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Data protection, ownership and portability: are current rules and regulations fit for purpose? A code of conduct for mHealth apps.

13. October 2016 | European Parliament, Brussels
„Towards an mHealth framework for Europe"
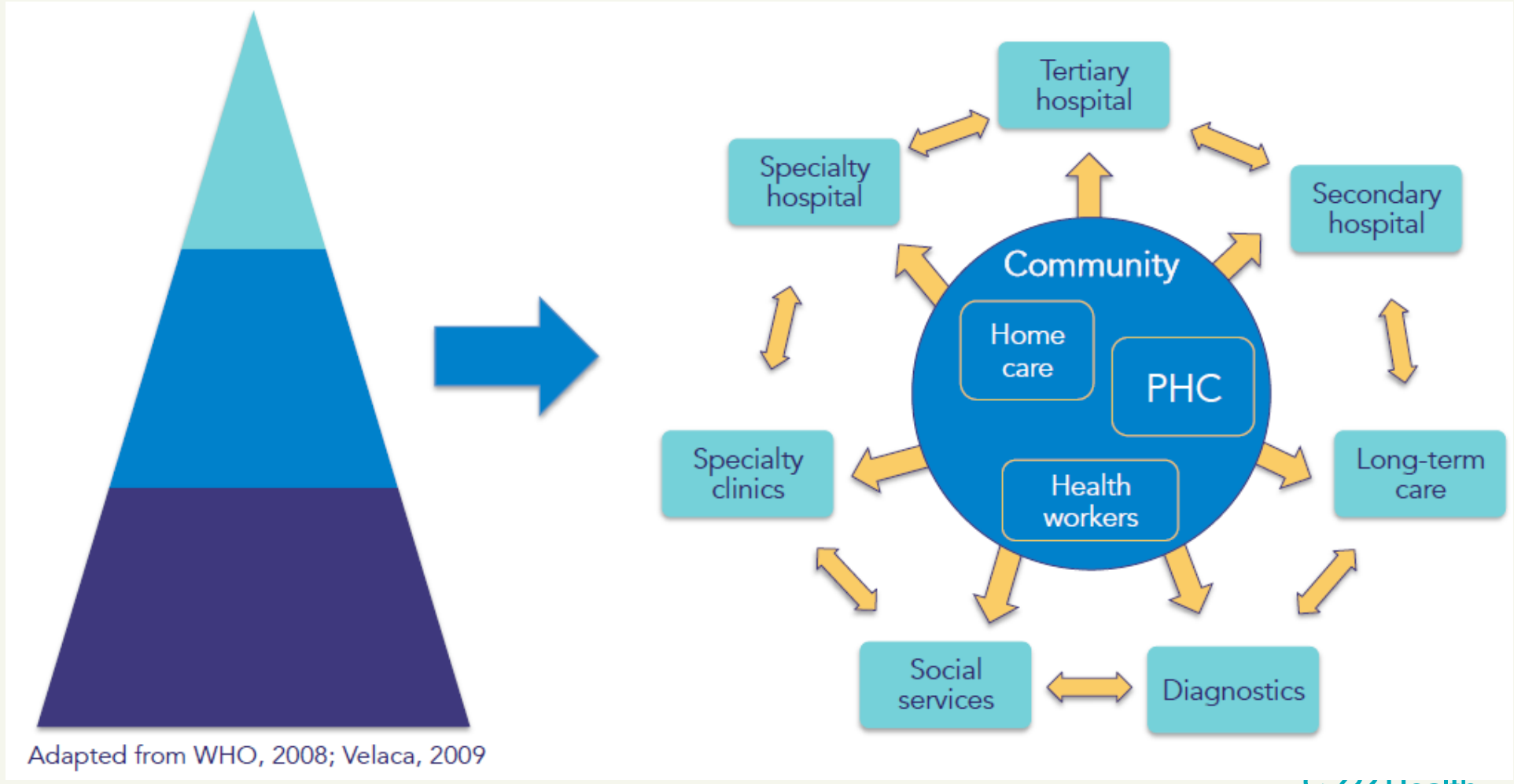
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Chair of mHealth subgroup of the eHealth Network, European Commission

Estonian Health 2025

Topics

1. Orientation

2. The history

3. Status report

4. Conclusions

Orientation

Changing care: integration vs hierarchy

Adapted from WHO, 2008; Velaca, 2009

Changing care: individual vs group efficiency

To find the most efficient solution for as many as possible

| Generalized average risk factors	Organ- and disease specific	Disease-specific diagnostics & treatment
Person-specific prediction & prevention	Risk-group based & molecular	Person-specific diagnostics & treatment

To help every individual as precisely and effectively as possible

Changing world – innovation is here and spreading

>2 Billion investments into digital health in 2016 (6 months)
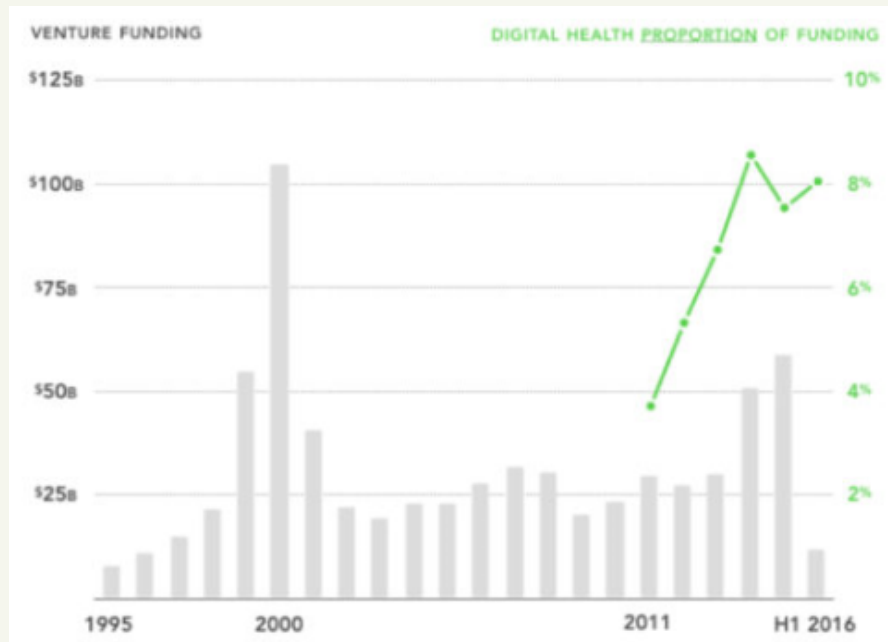
>66 EU project in eHealth

mHealth framework for Europe (Aaviksoo)

The history

How to achieve affordable, less intrusive and more personalised care?

1. My data, my decisions

2. Liberate the data

3. Connect up everything

4. Revolutionise health

5. Include everyone

eHealth Task Force Report

Redesigning health in Europe for 2020
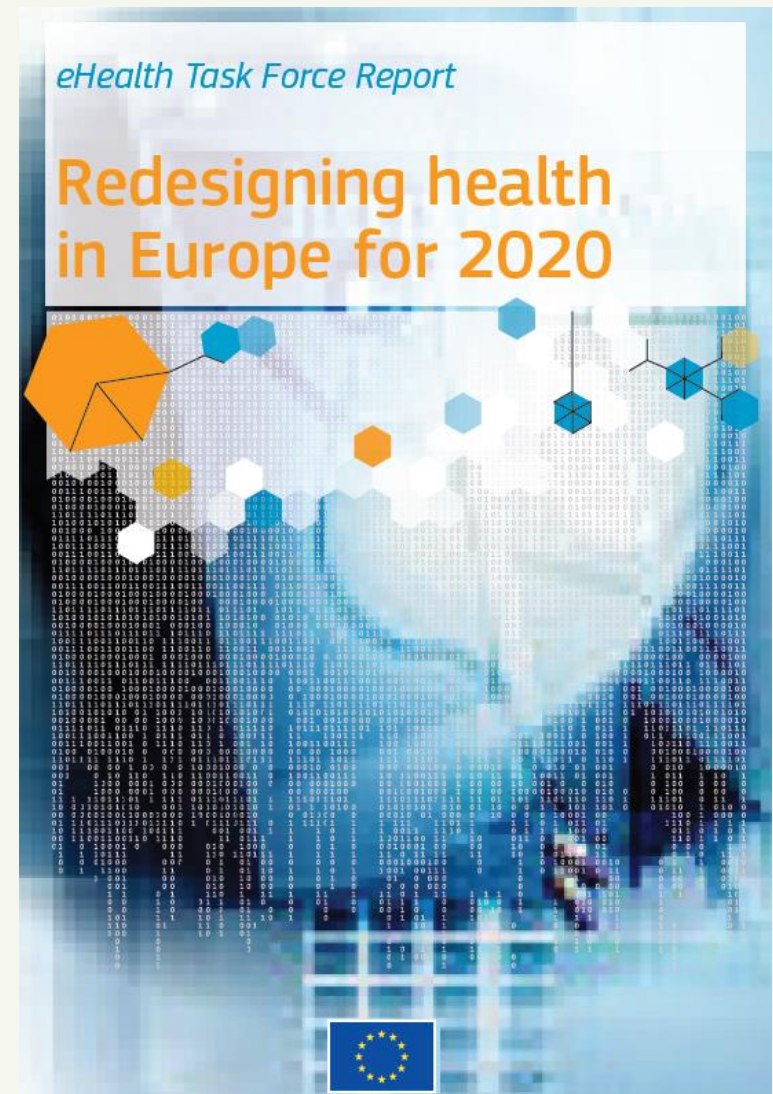
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Status report

Existing law at the EU level

- EU **SAFETY AND PERFORMANCE** REQUIREMENTS
  - *Medical Devices Directive & In vitro Diagnostic Medical Devices Directive*
  - *? General Products Safety Directive*
  - *? Directive on liability for defective products*

- APP USER'S RIGHTS TO **PRIVACY AND DATA PROTECTION**
  - *Data protection directive / General Data Protection Regulation**
  - *ePrivacy Directive*

- *OTHER APP USERS' RIGTHS*
  - *Consumers' Rights Directive*
  - *eCommerce Rights Directive*
  - *Unfair Commercial Practices Directive*

Source: Commission staff working document „on the existing EU legal framework applicable to lifestyle and wellbeing apps" (Accompanying the document GREEN PAPER on mobile Health ("mHealth"))

Situation and actions in the Member States

- ***Goals and ambitions related to mHealth***
  - *Patient-orientation of health systems*
  - *Increased mobility of services and citizens/patients*
  - *Improvement of quality and cost savings*
  - *Market development of healthcare industry*

- ***Legal situation and governance relating to mHealth***
  - *Application of general law related to digital health data (if any)*
  - *Authentication and authorisation of data use are critical*
  - *Certification/Endorsement of mHealth solutios as main public responsbility*
  - *Training and Education of Health Professionals and/or General Public*

Ongoing activities at the EU level

- Code of Conduct on **privacy** for mobile health applications

- Public consultation on the **safety of apps** and other non-embedded software

- Guidelines on the assessment of **data validity and reliability** of mHealth apps

- EU **quality standards** for mHealth apps

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Conclusions

Conclusions

- **Citizens** drive the society

- **Digital divide** is to be avoided

- **Authentication and authorisation** is critical in digital society

- Innovation comes from **action**

- **Legal framework** functions in combination with appropriate **technology** and **governance**

Everything should be made as **simple** as possible,
but not simpler.

- Albert Einstein -

Intelligence means goal-oriented adaptive behaviour

- Sternberg & Salter-

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