



TALK SERIES

CEs and the global use of medical devices in home and alternate care sites

Elliot B. Sloane, PhD, CCE, FACCE, FAIMBE, FHIMSS

- Foundation for Living, Wellness, and Health, USA

- Villanova University, USA

Briefly, about me:

- I am a Certified Clinical Engineer in practice since 1975.
 - VP of Operations and Information Systems at ECRI Institute for 15 years.
 - Device evaluations, forensic investigations, database publishing and research
 - VP of Operations, then Quality and Regulatory Compliance for 10 years for a medical device and pharmaceutical manufacturing and service firm, MEDIQ.
 - Professor of MIS and Clinical & Health Informatics at Villanova University since 2000.
- Have been a PAHO and WHO adviser and trainer since 1978.

Portions of this presentation were extracted from our
Canadian webinar earlier this year.

Clinical Engineering Opportunities and Challenges in Home Health Care

CESO Annual Conference, February 8, 2023

Matt Baretich

Bill Gentles

Elliot Sloane



To begin, let me briefly use one of Dr. Matt Baretich's representative forensics patient death investigations involving a ventilator used in the home.

Home Care for Ventilator-Dependent Patients



And, there are many “hazards” in the Home Health Care environment when using medical devices.

- Dr. Bill Gentles summarized a year-long research study that we performed for the Canadian Standards Association which I will share shortly...

**I believe the situation in
Canada is no different than
elsewhere in the world today!**



ECRI

Top 10 Health Technology Hazards for 2023

#1



Gaps in Recalls for At-Home Medical Devices
Cause Patient Confusion and Harm

1

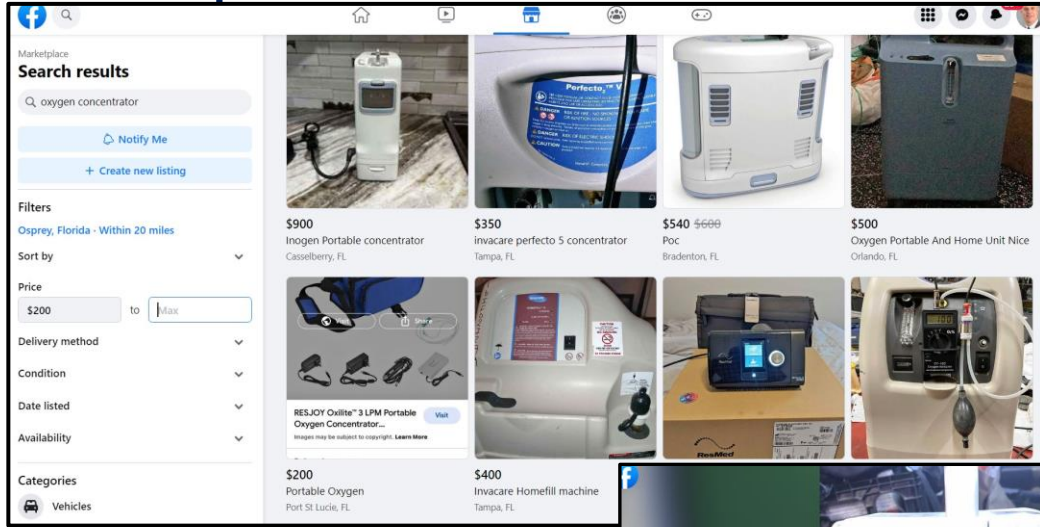
But it isn't just recalls! Many medical devices in the home receive little or no testing, repair, maintenance, or recommended updates!

MANY technologies are in widespread use in the Home Health care environment

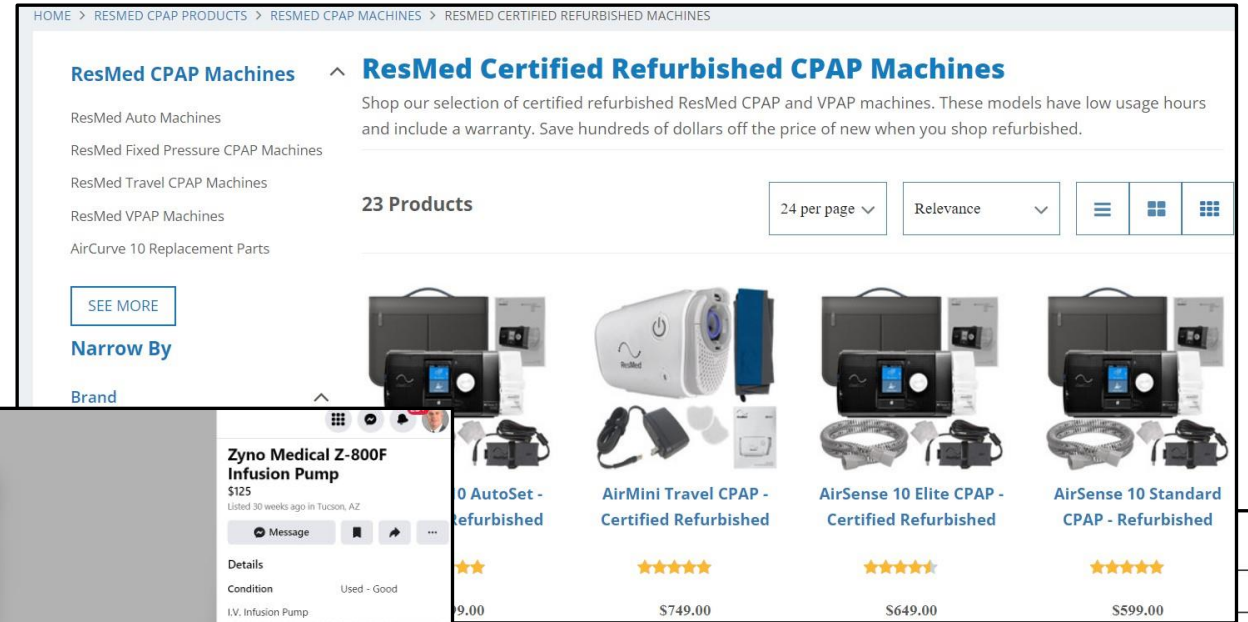
- Oxygen concentrators & LOx
- Pulse oximeters
- CPAP & BiPAP units
- Hospital electric beds
- Portable ventilators with heated humidifiers
- Home dialysis
- IV pumps for pain, insulin, chemotherapy, etc



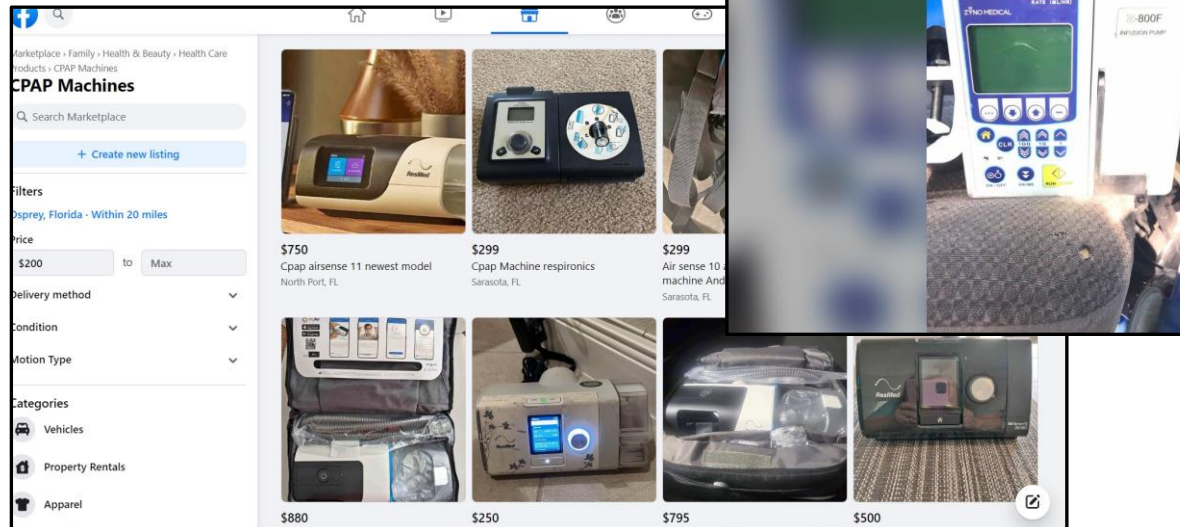
Used medical devices are readily bought on the open market for home and alternate sites



Marketplace Search results for oxygen concentrator. Filters include location (Opsey, Florida - Within 20 miles), price (\$200 to Max), and delivery method. Listings include Inogen Portable concentrator (\$900), Invacare perfecto 5 concentrator (\$350), and Oxygen Portable And Home Unit Nice (\$500).



ResMed Certified Refurbished CPAP Machines. Shop our selection of certified refurbished ResMed CPAP and VPAP machines. These models have low usage hours and include a warranty. Save hundreds of dollars off the price of new when you shop refurbished. 23 Products. Price range: \$9.00 to \$749.00. Models include AutoSet, AirMini Travel CPAP, AirSense 10 Elite CPAP, and AirSense 10 Standard CPAP.



Marketplace Search results for CPAP Machines. Filters include location (Opsey, Florida - Within 20 miles), price (\$200 to Max), and delivery method. Listings include Cpap airsense 11 newest model (\$750), Cpap Machine respironics (\$299), and Air sense 10 machine (\$299).



Zyno Medical Z-800F Infusion Pump \$125. Listed 30 weeks ago in Tucson, AZ. Condition: Used - Good. Seller information: Tucson International Airport, Tucson, AZ. Price: \$125.



(World Wide-Selling) 390\$ Used Metran Medical Humming Ventilator. Condition: Used. Price: US \$390.00. Buy it Now.

Pervasive global deployment of medical devices for homecare has been unfolding for 3 decades!

- From 1990-2000, medical device-based home- and alternate-site care had become nearly half of MEDIQ's 300,000 device rentals that I was responsible for in the USA
- Continues to expand in USA year after year, due to hospital bed and cost pressures
 - By 2010, began to be supplemented with “consumer” products
- Pre-pandemic, our global colleagues already reported growth
- From 2020-present, COVID-19 precipitated large global deployment, including LMICs!

Here are some examples from around the globe, focusing on LMICs.

In 2011, Saudi Arabia reported early trials

[Ann Saudi Med.](#) 2011 Sep-Oct; 31(5): 457–461.

PMCID: PMC3183678

doi: [10.4103/0256-4947.84621](https://doi.org/10.4103/0256-4947.84621)

PMID: [21911981](https://pubmed.ncbi.nlm.nih.gov/21911981/)

Home intravenous antibiotics in a tertiary care hospital in Saudi Arabia

[Salim Baharoon](#),^a [Hind Almodaimeg](#),^b [Haifa Al Watban](#),^c [Hamdan Al Jahdali](#),^d [Thamer Alenazi](#),^e

[Abdullah Al Sayyari](#),^f [Abdulaziz Al Dawood](#),^a [Mohammed Al-Sultan](#),^g and [Eiman Al Safi](#)^h

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Abstract

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BACKGROUND AND OBJECTIVE:

Home intravenous (IV) antibiotic programs are becoming increasingly popular worldwide because of their efficacy and safety. However, in Saudi Arabia these programs have not yet become an integrated part of the health care system. We present our experience with a home IV antibiotic program, as one of the major health care providers in Saudi Arabia.

In 2019, Brazil reported on O2 home therapy

ORIGINAL ARTICLE • Fisioter. mov. 32 • 2019 • <https://doi.org/10.1590/1980-5918.032.AO04> [COPY](#)

Characteristics of long-term home oxygen therapy users in the municipality of Curitiba, Brazil

Características dos usuários de oxigenoterapia domiciliar prolongada do município de Curitiba

Características de los usuarios de oxigenoterapia domiciliar prolongada del municipio de Curitiba

[Demetria Kovelis](#) [Paôla Luma Cruz](#) [Lígia Inez Silva](#) [Juan Ricardo Sierra](#) [Paulo Roberto de Miranda Sandoval](#)

[Silvia Valderramas](#) [ABOUT THE AUTHORS](#)

By 2020, other Arab countries were adopting

[Saudi Med J.](#) 2020 Jul; 41(7): 683–689.

PMCID: PMC7502921

doi: [10.15537/smj.2020.7.25119](https://doi.org/10.15537/smj.2020.7.25119)

PMID: [32601634](https://pubmed.ncbi.nlm.nih.gov/32601634/)

Quality of home healthcare among Arab countries

[Malak Al Anazi](#), HSQM, [Khaled Al-Surimi](#), PhD, MSPH, and [Amani Abu-Shaheen](#), MPH

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Abstract

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Objective:

To examine the quality of home healthcare services provided and to systematically review publications concerning the quality of home healthcare in Arab countries.

Methods:

In 2017, we conducted an online literature search to identify relevant published studies using the following electronic databases: Embase, CINAHL, PubMed, and the Cochrane library. First,

In 2020, home O2 for children was reported from Kenya

Original Article

Outcomes of home-based oxygen therapy in children discharged from Kenyatta National Hospital, a retrospective cohort study

Adil Waris, Varsha Vekaria-Hirani, Monica Saulo

Abstract

Background: Home based oxygen therapy (HOT) is often required in children with chronic respiratory conditions. Whereas this has become a standard practice in resource rich regions of the world it remains a major challenge in sub-Saharan Africa. Benefits of HOT include shorter duration of hospital stay with both reduced nosocomial infections and

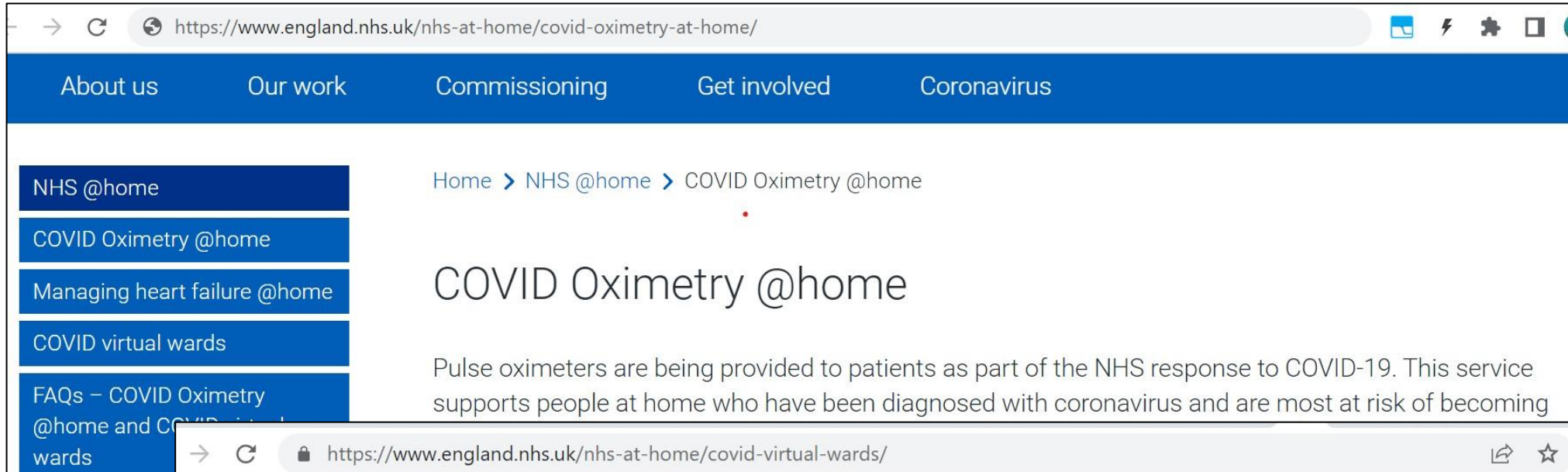
HOT due to inability to pay hospital bills, increased electricity costs at home and inability to pay for transport to clinic visits whilst dealing with fears of “oxygen addiction in their children”. The authors dealt with poor quality concentrators, unanticipated maintenance costs, increased oxygen cylinder use and difficulty in reaching slum dwellings. The lack of pulse oximeters at home led to either overuse or underuse of oxygen flow in almost all patients.

Source: African Journal of Respiratory Medicine: September 1, 2020

From 2020-2023, due to COVID-19 many home care interventions were reported globally, including oxygen concentrators, oximeters, IV therapy, O2 enriched CPAP, and many forms of “hospital in home” or “virtual patient wards” were reported.

Plus telehealth and telemedicine spread globally like wildfire!

2 great examples: UK NHS's COVID home care programs are interesting and useful **low-resource** home care innovations!



→ ↻ 🔒 <https://www.england.nhs.uk/nhs-at-home/covid-oximetry-at-home/>

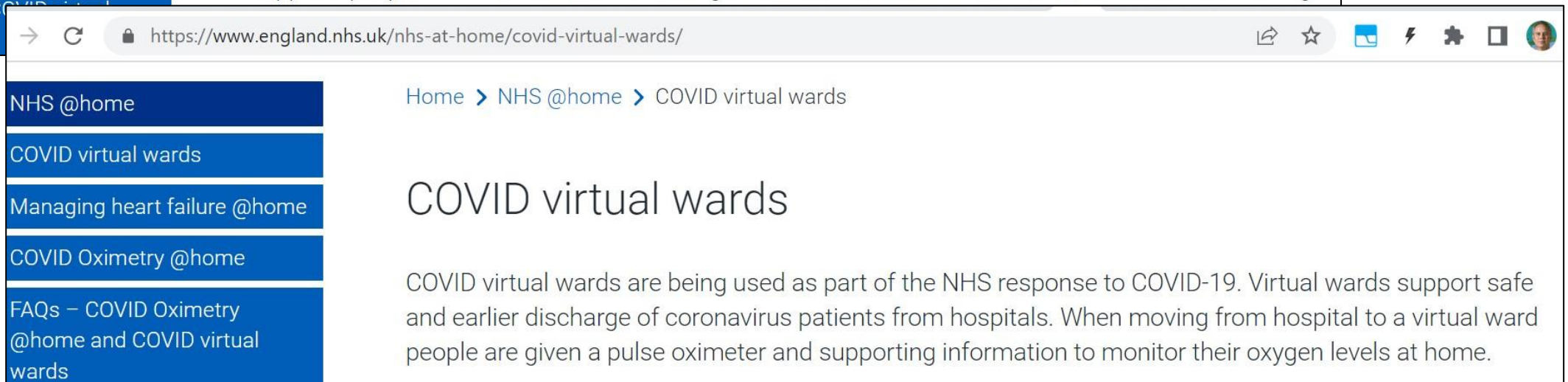
About us Our work Commissioning Get involved Coronavirus

NHS @home
COVID Oximetry @home
Managing heart failure @home
COVID virtual wards
FAQs – COVID Oximetry @home and COVID virtual wards

Home > NHS @home > COVID Oximetry @home

COVID Oximetry @home

Pulse oximeters are being provided to patients as part of the NHS response to COVID-19. This service supports people at home who have been diagnosed with coronavirus and are most at risk of becoming



→ ↻ 🔒 <https://www.england.nhs.uk/nhs-at-home/covid-virtual-wards/>

NHS @home
COVID virtual wards
Managing heart failure @home
COVID Oximetry @home
FAQs – COVID Oximetry @home and COVID virtual wards

Home > NHS @home > COVID virtual wards

COVID virtual wards

COVID virtual wards are being used as part of the NHS response to COVID-19. Virtual wards support safe and earlier discharge of coronavirus patients from hospitals. When moving from hospital to a virtual ward people are given a pulse oximeter and supporting information to monitor their oxygen levels at home.

Canadian Homecare Environment – growing & complex

- Download our CSA pub by CE authors Easty, Gentles, Sloane, Wong
Free PDF: <https://www.csagroup.org/article/research/evaluating-best-practices-and-gaps-in-equipment-and-medication-management-in-home-and-community-care-settings/>



STANDARDS RESEARCH

Evaluating Best Practices and Gaps in Equipment and Medication Management in Home and Community Care Settings

March 2022

Authors

Tony Easty, PhD., PEng., CCE, BT Medical Technology Consulting
Bill Gentles, PhD., PEng., CCE, BT Medical Technology Consulting
Elliot B. Sloane, PhD, CCE, BT Medical Technology Consulting
Eric (Wai Kit) Wong, M.Eng., EIT, BT Medical Technology Consulting

Project Advisory Panel

Andrea Carter, Saint Elizabeth Health Care
Cassandra Gardner, BD
Emily King, VHA Home HealthCare
Ian DaSilva, Ontario Personal Support Workers Association
John Llaguno, BD
Nadine Henningsen, Canadian Home Care Association
Cassandra Gullia, CSA Group (Project Lead)
Jennifer Teague, CSA Group
Nancy Bestic, CSA Group

In the CSA report, we identified common issues in the home and alternate care environment that put patient safety at risk, including:

- Inadequate wiring with overloaded circuits that may cause interruption of power to a critical device
- Ungrounded circuits that may present a shock hazard
- Lack of emergency sensors and alerts (e.g., smoke, carbon monoxide alarms);
- Lack of adequate heat, air conditioning, humidity, and ventilation;
- Lack of appropriate plumbing and safe water supply;
- Users with inadequate training or inability to remember what training they may have received

And yet MORE common issues in the home/alternate care environment that put patient safety at risk!

- Lack of appropriate, safe sanitation/waste disposal;
- Presence of trip hazards in living, cooking, sleeping, entry, exit, and common areas;
- Presence of pets or pests that may interfere with the operation of critical devices (e.g., pets and vermin may chew or bite the device);
- Exposure to the outside elements from lack of repairs to the roof or exterior of the building; and
- Presence of pollen, mold, chemicals, and other contaminants.

CE skills in the table of contents of our CSA report:

- 2.1 Federal, Provincial, Territorial Legislation, Standards, Guidelines and Processes
- 2.2 **Environmental Considerations** for Safe Home and Community Care
- 2.3 Managing **Human Factors** for Home Health Technologies
- 2.4 **Health Technology Assessment** for Safe Home and Community Care
- 2.5 **Health Technology Management** for Safe Home and Community Care
- 2.6 **Infection prevention and control** in home and community care environments
- 2.7 **Medication Management** for Safe Home and Community Care

My team's "Classical CE" approach to homecare I/PM management, circa 1990-2000

- Ref: Our 2001 Journal of CE article by Wang, Patel, & Sloane

PEER REVIEW PAPER

Quality Management for a Nationwide Fleet of Rental Biomedical Equipment

Binseng Wang, ScD, CCE*; Elliot B. Sloane, PhD**; Bhavesh Patel, MSEE***

*MEDIQ/PRN Life Support Services, Inc. One MEDIQ Plaza, Pennsauken, NJ 08110

**College of Commerce and Finance, Villanova University, Villanova, PA 19085

***Biomedical Engineering Department, Washington Hospital Center
110 Irving Street, NW, Washington, DC 20010

Abstract

A fleet of about 200,000 ventilators, IV pumps, monitors, and other moveable critical-care devices from various manufacturers is available for rent by American healthcare providers. This equipment is delivered around the clock by 106 branches covering all 50 states, usually within 2-4 hours of request. A PC in each branch and a central computer are used to track each device identified by a unique barcode tag. Simple repairs and PMs are performed in branches by qualified biomedical technicians; more extensive repairs are performed at three service centers strategically located. To ensure safety and performance, a comprehensive quality management program has evolved. Each unit is inspected before delivery, no matter how recently it was inspected for the previous rental. Recalls and patient incidents are centrally managed and documented, even if performed in the field. Equipment serviced at service centers and service reports filed by every biomedical technician are audited by an independent quality-assurance staff. In addition, service quality is also monitored when equipment is transferred between branches and rented to customers. A complaint system follows up on any reported problem. Some of the indicators used to identify opportunities for quality/reliability improvement are: a) number of problems found in audits, b) number of confirmed problems reported within 7 days of delivery, and c) number of confirmed problems per hundred units delivered. Branch compliance to the quality program is further reinforced by unannounced random on-site visits. This stringent quality program provides the users with confidence that the equipment is safe and can be used immediately on a patient.

1. Modeled after well accepted ECRI pattern of Inspections and Preventive Maintenance (i.e., based on an authoritative source, NOT mfr documentation.)
 1. I led ECRI's I/PM and CMMS initiatives 1975-2000
2. Adapted to large-fleet short- to mid-term rentals into homes, nursing homes, and hospitals
 1. Access to devices was "episodic," and often based on seasonal surges.
3. Pragmatic: e.g., 2-year mass battery replacement for devices.

Home Care can provide better value, access,
and equity for our patients!

If we don't address the appropriate selection,
deployment, and management of home
health technology innovations, who will?

CEs have a great role to play in Home Care!
*Let's not ignore this important opportunity
and challenge.*



Thank you!

*I hope to continue this important **Clinical Engineering** discussion very soon.*

Elliot B. Sloane
ebsloane@gmail.com

