



# ***Facets of Clinical Leadership***

## **AEMH Agenda 2019-2022**

by

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# OVERVIEW

- 1) Tackling new and emerging risks**
- 2) Elaboration of Guidelines for Good Prescription Practice of Novel Antibiotics**
- 3) Elderly Patients**
- 4) Liability issues of Senior Hospital Physicians**
- 5) European eHealth Record for transfrontier usage**
- 6) More Approaches to Continuing Education**



# Tackling new and emerging risks

**A.** To combat various new and emerging health threats, such as communicable health threats, strengthening ties with institutions on EU- and international level such as

- ***European Centre for Disease Prevention and Control***

<https://ecdc.europa.eu>

- ***WHO Regional Office for Europe***

<http://www.euro.who.int>

is pivotal in order to build up a *Rapid Information Service (RIS)* to give helpful forewarnings that could give rise to immediate preventive action(s) in hospitals.



## Tackling new and emerging risks (2)

**B.** Safety of Implantable Medical Devices (e. g. artificial joints, fibrillators, etc) must be obligatorily warranted by the manufacturer prior to the market entry by means of

- **more comprehensive mandatory *third party* validation/certification processes** to exclude conceivable future defects such as deformations, ruptures, abrasions, malfunctions/failure of function (incl. firmware and all firmware updates), etc. over more than 20 years;
- a **binding guarantee** for electronic devices that over a period of more than 20 years firmware updates will be available on e. g. an annual or semi-annual basis plus - when needed - additional “emergency updates”.

**C.** Safety of Internet-/user network-linked hospital equipment (Internet of things, IoT) such as x-ray equipment, sterilisers, data storage devices, etc. must be warranted by the manufacturer prior to the market entry via

- **more comprehensive *third party* validation/certification processes** to make the equipment “watertight” against invasions by criminal hackers;
- a **binding guarantee** for making available software-/firmware updates over a period of more than 15 years on e. g. an annual or semi-annual basis plus - when needed - additional “emergency updates”.

This is needed to exclude both, malfunctions of the equipment and/or theft of personal data by criminal hacking. The latter scenario would be considered a breach of the *EU General DataProtection Regulation*.



# Elaboration of Guidelines for Good Prescription Practice of Novel Antibiotics

Forthcoming antibiotic agents deserve meticulously defined application areas and comprehensive and precise application guidelines in order to avoid the development new resistance types covering at least per substance

- indication(s) and area of application (with comprehensive diagnostic details),
- mode of administration (oral - intravenous),
- age- and gender-dependent dosage level(s) (min - max, scheduled time-course),
- (approved) combination(s) with one or more antibiotic agents,
- approved adjuvant(s),
- administration period,
- concomitant supervisory diagnostics,
- cross reactions and side effects.



# Elderly Patients

In Europe the aging society is a major challenge for hospitals, too. For the hospital physician this involves inter alia

- the elaboration of customised communication techniques,
- the elaboration of customised diagnostic techniques.
- the elaboration of customised therapeutic techniques.

# **AEMH** **Liability issues of Senior Hospital Physicians**

Since liability litigation is on the rise all over Europe, liability issues on the job as well as post-tenure liability deserve comprehensive observation in order to work out regimes to defend against cases regarding e. g.

- theft/abuse of personal medical data,
- malfunctioning of medical devices e. g.
  - ◆ due to device defect(s) or
  - ◆ because of hacks due to defective/obsolete firmware;
- alleged malpractice.



# European eHealth Record with the aim of transfrontier usage

*COMMISSION RECOMMENDATION (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format [OJ L 039, pp.18-27 (11-02-2019)] is to be implemented in order to facilitate the transfrontier usage of the patients' eHealth Record within EU, EEA and CH.*

Key factors to achieve eHealth Record interoperability are:

- a) *health information domains and specifications for cross-border exchange as laid down in chapter 2. of the Annex to the EU Recommendation;*
- b) data safety (in order to avoid e.g. inadvertent data erasure or distortion of data);
- c) data security in order to
  - comply with all present and future legal EU Personal Data Protection requirements,
  - hermetically exclude all types of hacking attempts;



# European eHealth Record with the aim of transfrontier usage (2)

- d) consequent use of ICD;
- e) an integrated multilingual translation tool to read hospital discharge records in all official languages of the EU;
- f) establishment of a coordinating body for sections a)-e) comprising national experts of the participating countries;
- g) financial contributions from health insurance companies, national health programmes and EU programmes (e. g. related to “*Digital Economy*”);
- h) a pre-defined procedure for **coordinated updates** of aforementioned sections a) - e) among participating countries;



# More Approaches to Continuing Education

## A. Customised Continuing Education via

- traditional seminars,
- centralised Webinars to be broadcast on-line at a certain date,
- decentralised Webinar modules to be used off-line at a point in time the physician can freely fix in accordance with his professional obligations;

## B. Areas to be addressed:

- how to use the *European eHealth Record*, especially after updates,
- hospital hygiene,
- communication techniques to be applied vis-à-vis elderly patients,
- novel operation techniques,
- VR & AR support for preparation of and execution of operations in the hospital,
- other types of digital technologies such as
  - data evaluations via novel artificial intelligence software,
  - application and maintenance aspects of existing and novel medical devices,
  - updates / replacement of firmware in medical devices.