JASEHN
Joint Action to Support the eHealth Network

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INFORMATION PAPER
on
Main eHealth activities outside of the EU

Annex 11
Main USA eHealth policies and activities

LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
ACA	Patient Protection and Affordable Care Act ("Obamacare")
ACR	Association of American Radiologists
AHRQ	Agency for Healthcare Research and Quality
APHA	American Public Health Association
ASTHO	Association of state and territorial health officials
ATA	American Telemedicine Association
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Centre for Disease Control
CMS	The Centers for Medicare & Medicaid Services
CVT	Clinical Video Telehealth
DHHS	Department of Health and Human Services
DICOM	Digital Image Communication
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FEDTEL	Federal Telemedicine Working Group
FORHP	Federal Office of Rural Health Policy
HEW	Department of Health, Education, and Welfare (before DHHS)
HIMSS	Healthcare Information and Management Systems Society
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HL7	Health Level 7
HMO	Health Maintenance Organization
HPSA	Health Professional Shortage Area
HRSA	Health Resources and Services Administration
HT	Home Telehealth
IHE	Integrating the Healthcare Enterprise

IHS	Indian Health Service
LOINC	Logical Observation Identifiers Names and Codes
MACRA	Medicare Access & CHIP Reauthorization Act
NEMA	National Electrical Manufacturers Association
NIH	National Institutes of Health
NLM	National Library of Medicine
NSF	National Science Foundation
OCR	Office of Civil Rights
ONC	Office of the National Coordinator for Health Information Technology
PHI	Protected Health Information
PHR	Personal Health Record
PPO	Preferred Provider Organization
RN	Registered Nurse
SAMSHA	Substance Abuse and Mental Health Services Administration
SDO	Standards Development Organization
SFT	Store and Forward Telehealth
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms
STAR	Secondary Triage Additional Resource
USDA	US Department of Agriculture
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

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Preamble

Object

The present document is an Annex to Joint Action to support of the eHealth Network (JAseHN) Deliverable 8.1.4 in WP8 "Report on main eHealth activities outside of the EU". It has been prepared by Norbert Paquel (external, director of Canope cabinet – France) under the control of Michèle Thonnet (Work Package leader-FRNA), then corrected and approved by the sPSC.

The objective of D8.1.4 is to observe the situation in various countries in order to better understand the development factors and main trends in the worldwide movement towards a tighter integration of ICT tools in healthcare but also to be able to initiate cooperation when advisable and possible. To that end, concrete projects have been identified as potentially interesting for eHN Member States (MS) exchanges or cooperation. These opportunities would need deeper analysis, through direct contact with experts, notably local representatives of the concerned MS or participants in EU projects.

Methodology

As explained in the main D8.1.4 document, the research was based on a desk study carried out between 2017/02 and 2017/08. It is important to note that time runs often very fast in the eHealth and mHealth domains. Accordingly, contrary to healthcare organizations and fundamental policies trends, concrete programmes and projects can change rapidly. However, if they correspond to clear needs and sustainable methods, they should not disappear. Moreover, when possible, some of the main important developments that have occurred since August 2018 have been taken into account.

USA, a large federation, a lawful country: basic information on the country

The USA is different in many ways from other countries, whether industrialized, emerging or developing. It is also very different from its American neighbours. Its political and social organization and the links between different levels of power are specific. At the same time, the country size and its international role in the twentieth century have given it a great influence in organizational and technical evolutions worldwide. To understand US eHealth policy or policies, it is thus necessary to keep in mind some key aspects of the social and healthcare background. This is critical as US stakeholders and national vision holds a great influence worldwide and are unavoidable key partners in many actions and programs

When considering the development of eHealth in the USA, the special and unique characteristics of this great country must be kept in mind; it is at the same time a federation of very autonomous states and a strongly united great Nation.

With 326,474,013, the USA is the third most populated country in the world, after China and India.

There is a great heterogeneity between states, from California (39,25 M est. 2016) to Wyoming (0,59). Many contrasts appear between highly populated and relatively small states of the East Coast and some of huge size in the Middle West and West. Population density in the East Coast is 470 inhabitants/km2, whilst the less densely populated States have a mean of 2,3 (again Wyoming) and Alaska has 0,5. There are obviously great economic and social disparities between states. There are also legally special territories, from states (Alaska, Hawaï) to diverse status (Washington DC, islands such as Samoa, still evolving Porto-Rico…) and also Native Indian Tribe Reserves (inside states).

However, it is possible to identify common trends in many domains and, in our case, in healthcare system, ICT use and eHealth. These trends, often similar to those observed in other developed countries, express themselves very differently depending on states. Eventually, the Federal Government and Parliament get involved and promulgate an Act, a special regulation, a Law, under the Control of the Supreme Court. Then the states can adopt, promulgate special features, even attack the Act at national level etc. This progressive and often contradictory legal process is very important, because of a key aspect of US constitution and society: importance of the Law and importance of judges.

- I -
Health and Healthcare background

1. Elements on health situation

On the whole, health indicators are in the general trend of industrialized countries. Abundance of advanced medical and pharmaceutical technologies – and especially fast adoption of successful techniques by many of the described autonomous systems – make for a slight advance sometime.

However, there is a wide gap between those who can afford high insurance contracts and those who can't. As seen above, at every moment, there are about 32,5 M Americans with no protecting net, waiting emergency situations to get treatment.

Moreover, many of these disadvantaged people live in Health Professional Shortage Areas (HPSAs), rural and urban areas with shortages of primary care providers, where a total of 59 million Americans resided in 2013.

There are groups of population lacking health insurance coverage at any moment. Estimations vary around 10%. Despite a fast reduction in recent years due to Medicare and Medicaid extension (see under), this represents some 32,5M people. These groups rely on charity ensured by some healthcare providers. Non-insured patients often wait until their health situation has deteriorated a lot to get treatment and thus often have to be treated in emergency situations.

2. Healthcare system
[3] [4]

2.1 A healthcare system? Diversity of organizations and insurance systems

- **Variety of organizations**

Due to historical reasons, the majority of healthcare establishments are managed by not-for-profit associations, funds, unions, pension funds etc., a minority by commercial businesses (especially insurers). Important establishments are University Hospitals, in close relation with Universities and Research laboratories. Most are managed as businesses but often have charity activities. An impressive example is the huge Mayo Clinic[1], whose services and partnerships are deployed over the whole planet. The rest of US hospitals consist of public hospitals. With non-profit rural hospitals, public hospitals constitute the health care safety net for uninsured and poor underinsured populations. They receive a great part of their financial resources from local authorities, state or federal government.

Various forms of insurance or social protection systems have been developed, once again non-profit organizations as well as commercial ones, some largely financed by the Federal Government or the states *(see under)*. On the opposite end of the spectrum, it is possible for companies to set up their own system (not so frequent). The most frequent approach for big companies is to build, along with employees, a health insurance plan and negotiate with competing insurers and HMOs *(see under)* the cost of care acts and treatments.

Diversity of systems has led to great difficulties in managing establishments and insurances, aggravated unequal access for citizens and made extremely difficult any continuity of care and

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1 Non-profit healthcare and research Federation, often considered the best US hospital - 60 sites in Minnesota, Wisconsin, Iowa, with 21 hospitals, six nursing homes, staff 60,000, physicians and scientists 1,095 and 15,318 allied. Physicians are paid on a salary basis.

communication between healthcare providers. The solution could only come from more integration in wide organizations, so as to be able to develop what is called in the US Managed Care Organizations and even, depending on the level of contracts and associations, Integrated Manage Care Organizations. Of course, these organizations concern specific groups in the population, or for instance all people and providers contracting with a precise insurance (or more, especially for providers and professionals).

- **Islands of integration within a fragmented system**

The largest integrated health care system is the Veteran Health Administration. It is a very ancient organization, which was born after the Civil War and started building hospitals before the Second World War. The VHA [2]provides care at 1,233 health care facilities, including 168 VA Medical Centres and 1,053 outpatient sites of care of varying complexity (VA outpatient clinics), serving more than 8.9 million Veterans each year.

Two other important public systems exist: Medicare for the elderly and handicapped, Medicaid for certain economically disadvantaged groups.

Medicare is partially funded by taxes and contribution of beneficiaries (with possible complementary insurance). Medicaid is jointly financed by the federal and state governments and is administered by each state. Individuals who are elderly, blind, disabled or members of families with dependent children must be covered by Medicaid for states to receive federal funds. Medicaid covers approximately 12% of the population (benefits packages vary between states).

Apart from these specific integrated systems, 70% of employees are now currently enrolled in Managed Care Organizations, either Preferred Provider Organizations (PPOs) or Health Maintenance Organizations (HMOs). Both combine the insurer and producer functions. The PPO is a third-party payers that offers financial incentives to enrolees who acquire medical care from a pre-set list of physicians and hospitals. HMOs are the most closely integrated systems, managing directly hospitals and out-patients clinics. They have existed since the Health Maintenance Organization Act of 1973. They also arrange managed care, acting as a liaison with health care providers on a prepaid basis. The biggest HMO is Kaiser Permanente (created in California) with 10.2 million health plan members, followed by Blue Cross Blue Shield (created in Massachusetts).

- **Main weaknesses**

As is well known due to endless debates and controversial legal projects on general social protection, the system is not equitable and the health situation of the disadvantaged and uninsured is bad.

On the whole, practical communication in the "healthcare system" is gravely hampered by the fragmentation between structures and between diversity of insurance and protection systems. US healthcare experts acknowledge that patient centred relation between hospital and GPs are often more difficult than in European countries. In fact, continuity of care is the norm only inside HMOs and other integrated systems like Veterans.

Another problem is the growth of healthcare costs (Total health expenditure in 2014/ GDP: USA 17,1%, EU: 10,1%, OECD 12,3%). In this context, new actors are appearing: Accountable Care Organizations, intermediates that evaluate providers' activity and negotiate fees.

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[2] The VHA is part of the Department of Veterans Affairs, which manages the facilities. In most documents, abbreviation VA is used also for the Health part of the Department.

2.2 Governance and organization

The health system organization and eHealth development reflect the fundamental aspects of the US Federal Constitutional System.

- **Public Health: introducing states and Federal Government in health governance**

States retain the primary responsibility for health. The Association of state and territorial health officials (ASTHO), created in 1942 by public health agencies, is a national non-profit organization representing public health agencies from the US, the US Territories, and the District of Columbia, and over 100 000 public health professionals these agencies employ. At the local level (towns, various kind of communities), there are Local Health departments and Local boards of health which depend on legal representatives of the community.

The Centre for Disease Control (CDC) is a United States federal agency under the Department of Health and Human Services. Its main goal is to protect public health and safety through the control and prevention of disease, injury, and disability in the USA and internationally.

- **Fundamental rights of all US citizens and Federal role: the revolving debate**

The basis for Federal Government intervention in all domains is:

- Problems and threats that spam more than one state or region;

- Products and services that can be transported through border lines.

While conforming to respective competencies of Local, State and Federal authorities, key acts and laws have contributed to advance towards common pillars of a health system, after harsh debates and with modalities for applications often varying between states or even communities.

Here under: some recent key national Acts that were notable steps.

- 1995 The Social Security Administration becomes an independent agency

- 1996 Health Insurance Portability & Accountability Act (HIPAA) (considered by eHealth community as an important landmark): improve portability & continuity of health insurance coverage in the group & individual markets

- 2010 Patient Protection and Affordable Care Act (ACA – "Obamacare") (ICT tools feature prominently in this Act) – still harsh discussions

Of course, many of these reforms and regulations generate new public budget expenses, which are by definition subject to annual and political choices. The 2018 federal budget cuts $15.1 billion from the Department of Health and Human Services. This represents 18% of total 2017 budget of $83,9 billion.

Other federal agencies play a role in healthcare and eHealth development:

- Government Accounting Agency – controlling for instance Medicare and Medicaid that receive federal money, defining ways to prevent fraud (through perhaps Smart Card)…

- National Institutes of Health (NIH) - the primary agency of the Federal Government responsible for biomedical and public health research, founded in the late 1870s, now part of the Department of Health and Human Services. It conducts its own scientific research and provides funding to non-NIH research facilities.

- National Library of Medicine (NLM) - the world's largest medical library - is an institute within the NIH. NLM is a fundamental information resource and leads in world medical documentation standards (notably with the MESH thesaurus).

- **Legal aspects: What federal laws regulate the collection and use of personal data?**

[6] In the USA, there is no single, comprehensive federal (national) law regulating the collection and use of personal data. However, each Congressional term brings proposals to standardize laws at a federal level. Instead, the USA has a patchwork system of federal and state laws and regulations that can sometimes overlap, dovetail and contradict one another. In addition, there are many guidelines, developed by governmental agencies and industry groups that do not have the force of law, but are part of self-regulatory guidelines and frameworks that are considered "best practices". These self-regulatory frameworks have accountability and enforcement components that are increasingly being used as a tool for enforcement by regulators.

There are already a number of federal privacy-related laws that regulate the collection and use of personal data. Some apply to particular categories of information, such as financial or health information, or electronic communications. Others apply to activities that use personal information, such as telemarketing and commercial e-mail.

The Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. §1301 et seq.) regulates medical information *[see under 6.1]*.

3. Motivations for selecting the USA for eHealth study

- USA role in global economy and in ICT tools

- A federation of very diverse states and territories that is confronted to harsh debates and difficulties to implement eHealth at national or states level

- Necessity to better understand these difficulties in order to develop exchanges and cooperation, that are unavoidable in the modern world

- Important role in eHealth standards

- II -
Telemedicine and eHealth development

4. Preliminary remarks

4.1   Definitions

Before addressing progresses and obstacles in eHealth, it is useful to keep in mind a typology of "Telehealth" services, as this typology is of paramount importance in the USA as opposed to other countries, being not mainly technical but legal – and with different constraints according to states.

- Clinical Video Telehealth (CVT) - uses real-time interactive video conferencing, sometimes with supportive peripheral technologies, to assess, treat and provide care to a patient remotely;

- Home Telehealth (HT) - applies care and case management principles to coordinate non-institutional care using health informatics, disease management, and home remote monitoring technologies to manage diabetes, chronic heart disease, hypertension, obesity, and traumatic head injuries;

- Store and Forward Telehealth (SFT) - uses technology to acquire and store clinical information (data, image, sound, or video) that is forwarded to providers such as cardiologists, ophthalmologists, dermatologists, or pathologists at a distant location for clinical evaluation.

4.2   Organization of Part II chapters

This central part of the document is organized around the forces behind eHealth development or obstacles and the current situation they have contributed to. A key source here is the Report to Congress on eHealth and Telemedicine presented on August 12th 2016 by the U.S. Department of Health and Human Services. It is completed by various observations and documents. Information is organized in Chapters 5 - 10

Chapter 5: Innovation and strategies: the US dynamic

Chapter 6: The Federal level delivers strong impulses

A frequent misconception about the USA is that there are less bureaucratic – read administrative – actors. However, in the present document, many will be encountered that are key for Health System and eHealth.

In its 2016 report [1] the U.S. Department of Health and Human Services explains to the Congress that these agencies are coordinated [...*the majority of work by the Federal Government on the issue of telehealth has been monitored by an interagency task force established by the Health Resources and Services Administration's (HRSA) Federal Office of Rural Health Policy (FORHP). This Federal Telemedicine Working Group (FedTel) was established in April 2011 to help discuss and reduce organizational silos, facilitate telehealth education and information sharing amongst members, and summarize key telehealth activities of the participants. The current membership includes over 100 participants from 26 agencies and departments including the FCC, USDA, Justice, Commerce, Education, Transportation, the VA, Agriculture, Defense, Health and Human Services, Agency for Healthcare Research and Quality (AHRQ), CDC, CMS[3], the Food and Drug*

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[3] The Centers for Medicare & Medicaid Services, a federal agency within the United States Department of Health and Human Services that administers Medicare and works with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and HIPAA standards

Administration (FDA), HRSA, IHS, NIH, the Assistant Secretary for Planning and Evaluation, the Assistant Secretary for Planning and Response, ONC and the Substance Abuse and Mental Health Services Administration (SAMSHA), Labor, the NASA, and the NSF….].

Moreover, these federal actors have really poured money, when considered necessary, to facilitate and stimulate developments *(see "EHRs" in 10.2)*. *HHS' largest telehealth investments are in the form of payments for health care services through Medicare, Medicaid, and the Indian Health Service (IHS). Other HHS Operating Divisions including HRSA, SAMHSA, the CDC, the Agency for Healthcare Research and Quality (AHRQ), the NIH, and ONC also support telehealth activities, the development of mobile technologies (such as remote sensors), or research that assesses the effectiveness of care delivered remotely.*

Chapter 7: These impulses have encountered severe obstacles

Chapter 8: Despite powerful Standards Development Organizations

Chapter 9: Actors - towards managed care and eHealth?

A diversity of key actors needs to manage care or promote it. They are federal public organizations (notably Veterans), public programs adapted in all states local department with variations (Medicare, Medicaid), HMOs, insurers, also big providers. Even if they do not manage directly healthcare and eHealth, the role of associations is presented here, as this is a characteristic aspect of US culture.

Chapter 10: General situation. Fast advance in new technologies and in new risks?

5. Innovation and strategies: the US dynamic

Despite the difficulties the USA are confronted with in building a coherent national protection system, US healthcare actors are a very important force globally. As they have a strong impact on eHealth tools, important facts should be kept in mind:

- Dynamism of large parts of the system, due to autonomy, diversity of approaches, long term cooperation between university and private research and industry;

- Ancient orientation on information and data management, strengthened by the massive use of statistics in human sciences and in epidemiology, and then amplified with the fast appropriation of IT; this appears notably in the CDC's efficiency in detecting and analyzing medical threats on the planet; this is also the origin of "Diagnosis Related Groups", initiated by Medicare, used to define hospital payment categories based on characteristics of patients and treatment and hospital costs. They are used by many countries to better manage healthcare;

- Wide market, powerful venture capitalism and powerful IT companies facilitate start-ups growth and innovation;

- Simultaneously, differences in legal and economic conditions between states and even between communities (notably religious ones) maintain difficulties for new techniques and new usages diffusion (differences and obstacles concern sometimes very important aspects and rules); with differences in insurance and healthcare production multiple systems, this contributes to maintaining a fragmented health system.

6. Impulses
[1][4]

A regular flow of federal regulations and laws *(cf.-I – 2.2)* is aimed at bringing more coherence and equity and integrate ICT techniques to communicate and share.

6.1   1996: HIPAA

Among its main objectives: To combat waste, fraud, and abuse in health insurance and healthcare delivery, promote use of medical savings accounts, improve access to long-term care, simplify health insurance administration...

An important constraint restricts insurance use of pre-exiting conditions to make coverage decisions and set standards for medical records privacy.

HIPAA guidelines allow for safe development of eHealth as far as privacy and security are concerned. They apply to all entities that manipulate sensitive personal medical data, named "covered entities" – Health plans, Healthcare providers, clearinghouses and intermediaries. Main guidelines concern:

- Standardized Electronic Data Interchange transactions and codes

- Standards for security of data systems

- Privacy protections for individual health information

- Standard national identifiers for health care

Covered entities have to adopt and implement privacy procedures, notify patients about their privacy rights and in most cases obtain paper consent on how their information can be used, train employees so they understand the privacy procedures, designate a Privacy Officer, secure patient records containing Protected Health Information. Consumers notably have right of timely access to see and copy records for a reasonable fee, right to an amendment of records, right to restrict access and use, right to an accounting of disclosures, right to revoke authorization.

No one is permitted to use Protected Health Information for research without complying with HIPAA requirements.

Practical and technical recommendations to protect personal information are given in the Act. Furthermore, breaches notifications are mandatory (this is developed in the HITECH Act of 2009)

HIPAA application is controlled by the Office for Civil Rights, under the Director of Health and Human Services (HHS)

6.2   2004: Office of the National Coordinator for Health Information Technology (ONC)

Created by an Executive Order, legislatively mandated in the HITECH Act of 2009, located Office of the Secretary for the U.S. Department of Health and Human Services, the ONC is "a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care"[4]. A set of standards and interoperability rules on the Internet is recommended or mandatory. It is dubbed the Nationwide Health Information Network (NwHIN – not a physical network).

The ONC develops information centers. Notably, to stimulate adoption of EHRs, the ONC, through the American Recovery and Reinvestment Act, has established 62 RECs that assist primary care providers in the adoption and meaningful use of electronic health records.

6.3   2009: HITECH Act

The Health Information Technology for Economic and Clinical Health Act was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009. It was then considered by

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[4] https://www.healthit.gov/newsroom/about-onc

many to be the most important piece of health care legislation to be passed in the last 20 to 30 years and the foundation for health care reform. It aimed to promote transparency in health care effectiveness and to reduce regional differences. Technology certification and meaningful health records exchange are the cornerstones of the HITECH Act.

Stakes were immediately viewed as high, as all public investments and calls for tender have to conform to the Act. For example, the Washington Post reported the inclusion of "as much as $36.5 billion in spending to create a nationwide network of electronic health records."

The Act prepared the ACA.

- **Certified EHR**

HITECH refers to certification by the Office of the National Coordinator or by the Centers for Medicare & Medicaid Services. This certification is strictly enforced, and EHR vendors have even had their certification revoked for noncompliance.

- **Meaningful use**

Technologies have to be used efficiently in order to:

- Improve care coordination

- Reduce healthcare disparities

- Engage patients and their families

- Improve population and public health

- Ensure adequate privacy and security

- Accordingly, for EHRs use:

- Use of a certified EHR in a meaningful manner, such as e-prescribing.

- Use of certified EHR for electronic exchange of health information to improve quality of care.

- Use of certified EHR to submit clinical quality and other measures - providers need to show they're using EHR in ways that can be measured significantly in quality and in quantity.

6.4 ACA (2010) ("Obamacare")

(extracts of the PATIENT PROTECTION AND AFFORDABLE CARE ACT [2]

- Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology.

- The review committee shall ensure coordination, as appropriate, with the standards that support the certified electronic health record technology approved by the ONC.

- HIT (Health Information Technology) for reduce medical errors

- HIT enrollment standards and protocols - Verify interoperability

- Eliminate or update legacy systems

- Proposal for use of HIT in providing health home services and improving service delivery and coordination across the care continuum (including the use of wireless patient technology to improve coordination and management of care and patient observance).

- Use of HIT to link services

- Support care coordination for chronically ill applicable individuals at high risk of hospitalization through a HIT-enabled provider network that includes care coordinators, a chronic disease registry and home tele-health technology.

- In selecting models: whether the model utilizes, such as EHR and patient-bases remote monitoring system to coordinate care over time and across settings

- Independence at home medical practice means …uses electronic health Information System, remote monitoring and mobile diagnostic technology

- Preference to practices that use EHR, HIT and individualized plans of care – use standard EHR and PHR (Personal) - meet the requirements of certified EHR

- Consider the evolution of meaningful use of HIT

ACA envisions training courses and demonstrations, notably in nursing homes.

6.5   2010 Blue Button

The Blue Button is a voluntary engagement for all healthcare providers and insurers that manage personal citizen's data. If the button appears on a site, citizens know that they can download a view of all their data from a secure portal, in a known and usable format (structured pdf, word…). They can then send them to any actor able to manage or use it. More sophisticated formats are used to ease exchanges, but always with authorization given by the concerned person. The system builds a new type of foundation for citizen control of personal data.

The initiative was started by the Veterans Administration, has now expanded and is being led by the ONC, in order to ensure access for every American to their digital health information and help application developers using the data to build products and services for individuals.

6.6   2015 MACRA legislation

The Medicare Access & CHIP Reauthorization Act of 2015 (MACRA) includes several telehealth provisions. Notably, the use of remote monitoring or telehealth would fall under a care coordination subcategory of the Clinical Practice Improvement Activities performance, which is itself a category in the Merit-Based Incentive Payment System. This new programme aims to adjust physicians' and other practitioners' payment according to their performance. In essence, the MACRA provision offers a possible "reward" to those who coordinate care using telehealth modalities, even when direct reimbursement for such activity may not be available. Another provision gives CMS the authority to reimburse providers participating in Advanced Alternative Payment Models for telehealth services. Currently, the Medicare fee-for- service programme only reimburses for telehealth, which it requires to be delivered by a videolink and when the patient is at a certified health care facility in a Health Professional Shortage Area. Under MACRA, however, eligible providers participating in a qualifying Alternative Payment Model will have the capacity to provide a broad array of services at a distance using many different telehealth modalities irrespective of where the patient or the clinician is physically located.

Legislation (2015) allows for common licensure, if states accept it. Indeed, the process of licensure is an administrative burden that dissuades physicians to request possibility of providing telehealth in multiple states. As of January 2016, 26 states have moved to a more compact system.

7. Obstacles

7.1   Cultural and practical resistance

As in many cases, the first obstacle is acceptance of HIT and eHealth by health professionals, in ambulatory care as well as in hospitals. It must be stressed that this resistance is often the result of badly conceived software, which impose an excessive workload for health professionals and

that have not been developed in cooperation with professionals themselves. Furthermore, the importance of education and training is often underestimated.

Resistance is also strong at first when it comes to information sharing and to citizen implication through portals and through mobile health apps. This imposes new relations with the patient, inevitable questions and explanations.

Another growing source of resistance is fear of security, safety and security threats. It is a very reasonable fear *(see under "Security")*.

From the most powerful hospitals and insurers, there is also the fear of letting other big players enter the market and eventually control vital activities. However, financial and technical power is not enough, as shown by the failure of first big attempts by Microsoft (HealthVault) and Google (Google Health).

Other fears concern security and hence responsibilities – in a country where attorneys are prompt to sue healthcare providers.

Ultimately but probably quite essential is the subject of payment: who pays what, as this varies according to multiple evolving factors, contracts and regulation. It is difficult for actors to build sustainable economic model in such a regulatory context.

Many of these fears and uncertainty elements are now more and more addressed by communication campaigns, congresses, exchanges. ATA (American Telemedicine Association), HIMSS (Healthcare Information and Management Systems Society) are important actors in the field.

7.2 States legal differences

All national acts have to comply with states laws, very often not directly related to health. It is also necessary to prove the validity of all acts and regulation overriding states role in healthcare but also specific characteristics of a given State.

Example: House Bill 1437

This Bill aims to ease up the restrictions on telemedicine laws that were enacted in 2015 by eliminating the requirement that patients must be at a healthcare facility to receive telemedicine services. The companion legislation, Senate Bill 146, decrees the originating site can be wherever the patient happens to be at the time, but stipulates that a phone call alone is not sufficient to establish the initial professional doctor-patient relationship. In Arkansas, Teladoc, a company that conducts the majority of its visits over the phone, has argued the bill still leaves out a lot of Arkansans because they lack the internet speed required to conduct video visits as a first-time telemedicine visits. It's the 48th state in the nation for Internet access, with over 40 percent of residents without access to broadband at 25 mbps or faster needed to support video visits. Another problem is that the bill does not mention parental authority for children telemedicine consultation. The bill is discussed for amendments in the Arkansas Senate.

Even if a national act has been validated, it must be reminded that no two states are alike in how telehealth is defined and regulated. While there are some similarities in language, perhaps indicating states may have utilized existing verbiage from other states, noticeable differences exist. These differences are to be expected, given that each state defines its Medicaid policy parameters, but it also creates a confusing environment for telehealth participants to navigate, particularly when a health system or practitioner provides health care services in multiple states.

In most cases, states have moved away from duplicating Medicare's restrictive telehealth policy, with some reimbursing a wide range of practitioners and services, with little to no restrictions. [3]

States interpretation of eHealth lead to very different regulations for payment, according to the main categories mentioned in the foreword to this chapter.

Forty-eight states and Washington DC provide reimbursement for some form of live video in Medicaid fee-for-service. This number has remained relatively consistent over the past two years.

- Thirteen state Medicaid programs reimburse for store and forward, an increase of one state (NV) since the Aug. 2016 edition. Hawaii's Medicaid reimbursement of store and forward has been postponed pending approval of a State Plan Amendment.

- Twenty-two state Medicaid programs provide reimbursement for remote patient monitoring, up three states from Aug. 2016. Kentucky's law has not yet gone into effect, and Hawaii's' law hasn't yet been implemented.

- Nine state Medicaid programs (Alaska, Arizona, Hawaii, Illinois, Minnesota, Mississippi, Missouri, Virginia and Washington) reimburse for all three, although certain limitations apply. This is an increase of two states since Aug. 2016.

7.3   Technical difficulties

Telemedicine and eHealth need high speed Internet connections for many applications. This is a difficulty for deployment in the USA and rural and disadvantaged populations cumulate difficulties. Indeed, even Internet connections are rare in some areas: despite the USA being the third country in the world for total number of connected people, they rank only 40th in terms of proportion of connected population: in 2015 25% of Americans were not connected (this proportion is much higher than in most EU member states). According to the Report of the U.S. Department of HHS to Congress [1], the Federal Communications Commission (FCC) reports that 53% of rural Americans (22 million people) lack access to benchmark service (3-25Mbps). This represents a slim majority of rural Americans and broadband access is still severely underdeveloped on many Indian reservations. Moreover, the price of broadband services can be three times higher in rural areas than in urban areas. The federal Broadband Opportunity Council makes efforts but application for economic support is very complicated.

Of course, as it is the case in developing countries, mobile access situation is better and mHealth will be a way to improve healthcare services access. It should also be noted that powerful companies are confronting the problem of Internet wide band access at worldwide level – they are all American (Google, Facebook, SpaceX…). These remarks illustrate the US situation: strength due to global market size, inequality and difficulties due to the great proportion of disadvantaged areas and populations and also to state borders, private audacious and ambitious innovations.

8. Standards and Standards Development Organizations

To develop a coherent and open Nationwide Health Information Network, standards are necessary to ensure interoperability. This necessity is a cornerstone in all technical certifications for software and systems. However, it is not simple to remove legacy systems and a great part of existing information exchanges is always performing conversions between formats. Here, the role of industries associations and professional associations is paramount. A consequence of the US diversity is the development of these associations and their international strong influence. One has to remember that the standardization domain is also a conflicted one and that penetration of standards in a complex and complicated space is a slow process everywhere.

Some US SDOs have reached the status of partners in the official worldwide standardization system of ISO. Some of the most important are:

- Imaging: DICOM, from union between Association of American Radiologists (ACR) and National Electrical Manufacturers Association (NEMA)

- EHR: Continuity of Care Record (CCR) developed by the ASTM (standardization association), the Massachusetts Medical Society, the Healthcare Information and Management Systems Society (HIMSS), the American Academy of Family Physicians, the American Academy of Pediatrics. The CCR is a quite simple XML structure, which can be transported electronically but also printed – it was developed with physicians.

- HL7: now with affiliates in all countries except USA where the headquarters of the organization are located. Develops a whole system of model and messages and a general document structure, the Clinical Document Architecture. This is an example of divergence, manageable but at a cost, apparently conflicted in the USA, as HL7 has adapted the CCR in the CDA as transporter to produce CCD (document), which causes difficulties between CCR and CCD users.

Other notable standards setting organizations include IHE (worldwide) for workflow processes in Information Systems and Organizations, Continua (healthcare providers, communications, medical and fitness device companies) for connected objects, captors etc., LOINC for pathologists and laboratories – developed by a non-profit scientific association with the College of American Pathologists and the American Clinical Laboratory Association.

The world of semantic interoperability is not yet really concerned by current eHealth development, except for specific domains such as pathology. SNOMED CT has become a powerful international organization but is still limited principally to research and experimental or limited applications. Mainly, stakeholders already have to move to WHO ICD10. However, there is an important group at work in the Schema.org group. "Schema.org is a collaborative, community activity with a mission to create, maintain, and promote schemas for structured data on the Internet. In addition to people from the founding companies (Google, Microsoft, Yahoo and Yandex), there is substantial participation by the larger Web community, through public mailing lists such as public-vocabs@w3.org and through GitHub".

It is clear that the US standardization groups are powerful and credible associations, followed by professional and industry experts worldwide. However, their impact is still limited in the development of eHealth, even if their work is recommended in recent federal acts. Furthermore, new developments in eHealth are more directly international or coming from other countries. This is the case for genetics or for the Internet of things for instance.

9. Actors - towards managed care and eHealth?

Amongst all actors, the powerful Managed Care Organization is the natural breeding grounds for the development of eHealth, despite only between its members or the populations it protects and contracting partners.

9.1 Veterans

As previously mentioned, the VA was the first to implement some important solutions developed since 1994, the most recent one being the Blue Button. The VA is currently the largest provider of telehealth services in the country. [1]

The VA is especially praised for its efforts in developing **a low cost open source electronic medical records system, VistA**, which can be accessed remotely (with secure passwords) by health care providers and patients.[5] VistA consists of over 180 applications for clinical, financial,

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[5] started 1985, receiving high marks from HPs, notably since around 1995 *(see http://worldvista.org/AboutVistA, see also a description in Wikipedia)*

and administrative functions within a single, integrated database. With this system, patients and nurses are given bar-coded wristbands, and all medications are bar-coded as well. Nurses are given wands, which they use to scan themselves, the patient, and the medication bottle before dispensing drugs. This helps prevent four of the most common dispensing errors: wrong med, wrong dose, wrong time, and wrong patient. The system, which has been adopted by all veterans' hospitals and clinics and continuously improved by users, has cut the number of dispensing errors in half at some facilities and saved thousands of lives. The VHA has international ambitions to diffuse VistA worldwide *(see above the web site)*.

At some VA medical facilities, doctors use wireless laptops, putting in information and getting electronic signatures for procedures. Doctors can call up patient records, order prescriptions, view X-rays or graph a chart of risk factors and medications to decide on treatments. Patients have a home page that has boxes for allergies and medications, records every visit, call and note, and issues prompts reminding doctors to make routine checks.

The Senate has shown itself willing to **ease restriction on telehealth and mHealth for veterans**, especially those in rural areas. Currently, when care is delivered across state lines, both the doctor and the patient have to be in federal facilities. "The VETS Act will ensure that veterans can receive the timely and quality care they deserve from the comfort of their own homes including critical, and potentially lifesaving mental healthcare." (VA underscores that, for instance, "Iowa is home to more than 200,000 veterans, many of whom reside in more rural areas, distant from Iowa's VA facilities".

The VA has also launched a network of **Mental Health Telehealth Resource Centers** designed to tackle a growing population of veterans dealing with Post traumatic stress disorder (PTSD), chronic depression and bipolar disorder, among other issues. On the horizon are also a kiosk programme and a text-messaging programme for medication management aiming to accompany veterans towards the understanding and independent administration of medications.

Altogether, the VA oversaw 2.14 million telemedicine or telehealth visits in 2015, connecting more than 677 000 veterans with healthcare providers. The then-VA Undersecretary for Health According to David J. Shulkin, secretary of Veteran Affairs, more than 12% of the nation's 5.6 million veterans access healthcare through digital channels. This has helped to reduce the number of days that veterans spend in a VA hospital by some 56% and spawned more than 45 specialty telehealth platforms. The number of in-home video consultations with veterans has grown almost eight-fold in recent years.

Shulkin stated the VA was bolstering its online presence, with some 32 mHealth apps now available and an enhanced patient portal accepting secure messages from veterans to their providers, all designed to "encourage self-management among veterans."

According to the HHS Report to the Congress [1], *it is important to note some key distinctions between the VA and other health care settings, which facilitate implementation of telehealth: the VA is a closed system, with a defined patient population. Doctors are salaried employees and are not competing for patients. This structure promotes cooperation, coordination, and interoperability including a unified electronic health record system, which fosters better communication and continuity of care. This is more difficult to obtain in fee-for-service settings. Finally, the VA, by virtue of being "closed," is generally able to "regulate its own" providers. Unlike non-VA physicians who must be licensed in each state and credentialed by each separate institution where they practice, VA doctors are permitted (because of federal supremacy) to maintain just one active, unrestricted state license in order to practice in any VA facility in the states or the territories. Similarly, providers need only be credentialed once.*

9.2 Medicare, Medicaid and Telehealth

Medicare pays for a limited number of services furnished by a physician or practitioner to an eligible beneficiary via a telecommunications system. As a condition of payment, the professional must use an interactive audio and video telecommunications system that permits real-time

communication. Asynchronous "store and forward" technology is permitted only in Federal telemedicine demonstration programs in Alaska or Hawaii. All professionals are concerned: physicians, nurses, midwives, psychologists and social workers in some cases, dietitians or nutrition professionals. The list of paid services includes notably consultations, nursing care services, kidney disease education, individual or group diabetes self-management training, psychotherapy, pharmacologic management, home dialysis, nutrition, smoking cessation, sexually transmitted diseases education, behavioral therapy for cardiovascular disease etc.

Despite the launch of Telehealth services, Medicare spent approximately $14.4 million on services delivered via telehealth in 2015, representing less than 0.01% of total spending on healthcare services.

Medicaid is also a public supported programme, whose general rules are similar to Medicare and coordinated by the Centers for Medicare & Medicaid Services. The main difference is that criteria for being eligible to Medicaid varies with change of rules at federal level as well as more variations between states and with budget difficulties.

9.3 Private Insurers: the example of AETNA Telehealth

Commercial insurers that cover telehealth are focused on primary care. Several commercial insurers, including some of the largest insurers in the United States, have been using telehealth services more regularly in recent years. Insurers stated that their rationale for implementing telehealth services was multifaceted: improve quality, expand access and convenience, and reduce costs, particularly for underserved areas. Some also stated that clinicians were requesting the ability to use telehealth. In addition, several insurers contended that telehealth services are more compatible with capitated payment models because capitation controls the risk of overuse (in capitation model, a HP or an HcP is payed according to the number of people he takes in charge, independently of the number of acts he performs.)

Telemedicine parity laws are state laws that require private payers to reimburse telemedicine services the same way they would for in-person medical services. In 2015, 29 states plus DC had passed telemedicine parity laws. 8 others were discussing it. Of course, this depends also on the contract.

Apart from telemedicine, a first mHealth application is location. For example, an Aetna member can (and has to) find with his smartphone, anywhere in the USA, which doctor, dentist or other professional is not far and can be visited under his contract.

Like many insurers, after resisting to telehealth which seemed not controllable, Aetna is moving fast to the "telehealth visit". The process for companies having chosen Aetna in their health plan is as follows: employees complete their medical history and can request telephone or video consultation to a physician of the network, which they obtain in around one hour – the physician accesses EHR and can send a prescription to the employee' pharmacy of choice and consultation information is made available to the employee's doctor. The employee is charged according to his benefit plan.

9.4 Towards integration: HMOs

Strategies and even objectives differ according to the HMO and to the category of population they cover.

- **Blue Shield Blue Cross (originating in Massachusetts): a practical approach for non-critical needs, relying on a commercial specialized platform**

Telehealth enables employees to visit with a board-certified doctor by phone 24/7/365. The operator's doctors can provide consultations and they can treat many non-emergency medical

and behavioral health conditions, deliver counselling. They write and send prescriptions (when appropriate) to a nearby pharmacy. Employees can select the last doctor they met with or search for a new one.

- **Intermountain (originating in Utah): a specific objective: rural population and its local providers, with an internal platform**

This HMO first motivation is to increase healthcare access for those living in remote communities. In 2014, Intermountain TeleHealth Services was created in response to the following challenges: aging population, increased numbers of high-needs patients, shortage of medical providers, reforms to reimbursement systems, requests from rural hospitals for clinical expertise and support. Intermountain telehealth includes direct-to-consumer, remote patient monitoring and clinician-to-clinician services such as intensive care.

Since 2016, a team of 22 intensivists and 20 critical care nurses at Intermountain Critical Care Support Centre in Midvale, Utah directly works with local medical teams to care for intensive care units patients. Local providers connect with specialists in both Intermountain and outreach facilities; patients can gain immediate access to urgent care through Connect Care, a mobile app that can be downloaded on any personal electronic device. Intermountain providers can diagnose and prescribe certain medications through Connect Care, or refer patients to a provider for a face-to-face consultation if their condition can't be treated via telehealth.

In 2017, Intermountain introduced large-scale remote patient monitoring for various patient populations. These telehealth provider programs will include patient-generated data produced by wearable. These developments concern chronic obstructive pulmonary disease and cardiovascular conditions, then diabetes and other conditions.

Most patients can access their EHR directly through a portal; this allows sharing the same EHR system between physicians and patients.

- **Kaiser Permanente (originating in California): a cautious approach in this technically powerful state, first on documents and mail and only recently virtual visits**

"More than half of the interactions between Kaiser Permanente physicians and members in 2015 were conducted virtually", according to CEO Bernard Tyson. Indeed, members used Kaiser's digital health tools to view 37 million tests results, send 20 million emails to providers, refill 17 million prescriptions, and schedule 4 million appointments. Since 2016, "members are flocking to virtual visits".

9.5 The role of big providers

The objectives of a powerful provider concern more organization and efficiency of the patient pathway and professional training.

- **Example: The Mayo clinic (non-profit, biggest US "Health Care System" – Minnesota) – combining nurses experience, providers skills and knowledge, evidence based algorithms.**

The Mayo Clinic has been building since 2012 a telehealth triage system for ambulatory primary care, based on a team model for community care. The system organizes the different actors around the pivotal role of the telehealth triage nurse. On a phone call, "virtual centralization" utilizes triage nurses at different locations within primary care. The "complex patient programme" implements a reliable process for the management of complex patient care needs within the care team. The "Secondary Triage Additional Resource" (STAR) provider programme uses a secondary provider covering all sites while maintaining nurses' autonomy. Combining the

expertise of the telehealth triage nurses with the provider's clinical skill and knowledge has successfully expanded the services to provide more non-visit care and patient centred advice beyond the triage algorithm tools, while improving access and reducing emergency department visits. Most of the sites have access to an electronic display board showing triage RNs and STAR providers who are currently logged into the system.

More than 152 000 calls have been managed in 2016.

Telehealth nursing is a subspecialty of ambulatory care through the American Academy of Ambulatory Care Nursing and the American Nurses Association.

9.6 The powerful US Associations

An ancient characteristic of the USA is the role of multiple associations in all domains. Be it citizen organisations, or scientific, technical, professional industrial etc., they are most often respected and credible. It has to be noted that the trend in Europe, for instance, is towards more importance given to this type of organizations, which could become partners of the administrative system. Moreover, the Internet and social networks reinforce this trend. Hence, the role of associations should not be underestimated in take-off of eHealth in the USA. Under various forms, they are at work in most of the developments. They participate in the preparation of the main federal acts and regulations, they support and promote their application, they even validate and deliver certificates of conformity. They are the main actors in SDOs, communication and congresses as seen above (HIMSS, ATA…). There are associations for all different stakeholders, scientific societies, specific diseases, domains (for instance the huge American Public Health Association-APHA), etc. Very often, there are competing associations and conflicts. Many of them associate professionals, providers, users, industry. Super associations regroup wide range of organizations, as eHealth Initiative, HIMSS, ATA.

Associations also act together in difficult environments, such as the public hospitals domain. A typical example in telehealth concerns the key aspect of Rural Health stakeholders associations which are very active: American Hospital Association, American Hospital Association Rural Health Care, Critical Access Hospitals Centre, Disproportionate Share Hospitals, National Association of Community Health Centers, National Association of Rural Health Clinics, National Rural Health Association, Rural Health Clinics Centre, Rural Health Information Hub.

It has to be noted that many associations are extremely powerful and play a critical role without depending mostly on public financial support. This is due to the size of the country and the number of members, the cultural and fiscal traditions that allow them to receive donations, to associate fees for services to non-profit work, to associate industry and users in generally clear and transparent relationships – despite some conflicts sometimes happening as seen for instance in physicians states inscription. Citizens, professional, scientific, stakeholders association really play a critical role.

10. General situation - Fast advance in new technologies and in new risks?

10.1 Fast progression has started

Lately, Telehealth, eHealth, mHealth really started to progress, as seen above, in all segments of the US healthcare system, despite it being still fragmented and even contrasted. This is the case in the public sector, in non-profit and in commercial insurance systems.

In 2016, the U.S. Department of Health and Human Services presented a Report to the Congress on eHealth and Telemedicine.[1] This report noted that :

> "Accelerated by passage of the Affordable Care Act (ACA), health care delivery in the United States has been undergoing rapid and significant transformation. In addition to

expanding coverage to millions of previously uninsured individuals, the ACA ushered in a new era of delivery system reform (DSR) driven by payment models that emphasize value over volume and encourage greater coordination across the 59care continuum."

…

Technological evolution has accelerated the deployment. "For instance, it is estimated that sixty-one percent of health care institutions currently use some form of telehealth 5, and between 40 and 50 percent of all hospitals in the United States currently employ some form of telehealth.6 This figure includes rural/critical access hospitals, academic medical centers, and urban institutions. In 2013, the market for telehealth generated annual revenue of $9.6 billion, a 60 percent growth from 2012.7 Moreover, the ubiquity of internet- linked mobile computers, such as iPads, and video platforms, such as Skype, enable "direct" consultations between providers and patients located hundreds of miles apart."

…

HHS' largest telehealth investments are in the form of payments for health care services through Medicare, Medicaid, and the Indian Health Service (IHS). Other HHS Operating Divisions include Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH). Office of the national coordinator (ONC) also support telehealth activities, the development of mobile technologies (such as remote sensors), or research that assesses the effectiveness of care delivered remotely. As seen above, the VA is the largest provider of telehealth services.

…

Over the last several years, the majority of work by the Federal Government on the issue of telehealth has been monitored by an interagency task force established by the Health Resources and Services Administration's (HRSA) Federal Office of Rural Health Policy (FORHP). The Federal Telemedicine Working Group (FedTel) was established in April 2011 to help discuss and reduce organizational silos, facilitate telehealth education and information sharing amongst members, and summarize key telehealth activities of the participants. The current membership includes over 100 participants from 26 agencies and departments

…

The report also concludes there is insufficient evidence to judge the cost -effectiveness of telehealth broadly. However, between 2009 and 2015, the vast majority of patients (89-95 percent) reported satisfaction with their care experience

…

In the Report, the Department of HHS proposes easing restrictions for Medicare services that have now obligation to be provided exclusively through face-to-face encounters.

10.2 EHR

"Electronic health records (EHR) are not a new idea in the U.S. medical system, but surprisingly there has been very slow adoption of fully integrated EHR systems in practice in both primary care settings and within hospitals."

Progression started accelerating around 2010. Around 2005, nine out of ten doctors in the U.S. updated their patients' records by hand and stored them in color-coded files. By the end of 2017, approximately 90% of office-based physicians nationwide will be using electronic health records.

Some figures reveal aspects of this fast progression, supported by the ONC Regional Extension Centers (RECs) programme that provides practical assistance to meet the needs of local healthcare providers (see 6.2):

Between 2008 and 2015, office-based physician adoption of an EHR has nearly doubled, from 42% to 87%. 78% used a certified system.

In March 2017, 67% of all providers reported using an EHR, a 1% increase over September 2016. (includes hospitals and small clinic and local providers)

As of March 2014, eligible providers participating in Meaningful Use have received $22.9 billion in EHR incentive payments since the programme's first payout in 2011. Roughly 45% of providers reported spending more than $100,000 on an EHR. This figure is to be compared to total spending on electronic systems by providers in 2015, estimated $37 billion.

10.3 Is fast progression unsecure?

It seems that the progression of eHealth applications has very often compromised Information Systems security. Many factors have to be considered, not only the very visible hacks and attacks, real but emphasized by the media. Many EHR breaches are mainly due to human errors, which means that education and training of professional and employees need to be developed. A consequence is the reinforcement of the number of physicians fearing danger for their patients' privacy and hence their own responsibility.

In February 2015, health insurance giant Anthem made history when 78.8 millions of its customers were hacked. It was the largest health care breach ever, and it opened the floodgates on a landmark year. More than 113 million medical records were compromised in 2016, according to the Office of Civil Rights (OCR) under Health and Human Services.

The other threat concerns connected medical devices (internet of things); there hasn't yet been effective attacks but experiments have proved it is quite easily doable (for example connected pacemakers that can be blocked by a distant attack, equipment like injection pumps…).

Confronted to this situation, the Government refined the key acts: HIPAA and HITECH, with intervention of the FDA for medical devices security.

10.4 New research and new approaches

Experience has proved that US IT companies, however powerful in the world market, did not succeed developing national and international health services, data repositories and other applications. Of course, they have been a huge stimulator for development of mHealth but they retreated to technical support functions.

Building on their technical and economic power and wide market presence, they now enter strategic domains: data treatment and big data analysis, genomics, artificial intelligence diagnosis, research. In this domain, some new approaches are tested – for example Apple Research kit allows researchers to create large bases of patients using iPhones, with the consent of the patients. Once again, for ethical but also scientific reasons, those experiments have to, and will, evolve (for instance, the fact that the Kit runs only on iPhones introduces high bias, genome analysis gives only risks and neglects other factors etc.).

- III -
Main conclusions

11. eHealth in the USA : fragmentation vs communication

eHealth development in the USA depends on conflicting factors: growing need to reduce inequalities and develop universal access, strong fragmentation forces to maintain States characteristics as well as private actors (for profit and non-profit) specificity and position, growing necessity or communication as in all countries, to allow for continuity of care in space and time. A consequence is that key conditions for eHealth are very often initiated or supported by the national government and by associations.

This is why, quite surprisingly, a real take off of eHealth has been difficult. eHealth can benefit from the dynamics of the US economy but it is associated with laws and regulations which are themselves related to generalized social protection and equity. This has been the case in many countries but is still widely controversial in the USA.

11.1 Main diffusion mechanisms

eHealth tends to be developed inside organizations that are totally or partially independent of states and regulated or managed at federal level – the typical case is the Veterans Health Administration (VHA). With differences according to states, this is also the case for Medicare and Medicaid.

Other important actors are non-profit huge organizations: mainly HMOs.

Others systems depend on private insurers, that were not really eager to enter in unsure markets with possible juridical difficulties – critical in US Healthcare.

From regulated federal organizations, from private associations, or from other initiatives, new ideas emerge frequently. Then, the government writes or modifies Acts and submits them to the Congress. If adopted, the concerned laws and regulations, if not related to federal supremacy (as VHA or public health), are submitted to states Parliament and can be rejected in some states or modified according to State laws.

This makes for fragmentation with two factors: type of population and social protection on one hand and states legal systems on the other.

Another mean of eHealth development is to propose systems and let people ask for them (Blue Button).

However, eHealth development has started accelerating since 2009, under pressure from citizens, from associations and also, as in all industrialized countries, because of evolution towards more chronic diseases, greater elderly population, technical possibilities for home eHealth. Diffusion of EHRs is now more and more effective. Telehealth services are more and more reimbursed in the diverse insurance systems.

11.2 A general problem: continuity of care and freedom of choice

The difficulty for the US system, be it at federal or states level, appear to be similar to what is encountered everywhere: there is a certain level of contradiction between continuity of care and universal access with freedom of choice for patients. This difficulty is at the heart of eHealth.

This is of course especially true in the USA as there is always a close relationship between financial system or protection system, enterprises health plans and healthcare providers.

More and more, citizens choose a provider only among those that are authorized or recommended in their insurance contract. Those who are not covered in health plans and who cannot afford private insurance service are constrained inside the authorized providers for VHA Medicare, Medicaid.

At the very least, the national formula is to define common functional and technical rules for important data management platforms and tools, such as EHRs (mandatory) or Blue Button (non-mandatory).

11.3   A world success: public health

Due to federal supremacy and to the culture of scientific data massive management, public health research and policy as operated by the CDC and applied with cooperation of all concerned parties and citizens has obtained spectacular successes, even at world level (tobacco, asbestos have been identified as deadly after long population research and massive data analysis, work on epidemic diseases have fostered international programmes). However, this is not the case for general public health and everyday way of life, which rely on states and local communication.

11.4   The American diversity

One must remember that the US is a very vast country with very different territories but also very diverse communities, with few rules constraining everybody's way of life – as for instance the existence of Amish communities in the country can attest. This acceptation of difference concerns also health organizations. One can find, in the country of free enterprise, an organization such as the Veterans Health Administration that many praises because of his somehow "socialist" organization and methods. *(see II 9.1)*

12.   Good practices

Even if there are great differences between organizations and behaviours between the USA and EU countries, there are also profound similarities between the obstacles to be lifted, that are related to citizens and HPs trust and to institutions organizational rigidity. In that domain, it is very interesting to consider systematic good practices applied by the US Government or spontaneously by the US population: synergy between public incitation, citizens actions, powerful associations - charitable as well as technical, grouping HcPs, HPs, citizens, industry etc.

A typical example is the Blue Button programme and its development.

Thus, national programmes as HIPAA or, still under harsh discussion, ACA eventually find an equilibrium decided upon by all actors.

- IV -
Potential for cooperation

13. Main domains and axes for exchanges and cooperation

The USA is really the Union of 50 very independent states plus special territories, special communities (e.g. Indian tribes) etc. From that point of view, there are already many eHealth systems that follow common rules and share common data at the Nation level and are managed and controlled by the Federal Government.

For EU members in the eHealth Network, there is a great potential in exchanges with the USA, on an equal basis. There are already strong reciprocal influences but it should be better regulated and coordinated. Especially, in international standardization, it is necessary to correct structures until the European members can launch projects, open domains as well as the USA. In the domain of data analysis and epidemiology, cooperation is already strong and could probably be developed.

For continuity of care, patients access, digitization of hospital information systems, new start-ups, the best achievements are very often in Europe (this has been discussed with US specialists and analysts, as for instance International Data Corporation (IDC); many US managers and associations come to Europe to see European best hospitals for internal and external access for patients and professionals. Many European counterparts come to the US for exchanges. Time has probably come for systematic collective policy, building on these numerous existing relations.

14. Programmes and projects

The following paragraphs use basic elements of the provisional grid described in the D8.1.4 main document (II – 12.3). There are four categories:

- Learn: the project is a rich source of information for a country confronted to similar problems or working in a similar international action

- Mutual enrichment: development of exchanges between project actors and concerned parties among eHN MS, active in similar projects in their country or abroad.

- Help and support: which can be technical, promotion, financing.

- Participation: co-construction of the project and similar ones.

Due to the fragmented nature of the USA system and the development of semi-isolated ecosystems, the national programmes as ObamaCare or SDOs works are at the same time well known and defining general orientations and rules. Here, few projects are detected, which are mostly driven inside one of the great ecosystems.

14.1   Patient empowerment

Blue Button – *2010 (see 6.5)* – this is the example of a worldwide known project that has evolved from a VHA practice to become an evolving wide voluntary national programme.

> Objective for following
>
> Now Learn, soon Mutual enrichment: Blue Button is now a base for services and applications. Many EU MS prepare launch of similar system. At the same time, impressive challenges appear, due to the international nature of many stakeholders and different legislations, notably concerning organization of healthcare systems and privacy. It seems that eHN scrutiny necessitates a permanent effort.

14.2   Veterans Health Administration Projects
(see 2.1)

Being based on an Information System and Organizational Model not far from EU members ones, VTA manages many projects where cooperation could be fruitful. A flurry of mHealth applications have been developed. Most of them are oriented towards patient empowerment.

Medical records system VistA – *(9.1)*

> Objective for following
>
> Mutual enrichment or Participation: Studies and cooperation are already numerous. Moreover, the VHA has created the WorldVista non-profit corporation.

Mental Health Telehealth Resource Centers for patients with Post traumatic stress disorder (PTSD), chronic depression and bipolar disorder…. 2016 – *(9.1)*

> Objective for following
>
> Mutual enrichment: psychiatric diseases in a wide sense are one of the most validated eHealth and mHealth successes, to complement face to face treatments. VHA applications are ancient and coordinated.

Kiosk and text-messaging for medication management - 2016 envisioned – *(9.1)*

> Objective for following
>
> Learn: objective is to help patients while driving them to better control of their medication.

Enhanced patient portal accepting secure messages from veterans – 2009 – *(9.1)*

> Objective for following
>
> Learn: it would be very useful to see how the portal evolves, what indicators have been developed and followed and what impact can be evaluated.

14.3   Private programmes

Intensivists and nurses - Intermountain Critical Care Support Centre – 2016 – (9.4)

Objective for following

Learn: It is important to note that, instead of working with specialized tele health company, Intermountain work with local HPs in connection with intensive care units.

Intermountain patient monitoring including data produced by wearable – 2017 *(9.4)*

Objective for following

Mutual enrichment: key for NCD patients home and mobile follow-up.

The Mayo Clinic telehealth triage system for ambulatory primary care – 2012 *(9.5)*

Objective for following

Learn: Triage is everywhere important to organize the patient path. The role of the nurse has been recognized. It is important to see how it works – as it is started in 2012 and the Mayo clinic is a powerful and well managed actor. In particular see evaluations and evolution.

AETNA Telehealth visit – 2014 *(9.3)*

Like many insurers, after resisting to telehealth which seemed not controllable, Aetna is moving fast to the "telehealth visit". The process for companies having chosen Aetna in their health plan is as follows: employees complete their medical history and can request telephone or video

- V -
Key sources

Most data in this document have been gathered in different Web sites and numerous reports as well as long time contacts with USA relations. The following references concern synthetic documents which give an organized view from official structures or universitary specialists.

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