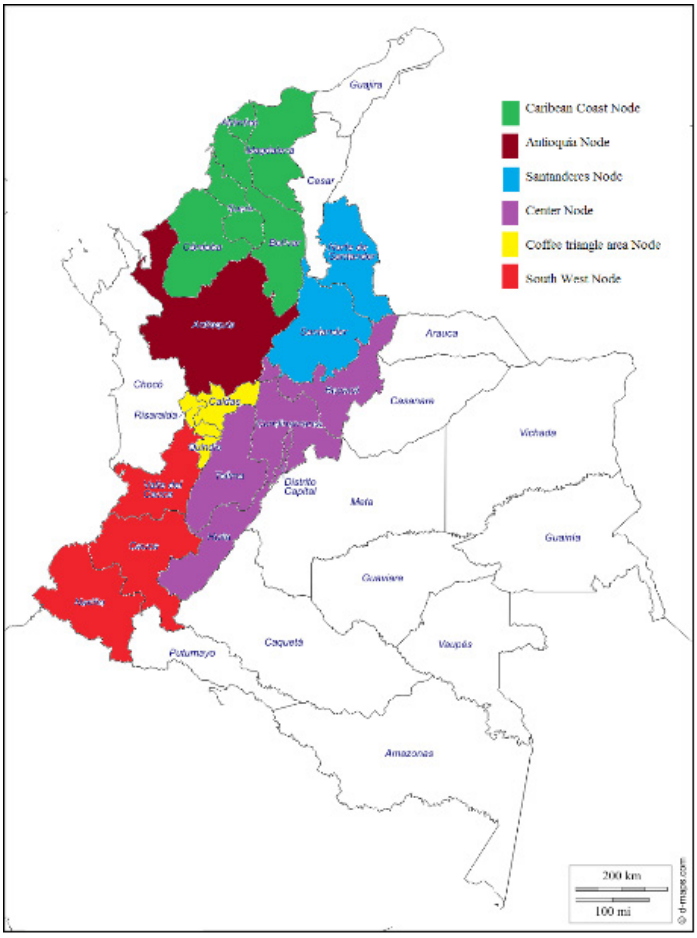

FIGURE 2. Colombian Nodes map.

Networking has proven to be an effective method to optimize resources, create and strengthen communication channels, share MEM experiences, and facilitate knowledge transference. As a result, every day, clinical engineers are looking to be part of the network on behalf of their institutions and universities that provide academic and methodological support to the network. Table 1 shows the current composition of the Regional Nodes in relation to the number of clinical engineers, health care institutions, and universities which are part of the network.

TABLE 1. Current Composition of the Regional Nodes

Region	Clinical Engineers	Hospitals	Universities
Bogotá	60	40	2
Antioquia	40	20	5
Southwest Colombia	55	35	2
Santanderes	25	10	2
Coffee Triangle Area	30	20	1
Caribbean Coast	30	15	1

Strengthening of the Regional Nodes has resulted in a positive impact on the MEM around the country, such as:

- Continuous training in Colombian regulations.
- Cooperation relationships among participants.
- Institutional referencing to improve processes.
- Positioning of clinical engineers as the main stakeholders in MEM.
- Institutional strengthening of the MoHSP in health care technologies field.
- Better health care for patients.
- Accessibility of MEM information.
- Improving efficiency of the MEM process in regional and local hospitals.
- Collaboration with the MoHSP in the validation of the Equipment Evaluation, Maintenance and Obsolescence Manual.
- Contribution on the development of a proposal for "mandatory requirements for the medical equipment management" for public and private hospitals and clinics, blood banks, and public health laboratories.

DISCUSSION

Every day the strategy of the Regional Nodes gathering and disseminating information is strengthened in Colombia. By May 2017 there were 200 clinical engineers, and by July 2017 there were 40 more. This shows that the Regional Nodes are responding to the needs of the clinical engineers.

The challenges we face as members and leaders of these Regional Nodes are to consolidate a networking culture, overcome communication barriers, approve criteria about clinical engineering, ensure credibility in the results that have been obtained, and engage the members to achieve results in the short term. Furthermore, as leaders we must look for ways to vitalize the National Board and Regional Nodes to ensure their operation in the long term.

Currently we are working on network consolidation, information flow improvement, referencing among the members, communication with the MoHSP, and promotion of the integration of different stakeholders in clinical engineering management, including the formation of new Regional Nodes across the country.

We identified strengths of the Regional Nodes as the ability to keep creatively holding meetings and integrating more participants, maintaining activities that facilitate the network of clinical engineers, and developing solutions to common challenges, the management of knowledge, and the development of human capital.

The main opportunities for improvement are the consolidation and recognition of the Regional Nodes, keeping members motivated, and including new members. Finally, there will soon be the delivery of tangible products designed and validated by the Regional Nodes which may be applicable to our country.

Future work proposed includes:

- Formation of the association or college of Colombian clinical engineering.
- Increasing the number of members and institutions.
- Supporting the Institute of Health Technology Assessment (IETS) in MEM projects.
- Working on joint projects with the American College of Clinical Engineering's international committee in Colombia.
- Strengthening interaction with professional engineering societies and health technology organizations around the world.
- Improving communication with health care regulation authorities, hospital managers, and administrators.
- Overcoming communication barriers supported by the use of WebEx platforms necessary to strengthen virtual work.
- Construction of a website to share experiences, knowledge and documents.

CONCLUSIONS

Currently, the network has a coverage of 40% in Colombian territory, with leadership from the MoHSP and 8 hospitals who have national or JCI accreditations. As well there is the participation of 240 clinical engineers who work in 140 hospitals. Additionally, we have the support of the academy represented in 13 universities.

To be part of the Regional Nodes, there should be no cost for registration or support fees. The members should only demonstrate an interest in meeting colleagues, sharing their experiences and knowledge, and working to improve practices in biomedical equipment management.

Colombia is a diverse country with large cities and dispersed rural areas. Regional meetings make it easier for areas far away from capitals, and clinical engineers with limited resources, to have access to information and tools of the best practices in biomedical equipment management.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

Received February 8, 2018, accepted March 12, 2018, date of publication March 25, 2018.

Survey and Analysis of Current State of Ventilator Alarms in the Intensive Care Unit

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ABSTRACT

This article reports on a survey and analysis of ventilator alarm state in a children hospital. Based on the evaluation of the alarm effectiveness, we designed a survey statistical table for ventilator alarm investigation. We evaluated the alarm situation synthetically through investigation and statistical methods. Result shows that the current ventilator alarms are not sufficiently effective, 26.84% of them are meaningless alarms and those leading to clinician's intervention make up only 2.26% of all the alarms generated. The reliability of statistical data was also analyzed. According to the survey results, we identified and analyzed the causes of the problem and proposed the corresponding alarm management methods.

Keywords – *ventilator alarm information, alarm effectiveness, alarm management, survey statistics*

INTRODUCTION

The intensive care unit (ICU) is one of the most critical clinical departments for patients in a tertiary hospital. Yet, the volume of medical equipment equipped in this clinical area also presents great challenges in terms of alarm fatigue due to overwhelming alarm information generated during daily operation. There are simply too many alarms that do not result in medical intervention in the ICU.[1] It was reported that an alarm sounded every 92 seconds in the ICU in 2006.[2] This was shortened to every 66 seconds by 2010,[3] and shortened further to every 42 seconds by 2014.[4] Too many alarms bring about auditory and visual confusion for medical staff.[1] They can't identify the sources of the alarms effectively,[5] which is a serious threat to the safety of patient care.[6] According to one report from the ECRI Institute, the number of adverse events related to alarm management is increasing yearly.[7] A hospital may experience tens of thousands of alarm messages every day, but 85–99% of them are nuisance alarms or do not need clinical intervention.[8] The presence of these alarms leads medical staff a to state of alarm fatigue and can cause alarm ignorance or even the turning off of the alarm function.[9]

However, above reports mainly focus on alarm issues for adult patients, there are few reports based on the same issue for pediatric patients. Children, especially newborns, with their language, awareness, and behavioral abilities not yet fully developed, bring more challenges to a health care team. Based on the above background, this paper presents an analysis method that integrates the statistical design of the survey, the investigation experiment, and the statistical analysis of the data, and analyzes the state of ventilator alarms in the neonatal ICU in a children hospital.

MATERIALS AND METHOD

Based on the literature review and our experience, alarms can be categorized into meaningful alarms and meaningless alarms. Meaningful alarms are those alarms that require a clinician's quick attendance due to changes in patient condition or those technical alarms originating from equipment malfunctions that require timely correction. Meaningless alarms are those that don't reflect the true changes of a patient's condition, do not improve patient management, and may be caused by false alarm, improper alarm settings, or recoverable transient artifacts.

In order to carry out an assessment of the common ventilator alarms, we first consulted with clinicians to categorize the three main alarm interventions for ventilators in their routine practice: (1) clinician's medical intervention, (2) clinical engineering and nurse's equipment correction; and (3) alarm elimination by silencing. Clinician's medical intervention means patients with clinically changed conditions requiring timely intervention of medical staff; clinical engineering and nurse's equipment correction means a technical problems with the ventilator occurred requiring clinical engineering or nurse's action such as immediate repair; while alarm elimination by silencing means that both the patient and instrument were OK and the alarm did not recur after silencing. We also collected and analyzed common alarm contents, common alarm intervention measures, and alarm causes. Since alarm limit settings are highly relevant with alarm occurrence, it is also important to record common alarm limit values accurately. Based on the key elements mentioned above, we design the Statistics of Clinical Meaningful Alarms, as shown in Table 1.

In this study, we selected the SLE5000 ventilator as an example, where this paper applies the designed survey table to the collection and observation of the SLE5000 ventilator alarms generated in daily use in the neonatal intensive care unit (NICU) over a period of 10 days.

RESULT

The Results of the Survey

This survey is based on 120 total questionnaires, with 486 events of recorded alarm information from 112 valid questionnaires, and 12 kinds of common alarms generated. The specific number of alarms shown in Figure 1. Among them, the high-pressure alarm, low pressure alarm, and cycle failure occur with higher frequency. The results of intervention are shown in Table 2.

According to the effectiveness of the alarm and the definition of meaningful alarms described earlier, we classify 354 alarms events as meaningful alarms, and the

TABLE 1. Statistics of Clinical Meaningful Alarms

Ventilator Model:		Patient Hospital Number:				Date:
Set value	PEEP H: L:	Amplitude	Hz	Frequency H: L:	Tidal volume H: L:	Minute ventilation H: L:
Alarm content	Intervention measures and their causes (multiple choice)					The result of the intervention
Event hints:	☐ Mute ☐Endotracheal secretions are much, should suck them out ☐ Abnormal machine and accessories ☐The patient is restless ☐ There is water in the tube ☐Replacement of the sensor ☐ Adjust the position of the endotracheal intubation ☐ pipeline discount, off ☐other☐					☐ Alarm elimination by silencing ☐ Clinician's medical intervention ☐ Clinical engineering and nurse's equipment correction
……	……					……

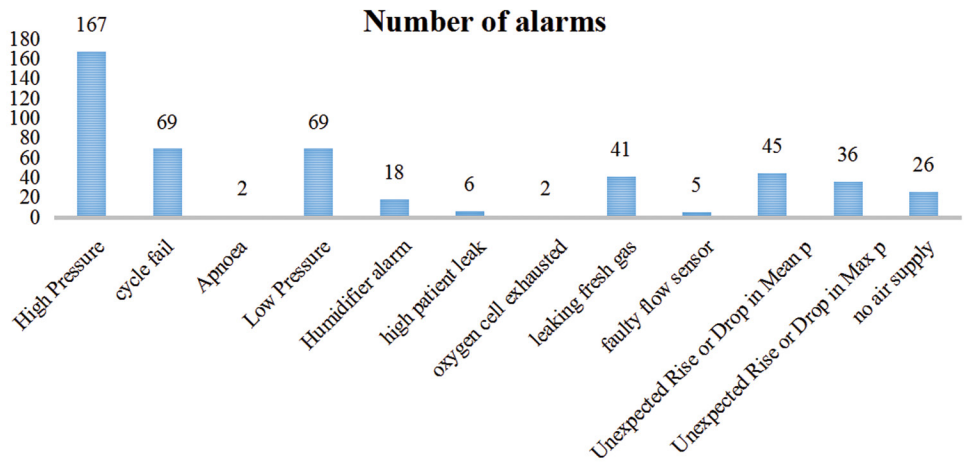

FIGURE 1. Alarm name and number of alarms.

TABLE 2. The Result of the Intervention

	Clinician's medical intervention	Clinical engineering and nurse's equipment correction	Alarm elimination by silencing
Number of alarms	11	343	132
Proportion	2.26%	70.58%	27.16%

TABLE 3. Overview of Alarm Data

Time	Total	Meaningful alarm	Meaningless alarm	Rate of meaningful alarm
1st day	50	43	7	86.00%
2nd day	46	31	15	67.39%
3rd day	36	28	8	77.78%
4th day	45	39	6	86.36%
5th day	59	46	13	77.97%
6th day	69	44	25	63.77%
7th day	48	31	17	64.58%
8th day	48	34	14	70.83%
9th day	45	29	16	64.44%
10th day	40	29	11	72.50%
Total	**486**	**354**	**132**	——
Average	**46.8**	**35.4**	**13.2**	**73.16%**

calculation of meaningful alarms rate per day is shown in Table 3.

The rate of meaningful alarms was 73.16% of all alarms generated. This included those alarms that really reflect the changes of patient condition which need the clinician's quick attendance or those technical alarms for equipment malfunction that require correction immediately or soon. Yet, the alarms that required clinician medical intervention reached only 2.26%. There is quite a large proportion of meaningless alarms, which consists of 26.84% of all alarms generated. This indicates that the alarm conditions should and could be improved greatly.

Reliability Test

Reliability refers to the degree of questionnaire results repeatability. The coefficient of Cronbach's Alpha is between 0 and 1, and the larger the value, the better the relevance of the items in the questionnaire and the higher the degree of internal consistency.[10] In general, the internal consistency is considered excellent, good, or poor accordingly if the coefficient of Cronbach's Alpha is greater than 0.8, within 0.6~0.8, and less than 0.6 respectively . Using the SPSS19.0 software to analyze the experimental data, the results show that the Cronbach's Alpha coefficient of our survey is 0.915, which indicates that the statistical experiment is credible and statistically significant.

DISCUSSION

The survey uses the designed form to collect and analyze the state of the SLE5000 ventilator alarms management. There were 486 recorded alarm events collected over a time period of 10 days. Though we believe the survey only collect the most common relevant alarms occurring, the actual alarms generated by a ventilator may be higher than this survey collected. Yet, the internal consistency reliability of the 10 days' survey data is analyzed by SPSS19.0 software and it shows overall survey data are solid and strong.

Survey results show that 26.84% of the alarm data is meaningless alarms, which means that those alarms did not contribute to better patient management and could have been avoided in the first place. Even some of those classified as meaningful alarms, in particular some technical alarms, there is still room to reduce their occurrence. Alarm management is teamwork. All stakeholders including hospital leadership, medical staff, clinical engineers, manufacturers, and independent service organizations should participate. We suggest the following strategies:

- First, urge manufacturers to improve the quality and reliability of equipment and improve the design of alarm system.
- Second, assure clinical engineering staff to perform service and preventive maintenance of relevant medical equipment timely and appropriately.
- Third, strengthen user training in terms of medical equipment operation as well as alarm management including setting alarm limits appropriately.
- Fourth, develop and apply alarm integration and management systems based on IT technology.

CONCLUSIONS

The article aims are a survey and analysis of the current state of ventilator alarms in an ICU. The results show that the current ventilator alarm management in the ICU needs to be improved. As well. collaboration among clinicians, clinical engineering staff, and ventilator manufacturer is important and necessary in terms of providing a better solution based on training, smart alarm design, and alarm integration management.

We believe the methodology mentioned in this paper is not only suitable for SLE5000 ventilator alarms information survey and assessment, but also could be used as reference for other types of ventilators or medical equipment such as monitors, infusion pumps, etc. Nevertheless, the systematic management of all instruments' alarm is a complex project. Further research is needed to learn best practices of other facilities currently and into the future.

ACKNOWLEDGEMENT

We would like to extend our sincere gratitude to Dr. Yadin David, director of Health Technology Task Group IUPESM, for his comments and suggestions. We are also deeply indebted to our other clinical engineering staff and NICU physicians and nurses who helped us to complete this survey.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest involved this paper.

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Publicly available March 12, 2014, revised March 22, 2018.

Building a Reliable Wireless Medical Device Network

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ABSTRACT

How to design and test the most effective and secure wireless medical device connectivity applications that will provide the true mobility experience that is needed in the 2018 healthcare marketplace. Today's medical devices will need to be connected to provide the data to the electronic medical record. This connectivity will be either real time or on a non real time basis. In either case; the majority of this data transfer will move toward a wireless medium from a legacy wired connection. The following will discuss best practices for wireless network design based upon application requirements; but also the protection of any data regarding cybersecurity requirements. The author has over three decades of medical device knowledge sense but also two decades of wireless and security integration knowledge sense. The take away is to understand the best practices and how to apply this to product design and the overall enterprise implementation into the healthcare ecosystem of connected devices.

Keywords – *wireless, WLAN, network, acute care, patient monitoring, IEEE802.11, WMTS, telemetry.*

INTRODUCTION

A brief history of the WLAN-enabled medical device.

Historically, patient-wearable monitoring – commonly referred to as telemetry – required its own custom designed and proprietary radio system and coaxial cable infrastructure for unidirectional communication. This infrastructure was built around regulatory domain-controlled technologies, such as Wireless Medical Telemetry Service (WMTS) in the United States. While these designs proved to be reliable, they were often expensive, unique to each manufacturer, and lacked enterprise management and/or troubleshooting capabilities. These telemetry systems were generally confined to individual care units within the healthcare facility and utilized several to 100 or more dedicated telemetry patient channels.

For the past several decades networked bedside (or acute care) patient monitoring was confined to proprietary, standalone networks for communication from the bedside monitor to the central station. This was, and is even today, often the de-facto standard methodology in the majority of critical care units on a global basis.

Over the past decade, many medical device manufacturers have incorporated WLAN in their devices for a multitude of use requirements. This has included the next generation of smart infusion pumps, portable patient monitoring, and within the past five years, telemetry.

Modern enterprise networks, both wired and wireless Ethernet systems, have progressed to the point where they, if designed and installed correctly, have proven to be cost effective and reliable – as demonstrated by hundreds of thousands of mission-critical WLAN networks deployed on a global basis in many industries. As a result, both medical equipment manufacturers and healthcare institutions are looking to leverage their nearly ubiquitous WLANs by utilizing them for network-enabled medical devices.

Clinical benefits of having a WLAN throughout the healthcare institution

The healthcare industry was an early adopter of WLANs because they enabled more timely and accurate bedside medical statistics recording, voice-over-IP-over-Wi-Fi, asset location, and guest Internet access – which benefitted clinicians, IT and biomedical groups, as well as patients and their families.

This new methodology of networked patient monitoring has many clinical benefits. Specific to telemetry and patient monitoring, an omnipresent WLAN can now enable the following:

- **Expansion of telemetry area coverage:** The telemetry system can operate across the entire facility, and not be limited to specific care areas. The trend is to increase telemetry usage across a common enterprise network, versus managing hundreds of standalone monitors.
- **Increased reliability:** Patient monitoring can leverage proven networking technology that is consistent in design and deployment. This networking infrastructure can provide true bi-directional communication for increased overall system reliability.
- **Increased space utilization and patient safety:** Having all monitors networked through the WLAN gives the hospital the flexibility to monitor patients anywhere in the hospital. For example, if the Emergency Department is at capacity, they can add extra monitored beds in another unit, thereby keeping the patient in the delivery network, versus having to divert the patient to another facility because of the lack of monitored beds. Having additional monitored beds also enables hospitals get patients out of higher acuity, and higher cost, settings.
- **Reduced risk of undetected events:** For example, if a prior cardiac patient comes in for an orthopedic procedure, the orthopedic nurse could easily have a cardiac trained nurse observe that patient using WLAN monitoring while the patient is being treated for that orthopedic procedure.

SUITABILITY OF WLAN FOR PATIENT MONITORING

Overview

Any wireless network is dependent upon proper planning, design, and implementation, taking into consideration the internal and external variables that may impact the network's performance and reliability. Such internal and external factors include high availability (HA) network infrastructure, radio frequency (RF) interference, Quality of Service (QoS) requirements, and cost budgets. In terms of suitability of the WLAN for patient monitoring, the healthcare institution must consider the requirements of the specific applications that will run over the WLAN. Any patient monitoring network has to be 100% reliable around-the-clock, 365 days a year, while communicating alarms, events, and recordings in real time.

Suitability Factors

The following factors influence the suitability of a WLAN to support a patient monitoring system:

- **Design of the WLAN:** Over the last 15 years, WLAN design has migrated from a simplistic paper-based approach to a very scientific methodology utilizing computer-based predictive modeling tools and onsite RF spectrum analysis to identify the sources of any potential RF interference. This methodology takes into account building materials, client device density, Wireless Access Point (WAP) placement, antenna patterns, RF link speeds, and RF channelization/ power and then creates a predictive model with 98% to 100% accuracy of design. In addition, a proper logical design must be created to define IP addressing, VLANs, multicast, DHCP, QoS, and other network-layer settings that affect WLAN quality and reliability. When using these tools, the hospital can have confidence that the network they install will need little to no modification after installation.
- **Installation and troubleshooting:** A well planned and designed LAN and WLAN is the foundation for

a well performing patient monitoring system. As mentioned above, predictive WLAN modeling tools ensure a design with over 98% accuracy before implementation. For the few instances where the WLAN design may incorrectly place Wireless Access Points (WAPs), WAP location modifications can easily be made in the field at the time of deployment. When installing a WLAN, all operational settings are configured in a central WLAN controller that interfaces with the facility's core network and allows for efficient network communication. In addition, depending on the size of the WLAN, a separate WLAN management system may also be implemented to provide a single "pane of glass" for the management, monitoring, alarming, troubleshooting, reporting, and assurance of consistent configurations across multiple WLAN controllers. All of these improvements make the implementation of a reliable LAN and WLAN scientific and predictable.

- **Interference:** While RF interference is always a possibility, the modern WLAN generally has spectrum analysis functions built into the network as a whole. This allows for constant monitoring of the network for any interference and acts to either issue an alarm to the network administrator or automatically mitigate those specific interferers. As good design practice, an onsite spectrum analysis should be performed to determine any RF interferers present in the facility in the 2.4GHz and 5GHz bands and their potential impact.
- **Reliability:** Today's WLAN is an intelligent network. Although WAPs have a mean time between failure (MTBF) of over ten years, this network can automatically sense and alarm if a WAP fails or is not performing as expected. Good WLAN design practices dictate overlapping adjacent WAP cells to ensure seamless client device roaming across the network. Even if an individual WAP fails, radio output power in adjacent WAPs can be set to automatically increase/decrease to ensure adequate coverage. In addition, High Availability (HA) designs feature redundant WLAN controllers that will failover in a seamless fashion in the event of a network controller failure.
- **Scalability:** In the past, understanding how the WLAN client density may increase was a challenge. WLAN designs must anticipate the potential number of client devices such as patient monitors that will be used over the life of the WLAN. Today there are tools from such companies as Ixia (www.ixiacom.com) that allow end users and WLAN device manufacturers to assess the scalability of a WLAN. Given the new higher-speed WLAN standards, it is common to build and scale networks to thousands of users to support data, voice, video, and WLAN-enabled medical devices.
- **Two-way communication:** Previous generations of proprietary wireless communication for telemetry was unidirectional; WLANs offer two-way or bi-directional communication. Two-way communication supports the latest generation of patient-worn monitoring devices. These devices send patient vital signs data to the central monitoring station for display and alarming, as did yesterday's telemetry transmitters, but they also display and alarm locally. So, if the patient accidentally walks outside of the Wi-Fi network coverage area, the patient will continued to be monitored locally. The caregiver is therefore able to monitor the patient without compromising the mobility of ambulatory patients.
- **Cost issues:** Healthcare systems are under tremendous cost pressures, so the more value that they can realize from a technology investment, the better. In the case of patient monitoring, this is yet another application across which to allocate the fixed WLAN cost. More than likely, the investment in the WLAN was made for Bar Code Medication Administration (BCMA), wireless voice-over-IP (VoIP), real-time location services (RTLS), and/or "smart" infusion pumps. Adding WLAN-based patient monitoring may add some small incremental costs, but this application can be amortized over a number years with the other applications to improve the return on investment (ROI).

Wi-Fi vs. WMTS cost comparison

The costs of implementing patient monitoring on Wi-Fi are significantly less than on a WMTS network. The following cost comparison tool provides a general indication of costs involved.

TABLE 1. WLAN vs. WMTS cost comparison tool

WMTS vs. WLAN Infrastructure Price Model		
WMTS DESCRIPTION	**INPUTS**	**COMMENTS**
Current area for WMTS telemetry	200,000 sf	Diversity antenna coverage
Desired area for WMTS telemetry	1,000,000 sf	Diversity antenna coverage
Cost psf for WMTS telemetry	$1.50	Cost per square foot
	RESULTS	
Additive new WMTS area coverage	800,000 sf	
Total cost for **additive** new area coverage (608MHz-1.4GHz)	**$1,200,000**	
WLAN DESCRIPTION	**INPUTS**	**COMMENTS**
% of 'Desired area for WMTS telemetry' currently covered by WLAN	60%	
Does WLAN provide for -67 dBm coverage?	No	
Cost psf for WLAN	$1.00	Hardware, software, licensing, design & deployment services
Qty of services currently on WLAN	3	Examples: data, VoIP-over-WiFi, video, biomed/infusion pumps, RTLS, guest access
	RESULTS	
Additional WLAN area for 'WMTS additive new area coverage'	400,000 sf	To satisfy the clinical requirements for patient monitoring
WLAN area needing remediation	600,000 sf	
Costs for extra WLAN coverage for patient monitoring	$400,000	
Costs for WLAN remediation coverage to -67dBm	$240,000	Remediation for the patient monitoring area only, not the complete WLAN coverage
WLAN validation services costs	$100,000	
Total WLAN costs	**$740,000**	
Total WLAN costs amortized over services	$246,667	
WLAN vs WMTS Infrastructure Cost	**$460,000**	**WLAN savings over WMTS**

BEST PRACTICES

The following are best practices for maximizing reliability and uptime when implementing patient monitors on an existing wireless LAN:

Start with the right "wireless radio design" within the medical device

One popular misconception that frequently compromises performance is that "all IEEE802.11a/b/g radios are created equal." On the contrary, the quality of radio devices varies, and if a medical device manufacturer selects a sub-par, low-cost radio, it can undermine the performance of a life-critical medical device that costs thousands of dollars. Device testing is the key to protecting

yourself from buying a device with a sub-par radio. More on that in the next section.

Another costly misconception is that a radio obtaining a stamp of approval from the Wi-Fi Alliance means everything will work fine; but there's more to it than that.

The Wi-Fi Alliance was founded in 1999, the same year that the IEEE approved the extended version of 802.11 (802.11b) standard for the specific purpose of ensuring interoperability between client radios and wireless access points.

The interoperability testing conducted does not include modeling the specific characteristics of a data, voice, video, or medical device client or the simulation of different mixed client traffic load environments; nor does it measure application performance. Obtaining the Wi-Fi Alliance's stamp of approval is a great start, but it's far from the end. The fact that a radio is Wi-Fi approved, or subscribes to 802.11i and 802.11e, does not demonstrate how well the roaming algorithms will work, or assess the passing of security supplicants. Many healthcare institutions employ WPA2 or other enterprise-level WLAN security methods but differ in how they implement security methodologies, which in turn impacts device and application performance.

In selecting the optimal WLAN-embedded radio, device manufacturers must assess the ability of the components to meet their intended use for quality of service, roaming, and varying security implementations. As the mobile healthcare ecosystem grows ever more complex, embedded radio strategies must be able to accommodate all enterprise-grade security strategies and effectively roam amidst a myriad of traffic types throughout a highly mobile environment.

It behooves the hospital to choose devices that contain radios that meet their current requirements in order to provide a foundation for future requirements.

Device testing: what it is and why it's important

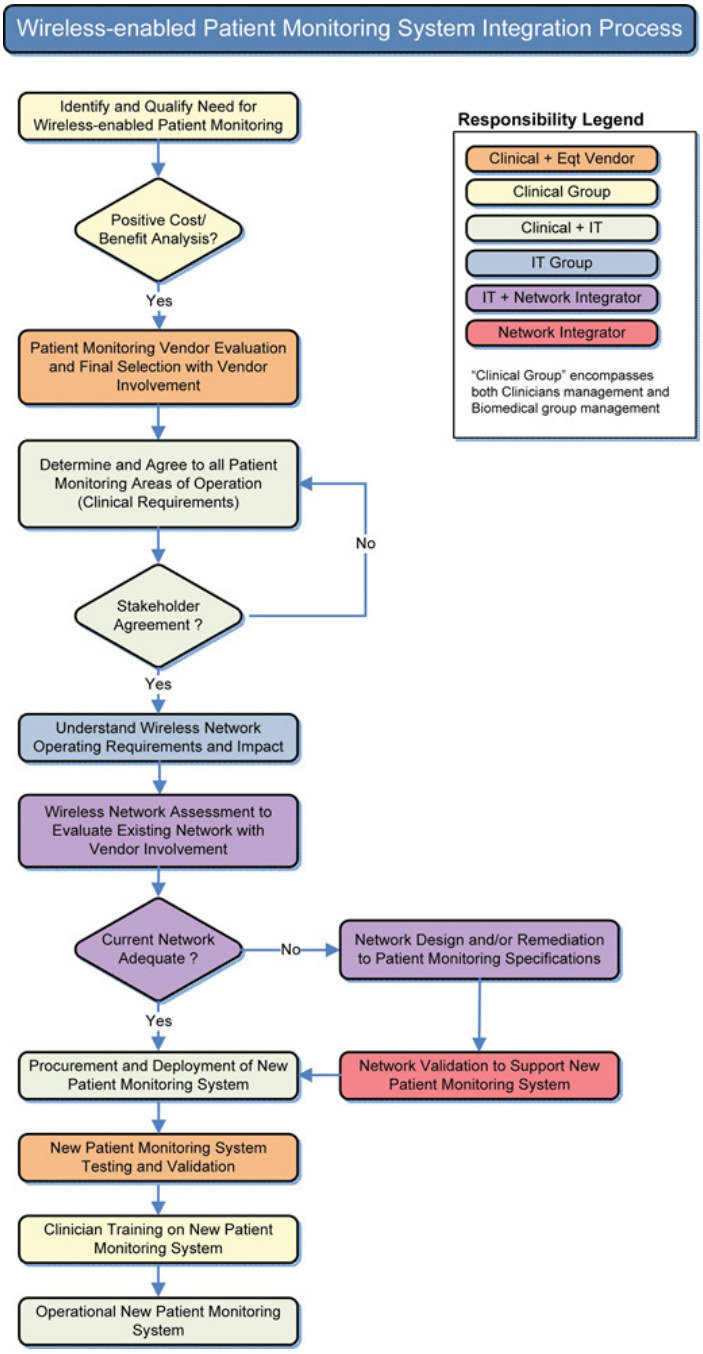
The device manufacturer is responsible for testing medical client devices during validation and verification. A comprehensive methodology for testing the device proceeds from highly controlled lab testing to assessing performance in the field via open air. Testing should include validating components such as radios, chipsets, and driver firmware and, once that is completed, progress to assessing the real-world performance of the medical device itself.

Hospitals have the right to ask manufacturers if their devices have been tested or installed successfully in a similar configuration to what they are considering. The proven methodologies should include:

1. Base-lining network performance using "golden" clients to obtain a "best-case" use model
2. Base-lining device performance under ideal network conditions where it's the only client communicating with WAPs under optimal conditions
3. Assessing range and roaming capabilities by varying RF signal attenuation to prompt devices under test (DUTs) to move away from and between specific WAPs. This includes:
   - Determining device association to the WLAN at various ranges
   - Measuring the accuracy of device throughput, latency, and packet loss characteristics
   - Assessing performance as devices travel across multiple WAPs to emulate patient mobility. Testing should progress from simple setups using only two WAPs at a time to complex scenarios where the device sees multiple available access points broadcasting at different signal strengths.
4. Assessing real-world performance and security by simulating live network conditions. Generating high traffic loads and interference allows the resilience, coexistence, and security capabilities of devices to be realistically and thoroughly assessed. User-configured clients should be generated to populate a realistic network ecosystem containing device traffic typically found in healthcare environments – voice over IP, data from wireless infusion pumps, wireless laptop transactions, video, etc. – all generating simultaneous network traffic.
5. Measuring interoperability with multiple WAPs and mobile clients and major customers' preferred WLAN equipment vendors
6. Quantifying application performance and quality of experience (QoE) from the user perspective

7. Reproducing field conditions and modeling "what if " scenarios in the lab to simulate individual hospital environments

FIGURE 1. Wireless patient monitoring integration process



8. Onsite assessment to ensure successful deployments out of the gate

9. Ongoing lab and site testing of network firmware changes and devices software upgrades

The WLAN patient monitoring deployment: what and why

In the area of patient monitoring, the actual patient-use model is critical to a successful monitoring selection and implementation. Before the technical requirements can be solved, the clinical requirements need to be addressed and understood, including:

- Where are the patients going to be monitored? A good starting point is to sit down with CAD drawings of the hospital floor plan and have clinical staff highlight all the areas where patients need to be monitored. For example, would a patient need to be transported from the ICU down the elevators to radiology and/or therapy areas? If so, then adequate wireless coverage would be needed to ensure real-time connectivity.
- How many patients are going to be monitored simultaneously, at maximum patient census?
- Where will the staff monitoring these patients be located?

Once the clinical requirements are vetted out and agreed to, then the technical requirements can be addressed. The following questions should also be discussed:

- What are the anticipated growth requirements (scale)?
- What is the current network infrastructure in place to support the new patient monitoring system requirements?
- What, if any, network remediation needs to be completed?

Based upon an understanding of the medical device's network characteristics and the existing network infrastructure, an accurate WLAN design can be initiated. The

FIGURE 2. Example of marked up hospital floor plan, highlighting all places where patients will be monitored

design tasks may include creating a completely new design or modifying the existing WLAN. This design can be then handed off to the hospital's integrator for any potential remediation and/or additional infrastructure.

FREQUENTLY ASKED QUESTIONS

Why is it common for hospitals to use Wi-Fi for bedside and transport monitoring, but not for telemetry?

It has been easier for medical equipment manufacturers to design Wi-Fi into a bedside and transport monitor due to the looser constraints around Wi-Fi power consumption and associated battery life. Portable monitors tend to be powered by battery and AC line power and tend to be used for shorter periods of time. Until most recently, Wi-Fi radios tended to be relatively power hungry. Telemetry monitoring is wearable, requiring smaller batteries to conserve weight and space, and has a requirement for the devices to be worn for days.

When I look for Wi-Fi based patient monitoring, is the particular WLAN technology important – such as 802.11a, b, g, n, or ac?

	Year Approved	Year Marketed	Radio Band (GHz)	Max Speed (Mbps)	Comments
802.11	1997	1998	2.4	2	Limited speed, limited adoption
802.11b	1999	2000	2.4	11	First widely adopted WLAN standard
802.11g	2003	2003	2.4	54	Backward compatible to .11b
802.11a	1999	2004	5	54	First widely adopted 5GHz WLAN standard
802.11n	2009	2009	2.4 & 5	300	Backward compatible to .11b/g/a, very widely adopted
802.11ac	2014	2014	5	~800	Next-generation Wi-Fi

TABLE 2. History of IEEE 802.11

The evolution of Wi-Fi has been driven by the radio manufacturers and IEEE standards seeking increasingly higher performance networks with increased radio spectrum efficiency. Here is the history of IEEE 802.11.

What is important is to focus on the application and use model. Patient monitoring data throughput requirements are extremely low and do not need the high speed capabilities of 802.11n and 802.11ac chipsets. The choice of radio is really dictated by chipset availability (for example, one would be hard pressed to find an 802.11b radio in 2014), power consumption, and feature set required by the patient monitor. Wi-Fi clients built on earlier 802.11 standards will communicate with the same QoS (Quality of Service) and security but simply may not be able to take advantage of capabilities inherent in 802.11n and 802.11ac. These include but are not limited to Channel Binding at 40/80MHz, MIMO Spatial Streams and Multi-Use MIMO, High Modulation 64 QAM and 256 QAM, beam-forming and co-existence mechanisms for 20/40/80/160MHz. When the healthcare enterprise desires to move forward with 802.11n and then 802.11c, adding the low bandwidth requirements of patient monitoring will have little to no impact on the overall wireless infrastructure.

How do I know that Wi-Fi will be reliable for a life-critical medical application when the spectrum is already crowded with data, voice, etc.?

The evolution of Wi-Fi has been to primarily increase networking speed, quality of service, and security. Wi-Fi has evolved to a level of performance capability whereby it is now displacing the wired Ethernet network at the access layer. Those applications with low bandwidth requirements, such as infusion pumps and patient monitoring, will reliably function in the 802.11g (2.4GHz) and/or 802.11a (5GHz) spectrums. Since 802.11n is backward-compatible with both 'g' and 'a', those same monitors will work well in a 802.11n WLAN infrastructure. Applications such as high-end video will tend to migrate to 802.11ac operating in the 5GHz band. Therefore, all applications can co-exist successfully on a modern WLAN network.

Modern WLAN systems increase overall system reliability using:

- Persistent spectrum analysis to identify RF interferers and proactively reconfigure RF channelization to work around the interference
- Applying best practices for networking design and deployment for Quality of Service (QoS) to prioritize patient monitor system traffic over other traffic types
- Applying best practices for networking design and deployment for network segmentation via VLANs that address scalability, security, and network management

I'm adding Wi-Fi patient monitoring to my hospital network. How can I design wired and wireless redundancy into the network?

The practices for designing redundancy into a network do not change by adding patient monitoring. Standard networking practices which can be planned in conjunction with hospital networking staff and/or third-party providers will meet your needs. Most WLAN vendors have capabilities for High Availability (HA) for their WLAN controllers (WLC) and offer near zero failover time to a secondary or tertiary WLC. In addition, modern WLANs can automatically modify the WAPs output power to increase the surrounding WAPs cell coverage in the event of WAP malfunction.

Although the network access-layer is typically not configured for redundancy, the access layer switches generally will, in healthcare facilities, have redundant Ethernet connections to the core network.

Are there differences in the way redundancy works with Wi-Fi wireless monitoring compared to monitoring suppliers that utilize WMTS?

The principal difference is that redundancy can be cost-effectively built into an 802.11 wireless network. Due to the proprietary nature of WMTS telemetry antenna systems, it is either technically impossible or too costly to design redundancy into the system.

WMTS, or realistically all "telemetry" antenna and receiver designs, use antenna diversity: if there were a null (lack of signal) from one antenna, the other adjacent antenna may likely receive the signal. However, this is highly dependent upon the quality of design which is more of an art, versus a proven, scientific WLAN enterprise design.

Several things need to be taken into consideration for a WMTS implementation. Upon installation of a WMTS antenna system, it must be balanced. These coaxial antenna designs consist of splitters, power supplies (to supply power to the specific legs of the antenna system), attenuators, exact cable lengths, and connections. In large designs this could amount to thousands of connections and hundreds of antennas, which have be at the exact right place and with the right connections made with the ultimate two home runs to the receiver sections.

Multiple points of failure potentially exist to either cause dropout of the signal or the introduction of noise into the system as whole. This could result from a bad connection, removing an antenna, adding an antenna, relocating an antenna, or a receiver section failing. This coaxial WMTS antenna design is what is considered to be "non-intelligent". It is simply an active powered coaxial TV based diversity antenna infrastructure that is connected to powered telemetry receivers.

Unlike with WLAN, no software exists in a WMTS design to actively monitor the air space for interferers or adjust power for changes in WLAN signal coverage. Nor are there provisions for redundant failover of receivers (in case a receiver fails). In addition, the network management for a patient monitoring system operating on a WLAN will be absorbed into the overall network management costs as the patient monitoring system is operating on a common network infrastructure versus a proprietary WMTS-based system.

CONCLUSIONS

1. Wi-Fi is safe and reliable for patient monitoring.
2. The key to success is in the design, implementation and management of the network.
3. Wi-Fi opens the door to unprecedented benefits to the hospital, such as the ability to monitor a virtually unlimited number of patients house-wide, improved patient mobility, significant cost savings and more.
4. Wireless monitoring gives hospitals the ability to provide continuity of patient care across the enterprise for the entire patient stay, which is only financially feasible with Wi-Fi.

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