Reforming Europe’s healthcare systems: the European Commission perspective

Tapani Piha
Head of Unit
eHealth and Health Technology Assessment
Health Systems and Products
"The physician's role is changing significantly, and the ways how patients use the know-how of the doctor will diversify."

Dr Heikki Pälve, CEO, Finnish Medical Association
Finnish Medical Journal  27 March 2015, p. 849
Consequences for Patients & Doctors

- Responsibility moves more to the patient
- Role of the doctor changes substantially: guiding treatment and coaching
Article 168 on Public Health - Subsidiarity

- Union action shall respect the responsibilities of the Member States for
  - the definition of their health policy and
  - the organisation and delivery of health services and medical care.

- The responsibilities include
  - the management of health services and medical care and
  - the allocation of the resources assigned to them.
Regulation on eIdentification

- Creates an EU legal framework for mutual recognition and acceptance of eID and eSignature

- The Regulation supports a cross-sectorial use of the notified eIdentification systems

23 July 2014
Published in OJ L 257/73
European health systems, basic facts and figures

Healthcare expenditure on GDP, in the EU: 10.2% of GDP (2009)

Composition of Public expenditure in the EU (2010)

Sector with high potential of innovation and competitiveness:
- Highly specialised labour force
- Innovation-driven sub-sectors: pharmaceuticals, medical devices, ...
"Investing in Health"

Key messages

• Health is part of the Europe 2020 policy framework (the Annual Growth Survey 2013 recognises the contribution of health to prepare a job-rich recovery).

• Health is a value in itself and also a growth-friendly type of expenditure: a healthy population and sustainable health systems are decisive for economic growth.
• Strengthen effectiveness
• Increase accessibility
• Improve resilience
EU agenda for effective, accessible and resilient health systems

- Strengthening effectiveness
  - Health systems performance assessment
  - Patient safety and quality of care
  - Integration of care

- Increasing accessibility
  - Planning of EU health workforce
  - Cost-effective use of medicines
  - Optimal implementation of Directive 2011/24

- Improving resilience
  - HTA
  - Health information system
  - eHealth
Patients’ rights in Cross-border Healthcare

Directive 2011/24/EU

A major step towards a Europe for Health
Patients’ rights in Cross-border Healthcare

Three aims

1. Help patients to exercise their rights to reimbursement for health treatment in any EU country
2. Provide assurance about safety and quality of cross-border care
3. Establish formal cooperation between health systems
Directive on patients' rights in cross-border care

- **eHealth Network - Article 14**
  - *Leads the cooperation of Member States*
  - *Gives direction to eHealth developments*
  - *Adopts guidelines*
    - patient summary data
    - E-Prescriptions
Digital Economy

- **72%** of EU individuals use the internet regularly
- **150 Million** subscriptions fixed broadband
- **130 mobile subscriptions** per 100 people

**Digital Business**

- **HALF** of EU enterprises provide mobile devices for business use
- **276.5 Million EUR** turnover of EU B2C eCommerce (2012)
- **14%** of EU SMEs selling online
- **28%** EU enterprises use Social media
- **29%** of EU enterprises use e-Invoices

**ICT drives 1/3** of EU GDP growth 1995-2007

- **17% of business R&D** by ICT sector
- **6% of Gov't R&D**
- **7% of GDP** size of the digital economy
- **38% EU venture capital**
- **17% EU patents**

- **7%** of workforce
- **900,000** estimated demand/supply gap by 2020
- **4.1%** yearly employment growth
- **55%** work outside ICT sector

- **1.5 Million subscriptions** fixed broadband
- **130 mobile subscriptions** per 100 people

**ICT Professionals**

- **1995-2007**
- **2.4%** ICT professionals
- **55%** work outside ICT sector
- **72%** of EU individuals use the internet regularly
- **150 Million** subscriptions fixed broadband
- **130 mobile subscriptions** per 100 people
All sectors are dependent on ICT

ICT spending by category of actors (% of total spending on ICT in 2012)

Source: OECD

Healthcare 4%

SG/tp 16/6/2015
Better access for consumers and businesses

- Geoblocking
- Copyright
- E-commerce
- Parcel delivery
- Reducing VAT burden

Advanced digital networks and innovative services

- Telecoms market
- Media services
- Platforms and intermediaries
- Trust and security

Enhance the digital economy

- Data economy
- Inclusive digital economy and society
- Interoperability and standardisation

Health → telemedicine + m-health
Health in the Digital Single Market Strategy

• Health and eHealth mentioned in several places.

• Interoperability and Standardisation:
  • *Commission will launch* an integrated standardisation plan ... including *essential sectoral interoperability and standards in ... health (telemedicine, mhealth)* ...
Connecting Member States for health data exchange
eHealth Action Plan 2012-2020

• Objectives include
  • Interoperability of eHealth services
  • Research, development and innovation
  • Uptake and wider deployment
  • International cooperation

• eHealth Network ⇒

• Green Paper on mHealth ⇒

• eHealth Interoperability Framework ⇒ Legal issues
The eHealth Network – A Strategic Tool

Political body > eHealth Network

Preparatory body > eHealth Governance Initiative (eHGI)

Guidelines on minimum/non-exhaustive patient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/EU

Release 1

EPSOS

European Patients Smart Open Services
Guidelines on ePrescriptions dataset for electronic exchange under the cross-border Directive

eHealth Network
Brussels
18 November 2014 Release 1
What do the guidelines address?

Rules in the guidelines
eHealth Digital Service Infrastructure
the CEF funded project

Core services:
Horizontal Building Blocks: eID, ...

**eHealth** Building Block: terminology server

NCP: National Contact Point
Member State's connection to the EU network

NCP

Hospitals
GPs
(...)

tp 16/06/2015
Connecting Europe Facility - CEF supports the building of connections

December 2014
The 2015 Work Plan allocates 15 million euro to eHealth

January 2016
Member States sent proposals

June/September 2015
Call for proposals for Member States

2016-2018
Implementation

tp 10/05/2015
Green Paper on mHealth feeding into policy

• Potential for healthcare
  • Efficient and sustainable healthcare, quality
  • Empowering patients (treatment) and citizens (prevention)
  • Use of the data for public health

• mHealth market
  • From app developers to device manufacturers and network operators

• EU contribution to mHealth
  • Legal certainty and trust
  • Stimulating innovation and entrepreneurship
Results: Legal framework - unclear application of rules and legal vacuum

Actions requested from the EU:
- Clear EU guidelines on when apps are medical devices
- Assess need to legislate the safety of digital goods
- Increased obligations on app stores to ensure compliance with the EU rules (e.g. on data protection and medical devices)

National:
- Stronger enforcement of rules by competent authorities (e.g. DPAs and medical devices)
Legal Study on Electronic Health Records: Overview of national laws

• Every country/region is in the process of progressively adapting legal rules to enable EHR sharing

• Each national/regional legal framework is different and needs to be read in its specific context

• Typologies or classifications of these frameworks are difficult to make and not very useful

• Question: is diversity of national/regional legal frameworks an obstacle for cross-border sharing?
Priorities for healthcare

- Enabling all to benefit from telemedicine and mHealth through actions in the context of Digital Single Market
- Creating European infrastructure to exchange data
  - Legal and technical arrangements for exchange
  - For European Reference Network
- Align EU standardisation activities in health
- Electronic patient access to health records
- Secondary use of health data (Big Data)
Summary:
Policy Instruments for eHealth in the EU

✓ eHealth Action Plan 2012-2020

✓ Directive on patients’ rights in cross-border care
  ✓ eHealth Network
  ✓ 2nd Joint Action on eHealth

✓ Financing
  ✓ Horizon 2020: research and innovation (since 1989)
  ✓ Connecting Europe Facility: implementation (2015)

✓ Strategy for the Digital Single Market
  ✓ Adopted by the Commission 6 May 2015
DG Health and Food Safety site

DG Connect site
Telehealth in French Healthcare: Accomplishments and opportunities

P Jourdain
Ass Prof Of cardiology
Telemedicine National medical adviser
DGOS (Health and social Affairs ministry)
Looking for optimization of medical strategies using new technologies … Why?
2-year mortality rates for HF patients compared to general scheme beneficiaries

All ages RR standardized = 29
< 50 yrs (RR = 82, CI95% 72-94), 50-59 yrs (RR=17, CI95% 15-19), 60-69 yrs (RR=12, CI95% 11-13), 70-79 yrs (RR=7, CI95% 7-7), 80-89 yrs (RR = 4, IC 95% 4-4)
### Duration after index hospitalization (months)

<table>
<thead>
<tr>
<th>Survival *</th>
<th>1</th>
<th>6</th>
<th>12</th>
<th>24</th>
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<tbody>
<tr>
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<tr>
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<td>96,3</td>
<td>91,9</td>
<td>88,8</td>
<td>84,6</td>
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<tr>
<td>55-69</td>
<td>94,7</td>
<td>88,6</td>
<td>84,0</td>
<td>77,1</td>
</tr>
<tr>
<td>70-79</td>
<td>92,6</td>
<td>83,7</td>
<td>77,4</td>
<td>68,0</td>
</tr>
<tr>
<td>80-89</td>
<td>87,2</td>
<td>74,6</td>
<td>65,7</td>
<td>52,3</td>
</tr>
<tr>
<td>90 or more</td>
<td>78,5</td>
<td>60,6</td>
<td>49,7</td>
<td>34,3</td>
</tr>
</tbody>
</table>

### Survival without re-hospitalization for HF

<table>
<thead>
<tr>
<th>Total</th>
<th>84,6</th>
<th>64,7</th>
<th>54,8</th>
<th>42,6</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;55 ans</td>
<td>91,5</td>
<td>77,5</td>
<td>70,0</td>
<td>64,5</td>
</tr>
<tr>
<td>55-69</td>
<td>89,4</td>
<td>73,9</td>
<td>64,9</td>
<td>56,4</td>
</tr>
<tr>
<td>70-79</td>
<td>87,8</td>
<td>68,9</td>
<td>59,5</td>
<td>48,5</td>
</tr>
<tr>
<td>80-89</td>
<td>82,8</td>
<td>61,6</td>
<td>51,0</td>
<td>36,9</td>
</tr>
<tr>
<td>90 or more</td>
<td>75,0</td>
<td>49,6</td>
<td>38,8</td>
<td>24,4</td>
</tr>
</tbody>
</table>

### Survival without all-cause re-hospitalization

<table>
<thead>
<tr>
<th>Total</th>
<th>73,1</th>
<th>38,7</th>
<th>26,8</th>
<th>16,7</th>
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</thead>
<tbody>
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<td>75,4</td>
<td>40,3</td>
<td>32,2</td>
<td>26,2</td>
</tr>
<tr>
<td>55-69</td>
<td>74,1</td>
<td>39,5</td>
<td>28,5</td>
<td>19,9</td>
</tr>
<tr>
<td>70-79</td>
<td>74,2</td>
<td>39,2</td>
<td>27,3</td>
<td>17,0</td>
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<tr>
<td>80-89</td>
<td>73,0</td>
<td>39,1</td>
<td>26,4</td>
<td>15,2</td>
</tr>
<tr>
<td>90 or more</td>
<td>68,6</td>
<td>34,3</td>
<td>22,5</td>
<td>11,6</td>
</tr>
</tbody>
</table>

### At least one re-hospitalization for HF without death

<table>
<thead>
<tr>
<th>Total</th>
<th>4,6</th>
<th>13,6</th>
<th>15,8</th>
<th>16,5</th>
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</thead>
<tbody>
<tr>
<td>&lt;55 ans</td>
<td>4,8</td>
<td>14,4</td>
<td>16,4</td>
<td>18,5</td>
</tr>
<tr>
<td>55-69</td>
<td>5,3</td>
<td>14,7</td>
<td>17,5</td>
<td>19,4</td>
</tr>
<tr>
<td>70-79</td>
<td>4,9</td>
<td>14,8</td>
<td>17,5</td>
<td>19,5</td>
</tr>
<tr>
<td>80-89</td>
<td>4,4</td>
<td>13,0</td>
<td>15,2</td>
<td>15,2</td>
</tr>
<tr>
<td>90 or more</td>
<td>3,5</td>
<td>11,1</td>
<td>12,0</td>
<td>12,4</td>
</tr>
</tbody>
</table>

* Including hospital deaths.
Télémedicine evolution or revolution?

- Connected tools and devices are more and more included in our daily life.
- Technology improvement change our perception and open new possibilities in diagnostic, follow up, education of patients and management of diseases.
- More than sensors, the geometric increase of analysis capabilities and speed change the relationship between indicators and healthcare professionals.
- TLM open a new field for medical art
Telemedicine challenges or opportunities?

- Chronic diseases are more and more costly and prevalent.
- Most of costs are due to hospitalizations and a large percentage of it could be prevent.
- There is in France a large decrease of GP and specialists (cardiologists) and we have only few internists.
- The 2010 reforms has open the way and the government really wants to reform the healthcare system.
Pitfalls: The E health jungle

• Ehealth seems promising but E health and qualify self is not telemedicine.
• Due to the simplicity of the creation of sensors there are many small starts ups many models (and too many) possibilities.
• Most hope to benefit from public financing rather to invest in clinical studies.
• Many communications but still few evidences
<table>
<thead>
<tr>
<th>Vital Parameters</th>
<th>Data Flow</th>
<th>Medical Instruction</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. ECG</td>
<td>Database</td>
<td>GP/Cardiologist</td>
<td></td>
</tr>
<tr>
<td>II. Weight, Blood Pressure, ECG</td>
<td>Callcenter</td>
<td>In case of deviations</td>
<td>GP/Cardiologist</td>
</tr>
<tr>
<td>III. Weight, Blood pressure, ECG</td>
<td></td>
<td>Individual algorithms</td>
<td></td>
</tr>
<tr>
<td>IV. Weight, Blood pressure, ECG, Biomarker, Implants</td>
<td></td>
<td>Individual algorithms</td>
<td></td>
</tr>
</tbody>
</table>

Anker SD, Koehler F et al. Lancet. 2011 Aug 20;378(9792):731
Telemedicine a new challenge?

- Telemedicine is not only measuring old or new indicators or creating a «big Data» compendium..... Its integration of data in a medical algorithm in order to improve medical decision or management.

- Telemedicine is not a «big brother» survey program but a mean to autotomize patients and to improve efficiency of «health care plans».

- Telemedicine is not a solution to palliate to system problems but a new deal between institutions, patients, healthcare professionals and industry in order to provide the best care at the best time for all patients that need it.
Strategic planning

• Analysis of real « daily practice » needs.
• Analysis of technical possibilities in order to protect the patient and to help healthcare professionals.
• Definition of TLM and definition of a strategic perimeter
• Political impulsion in order to optimize the Health care offer to the population for improving quality of care and equity for all the patients
Frameworks and contents

• Framework:
  – Definition of TLM
  – Regulatory
  – Norms
  – Confidentiality/data security

• Contents
  – Indicators connected tolls.
  – Algorithm's
  – Guidelines in order to help clinicians to built their own TLM programs
  – Quality control
  – Evaluation
French Health system

- **CNAM** is the national public insurer. It will determine the level of reimbursement of the therapies in accordance with the health benefit created by the new therapy or device.

- **HAS** is the health national independent authority that analyses the respective performance of therapies and publish « good practice » recommendations.

- **Health ministry** is in charge of the strategic decisions.

- **Regional agencies** have to deploy and to organize health systems and find solutions to conform to health ministry decisions.
Regulation strategy First look Synthetic tools for main actors Sélection of 8 pilot studies 2d look

2009 / 2010

Définition of TLM and legal pathway

- Loi 21 juillet 2009
- Loi LFSS 2010 : Décret 18 mai 2010 : de TLM (PRT)
- Décret TLM 19 octobre 2010

strategic prioritization. Determination of specific leaderships

2011 / 2014

January 2011

- Copil (ministries)
  - National coordination team
- 256 projets, 113 on going most Hosp

Déc. 2011

- Guide PRT (DGOS)
- Guide contrats et conventions (DGOS)
- Recommandations SI (DSSIS / ASIP)
- Monographies (ANAP)

Déc. 2011 / March 2012

- Instruction 31.01.12
- Sélection 28.03.12

March / January 2014

- 331 projets, 50% on going

Documents

- Information system
- Lawyers
- Evaluation and security:

http://www.sante.gouv.fr/deploiement-de-la-telemedecine-tout-se-joue-maintenant.html
Framework - definition of TLM

- **Teleconsultation**: Medical advice to a patient without physical contact. Same insurance responsibility as on site medical appointment (HC professional – Patient)

- **Teleexpertise**: medical counseling between an expert and a non expert HC professional. Shared insurance responsibility between the two HC professionals. (HC pro to HC pro)

- **Medical regulation**: Specific to French mobile ET units.

- **Telemonitoring**: medical follow up of home measured indicators automatically transmitted with interaction between patients and HC professionals
Security control

- Patient personnel data protection / CNIL
- Data storage / connexions ASIP sante-DSISS.
- Algorithms validity / medical societies
- Deployment in each hospital / SI director
- Insurance responsibility / Health care professional
Norms - Confidentiality/ data security

- Normalization is helpful in order to standardized communication tools / sensors/ software's.
- Norms improve interoperability and are crucial for guaranty of some security levels for confidentiality data security and privacy.
- 2 aspects:
  - Focusing on new devices
  - Focusing on preexistent systems
- In France CNIL is in charge of these aspects and has published some specific guidelines.
Contents
Medical societies / HAS / Patients associations / DGOS

• Inclusion / exclusion criteria:
• Indicators connected tolls:
• specific logarithm's
• Alerts generation
• Additional services:
  • Patient education
  • Relatives and caregivers information
  • Adherence stimulation for HC professionals and patients.
• Agenda, quizz,…
Contents- specifications

DGOS

– Guidelines in order to help clinicians to build their own TLM programs.

– Cooperation with national societies of HC professionals and National society of telemedicine and patients associations.

– Prioritization depending on national strategic priorities and public health problematic.

– Examples: specifications on chronic wounds and ulcers / HF and TLM (on going).
Contents-quality control
DGOS/ ASIP santé/ CNIL

• QC of data collection, tools connections and data storage is mandatory due to the potential risk of privacy violations and data base corruption.

• QC of industrial process is a key point as it is for all the industrial process with service interruptions, time for restarting nominal activity,…

• QC of sensors activity because of their importance regarding medical decision and eventually alerts generations when including in algorithms.
Contents-Evaluation
HAS- DGOS

- a complex process due to TLM specificities.
- Focusing not only on patient security/ privacy but also on different facets like:
  - Impact on health care plans and organization
  - Impact on medical events
  - Impact on costs
  - Impact on QOL
  - Acceptability / adherence
Communication

• Between health agencies and highly specialized agencies like CNIL or HAS.
• CNAM in order to analyse cost efficacy inbalance and to remove the codification brake.
• Healthcare professionals and medical national societies in order to analyse the best combination between real needs and technological possibilities.
• Industrials in order to stimulate innovation about TLM and transform technological progress into patient progress…
• Patients in order to facilitate the acceptation of this new medical approach.
Patient information on telemedicine

- Films with patient’s associations.
- Flyers.
- Partnership with national scientific societies.
- Conventions.
experimentations?

• Hospital patients health and territories law in 2010 identifies telemedicine as a promising component of health management.

• In 2012 and 2014, regional agencies launch an ambitious program on medical applications of E health.

• In 2014, the health ministry creates the telemedicine territories program

• In 2015:
  – the national health insurance initiates a telemedicine open survey
  – TLM experimentations will open in most of French Health regions according to DGOS guidelines and ARS management
« On going » experimentations

- **Acute setting:**
  - Transmission and out of site TDM or MRI analysis for stroke suspicion (teleAVC).
  - Out of site dermatologic lesions analysis in detainees people (teledermato).

- **Chronic setting:**
  - Experimentations in some Health regions focusing on chronic disease (from HF to obesity).

- **Organisational setting:**
  - TSN (numeric health territories)
We are probably outsiders … but

And integration of TLM in health care plan has to be anticipated in order to improve patient care for a sustainable cost.
Digitizing and Personalizing Health Care
- The Continua Pledge

Horst Merkle
President Continua
Chair of the Board, PCHA

Mission
Personal Connected Health Alliance

Generating greater **awareness, availability and access** to plug-and-play, consumer-friendly personal health technologies to empower individuals to better manage their health and wellness, anywhere, at any time.

**Continua Value Chain**

- Components
- Integrators
- Product Solutions
- Network Solutions
- Standards & Testing
- Service Providers
- Users / Professionals
Continua - Partner in a Compelling Collaboration

Personal Connected Health Alliance
- Global Access, Recognition & Leadership
- Promotion & Market Development
- Advocacy in Policy & Regulation

Continua
- Plug&Play Interoperability
- Standards Development
- Product Test & Certification Program

mHealth Summit
- Thought Leadership
- Stakeholder Networking
- Education, Awareness & Publicity
End-to-End Architecture

mHealth / Personal Connected Health Ecosystem

- Personal Health Devices Interface (PAN, LAN, TAN Interfaces)
- Services Interface (WAN Interface)
- HIS Interface (HRN Interface)

- Personal Health Devices
- Secure Interface
- Services Secure Interface
- HIS Secure Interface

Many more devices are compatible.
Guideline Development Process

Development Cycle
1. Submission of use case ideas
2. Use Case development
3. UC balloting
4. UC sponsorship
5. UC review – architecture, regulatory, feasibility, effort
6. Decomposition (Work items)
7. Gap Analysis
8. Guidelines Development
9. Balloting
10. Approval
11. Testing, test tools development
12. Public Release & Comment Period
13. Certification Program
Open Source Code - CESL

- Speed up adoption
- Reference source code
- Testing Prototypes
- Basis for Continua Test Tool
- Creation of reference devices for IOP
- Commercial Ready Platforms

Continua Enabling Software Library
Developing the mHealth Market
Example: Nordics

- Market Acceleration
- Large Scale Deployment
- Test Piloting
- Reference Architecture
- Standards Adoption

Adoption of Continua Design Guidelines

**Norway:** (Dec. 2014) Parliament adopted Continua standards as the framework for its new national health program.

**Sweden:** is on its way to follow its neighbors in 2015/2016.

**Finland:** (May 2015) announced adoption of the Continua Guidelines in its HIT framework.

**Latvia:** eHealth Week closing plenary: Continua Commitment to support ecosystems with Continua Guidelines.

**UAE / Qatar:** Discuss PCH/Continua as part of HIT plans.

**Singapore:** embarks to implement Continua based HIT to serve SE-Asian region.

**Taiwan:** New promoter member planning of an Asian Summit to promote standards.

**China:** Momentum is building toward utilization of standards in HIT.

**Denmark:** (2012) Nationwide health IT framework mandates compliance with interoperability standards (Continua).

**USA:** FDA shows keen interest to collaborate in Guidelines and Certification program development.
Momentum is Building

Continua primed to coordinate all stakeholders in Personal Connected Health

The markets are forming and interoperability is a key driver:

- Personal Connected Health an opportunity for better care delivery
- Interoperability key success factor
- Consumers demand it
- Technology is accessible
- Standards are available
- Positive political environment
- Nations start implementation
Get Involved with PCHA!

[Logo]

Web:  www.pchalliance.org

Email:  ask@pchalliance.org