WHO Medical Devices Newsletter, April 2019.



1. 7th April 2019 was World Health Day.

Universal health coverage is WHO's number one goal, and this was WHO's focus for this year's <u>World Health</u> <u>Day</u>.

2. Nomenclature of medical devices at 145th Executive Board meeting

Standardization of medical devices nomenclature will be discussed at the 145th Executive Board meeting, held the 29 May, in Geneva. See the <u>annotated provisional agenda</u> for more details. For a better understanding of the need for a standardized nomenclature system, <u>see presentations</u> and r<u>equest for collaboration</u>.

WHO publications:

3. The WHO global regulatory framework model for medical devices including in vitro diagnostic medical devices in French

The Model recommends guiding principles, harmonized definitions and specifies the attributes of effective and efficient regulation, to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF).

The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. More information regulations website: French, English

4. First WHO Model List of Essential In Vitro Diagnostics is now a book and can be found here.

As was announced last year, the 1st WHO Essential in vitro Diagnostics List was launched May 2018. It includes:

35 general laboratory tests that can be used for routine patient care as well as for the detection and diagnosis of a wide array of disease conditions – communicable and NCDs. These IVDs are grouped by test discipline (e.g. clinical chemistry, serology, haematology, microbiology and mycology) and specific test type (e.g. bilirubin, complete blood count, etc.).

27 test categories of IVDs designed for the detection, diagnosis and monitoring of each of the following WHO key disease areas: HIV, TB, malaria, HBV/HCV, and HPV and syphilis. These IVDs are grouped by disease area and analyte tested.

To support the implementation of EDL, WHO has recently developed a new clinical laboratory and in vitro diagnostics <u>website</u> that hosts all WHO information.

The Second WHO Model List would be published by June 2019. Questions or comments <u>edlsecretariat@who.int</u>. More information on <u>EDL website</u>

5. WHO Guideline: Recommendations on Digital interventions for health systems strengthening.

The use of digital technologies to improve health has grown over the years, and will only continue to expand. Despite the heightened interest, digital health has been characterized by implementations being widely rolled out in the absence of careful examination of the evidence base on benefits and harms. On 17 April, the World Health Organization (WHO) will release a guideline featuring recommendations on different digital health interventions, primarily accessible via mobile devices. The livestream of the event will be available here: <u>http://bit.ly/DHGuidelineLaunch</u>. Guideline Launch and Briefing. 17 April 2019 | WHO Headquarters Salle B, 14h00-15h30 Geneva time

6. Decontamination and Reprocessing of Medical Devices for Health-care Facilities, 2016

Released in 2016, this <u>manual</u> is a very important instrument to provide guidance to health managers and health workers on required infrastructures and standard procedures for effective sterilization, and decontamination reprocessing of medical devices.

7. Safe management of wastes from health-care activities, 2nd edition, 2014

Published in 2014, this <u>handbook</u> - the result of extensive international consultation and collaboration – provides comprehensive guidance on safe, efficient, and environmentally sound methods for the handling and disposal of health-care wastes in normal situations and emergencies.

Consultations due before 30 April:

8. From WHO: <u>Public Consultation on the Draft Global Strategy on Digital</u> <u>Health</u>

The Strategy aims to identify areas where WHO, its partners and stakeholders should most usefully focus their efforts.

The draft document has identified four strategic objectives and a proposed framework for action. The strategic objectives aim to: 1) work together as a set, 2) help to accelerate the digital health agenda in countries, 3) address global issues and 4) set the future direction for innovation and research. The field of digital health involves a wide range of stakeholders from policy-makers to technology developers, healthy individuals and patients. The target audience for this consultation is all stakeholders in the digital health arena, who are welcome to submit their comments.

The web-based comment period will close on 30 April 2019, 00:00 CEST. Please contact <u>digitalhealth@who.int</u> for queries or further information. You can access and review the questions <u>here</u>.

From HTAi - an NGO in official relations with WHO- INAHTA - working with WHO and other organizations- Updating the definition of Health Technology Assessment

See <u>here</u> for further information and instructions on how to provide comments to this Call for Consultation. **The deadline for comments is 30 April 2019.**

10. Careers at WHO

- a. <u>WHO Internship programme</u>
- b. New positions under recruitment by WHO
- c. The Essential in vitro diagnostic list requires consultants to support: compilation of technical specifications for IVDs, support on HTA for IVDs, and other related activities. Interested candidates, with more than 10 years expertise on in vitro diagnostics from academia, hospitals or consultants please send cv to edlsecretariat@who.int. (candidates from industry cannot be considered).

11. Calendar of events

At WHO

World Health Organization 72nd World Health Assembly, 20 – 28 May, Geneva, Switzerland

WHO Executive Board 145, 29-30 May, Geneva Switzerland

Other organizations

- Africa Health, 28-30 May, Johannesburg, South Africa
- AAMI 2019, 7-10 June, Cleveland, USA
- <u>HTAi, Annual Congress</u>,15-19 June, Cologne, Germany
- <u>CLAIB</u>, 2-5 October, Cancun, Mexico
- <u>3rd ICEHTMC</u>, 21-22 October, Rome, Italy
- World Hospital Conference (IHF), 7-9 November 2019, Oman