Clinical Engineers Support Access
To Medical Devices and Health Interventions Globally

Adriana Velazquez, Senior advisor on medical devices, 21 October, 2019.
Clinical Engineer, member of health workforce

How can you help global health problems?
1. Ensure medical devices improve patient Safety

<table>
<thead>
<tr>
<th>Magnitude</th>
<th>Incidence</th>
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<tbody>
<tr>
<td>4 out of 10</td>
<td>134 million</td>
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</table>

Up to 4 out of 10 patients are harmed in primary and ambulatory care settings.

134 million adverse events occur each year in hospitals in LMICs, contributing to 2.6 million deaths annually due to unsafe care.

Speak up for patient safety!

No one should be harmed in health care.

Ensuring safe care is a major challenge in all countries, rich and poor.
2. Support those at the Front Lines
3. Define Appropriate devices for Outbreaks
Ensure BPM for Hypertension

- 1.1 billion adults have raised blood pressure
- Less than 1 in 5 have it under control
- 17.9 million people die every year from cardiovascular diseases
- That’s 31% of all global deaths
Support access to safe and affordable surgery for 5 BILLION PEOPLE that lack access

Lancet commission on Global Surgery
9 out of 10 cannot access basic surgical services!

In general: manage medical devices to support Goal 3: Good health and well being
What is THE role of a CLINICAL ENGINEER and which competencies we require?
1 Consider all Medical Devices

- Patients
- Self-used
- Doctor/Nurse/Technician

- Medical Equipment
- IVDs
- Implantable Medical Devices
- Medical Software
- Single Use Medical Devices
- Surgical Instruments
2. Ensure your role for improved access of safe, quality medical devices

- Industry and Academics: Research and development should be based on needs
- Health Technology Assessment
- Lists of MD for reimbursement or procurement
- Regulation process of medical devices
- Lists of approved MD for marketing in country.
- Needs Assessment, Selection, procurement, donations, loan...
- Installation, inventories, training, maintenance, operations
- Safe use, operating costs and clinical effectiveness
- Post market surveillance and adverse event report
- Decommissioning, Replacement
3. Work with other professionals!
Here, NGO in official relations with WHO
6. Be knowledgeable of regulations of medical devices and intervene! (WHA67.20)

Global current status of medical device regulations; existence of a national legal framework for medical devices
7: Identify common sections of dossiers for HTA, regulation and management that can be used along the life of a medical device
7. Know the clinical environment and needs

- Infrastructure
- Clinical protocols
- Support nursing and medical staff
- Provide costs and economic information
- Do team work
8. Present HTM messages to non HTM community to support decision making

Share expertise, data, impact of your work with:

- National regulatory agencies
- Hospital administrators
- Economists
- Clinical nurses and doctors
- Policy makers
9. Participate in the studies to determine recommendations of biomedical / number of equipment / type of hospital / beds? Searching evidence from HIC and LMIC

CE-HTM Indicators Project- Work to Update Pending

<table>
<thead>
<tr>
<th>Density of Biomedical engineers, (2017)</th>
<th>Need to be defined</th>
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<tbody>
<tr>
<td></td>
<td>Qualifications</td>
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<td></td>
<td>Activities</td>
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<td>Profile</td>
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<td>Functions</td>
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<td></td>
<td>Indicators</td>
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<td></td>
<td>Evidence</td>
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</tbody>
</table>

Collaborate with IFMBE Working Group

To make a WHO recommendation

http://apps.who.int/gho/data/view.main.BIOENGHWF8v
What is WHO doing 2019-2020 and how can you help?
13th WHO Global Programme of Work: “Triple Billion” targets

- Universal Health Coverage: One billion more people benefiting from
- Health Emergencies: One billion more people better protected from
- Health and Well-being: One billion more people enjoying better
List Medical devices that are required to achieve SDG3: universal health coverage, including financial risk protection, access to quality essential health-care services.
Guide & Technical specifications for different Devices

- Blood pressure measurement
- Radiotherapy equipment
- Oxygen delivery systems
- Devices for screening and treatment of precancerous lesions

WHO Technical specifications of Neonatal Resuscitation Devices

TECHNICAL SPECIFICATIONS FOR OXYGEN CONCENTRATORS

World Health Organization

2019
2. Priority Medical Devices (PMD)
And
2. Essential in vitro diagnostics (EDL)
To be used for procurement and reimbursement of public insurance
### Assessment elements for inclusion in the 2nd EDL

<table>
<thead>
<tr>
<th>Basic test characteristics</th>
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<tbody>
<tr>
<td>Test purpose</td>
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<tr>
<td>Test format</td>
</tr>
<tr>
<td>Specimen types</td>
</tr>
<tr>
<td>Equipment required</td>
</tr>
<tr>
<td>Regulatory status</td>
</tr>
<tr>
<td>Global availability</td>
</tr>
<tr>
<td>Price per test range</td>
</tr>
<tr>
<td>Instrument price range</td>
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</tbody>
</table>

### Ethics, equity and human rights issues

### Evidence for clinical usefulness and impact

### Evidence for economic impact and/or cost-effectiveness

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The selection and use of essential in vitro diagnostics

Report of the second meeting of the WHO Strategic Advisory Group of experts on In Vitro Diagnostics, 2019 (including the second WHO model list of essential in vitro diagnostics)
NEW- Clinical Engineering Resource
Decommissioning of Medical Devices Guide

- Decommissioning
- Disinvestment
- Risk Auditing
- Single Use & Reusable Medical Devices

2019
Defining medical devices by levels of care
80% done but need experts to complete!

WHO list of priority medical devices for diabetes, stroke in progress - 2019/2020

- Height and weight
- Blood glucose
- Blood pressure
- Total cholesterol
- Urine strips for albumin assay

AFR: WHO African Region; AMR: WHO Region of the Americas; EME: WHO Eastern Mediterranean Region; EUR: WHO European Region; SEAR: WHO South-East Asia Region; WPR: WHO Western Pacific Region.

* Blood glucose measurement or oral glucose tolerance test
WHO working on an international nomenclature of medical devices including IVDs for use by regulators, procurers, supply and use.

Developing and adapting a global standard for naming medical devices is a perfect example of WHO's core normative standard-setting work

Tedros Adhanom Ghebreyesus
WHO process as requested by EB members:
Technical steps

**Q3**
- Develop analysis as requested by MS
- **CND Italian nomenclature being revised by EU**

**Q4**
- Country web based consultation November-December
- Eu to EMDN
- Missions briefing in WHO

**Q1**
- Analyze results of consultation
- Provide results in report to EB 2020
- **WHO RELEASE OF International Medical device Nomenclature (IMDN)**
Analog or mechanic medical devices

Digital Medical devices in hospitals and patients

Digital health systems with no clinical or patient interface

Participate in Digital Health initiatives

- Wearables
- all that use ICT
- Systems under digital health
- Clinical decision support systems
- Software as medical device
- Personalized medicine
- CADx
- AI
- Surgical instruments
- Most single use devices
- Implantable prosthesis
- Surveillance
- Education
- Public health

2019
Plans for 2020

Safe use of medical devices

MeDevIS: WHO clearinghouse of medical devices information

5th Global Forum medical devices

3rd EDL and PMD respiratory
contact

Info: www.who.int/medical_devices

Requests of information or
Expert support to WHO

Please send email to
medicaldevices@who.int
Remember a patient is at the end of all our activities, they deserve our:

- Technical knowledge
- Passion
- Transparency
- Hard work
- Collaboration
Gracias
Thank you

Merci
Shokran
Xie xie
Spasiva

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