Medical Devices Post-market surveillance experiences

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Disclosure

• The presenter declares no conflict of interest with the materials provided.
1. CURRENT STATE AND RESEARCH STUDY
2. LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES – DEVELOPMENT
3. LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES – SOLUTION
PART 1

CURRENT STATE & RESEARCH STUDY
Today, a person who comes to the hospital for a routine checkup goes under a series of tests, and the results of the tests (measurements) are used in making a diagnosis. The doctor, the patient, family members and other medical staff rely on test results - the numbers, graphs or images gathered using all sorts of medical devices, from simple electrocardiograph (ECG) devices to highly sophisticated computer topography (CT) scanner or Magnetic Resonance Imaging (MRI).

FACTS

RELIABLE MEASUREMENTS? SAFETY?

Which medical device directive defines medical device safety and performance requirements?

What about medical device measurement? Are they the same everywhere?

Which international standards apply for medical devices and who is responsible for implementing international standards in the country?

IMPORTANCE OF MEASUREMENT

DOES IT MATTER HOW IT IS MEASURED?

WHY IS RELIABLE MEASUREMENT IMPORTANT?

Weights and Measures measurements affect more than $6.6 trillion of the $13.2 trillion U.S. GDP.

BECAUSE EVERYBODY IS AFFECTED BY MEASUREMENT!

YES!
EXAMPLE

1 kg DEFINITION - The kilogram, symbol kg, is the SI unit of mass. It is defined by taking the fixed numerical value of the Planck constant $h$ to be $6.626070\times10^{-34}$ when expressed in the unit J s, which is equal to kg m$^2$ s$^{-1}$, where the meter and the second are defined in terms of c and $ΔνCs$. 

global map with indicators North America, USA, Asia, Australia showing kg equivalence.
HEALTHCARE SYSTEM IN BOSNIA AND HERZEGOVINA

- Public healthcare institutions
- Private healthcare institutions

The healthcare system is highly decentralized, with 10 cantons (regional)-level organization and financing of health care.

Private sector consists mainly of dentist offices, ambulant and clinics and policlinics providing specialist and primary level services.

BOSNIA AND HERZEGOVINA CASE STUDY

3 University Hospitals (CoE)
45 Hospitals
363 Primary Care Units
Research study in 2014: *All public and private healthcare institutions were involved in research study*

1. Health Care Institutions in Bosnia and Herzegovina:
   - Huge number of medical devices older than 20 years;
   - Insufficient number of educated stuff for medical devices;
   - Deficit of biomedical engineers (not provided by systematization of workplaces);
   - Poorly equipped technical departments;
   - Large financial debts.
2. Suppliers of medical devices and supplies:

- Large prices of medical devices (comparing with EU countries);
- Large prices of supplies and reagents for medical devices;
- The big difference in prices for supplies between public and private hospitals;
- Monopoly in the market for medical devices (devices, supplies, service, verifications, calibrations, attestation, preventive maintenance, certification,...);
- „Locked“ tender specifications.
Basic elements of medical device regulations
(Premarket and post-market regulations)

- 34% of 145 countries have a health technology national policy that is part of the national health programme
- 9% of 145 countries have an independent health technology national policy
- 65% of 145 countries have an authority responsible for implementing and enforcing medical device specific product regulations

World Health Organisation: Regulatory Status desk survey - Data of 2016 update
**FDA MAUDE (Manufacturer and User Facility Device)**

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

### Data on deaths and injuries caused by faulty medical device (10-year available data)

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Deaths</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion and perfusion pumps</td>
<td>&gt;800</td>
<td>&gt;1300</td>
</tr>
<tr>
<td>Defibrillators</td>
<td>&gt;700</td>
<td>&gt;1000</td>
</tr>
<tr>
<td>Paediatric incubators</td>
<td>&gt;300</td>
<td>&gt;500</td>
</tr>
<tr>
<td>Therapeutical ultrasound</td>
<td>&gt;200</td>
<td>&gt;400</td>
</tr>
</tbody>
</table>

*Data on deaths and injuries caused by faulty medical device (10-year available data)*
PART 2

MEDICAL DEVICES: LEGAL METROLOGY FRAMEWORK

DEVELOPMENT
“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.”

SOURCE: European Commission
Application in healthcare institutions

Various Medical Devices used in everyday practice in healthcare institutions for:

- **Diagnosis**
- **Treatment**
- **Rehabilitation (therapeutic)**

**Blood pressure devices**

**Defibrillators**

**Anaesthesia machine**

**Mechanical ventilators**

**Infusion pumps and perfusors**

**ECG devices**

**Patient monitors**

**Therapeutic ultrasounds**

**Rehabilitation**
THE MEDICAL DEVICE DIRECTIVES

- Procedures for production, marketing and post-market surveillance of medical devices

- Member countries of EU must comply with following Medical Devices Directives (MDD)
  - **MDD - 93/42/EEC**: from bandages, tongue depressors, thermometers to contact lenses, stethoscopes, splints, first-aid kits, breathalysers, heart valves and imaging equipment
  - **In-Vitro Diagnostic MDD – IVDD 98/79/EC**: reagents, control standards, test-kits, equipment ... intended for the in-vitro examination of human specimens e.g. blood grouping reagents, pregnancy test kits, Hepatitis B test kits
  - **Active Implantable MDD – AIMDD 90/385/EEC**: active (i.e. include an energy source) implants or partial implants e.g. heart pacemakers

**DIRECTIVES OF NEW APPROACH**

Most EU countries have transposed these directives into a single national legislation
(e.g. UK Medical Devices Regulations 2002)

SOURCE: European Commission
### EU - TRANSITION PERIOD

<table>
<thead>
<tr>
<th>Regulation (EU) 2017/745</th>
<th>Medical Device Regulation (MDR)</th>
<th>Replacing</th>
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<tr>
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<th>In vitro diagnostic medical device Regulation (IVDMDR)</th>
<th>Replacing</th>
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<td>• Directive 98/79/EC</td>
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**Will apply May 2020!**

This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a [high level of protection of health for patients and users](https://www.gov.uk), and taking into account the small- and medium-sized enterprises that are active in this sector.

At the same time, this Regulation sets [high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products](https://www.gov.uk).
LEGISLATION IN THE EU – TRANSITION PERIOD

3-year transition period: Certification possible in line with old or new legislation (MDR)

- Comes into effect on May 5, 2017
- Published in the Official Journal

- Legal acts relating to application of Notified Bodies

No scope extension and substantial changes of MDD/AIMDD certificates

- Application Date of MDR on May 25, 2017
- Nomination of Notified Bodies strongly depending on activities of national authorities and EU Commission

- MDD/AIMDD certificates as per Annex IV/4 become void on May 27, 2024

SOURCE: European Commission
As defined by the **International Bureau of Weights and Measures** (BIPM), is “the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology”.

It establishes a common understanding of units, crucial to human activity (trading manufactured goods, the ability to accurately diagnose illnesses, ...)

The consumer **confidence** during the purchase of goods and services all depend on confidence in the measurements made during these processes.

This confidence is achieved by metrology’s three basic activities:  
- the definition of internationally accepted units of measurement,  
- the realisation of these units of measurement in practice,  
- the application of chains of traceability (linking measurements to reference standards).
There are three main fields in metrology:

- **scientific** (fundamental) metrology
- applied, technical or **industrial** metrology
- **legal** metrology

The mission of the OIML is to enable economies to put in place effective legal metrology infrastructures that are mutually compatible and internationally recognized, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonize the level of consumer protection worldwide.” - [OIML B 15:2011](https://www.oiml.int/)
**Uncertainty** - is a value associated with a measurement which expresses the spread of possible values associated with measurand — a quantitative expression of the doubt existing in the measurement.

**Traceability** – property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

**Calibration** - Set of operations that establish the relationship between values of quantities indicated by a measuring instrument and a reference standard

**Source:** BIPM – Wuraiwiwae metrology
They are essential components of nation's technology infrastructure — vital to industry and commerce, crucial to the health and safety, and basic to the nation's economic performance.

**International Organisation for Standardization (ISO)**

ISO is an independent, non-governmental international organization with a membership of 162 national standards bodies.

**International Electrotechnical Commission (IEC)**

IEC is the world’s leading organization for the preparation and publication of International Standards for all electrical, electronic and related technologies.

**The Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA)**

IEEE-SA is an organization within IEEE that develops global standards in a broad range of industries, including: power, energy, biomedical and healthcare, information technologies and robotics, telecommunication and home automation, nanotechnology and many others.

**Source:** ISO - Standards
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<td>Vertical Standards</td>
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<td>ISO 10993 – 1 Biological evaluation of medical devices</td>
<td>Apply to specific products or product groups</td>
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<td>IEC 62366-1 Medical devices – Application of usability engineering to medical devices</td>
<td>IEC 62304 Medical device software – Software life cycle processes</td>
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- **Vertical Standards**
- **Apply to specific products or product groups**
OIML TECHNICAL COMMITTEEs

- TC 1 Terminology
- TC 2 Units of measurement
- TC 3 Metrological control (5 SCs)
- TC 4 Measurement standards and calibration and verification devices
- TC 5 General requirements for measuring instruments (2 SCs)
- TC 6 Prepackaged products
- TC 7 Measuring instruments for length and associated quantities (4 SCs)
- TC 8 Measurement of quantities of fluids (5 SCs)
- TC 9 Instruments for measuring mass and density (4 SCs)
- TC 10 Instruments for measuring pressure, force and associated quantities (5 SCs)
- TC 11 Instruments for measuring temperature and associated quantities (3 SCs)
- TC 12 Instruments for measuring electrical quantities
- TC 13 Measuring instruments for acoustics and vibration
- TC 14 Measuring instruments used for optics
- TC 15 Measuring instruments for ionizing raditions (2 SCs)
- TC 16 Instruments for measuring pollutants (4 SCs)
- TC 17 Instruments for physico-chemical measurements (8 SCs)
- TC 18 Medical measuring instruments (3 SCs)

Source: OIML (International Organization of Legal Metrology)
LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES

✓ Safety
✓ Performance
✓ Accuracy
✓ Reliability
✓ Inspection
✓ Etalon
✓ Calibration
✓ Traceability
✓ National Body

✓ ISO 9001
✓ ISO 17020
✓ ISO 17025
✓ IEC 60601

SOLUTION MEDICAL DEVICES METROLOGY STANDARDIZATION

MEDICAL MEASUREMENT RELIABILITY IS ENSURED BY TRACEABILITY CHAIN

- National Institute of Metrology
  Represents the SI units and ensure international comparability
- Calibration Laboratory
- Calibration by National Institute of Metrology
- Testing laboratory
  Calibration by accredited laboratory
- Measuring equipment
  Measurements and tests as part of quality assurance process

ISO 17020
ISO 17025
ISO 9001

SOLUTION
CMBEBIH 2019
International Conference on Medical and Biological Engineering

Share the Vision!

Bosnia and Herzegovina

FINAL CALL FOR PAPERS
Extended deadline paper submission: 15. December 2018.

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