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

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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.
Clinical Engineering Opportunities and Challenges in Home Health Care
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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!
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.
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.
In 2019, Brazil reported on O2 home therapy

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...
In 2020, home O2 for children was reported from Kenya

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!

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**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 critically ill.

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**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

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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

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.

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