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INFORMATION PAPER

on

supporting preparatory convergence meetings between the eHN and WHO

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
AECID	Spanish Agency for International Development Cooperation
AFRO	World Health Organization – Africa Regional Office
AIOTI	Alliance for Internet of Things Innovation
ALAC	At-Large Advisory Committee of Internet Corporation for Assigned Names and Numbers
AMRO	World Health Organization – America Regional Office
CoIA	United Nations Commission on Information and Accountability for Women's and Children's Health
EASA	European Authority on Aviation Safety
eHSCG	eHealth Standardization Coordination Group (ITU)
eHTAG	WHO eHealth Technical Advisory Group
EMRO	World Health Organization – East Mediterranean Regional Office
EpSOS	Smart Open Services for European Patients
GAC (ICANN)	Governmental Advisory Committee of Internet Corporation for Assigned Names and Numbers
GOe	WHO Global Observatory for eHealth
gTLD	generic top-level domains
HEALTH	.HEALTH is an industry-specific TLD (top level domain) owned by the Canadian company TUCOWS
HIE	Health Information Exchange
HIV	Human immunodeficiency virus
HL7	Health level Seven (Standard devlopment Organization)
HON	Health on the Net Fundation
ICANN	Internet Corporation for Assigned Names and Numbers
ICD	International Classification of diseases (WHO)
ICF	International Classification of Functioning, Disability and Health WHO)
ICHI	International Classification of Health Interventions (WHO)
ICPC-2	International Classification of Primary Care, 2nd Edition
IDMP	Set of five ISO norms for Identification of Medicinal Products
IDRC	International Development Research Centre (Canada)
IDSR	Integrated Disease Surveillance and Response
IHE	Integrated the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IMIA	The International Medical Informatics Association
Io (ICANN)	Independent Observer of Internet Corporation for Assigned Names and Numbers
IoT	Internet of Things
ISfTEH	International Society for Telemedicine and eHealth
ITU	International Telecommunication Union
ITU-D	International Telecommunication Union- Telecommunication Development Sector
ITU-R	International Telecommunication Union – Radiocommunication Sector
ITU-T	International Telecommunication Union- Telecommunication Standardization Sector
JAA	Joint Airworthiness Authority
JAR	Joint Aviation Requirements

LDC	Least Developed country
LMIC	Lower and middle income country
LOINC	Logical Observation Identifiers Names and Codes
MCH	Mother and Child Healthcare
MDR-TB	Management of multidrug-resistant tuberculosis
mhGAP	WHO Mental Health Gap Action Programme
MMS	Mortality and Morbidity Statistics
Mterg	WHO mHealth Technical and Evidence Review Group
NCD	Non Communicable Disease
OECD	Organisation for Economic Co-operation and Development
PAHO	Panamerican Health Organization
PANACeA	PAN Asian Collaboration for Evidence-based eHealth Adoption and Application
PCHA	Personal Connected Health Alliance (Ex Continua Health Alliance)
PHS	Personal Health System
RFE	Reasons For Encounter
RMNCH	Reproductive, Maternal, Newborn and Child Health
SDMX	Statistical Data and Metadata eXchange
SDO	Standards development Organization
SEARO	World Health Organization - South East Asia Regional Office
SNOMED-CT	Systematised Nomenclature of Medicine-Clinical Terms
TB	Tuberculosis
TSAG	ITU-T Telecommunications standardization Advisory Group
UDI	Unique Device Identification
UIFN	Universal International Freephone Numbers
UNDP	United Nations Development Programme
WHA	WHO World Health Assembly
WHO	World Health Organization
WHOCC	World Health Organization Collaboration Center
WPRO	World Health Organization - West Pacific regional Office
WTSA	World telecommunications standardization assembly (ITU-T)

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1. Introduction: context, objectives and scope

Since the beginning of this century, eHealth -and more globally the impact of digitalization on the health sector- has become progressively an issue of strategic importance which has questioned Governments and major EU and international organizations. Each organization has thus launched a number of initiatives, within the premises of their mandate and governance, to provide MS with information which could accelerate sharing of knowledge and best practices, and hence support the development of adequate policy and implementation. Given the complexity and number of actors at stake, a few actions have also focused on attempts to create the fora and/or structure which could improve coordination on aspects considered of critical importance for the global eHealth ecosystem.

During the meetings of the eHealth Network, representatives of MS have repeatedly stated that having a global understanding of those initiatives, their purpose, status, resources and results, was particularly challenging.

The principal objective of the WP8 "global cooperation and positioning" is thus first of all to provide a synthetic and critical overview of the initiatives related to eHealth undertaken by the major international organizations to date.

The deliverables produced by WP8 have thus as main objectives:

- To put in perspective the initiatives related to eHealth undertaken by each major organization (and notably the OECD and WHO).
- To identify the main resources available developed by each organization and describe their possible added value for the members of the eHealth Network.
- To identify the main gaps and overlaps between organizations and therefore suggest areas of improvement taking into consideration the mandate, governance and resources of each organization.
- To propose short and medium terms actions or initiatives in order to make better use of the existing, optimize the complementarity of work between all organizations and set the basis of a basic global action plan shared by all organizations. The plan would first be discussed within the premises of the eHealth Network.

2. Methodology

The decision to split the work of WP8 in four different reports is contractual. However, each deliverable will respect roughly the same structure in order to allow easy future consolidation.

Organizations and countries have been selected based on at least one of the following criteria:

- Documented work on eHealth of possible value for members of the eHealth Network
- Possible normative or referential role of the organization, and thus possible impact on eHealth policies and strategies
- Degree of involvement in major projects developed by international organizations
- Current achievements and impact of national strategy on regional/international agenda and priorities

The information collected for each organization/country is first provided in a descriptive way in order to better apprehend the context, purpose and ambition of each initiative. The main relevant outputs are then synthesized according to a pre-defined broad categorization (policy support, reference database, discussion paper, guideline, toolkit, thematic report, recommendation) and in order to:

- Make possible the grouping of those outputs by categories.
- Consider the possible common future feeding of strategic information sources.
- Base the recommendations on grounded materials.

3. Synthetic presentation of the World Health Organization (WHO)

WHO eHealth Unit
Service Delivery and Safety
Health Systems and Innovation
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland
Email: ehealth@who.int
Website: http://www.who.int/ehealth/about/en/

3.1 Introduction and background

The World Health Organization (WHO) is the United Nations' specialized agency for health. It formally came into existence on 7 April 1948. Its work is governed by the World Health Assembly and the Executive Board and is carried out by the Secretariat.

The constitution of the World Health Organization provides the following definition of health as its first principle: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity." The objective of the World Health Organization is the attainment of the highest possible level of health for all people. Given its mandate, WHO focuses however more on **population** than individuals with as a corollary a specific emphasis on **public health**.

Figure 1 : Health in the Sustainable Development Goals era

WHO defines its role in public health as follows:

1. Providing leadership on matters critical to health and engaging in partnerships where common action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity; and
6. Monitoring the health situation and assessing health trends.

eHealth is a strategic facilitator for each of those roles. Many of the tasks historically devoted to WHO are thus impacted and need to be realigned with the vision of a widely connected (health) world and the critical need to align finalities (Public health, healthcare, research, etc..) which previously were each dealt with separately. At its own level, WHO is confronted with the necessity to get out of its usual zone of comfort and, given its governance and (limited) resources, to identify the strategic needed partnerships which should allow the organization to keep its overall coordinating role.

From a formal point of view, eHealth is part of the "health systems (and policy)" component which has the following objectives:

- Improving policies, plans and health financing strategies aimed at moving towards **universal health coverage**
- Increasing access to **integrated, people-centred health services** through different models of care delivery and safety and quality assurance strategies.
- Improving **access to**, and rational use of, safe, efficacious and quality **medicines and other health technologies**
- Enabling **well-functioning health information, eHealth, research, ethics and knowledge** management systems

The organization also develops and promotes the use of evidence-based tools, norms and standards to support Member States (MS) to inform health policy options. It oversees the implementation of the International Health Regulations, and publishes a series of medical classifications; of these, three are overreaching "reference classifications": the International Statistical Classification of Diseases (ICD), the International Classification of Functioning, Disability and Health (ICF) and the International Classification of Health Interventions (ICHI).

In terms of health services, WHO looks to improve "governance, financing, staffing and management" and the availability and quality of evidence and research to guide policy making. WHO -working with donor agencies and national governments – aims also to improve their use of and their reporting about their use of research evidence.

3.2 WHO resources and priorities

This section aims to help the reader not familiar with WHO internal governance to understand how resources are collected and priorities decided upon. It provides a number of details which can be disregarded by the reader more familiar with the issue.

Until 1998, WHO budget allocation was mainly based on initial allocation and previous practice and not objective criteria. The resolution WHA51.31 (May 1998) recommends that allocation of resources draws upon UNDP's Human Development Index, possibly adjusted for immunization coverage and incorporates population statistics of countries.

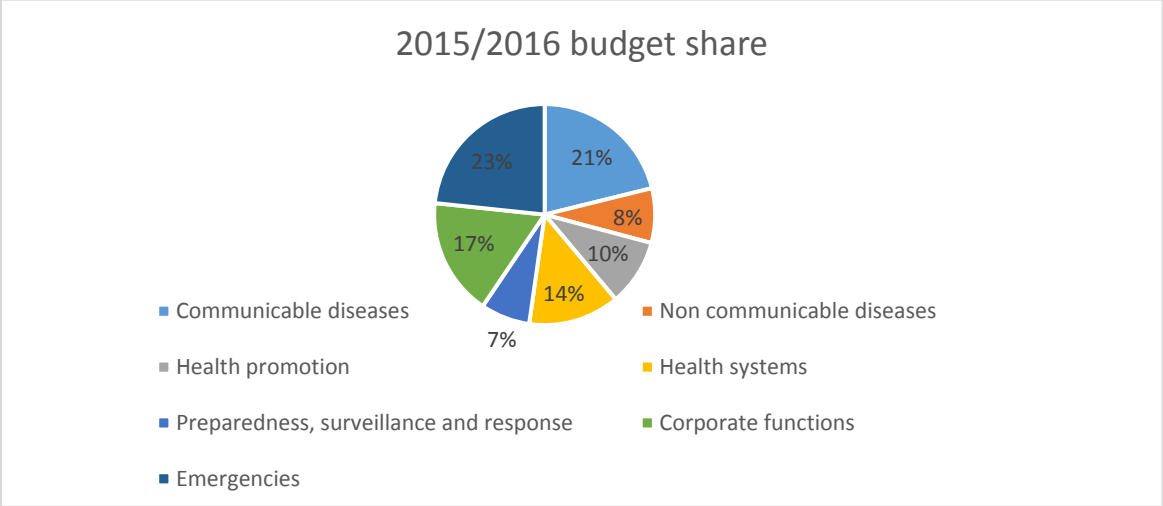


Figure 2 : Share of WHO 2015/2016 Budget (Gross categories)

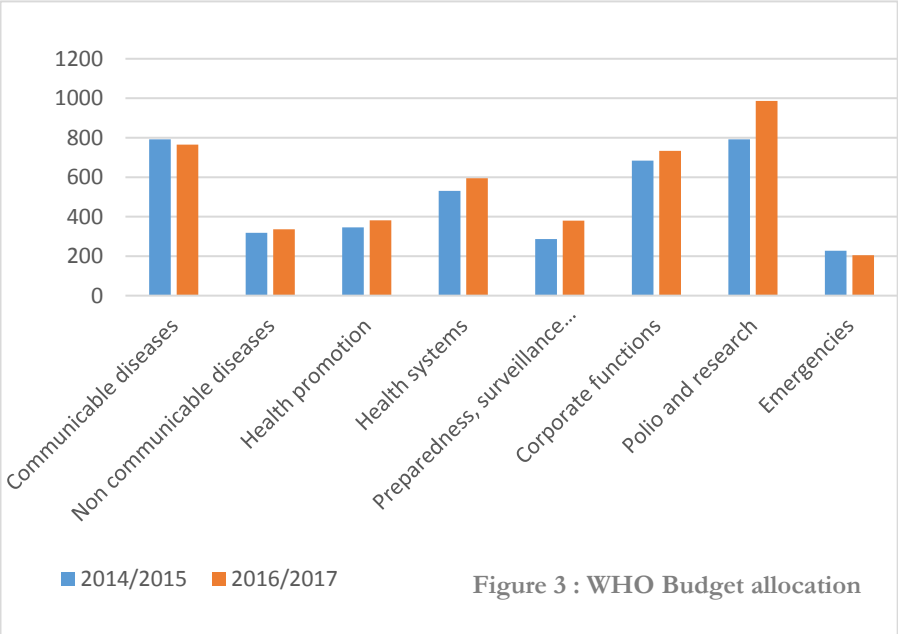


Figure 3 : WHO Budget allocation

The result in financial terms over the period 1998-2004 was an increase (assessed contributions) in the share of the African Region from about 28% of regular budget allocations in 1998-1999 to around 34% in 2004-2005. The share of the European Region increased from about 9% to 10% over the same period. The allocations of the remaining four regions were reduced in order to accommodate these increases. This proved however unsatisfactory and the 2004 World Health Assembly requested that the guiding principles be based on more objective criteria, applied to funds from all sources (assessed contributions **and** voluntary contributions), and that the principles of equity, efficiency and performance, and support to countries in greatest need, in particular least developed countries, be considered.

In January 2006, the Executive Board endorsed then a new set of guiding principles and validation mechanisms for a results-based budget framework that included all sources of funds. The 2006 model however fell short of expectations. priorities were largely driven by available resources, outputs did not always reflect a clearly defined division of labour across the three levels of the Organization (Fixed component 43%, engagement component 2%, needs component 55%)[1] , and performance was not an explicit criterion in resource allocation. These issues, coupled with a changing world environment have led to the request by the World Health Assembly in May 2013 for (again) a new approach to strategic resource allocation. From then on, allocation is based on (past) implementation capacity, grounded on agreed-upon Organization-wide deliverables and programme shifts in health priorities.

[1] A fixed component of 43% (28% for Headquarters; 15% for regional offices) to finance normative and statutory functions; an engagement component of 2% towards regional functions, the costs of which vary according to the number of countries served and a needs-based component of 55% based on relative health and socioeconomic status along with a population factor.

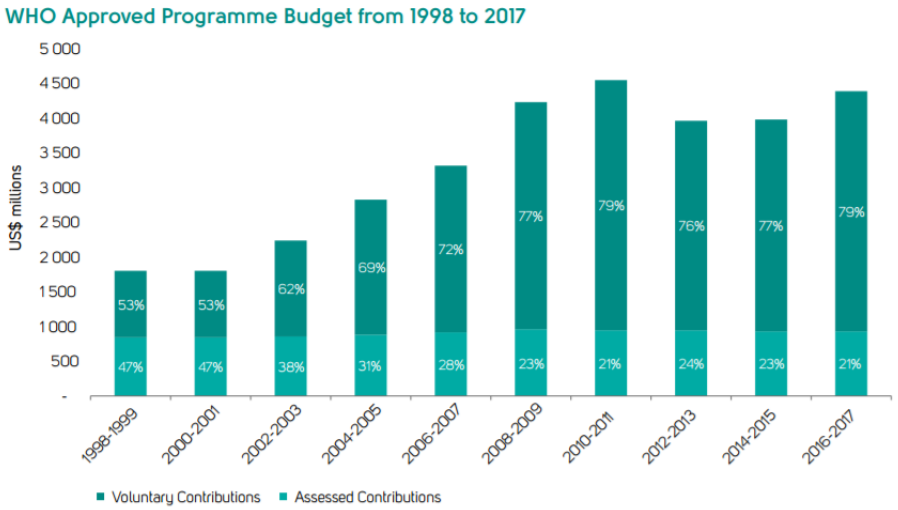


Figure 4 : WHO approved budget from 1998 to 2017

The 2014/2015 proposed budget of the WHO was about US$4 billion.[1] About US$930 million were to be provided by MS with a further US$3 billion to be from voluntary contributions. The major contributors are the United States ($110 million), Japan ($58 million), Germany ($37 million), United Kingdom ($31 million) and France ($31 million). The proposed programme budget 2016–2017[2] amounts to nearly US$ 4400 million overall. Assessed contribution 929 – 21.2%and voluntary contributions 3456- 78.8%) This budget builds on lessons learnt in 2015, mainly the Ebola crisis, a focus on universal coverage (Malaria, Reproductive health, NCDs) and new emerging threats (resistance, ageing, dementia...).

With a budget increase funded exclusively from voluntary participations (from 53% in 1998 to 79% in 2016), one can observe an overall pressure to reorient efforts on Millennium Goals versus global role in designing health programmes and health systems and in designing norms and standards (e.g. trade disputes…). The creation of a new independent financial instrument, the Global Fund for Tuberculosis (TB), malaria and HIV-Aids, which at the end of 2015 had accumulated since its inception in 2002 33 billion US$ contributions has however somewhat reduced this pressure although WHO remains "structurally" limited in implementing new endeavours which require significant long term investment.

Since 2011 WHO has initiated a global reform with the objective to better reflect and monitor priorities, improve management, accountability and emergency response. The creation of a specific agency or entity has however often been the response provided by the Institution to give the issue the attention it believes it should grasp. With the creation of the global observatory for eHealth in 2005, eHealth is here no exception. The budget specifically allocated to eHealth remains however rather modest with the more resource intensive, technically oriented or operational work being today implemented in cooperation with (but under the leadership of) ITU. Altogether WHO main **independent** input to date is thus related to the organization of world surveys, their analysis and their dissemination.

2 http://who.int/about/finances-accountability/budget/PB201617_en.pdf and http://www.who.int/about/finances-accountability/funding/financing-dialogue/Programme-Budget-2016-2017-Prospectus.pdf?ua=1

3.3 WHO and eHealth positioning- a brief history

eHealth is per se a transversal and transformational issue. It can support most of the WHO Public Health priorities but is mainly dealt with under the "health policy" section. From WHO point of view, eHealth can ambition to support a **wider access to services and knowledge** and has thus the potential to break a number of fundamental internal and external barriers. More fundamentally, the strengthening of health systems through eHealth may contribute to the enjoyment of fundamental human rights by improving **equity, solidarity, quality of life and quality of care.**

The first formal reference of WHO to eHealth dates back to **December 1997** when it convened an international consultation to prepare input on "telematics" for WHO's **health-for-all policy for the twenty-first century**. As a result, the Resolution WHA51.9 (1998) sets out lines of action in relation **to cross-border advertising, promotion and sale of medical products through the Internet**.

It is however only in **December 2003** that eHealth is shortlisted as a topic to be discussed at the World Summit on the Information Society (Geneva, December 2003). WHO's Secretariat had prepared a draft strategy for eHealth that would serve as the basis for coordinating both eHealth policies internationally and WHO's activities on eHealth. It indicates ways of providing support to MS in the use of eHealth for **public-health purposes, health-care delivery, capacity building, and governance**. It also includes **eLearning** for the public, meaning, in this context, the use of any electronic technology and media in the support of learning.

eHealth is also seen as an opportunity for **faster and more comprehensive epidemiological surveillance** and thus the need for a **global approach to handling data flows** requiring standardization and low-cost services.

WHO stresses however that, in particular for low income countries, Information and communication technologies **should maximize the use of scarce resources**, rather than divert resources from meeting people's basic health needs.

WHO claims it has a constitutional role to act as the directing and coordinating authority on international health work. It can thus engage in, and **serve as convenor for**, any area or endeavour that can be of benefit to global health. As such, it can **provide an interface between public and private bodies, draw up relevant standards and guidelines, and develop methods for assessment.**

WHO's Secretariat intended to establish a **networked global eHealth observatory** to document and analyse development and trends, inform policy and practice in countries, and report regularly on the use of eHealth worldwide. Drawing on national centres and promoting networks of excellence in eHealth, the observatory is also meant to **help to identify best practices and opportunities for policy coordination**, and identify needs for the provision of technical support and capacity building.

Discussion took place during the 115th Executive Committee (January 2005): Western countries (in particular the USA) insisted on **facilitation work** rather than normative approach (support rather than guarantee). The resolution 58.28 adopted by the Fifty-eighth World Health Assembly (May 2005) officially gives an official eHealth facilitating/supporting mandate to WHO while it requests to submit to the Executive Board, at its 117th session (December 2005), a list of proposed specific activities upon which the Secretariat will focus, which should be **entirely aimed at tools and services that MS can incorporate into their own national solutions or adapt** as necessary;

A list of the proposed actions and an outline of the budgetary implications of the proposed activities (May 2005) is reproduced here under:

Activity	Output	Timeframe	Organizational level	Estimated budget (US$ m)
Legal and ethics committee	• Ethical and legal guidelines • Network of experts for technical support to Member States	2006-2007	Global	0.5
Global Observatory for eHealth	• Annual eHealth report • Topic-specific guidelines and reports • Best practices and standards reports • Guidelines and frameworks for eHealth policy and strategy	Started 2005	Global; regional	1.5
Public-private partnerships	• Platform for public-private partnerships, in eHealth • Principles for governance of eHealth partnerships	2006-2007	Global	0.5
Information and communication technologies in support of human resources for health	• Framework for education and training, including competency in information and communication technology • Multilingual initiatives	2006-2007	Global; regional	0.75
Health education and promotion	• Support for Member States • Quality criteria for health content	2006-2007	Global; regional	0.5
eHealth in health care	• "eHealth essentials" • Model solutions, demonstrated in national centres of excellence	2006-2007	Global; regional	1.5

Figure 5 : WHO eHealth related actions and budget (2005)

The concrete eHealth initiatives taken by WHO are described and analysed later in in the document. Some of the proposed actions did not really materialize while other initiatives have been launched by the WHO eHealth unit. While the Global Observatory for eHealth has actually taken shape in 2005 with the organization of the first world survey, the other objectives seem to have had a slower or more limited take-off. The platform for public-private partnership has not materialized yet.

The World Health Organization defines eHealth as "…the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research..." (Resolution 58/28 of the World Health Assembly, Geneva, 2005).

The 66th World Health Assembly (May 2013) recognized the need for health data standardization as part of eHealth systems and services, and the importance of proper governance and operation of health-related global top-level Internet domain names, including ".health" (May 2013).

It gives a mandate to the General Director, within existing resources, to promote standards and interoperability in cooperation with relevant organizations; it also requests to provide guidance and technical support, as appropriate, to facilitate the coherent and reproducible evaluation of information and communication technologies in health interventions, ***including a database of measurable impacts and outcome indicators***; it stresses the need to make full use of WHO network of collaborating centres.

The approved WHA66.24. Resolution also emphasizes that health-related global top-level domain names in all languages, including ".health", should be operated in a way that protects public health, including by preventing the further development of illicit markets of medicines, medical devices and unauthorized health products and services. It urged MS to "consider ways for ministries of health and public health authorities to work with their national representatives on the ICANN Governmental Advisory Committee (GAC) in order to coordinate national positions towards the delegation, governance and operation of health-related global top-level domain names in all languages, including ".health", in the interest of public health."

Finally, the 139th Executive Board, 2016 considered "mHealth: use of mobile wireless technologies for public health," reflecting the increasing importance of this resource for health services delivery and public health due to their ease of use, broad reach and wide acceptance. "mHealth" or mobile health has been shown to increase access to health information, services and skills, as well as promote positive changes in health behaviours and manage diseases. It refers to the joint initiative with ITU "Be He@lthy Be Mobile" for the prevention and management of non-communicable diseases. It mandates WHO to work further on **evidence-based guidance on the use of mHealth** in order to advance integrated person-centred health services and universal health coverage, to provide guidance on mHealth adoption, management and evaluation, to work with MS and partners to build platforms for sharing evidence and finally -to support building capacity and the empowerment of health workers

WHO current orientation and priorities related to eHealth are shortly described in the budget document of the biennium 2016–2017: "WHO will monitor and disseminate data on the health situation and trends at global, regional and national level through global and regional health observatories. It will further update the international classification systems used to guide the provision of health services and to maintain epidemiological and other records, including accurate mortality statistics. The Organization will continue to provide strategic guidance and support to countries for developing national eHealth strategies; improving the

standardization and interoperability of eHealth services and information systems, innovation and eLearning in the context of health promotion and human resources capacity development; and assessing global trends and building the evidence base for eHealth. Work on eHealth and mHealth will continue to be conducted jointly with ITU, in collaboration with international standard-setting organizations."

The key objectives can thus be summarized as follows:

• Support **capacity building** and partnerships in developing and implementing a national eHealth strategy Regional office deliverables

• Collect and **synthesize good practices and facilitate access to knowledge**, experience, resources and networks in order to build the evidence base in eHealth

• **Support country offices** in the development and implementation of national eHealth strategies

Headquarters deliverables:

• Collaborate with other organizations of the United Nations system and stakeholders to **develop standards and provide guidance**, tools and resources for the development of national eHealth strategies and the adoption of eHealth standards

• Build the evidence base on eHealth and **disseminate the evidence collected by means of the Global Observatory for eHealth**

The main output indicator related to eHealth proposed by WHO for the period 2016-2017 is the **Increase of the number of countries enabled to plan, develop and implement an eHealth strategy by 20 countries** (from 90 countries in 2015 to 110 in 2017 on a total of 194 countries**).**

Here below is an overview of the budget for the period 2016-2017. eHealth activities are listed under "health systems, information and evidence" with a total of 124.3 US$ Million. eHealth related activities however only represents a percentage of this amount (detail unknown).

BUDGET BY MAJOR OFFICE AND PROGRAMME AREA (US$ MILLION)

Programme area	Africa	The Americas	South-East Asia	Europe	Eastern Mediterranean	Western Pacific	Headquarters	Total
National health policies, strategies and plans	21.0	16.1	20.8	15.0	12.2	17.0	40.0	**142.1**
Integrated people-centred health services	35.0	6.3	17.2	15.4	21.8	14.9	45.9	**156.5**
Access to medicines and other health technologies and strengthening regulatory capacity	16.6	6.2	13.1	7.1	11.7	11.2	105.7	**171.6**
Heath systems, information and evidence	16.4	6.2	10.0	10.7	11.9	10.8	58.3	**124.3**
Category 4 total	**89.0**	**34.8**	**61.1**	**48.2**	**57.6**	**53.9**	**249.9**	**594.5**

Figure 6 : 2016-2017 WHO Budget by major items category 4 (health systems)

More recently (2016), the WHO eHealth team with the support of the Health Ethics and Policy Lab, Epidemiology Biostatistics and Prevention Institute, University of Zurich, have tried to capture the evolving health data ecosystem in a conceptual diagram. This diagram focuses on 4 parameters: stakeholders, capabilities, standards and (expanded) sources of data.

The diagram provides a good illustration of the increasing and urgent need to "think wide" to create the expected major added value of big data while putting in parallel the necessary policies and mechanisms to ensure that the coming new era will keep on respecting individual rights.

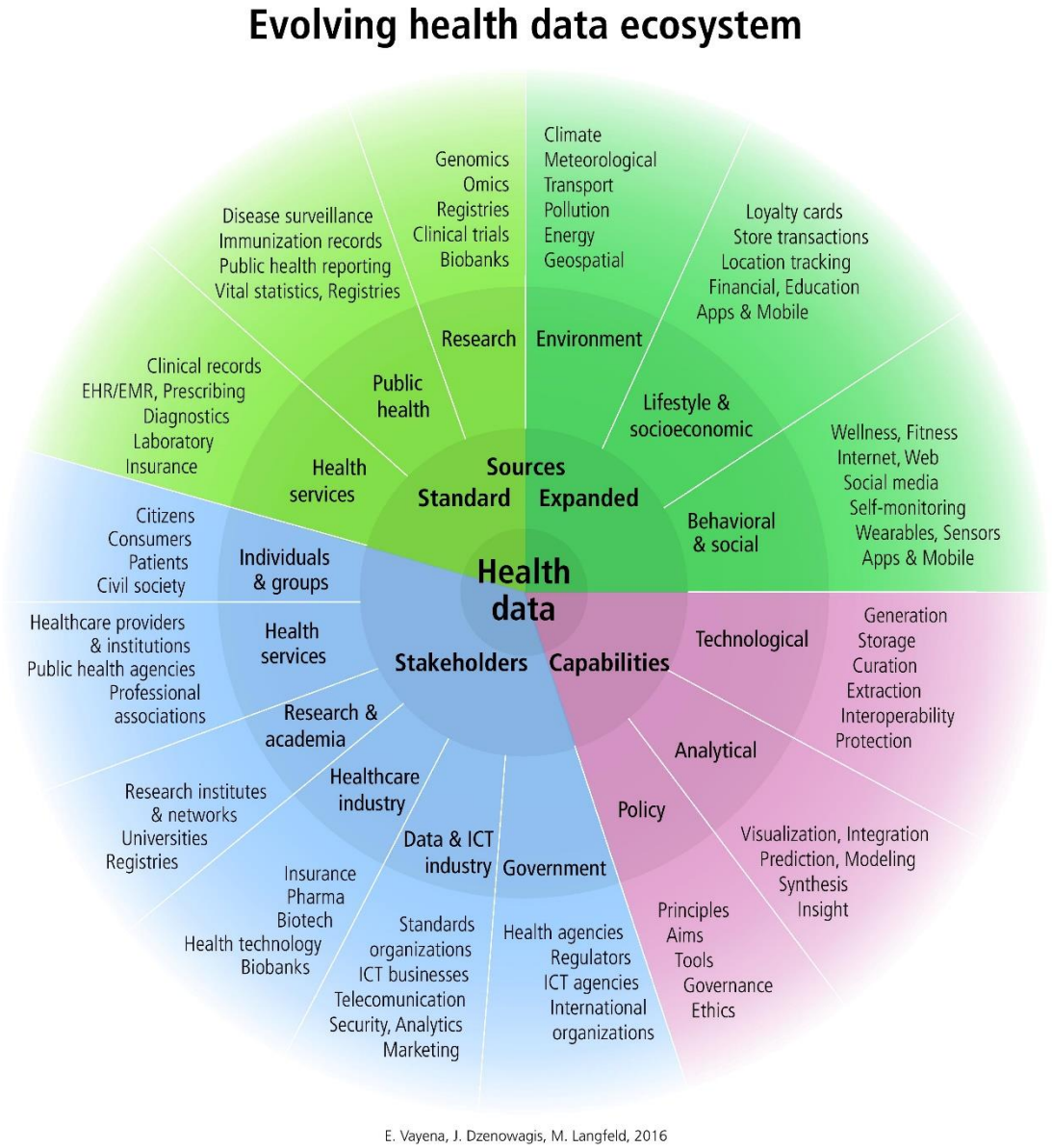


Figure 7: Evolving health data ecosystem (2016)

4. Review of WHO eHealth related initiatives

4.1 The Global Observatory for eHealth (GOe)

This is the main WHO eHealth vitrine and the most important activity performed by WHO independently.

The observatory official goal is "to provide relevant, timely, and high-quality evidence and information to support national Governments and international bodies in improving policy, practice and management of eHealth; increase commitment among governments and the private sector to invest in, promote and advance eHealth; generate knowledge that will significantly contribute to the improvement of health through the use of ICT; and disseminate research findings through publications on key eHealth research topics as a reference for governments and policy-makers."

To date, it organized 3 world-wide surveys (2005, 2009, 2015) which tried to capture the eHealth evolving reality while addressing some of WHO pivotal values or key themes such a Universal Health access, public epidemiological surveillance or maternal and child care.

While the first survey was rather general and had as a first objective to deliver initial benchmarking, the following ones have tried to address the issue in a more comprehensive way. WHO has tried to use the results obtained to maximize dissemination and knowledge, targeting in particular the countries which had few experience or expertise with eHealth.

This is particularly the case for the second survey (2009) whose key focus was "telemedicine" and which led to the publication in 2011 and 2012 of 6 "volumes" which, aside from the country profiles, address the results of each of the main chapters of the survey (Telemedicine, mHealth, security on the internet, legal frameworks and patient information management). The surveys compare the data of the different world regions and also provide a comparison using the World Bank countries categories (high income, upper-middle, lower-middle and low income) which offer for a number of indicators a somewhat different perspective from the regional approach.

Aside from the survey results, the volumes provide a number of examples which try to showcase the diversity of situations and needs around the continents but try in particular to bring the perspective of lower income countries.

While the surveys provide altogether a global valuable analysis of the world trends, they however had to face a number of constraints and limitations due to the increasing complexity and the willingness to reflect all evolutions at stake. This required from the respondents a level of knowledge and expertise which proved often to be challenging, even for countries with a proved eHealth history track.

The last survey (2015) tried to address this issue by requesting answers to be validated by a team representing key national stakeholders rather than just an individual/institution and by providing a glossary which tried to clarify the key underlying concepts. This certainly helped to prevent some of the biases observed in previous surveys.

Aside from the survey reports per se, WHO provides a portal which allows to consult the country profile of most of the respondent countries providing thus a snapshot of the situation in 2005, 2009 and 2015. It is however not possible to measure progress over the years as the questions are different for each survey and the data from the two surveys are not connected.

WHO has also tried to compile the most important national documents in a Directory of eHealth policies. The information made available was submitted by the respondents to the 2015 survey. A minimum of information is usually available in English and in national language.

To be complete, a survey targeted on the role of ICT to support Mother and Child Healthcare (MCH) and addressed to a selected number of lower income countries has been organized in 2013.

WHO Europe has taken the initiative to produce a number of reports which are based on the results of the survey. Those reports are shortly described under 4.3.

4.2 Support to the elaboration of national eHealth strategy

The National eHealth Strategy Toolkit is the main contribution of WHO to its "policy support" objective. The toolkit has been elaborated in close collaboration with ITU.

This is a high level tool whose main goal is to provide the WHO members with a **process based** methodology which should help to define a vision, develop an incremental action plan and monitor the progress. It also introduces **results based management** which is described as a critical element for the successful implementation of the part 3 of the strategy (monitoring and evaluation). Each part of the document is written in such a way that each part can be read independently. It is a very valuable reference material which has been drafted on the analysis of the best practices coupled with the use of methodologies adapted to policy making.

Figure 8 : Toolkit for developing a national eHealth strategy: Key components

When comparing with other policy support initiatives, the originality of the toolkit is to try approach the development of an eHealth strategy and the prioritization of related actions according to the initial "global" situation in the country, featured by three different scenario: experimentation and early adoption, developing and building up and scale up and mainstreaming. It refers to markers such as population health, health system status, strategy, goals and priorities, economic and social development goals and more specifically on availability of (basic) infrastructure and skills, comprehensiveness, ownership by authorities, market development, ICT use in the general population, ICT uptake in other (public) sectors, technology deployed, government funding, incorporation of eHealth in health service delivery models, etc. and therefore links eHealth development to specific drivers such as access to care, quality of care, costs containment and efficiency.

Context	Characteristics	Example focus	Example actions
I. Experimentation and early adoption	• eHealth is project-based with initiatives usually small, few in number and disconnected • Projects are proof-of-concept pilots where ICT is introduced in a limited context • Projects are rarely sustainable due to the lack of infrastructure, skills and integration • The commercial ICT market is fragmented with little local expertise available • Funding and technical support is often provided by aid agencies, donors and external actors • International obligations for public health reporting cannot be met	Strengthen infrastructure; establish core services and platforms; engage investors; make the case for eHealth.	• Create awareness of eHealth; highlight outcomes of successful pilots and proof-of-concept projects • Make the case for eHealth investment in priority areas • Establish initial mechanisms for national eHealth governance, coordination and cooperation • Establish a foundation for investment, workforce education and adoption of eHealth in priority systems and services
II. Developing and building up	• eHealth is still project-based, but larger in scale with greater awareness of its potential • eHealth systems (e.g. health information systems, supply-chain management systems, electronic medical records systems) emerge, but remain vertical, fragmented and unable to scale up • Growth occurs in the commercial ICT market, with significant effort to attract international ICT vendors. Local vendors emerge and government interest grows • Initiatives such as e-government, e-banking and other commercial ICT services begin to take hold; but the health sector lags behind • There is a lot of activity, learning by doing, and significant project risk • Aid agencies and donors are still active funders; there is more private sector and government investment in development and adoption of cost-effective technologies • Public-private partnerships increase in number • eHealth is viewed as part of a broader effort to expand ICT and economic development • Early successes are promising, but scale-up is not possible and health impact remains limited • International obligations for public health reporting can sometimes be met through vertical systems • Examples of eHealth include more extensive telemedicine networks, adoption of EMR systems on a limited basis, procurement and stock tracking systems, and mHealth trials	Focus on scale up and integration of services; cost-effectiveness of investments; incentives for quality and broader adoption; policies for privacy, security, innovation.	• Ensure broad adoption of standards by health ICT vendors • Continue development of data and interoperability standards to support broader and deeper types of health information flows • Create incentives for integration of eHealth into core health services • Provide education and awareness programmes to health-care providers and citizens • Respond to expectations of citizens for more efficient, effective and personalised services • Leverage emerging health information data sources to support public health planning, management and monitoring • Undertake evaluation and monitoring to ensure that eHealth delivers according to health priorities
III. Scale up and mainstreaming	• Investment and adoption scales up with a more comprehensive policy basis • The commercial ICT market is well established with larger vendors, both international and local • The health sector takes a leading role in planning and using eHealth to deliver on health objectives • The health ICT industry is active; with new business models and competition, paid services commonplace, and insurance reimbursement increasing • New businesses and economic opportunities arise; there are new platforms for innovation and services, including for other markets • International obligations for public health reporting can be met • Health information systems are increasingly linked, but still face problems due to legacy systems • Examples of eHealth include hospital and care networks, home health monitoring, chronic disease management applications, and tailored online services for self-management of health records	Strengthen and link core systems; create a foundation for investment; ensure legal certainty; strengthen the eHealth enabling environment.	• Establish eHealth data and interoperability standards, and associated compliance and accreditation mechanisms • Establish the policy context to support investment in and adoption of ICT in health services • Address legislative requirements and barriers (e.g. data protection and privacy) • Implement changes to education and training programmes to improve eHealth workforce capability and capacity • Secure long-term funding for investment in national eHealth infrastructure and services • Establish national eHealth planning processes, which have broader cross-sectoral stakeholder representation and participation

Figure 9 : Toolkit for developing a national eHealth strategy: Contexts of implementation

The toolkit identifies a **number of strategic components** which need to be addressed when developing a eHealth strategy. Those elements are roughly similar to the building blocks which had been described by the Calliope European Interoperability Roadmap and had later on been endorsed by the Barcelona eHealth high level conference in 2010 with however a specific emphasis on the workforce component. The annex E (pp 85-86) provides however a detailed and updated example of the possible components of a national eHealth strategy.

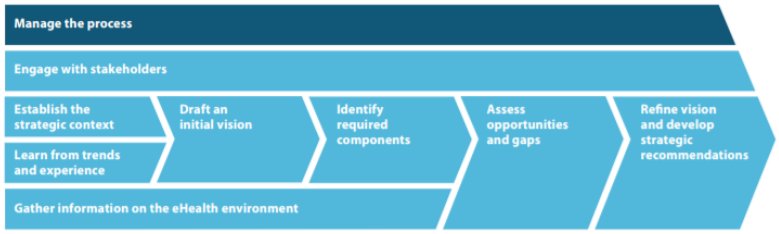


Figure 10: Toolkit for developing a national eHealth strategy: Process management

The vision to be developed requires a **thorough preliminary analysis of the health system "as is"** focusing on a number of key areas. The identification of expected and timed realistic outcomes "to be", taking into account the windows of opportunities that eHealth may provide, can then lead to the drafting of high level recommendations which will be used as starting point for the action plan. The strong emphasis put on the vision within WHO finds among other things its rationale in the willingness to avoid seeing eHealth being developed without real connexion to health needs with therefore the risk of misuse of sometimes very scarce resources.

Area	Sample questions
Population health	• What are the strategic goals for improving the health outcomes of the population? • What challenges will be created by current and expected changes in population health?
Equity and accessibility	• What are the challenges impacting the delivery of equitable and accessible health services across the population?
Health workforce supply and distribution	• What are the challenges facing the supply of the nation's health workforce and its ability to support effective and efficient health-care delivery at all levels of care? • What are the challenges related to the distribution of a nation's health workforce and its ability to support effective and efficient health-care delivery in metropolitan, regional, rural and remote parts of the nation?
Health system structure and organization	• What are the challenges caused by the existing structural, funding, governance and leadership arrangements of the nation's health system?
Effectiveness and efficiency of health-care delivery	• What are the challenges that affect the quality and safety of health services delivered to the population? • What are the challenges affecting the effort, time and cost associated with delivering health services to the population?
Emergence of advanced medical treatment regimes	• What are the opportunities and challenges associated with the emergence of advanced medical treatment regimes and the demand for these by the population and health-care providers?
Funding	• What are the funding challenges for health systems, trends in public and private spending, sustainability of the health system, projected funding and its impact on future health services?

Figure 11 : Toolkit for developing a national eHealth strategy: Sample strategic questions

The document explores the main conditions to guarantee an efficient governance while identifying in a detailed manner all the stakeholders which need to be associated to the

process and the process of consultation/association (including associated methodologies) per se. For that purpose stakeholders are classified as decision makers, influencers, broader stakeholders or general public. It describes the government's role (facilitator, coordinator, manager) according to the role allocated to the market in the health sector (free market, guided market or fully regulated).

The document also encourages countries to learn from existing experiences and to focus on countries that may be similar in terms of health system structure and operation, goals and challenges. This remains however challenging given the current lack of accessible and translated materials, especially for low income countries. The document provides in annex B a number of references to national documents but most of them are either outdated or not available anymore. The 2016 Directory of eHealth policies already mentioned under 4.1 does however provide links for each surveyed country to reference resource in English or national language. There is however no procedure in place to guarantee update and material referenced is thus sometimes already quite outdated.

Figure 12 : Toolkit for developing a national eHealth strategy: Key steps

The vision should ideally be translated into a number of scenarios describing the user experience "to be" and a number of high level statement such as "By…., EHealth will enable (health system goal) by (eHealth outcomes)….". Key components need then to be linked to an eHealth outcome. Inventory of standards and preliminary choices of interoperability strategy need to be included in those statements. A reality check is also performed to measure impact on key stakeholders with a description of the (new) roles expected. A thorough analysis of the current eHealth situation in country allows then to perform a gap analysis and describe priority actions to be undertaken and refine the initial vision. Each final strategic recommendation should be uniquely referenced to enable traceability to the national action plan (Part 2) and should include the rationale for the recommendation, a description of the high-level actions to be undertaken, dependencies with other recommendations, and the nature of this dependency and associated risks and barriers.

The action plan per se should enable a government to "identify all components and how they should be governed, funded and coordinated to ensure that results are achieved at a national, state and local level; and to work closely with multi-sector stakeholders who will be involved in implementing the plan". It has thus the ambition to describe the activities, actions and resources needed to achieve the goals. It uses roughly the same tools and methodologies than for part 1 having in mind an iterative approach with a specific emphasis on availability and resources (human and financial) and the need to plan each action in a number of (yearly) phases. Governance aspects and stakeholders involvement are here again described in details. Examples provided are meant to provide ideas of possible solutions covering a wide array of situations and describe the possible modalities of public-private partnerships. The document also provides a standard canvas for eHealth action plan.

Part 3 -monitoring and evaluation- focuses on the development of indicators and targets to be measured and the definition of the governance and processes required. It starts from the assumption that a national eHealth vision and an action plan have been drafted according to the methodology suggested in parts 1 and 2 and thus that related outputs are available.

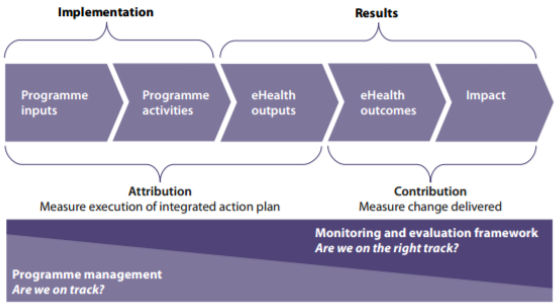


Figure 13: Toolkit for developing a national eHealth strategy: Programme management and monitoring framework

The originality is to differentiate between the evaluation of the implementation of the action plan (outputs) per se which is part of a global programme management from a monitoring and evaluation framework which is related to the impact of eHealth outcomes on the global health ecosystem. The challenge is here to identify indicators that provide insight into the adoption of eHealth and the tangible results for health and non-health stakeholders coupled to baseline and target measures which allow evaluation of progress while describing the governance and processes required. As for programme management, the document refers to well established existing generic project management methods such as PMBOK® or PRINCE2® and thus explores mainly aspects related to the impact assessment.

The document provides a number of high level examples of quality (smart) outputs and outcomes indicators classified by stakeholders and describes how to make them measurable. More ambitious impact assessment (such as contribution to health system quality or efficiency, impact on morbidity or mortality) is however not specifically discussed.

Overall the toolkit provides a valuable methodological process based high level input to its intended target group: government, ministerial and health sector leaders. In order to use the tool effectively, a comprehensive knowledge of health and eHealth ecosystems is however necessary. As the kit is meant to be used by countries with different needs and situations, it does not for example discuss a priori the need to invest in a number of strategic basic components which are considered as essential for the implementation of services with added value (e.g. identification, authentication services and encryption services, availability of reliable data sources…).

Complete report can be downloaded here: http://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf. It has been translated in French, Arabic and Chinese.

4.3 Initiatives and Support provided by Regional Offices

Each WHO Regional Office is also free to develop its specific initiatives, either focusing on the diffusion of the materials and tools developed by the EHealth Unit and/or

complementing it with specific action plan. There is no formal recent update on the actions pursued by all WHO regional offices.

Regional offices usually mobilize action on WHO's global eHealth mandate by supporting MS in their implementation of national health sector reforms or through capacity-building in the context of national strategic programmes for eHealth.

AFRO (Africa Regional Office) has been focusing on development of the African Regional Observatory and supporting MS to establish national health observatories, eHealth plans and capacity building. It produced its own recommendations such as the Resolution. eHealth solutions in the African Region: current context and perspectives (AFR/RC60/R3, 2013) based on the working document. eHealth solutions in the African Region: current context and perspectives (AFR/RC60/5, 2013)

AMRO (America Regional Office)/PAHO (Panamerican Healh Organization)'s claimed priority is to promote eHealth standards and interoperability. Based on the results of the 2015 survey, it produced in 2016 a specific report for the region: "breaking the barriers to implementation" and had produced earlier with the support of the Spanish Agency for International Development Cooperation (AECID) "eHealth Conversations: Using Information Management, Dialogue, and Knowledge Exchange to Move Toward Universal Access to Health." Through virtual dialogues, this document provides insights from experts who contributed with knowledge and reflections on the present and the future of eHealth in the Americas, analyze the situation, and make recommendations for the implementation of electronic health initiatives. The Region has established an action plan for the period 2012-2017 which has been evaluated in 2016.

EMRO (East Mediterranean Regional Office) has established a eHealth taskforce which convened twice (last in 2015) and sets the basis for a regional action with the eHealth strategy toolkit as a main reference. It identifies a number of key building blocks which should receive priority but also recognizes that the use of the toolkit requires the mobilization of resources which are not widely available and calls therefore for a pooling of resources. It also advocates to support the "beHealthy, beMobile" initiative, later described in the document.

SEARO (South East Asia Regional Office) has mainly been diffusing the tools made available by the eHealth unit/ITU. A Regional strategy (2014-2020) has been adopted to strengthen eHealth in the region. The document captures well the eHealth challenge for low and middle countries in the area, tries to classify the countries according to a scale of 5 stages eHealth maturity which are more related to the development of national HIS than to the integration in health practice although both aspects are coupled. Service delivery (telemedicine) and knowledge management are also listed as priorities to reinforce the health system.

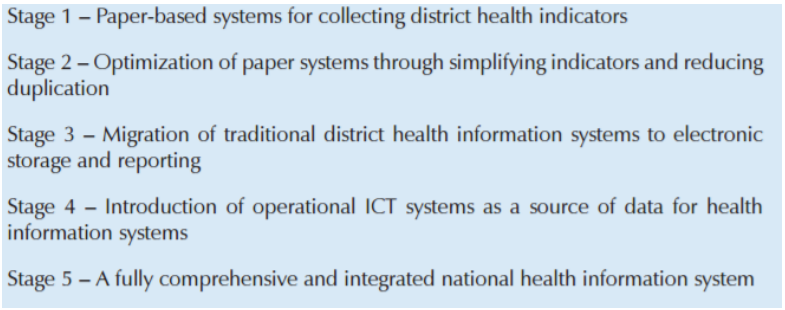


Figure 14 : 5 stages eHealth maturity –Regional eHealth strategy for South East Asia

Standards adoption is also briefly discussed with technical support being focused to encourage adoption of health data standards such as LOINC (Logical Observation Identifiers Names and Codes), HL7 (Health Level Seven), SNOMED (Systematized Nomenclature of Medicine) and SDMX (Statistical Data and Metadata eXchange) by the countries. The strategy proposed follows an iterative approach globally in line with the toolkit focusing on policy/strategy, tools/methods, collaboration/partnership and human resource development) but also mandates the Regional Office with potentially a role which goes beyond mere facilitation or coordination with e.g. the possibility to become a service provider (decision support tools, terminology services etc…).

WPRO (West Pacific regional Office) focuses on capacity building and networking in countries in the region. Like SEARO, its main focus has been on HIS (Health Information System). WPRO collaborates actively with the Asia eHealth Information Network. This network, which is open to both public and private members, has built upon the PAN Asian Collaboration for Evidence-based eHealth Adoption and Application (PANACeA). In 2007, PANACeA brought together 16 researchers from 10 Asian countries to learn about eHealth and eHealth research, and join hands to implement 8 multi-national research projects with the support of the International Development Research Centre (IDRC), a Canadian federal Crown corporation. It focuses on peer-to-peer assistance and knowledge sharing and learning through a regional approach for greater country-level impacts across South and Southeast Asia.

Within the European Region, WHO European Regional office states that it delivers on its eHealth mandate in three ways: by fostering partnerships, through sharing of global best practices and standards and by working directly with governments to address their technical and strategic needs for eHealth and health information. Its geographical area is of course wider than the European Union.

The European reality presented here somewhat differs from the one of the EU as it includes also other countries, including the federation of Russia and ex-soviet Republics. Europe has received somewhat more attention than other regions of the world with the production in 2008 of a specific report on Europe "Building Foundations for eHealth in Europe" exploiting the results of the 2005 survey and the publication in December 2014 by ITU/WHO of a discussion paper on Legal and Regulatory Challenges of Mobile Health (mHealth) in Europe. mHealth (and telemedicine) has thus received a specific attention in Europe with this publication which- among other things- reflects on recent EU initiatives such as the EU green paper on mHealth and the volume 3 of the WHO eHealth series of the Global Observatory for eHealth: New horizons for health through mobile technologies, based on the results of the 2009 survey. This discussion paper is briefly discussed later in the document.

As far as the EU is concerned, the surveys did however not use or refer to the materials already collected through other surveys (such as for example the Ehealth strategies ERA project surveys organized in 2007 and 2010) with as, as result, a lack of consistency in some in the analysis provided.

Like in 2008, WHO Europe has also taken in 2016 the initiative to produce a specific report on Europe, based on the results of the 2015 survey. This report called: "from innovation to implementation" goes beyond the mere description of the results of the survey and provides a number of recommendations elaborated after consultation with a number of stakeholders, including the European Commission and the chair of the eHealth Network (eHN).

For readers' comfort, those recent key recommendations are reproduced here below:

Political commitment: Explicit political commitment by governments in the European Region to adopting eHealth is required. This commitment needs to be backed by sustainable funding for the implementation of eHealth programmes and actions for capacity-building and evaluation that are aligned with a national strategy for eHealth.

Dedicated eHealth strategies: An inclusive and inter-sectoral approach to the development of national eHealth strategies is recommended – to ensure their relevance to all stakeholders and to promote shared action in achieving health objectives. MS are further recommended to use the methodology described in the WHO and International Telecommunication Union (ITU) National eHealth strategy toolkit as a basis for developing their national vision, action plan and monitoring and evaluation frameworks for eHealth. Having a national eHealth strategy that embodies the elements of achieving Health 2020 policy is a key enabler for strengthening people-centred health systems and public health capacity.

Legislation on electronic health records: Detailed legislation surrounding the use of national electronic health records should be further developed and harmonized by MS. Such legislation should ensure that patient rights in relation to access and management of data are appropriately addressed.

Guidance on telehealth: MS should consider the development of targeted, inter-sectoral strategies and policies to guide national telehealth implementation.

Adoption of standards: A systematic approach to the adoption of eHealth standards for data exchange and interoperability needs to be taken, with a national body in each Member State clearly identified to govern this process. MS are recommended to adopt ***the European Union's Refined eHealth European Interoperability Framework*** and to ***introduce a quality management system for interoperability testing***, a set of appropriate testing tools and quality label and certification processes.

Regulation in mHealth: MS are recommended ***to establish an entity responsible for the regulatory oversight of mHealth applications*** and to carry out evaluations on the impact and benefits of mHealth applications operating in their national settings.

Increasing digital and health literacy: Digital and health literacy among both health professionals and the public should become an area of focus to ensure that eHealth is successfully adopted and that health inequalities are reduced with the digitization of services.

Increasing the use of eLearning: eLearning in health for both students of health sciences and health professionals should be increased, where appropriate. MS are also encouraged to formally evaluate their eLearning programmes.

Increasing guidance on social media use in health and big data: National policies and strategies on regulating the use of big data in the health sector need to be addressed by national health and information and communication technology entities, and should include a clear position on the use of big data by private companies. Similarly, MS are recommended to develop national policies governing the use of social media in health professions.

The report proposes the following set of actions for WHO in Europe:

- intensify ***open and active partnerships*** with the European Commission, Organisation for Economic Co-operation and Development, World Bank, nongovernmental organizations and other international stakeholders engaged in developing and promoting eHealth, with the aim of leveraging the collective strengths of each in providing harmonized support to MS;
- under the umbrella of the ***WHO European Health Information Initiative***[3] created in 2015, engage with MS in the European Region (21 MS in 2016) to build capacity for implementing and managing ***eHealth as a national strategic asset*** and to further its role in reforming national health information landscapes**;** "health information systems" include all activities and resources related to public health monitoring and reporting. It also includes some less tangible elements necessary for operating a health information system, such as governance mechanisms and legal frameworks, inter-institutional relationships and values. It aims to achieve a stronger, more accessible and sustainable evidence base for health policy making, a reduced administrative burden for MS through increasing harmonization of international data collection, a better clarity about Health and well-being indicator values in different databases and a more efficient use of resources as a result of reduced duplication and better use of existing information

3 More information : http://www.euro.who.int/en/data-and-evidence/european-health-information-initiative-ehii

and knowledge. Links with OECD and the European Union have been established.

- continue to support international development of ***eHealth standards and frameworks for interoperability***;
- act as a **knowledge broker for development of best practices** for eHealth and innovation within a European context.

4.4 Advances in eHealth in other WHO technical departments

Aside from the initiative "beheathy-bemobile" targeted at NCDs ((non communicable diseases) discussed later in the document, eHealth is also increasingly being adopted by a number of technical units across WHO, as programme staff begin to recognize its benefits and relevance to many public health challenges. Particularly worth mentioning are the WHO Mental Health Gap Action Programme (mhGAP) which includes e.g.an iSupport portal for dementia caregivers, making available guidelines for the management of multidrug-resistant tuberculosis (MDR-TB) for use with smart phones or a specific interest of the Reproductive Health and Research (RHR) with an mHealth Technical and Evidence Review Group (mTERG) for Reproductive, Maternal, Newborn and Child Health (RMNCH) aiming at measuring the potential impact of mHealth on maternal and child health, and the development of a ***framework for grading mHealth*** evidence.

4.5 Health academy, E-learning for health professionals and ePORTUGESe

WHO claimed objective is to provide open and widely accessible information on a number of priority topics. It has not thus to date invested in the promotion of e-learning through an active proactive collaboration with external partners and the creation of global curriculae.

The health academy targets a wide audience with a specific focus on school-age children, aged from 12-18 years, in particular. It aims to provide basic health guidance in terms easily understood by a wide range of people, and in consideration of cultural sensitivities and traditions on disease prevention and health promotion.

The Health Academy team works closely with WHO regional offices and national Ministries of Health and Education to ensure the package complements existing national health promotion and education programmes. There are 15 eLearning courses available, in English and sometimes in Arabic or French and three more are in development.

E-Learning resources for health workforce training have also been developed, based on the guidelines previously developed by WHO. They cover mainly priority topics to emergency situations or global health policy such as vaccination, management of rape survivors or international health regulations). To date 11 courses are available on the Inter-agency portal.

Created in 2005, ePORTUGUESe was a response to health professionals from Portuguese-speaking countries in Africa to provide them with reliable and up-to-date health information in their own language. It resulted in the creation a network of Institutions and health

professionals in eight countries that share their information and exchange their experiences through the Virtual Health Library, discussion group, collaborative space and the use of Social Media. The initiative has been evaluated in 2013 and stresses the necessity to give more visibility, support and stability to the programme within WHO.

4.6 Governance of health internet and certification of health content

Together with health data standards and standardization, the governance of health internet was a key topic of the approved WHA66.24 Resolution in 2013. It stresses the need to keep the management and operation of health-related generic top-level domains (gTLDs), including .health, be consistent with public health objectives in order to serve the public, civil society, governments and industry on a global scale. The "health" generic TLD is of particular concern. WHO has thus requested from ICANN (Internet Corporation for Assigned Names and Numbers) that it adopts the organic safeguards and principles proposed by the Governmental Advisory Committee (GAC). These principles refer to the adoption of an appropriate governance and management model which should support transparency, privacy, security, individual control choice with the support of codes of conduct and legal and regulatory framework. Principle also refers to the importance to refer to global services understood as "in a manner that promotes interoperability of services and technologies".

Several warnings/objections to the creation of .health domain have been filed, notably by the GAC (Governmental Advisory Committee) and individual countries then by the ALAC (At-Large Advisory Committee) and the IO (Independent Objector). The European Commission issued a letter to all applicants within the new gTLD program highlighting 58 applications that "could raise issues of compatibility with the existing legislation and/or with policy positions and objectives of the European Union.". Most of the objections were dismissed and in August 2014, a private deal was settled with the sole remain applicant, an American register company named DotHealth, LLC. In order to respond partially to the EU objections, the company signed a **public interest commitment** which inter allia states that ".heath TLD will not be used for the illicit promotion or sale of prescription drugs, and prompt action shall be taken against rogue Internet pharmacies operating in the .heath TLD"/

Based in Switzerland and created in 1996, the Health On the Net foundation (HON) is an independent financially independent non-governmental organization with ties to the World Health Organization. It has also benefited from an important support from the European Union. HON main activity has been to certify on a voluntary basis health related websites. The certification is based on the proved respect of 8 key principles. Aside from the HON certification per se, HON has also developed a number of useful tools, for some of them with the support of the European Union, aiming at a better use of health related quality content over the Internet. Khresmoi for Everyone is a search engine that identifies high-quality health information online in the European Union with an interface available in all EU languages. KConnect provides healthcare professionals, researchers in the bio-medical industry, and the public with the very latest and most relevant medical information through medical text analysis, semantic annotation and semantic search services.

HON has also invested in some specific content such as Provisu which focuses on eye diseases and 3D Anatomy Quiz which contains a range of free online quizzes to help anyone learn the anatomy and physiology of the human body.

4.7 Who forum on health data and standardization

In 2012, WHO took the initiative to create the forum on health data standardization and interoperability which convened for the first time on 3-4 December 2012. The 200 Participants of the Forum included representatives from health data Standards Development Organizations (SDOs), WHO MS, academic and research institutions, implementing partners, the donor community, and subject matter experts concerned with development, adoption and implementation of health data standards at national and sub-national level in addition to WHO technical programmes and regional offices. It was asked to answer 15 questions slit over 7 thematic areas (including needs, national contexts, barriers, funding,..) discussed in 7 different panels which resulted in a number of high level statements. The final report provided the following final follow-up recommendations:

• Continue to host the Global Forum on eHealth Standardization and Interoperability on a regular basis with in-depth discussion on each of the thematic areas that formed the agenda of the first event.

• Facilitate more opportunities for participants from LMICs (lower and middle income countries) to actively engage in the standards development and maintenance process.

• Engage MS, **conduct a high-level policy dialogue** and develop policy guidance for full implementation of standards-compliant eHealth systems and services.

• **Facilitate a mechanism to periodically convene** standards development and maintenance organizations to discuss the gaps in standards, and mechanisms to address them.

• Facilitate a **mechanism to provide free and open access** to existing standards to MS through an innovative financing mechanism.

• **Host a 'gateway' on eHealth standardization and interoperability** to serve as a single source of information for MS and other stakeholders.

In 10-11 February 2014, WHO organized a Joint Inter-Ministerial Policy Dialogue on eHealth Standardization and the Second WHO Forum on eHealth Standardization and Interoperability. While the Policy dialogue was meant mainly to support the objective of **awareness and engagement** of MS, the objectives of the Second Forum were rather to facilitate a dialogue on the need **for policy and governance mechanisms for adoption of health data standards** in countries and to draft a policy and governance framework for full adoption of standards at national and sub-national levels.

The Forum addressed 19 key questions[4] related to six thematic areas which led to a number of high level recommendations which are listed here:

4 Namely: Policy approaches in eHealth standardization and interoperability; successful policy interventions to overcome barriers in standards adoption; governance, stewardship, equity and health systems integration of data standards and interoperability; Policy and statutory authority components; Regional perspectives on governance and

"eHealth policy for standardization and interoperability in a national context should:

- **Be embedded in a national health plan**, **and an eGovernment plan** if one exists. Its view must be long term, provide continuity, and commit to long-term investment.
- **Be patient-centred**, emphasising service quality, equity, patient outcomes, patient safety and population outcomes.
- Be based on mutual trust and understanding and genuine collaboration between all Stakeholders…and encompassing public and private partnerships where necessary.
- Support an **evidence base for the socio-economic benefits** of eHealth, and encompass user utility and outreach programmes (…)
- Adopt appropriate **electronic Health Information Exchange (HIE) technology**, including at national and subnational levels, in vertical programmes, and in public and private health care facilities.
- Set health data and health IT standards to ensure interoperability at data-, device and system-levels, in a framework containing **a fixed core set of maintained standards allowing for a degree of innovation outside that core set** and allowing for development based on the capacity and maturity of eHealth systems and services; and regulate an appropriate degree of adoption in the country context.
- **Use existing international standards where possible and adapt specific standards to suit national contexts** (taking necessary care to ensure interoperability and backward compatibility, as applicable).
- Provide **unique identifiers for patients, health care workers and health care facilities**, with verification and authentication procedures.
- Ensure the **safety of interoperable medical devices**, and ensure security, defining privacy and security policies addressing technology use in health care delivery.
- Build capacity from country and ministry level down to that of frontline health workers. This includes financial and academic capacity as well as technical and human resource capacity.
- Ensure good governance, **balancing top-down and bottom-up approaches**, encompassing: equity and accessibility; legality; user rights in line with human rights; privacy; responsibility; and accountability to citizens and to the state. Compatibility of technologies, efficiency, open dialogue and a shared vision on use of data are necessary for implementation.
- In **monitoring compliance, clear goals and key indicators for monitoring and evaluation** are needed, with mechanisms for social participation.
- Support **competency-based education and capacity building in health informatics**, with standardized curricula and measurable learning objectives at

stewardship of eHealth standardization ;Essentials of a good policy framework for adoption of standards for interoperability of eHealth systems.

national and subnational levels. Training should be for the health workforce, including social workers, and should cover eHealth policy development and planning, communications and leadership as well as technical content. Training, including in-service training, can provide a valuable opportunity for partnership with academia, technical colleges and other relevant bodies.

- Encourage relevant ministries of national governments to **include eHealth core competencies in job descriptions** for relevant posts.

The forum addressed the following **follow-up requests** to WHO:

- Identifying and providing a **core set of minimum standards**
- Providing technical **support for implementation of standards** in collaboration with IGOs, NGOs and SDOs
- **Helping unify data and setting standards for coding and data sharing** across countries
- Helping build policies for **data sharing**.
- Setting interoperability goals and providing support to countries in achieving them
- **Coordinating activities of health data and health IT standards** development and maintenance organizations to serve WHO MS.
- Continuing to facilitate discussion on aspects of standardization and interoperability
- Providing **guidelines to support countries in decision-making** on standards and related policy.

4.8 Initiatives driven by ITU (International Telecommunication Union)

Founded in 1865, ITU (International Telegraph Union) is the first specialized international agency. It changed its name in1932 to become the "International Telecommunication Union" and became a specialized United Nations official agency in 1947. ITU is an International organization where governments, industries, telecom operators, service providers and regulators work together to coordinate global telecommunication networks and services; ITU brings together 190 MS (Government) and 700 Sector Members and Associates from industry, international and regional organizations, as well as academia**.**

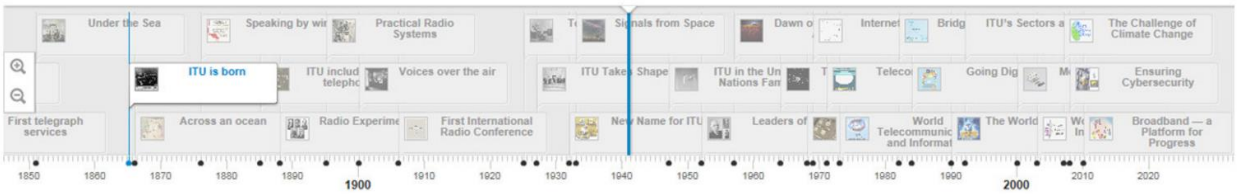


Figure 15 : ITU historical evolution

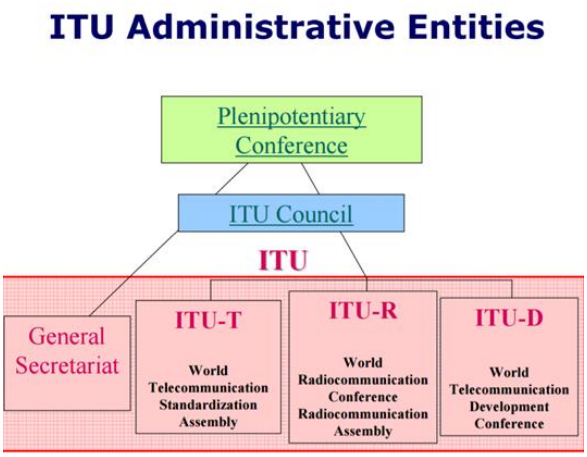


Figure 16 : ITU Administrative Entities

The highest decision making level is the plenipotentiary conference which gathers MS every 4 years, adopts a 4 years strategic and financial plan and elects senior management team of the organization. The ITU Council is elected for 4 years (2014-2018), meets yearly and is composed of 48 members from the 5 regions (8 for Western Europe) and controls the implementation of the plan. ITU is divided in three branches supported by a General Secretariat which coordinates and manages the administrative and financial aspects of the Union's activities (provision of conference services, information services, legal advice, finance, personnel, etc.). Those branches are:

• ITU-R: Coordinate radio communications, radio-frequency spectrum management and wireless services.

• ITU-D: Technical assistance and deployment of telecom networks and services in developing and least developed countries to allow the development of telecommunication.

• ITU-T: Telecommunication standardization on a world-wide basis. Ensure the efficient and on-time production of high quality standards covering all fields of telecommunications (technical, operating and tariff issues).

ITU is financed according to a biennial budget, set at CHF 331 million for the 2014-2015 period. ITU Members – MS, Sector Members, Associates and Academia – provide around 80 per cent of annual funding; ITU generates around 19 per cent of total funding as cost recovery, mainly from activities such as sales of ITU publications, satellite network filing fees, and registration of Universal International Freephone Numbers (UIFN). In addition, ITU develops partnerships with other organizations and entities that can provide voluntary contributions earmarked for specific projects to be developed and deployed – particularly in the UN-designated Least Developed Countries (LDCs). Implemented projects from voluntary contributions totalled over CHF 17 million in 2013, compared to CHF 10 million in 2012. Member State and Sector Member contributions are made under a free choice system from a scale of stepped amounts. The top 10 Member State contributors provided approximately 56 per cent of total funding in 2012-2015. Since 2006, a single contributory unit has been worth CHF 318,000. The EU MS contributors part of the top 10 are France (25 Units), Germany (25 units), Italy (15 units) and the UK (10 units).

In fact the role of ITU goes beyond mere standardisation. ITU-D e.g. also provides policy support and guidance, especially (but not only) for developing countries. For practical reasons, all information related to ITU is thus summarized under this section. ITU-R is not discussed here.

Contact:

International Telecommunication Union (ITU) Telecommunication Standardization Bureau (TSB)

Place des Nations, CH-1211 Geneva 20 Tel. +41 22 730 5852

E-mail: tsbmail@itu.int central address)

URL: http://www.itu.int/IT

4.8.1 ITU-T (telecommunication)

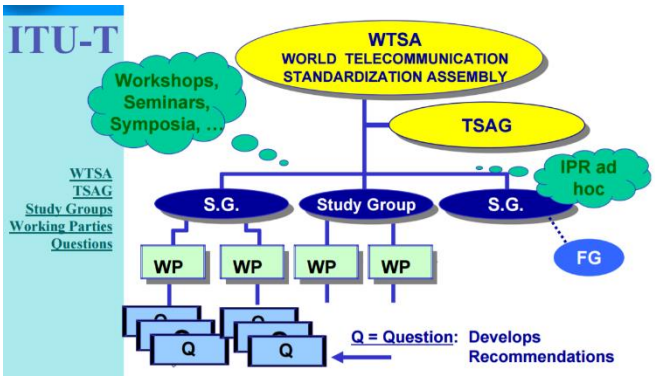


Figure 17 : ITU –T organizational structure

ITU-T is of particular interest for eHealth as it has standardization as focus.

The branch has its own governance and members with a world telecommunications standardization assembly (WTSA) which approves study groups which meets every 4 years and a telecommunications standardization Advisory Group (TSAG) overseeing progress every 9 months. The work is (mostly) done in Study Groups (11 of them currently) and produces normative recommendations related to standards (e.g. • Example: G992.1 (ADSL), G993.1 (VDSL) and non normative supporting material (implementation guidelines, directives, reports etc.. The recommendations can be downloaded on ITU website. Currently, **95% of the work is done by the private sector** (with a strong participation from Asia, esp. China) **while the remaining 5% is rather handled by public actors** when it has a regulatory impact. Depending on the fact that a recommendation is subject or not to policy or regulatory implications, two different approval processes exist. The existence of fast and transparent procedures has allowed to improve significantly the efficiency and the flexibility of the work performed by the study groups.

eHealth being a transversal issue, issues related to the implementation of a national eHealth plan are dealt with in several study groups. The study group (SG) 16 is certainly the one which is the most directly eHealth oriented but several other Groups need to be mentioned such as **SG 11** which deals with protocol and tests[5], **SG 12** which is responsible for the development of

Study Group 16: Multimedia Terminals, Systems and Applications

- *Lead Study Group on multimedia terminals, systems and applications*
- *Lead Study Group on ubiquitous applications ("e-everything", such as e-health and e-business)*

5 See in particular the Focus group under this SG which worked in 2012/2013 on Machine to machine 3 communication (M2M) in eHealth.

international standards on performance, quality of service (QoS) and quality of experience (QoE),**SG 13** on future networks & clouds[6], **SG 17** which deals with security and cybersecurity (see also in particular question 9 related to telebiometrics) or **SG20** which develops international standards to enable the coordinated development of IoT (Intenet of things)technologies, including machine-to-machine communications and ubiquitous sensor networks.

The impetus behind the formation of Question 28/16 (**Multimedia Framework for eHealth Applications)** in 2003 which specifically targets eHealth within SG16 was motivated by the understanding of the critical and growing requirement for global interoperability among fragmented eHealth systems based on various standards and the need for coordination among major global players. It had originally identified the following priority objectives and tasks:

- Develop a Recommendation on "Generic Architecture for Multimedia (and Telemedicine in particular) Applications"
- Construct a general architecture for eHealth applications
- Conduct an inventory of existing eHealth / Telemedicine standards and develop a roadmap for eHealth applications/ Telemedicine standards, compiling and analysing standardisation requirements from eHealth stakeholders and identifying standardisation items with priorities
- Identify particular characteristics and requirements for eHealth applications including video and still picture coding, audio coding, security, and directory architecture.
- Provide inputs for extension and improvement of existing Recommendations on multimedia systems (e.g. H.323, H.264, V.18, etc)

Other objectives were added later on, such as:

- Identification of user requirements;
- Creation of **glossary of eHealth** (telemedicine, in particular);
- Methods for inputting, transmitting and processing data for eHealth (telemedicine, in particular);
- **Databases and knowledge-bases of information** and expertise on, and technologies for, eHealth (telemedicine, in particular) as well as consultants and specialists, and potential customers of eHealth (telemedicine, in particular);
- Mechanism for querying, finding, identifying, and categorizing consultants and customers in the area of eHealth (telemedicine, in particular);
- **Personal terminals** for eHealth (telemedicine, in particular);

[6] ITU-T Study Group 13 is e.g. currently developing a Recommendation that will define a methodology to classify and describe the features of eHealth monitoring services, as well define requirements and service capabilities from a network perspective.

No normative recommendation related to question 28/16 has been adopted to date. The materials produced are thus **non normative**. Compliance with the recommendations is thus **voluntary**. Herebelow is a list of the currently approved deliverables which can be downloaded:

- Recommendation ITU-T H.810 (2016),*Interoperability design guidelines for personal health systems: This document is the transposition of* Continua (now called **Personal Connected Health Alliance**) guidelines for PHS.
- Suite of conformance testing specifications of ITU-T H.810 **personal health devices** (Recommendations ITU-T H.820 to H.850 sub-series): This is the transposition of the suite of Continua (now called **Personal Connected Health Alliance**) Test Tools, Test Suite Structure & Test Purposes. The recommendation includes an electronic attachment with the protocol implementation conformance statements (PICS) and the protocol implementation extra information for testing (PIXIT) required for the implementation of Annex A.
- Technical Paper ITU-T HSTP-H810 (2014),***Introduction*** *to the ITU-T H.810* ***Continua Design Guidelines****: This document provides for end-to-end, plug-and-play connectivity in personal connected health devices, which are based on global industry standards for interoperability*
- Recommendation ITU-T H.860 (2014), *Multimedia eHealth data exchange services: data schema and supporting services:* The document specifies a basic common health schema applicable to a wide range of health systems – e.g., clinical and wellness –, describes the supporting services and systems architecture for a *health data exchange that allows an exchange of multimedia health data between a health provider, a controlling function and a patient* and proposes a health system level governance model called the "collaborative development process". The services this Recommendation describes include both point-of-care and personal healthcare services.
- Technical Paper ITU-T FSTP-RTM (2006), ***Roadmap for Telemedicine****: This document is freely downloadable.* Although already quite outdated, it provides very comprehensive inventory of standardization issues and initiatives, including aspects linked to personal health systems.

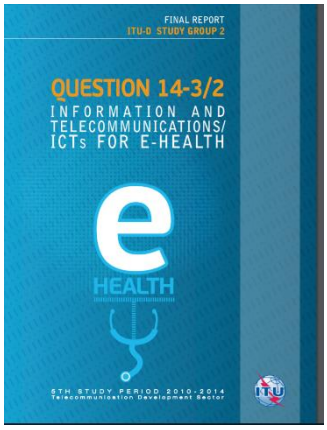
In conclusion: If one thus excepts the transposition of the standards and tests proposed by Personal Health Alliance (ex Continua Health alliance) and their evolution, the main recent technical contribution of ITU-T is thus related to a proposal for health data schema and supporting services, which is itself based on the work performed by HL7 and IHE. There does not seem to have any other work under development. Considering the ambitious objectives announced initially, the results obtained are thus for now limited.

4.8.2 ITU-D (Development)

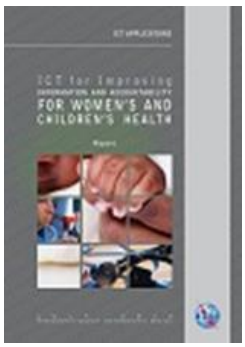
ITU-D (development) is also of importance for eHealth as its Study Groups provide an opportunity for all MS and Sector Members (including Associates and Academia) to share experiences, present ideas, exchange views, and achieve consensus on appropriate strategies to address ICT priorities. ITU-D Study Groups are responsible for developing **Reports**, **Guidelines** and **Recommendations.** The Study Groups examine

specific task-oriented telecommunication/ICT questions of **priority to developing countries**, to support them in achieving their development goals.

Currently two study groups exist with the **Study Group 2** focusing on ICT applications, cybersecurity, emergency telecommunications and climate-change adaptation and specifically the **Question 2/2** related to Information and telecommunications/ICTs for eHealth. Materials developed by ITU-T is used as inputs for ITU-D and vice-versa. Study Group 2 Question 14/2



The main recent document produced has been released in 2014 and tries to capture the perspective of developing countries. It provides a global overview of the eHealth rationale, possible outcomes and building blocks including the standardization issues, proposes a number of high level recommendations but mainly focuses on the analysis of eHealth implementation case studies originating from 19 countries (Argentina, Bangladesh, Ghana, Central African Republic, Ivory Coast, Guinea, India, Indonesia, Kyrgyz republic, Laos, Lebanon, Mali, Niger, Pakistan, Tanzania, Turkey, Uganda, Uzbekistan, Zambia) and lessons learnt from more advanced countries and Japan in particular. It addresses also specifically information and accountability for Women's and Children's Health which had already received an earlier attention through the high level UN Commission on Information and Accountability for Women's and Children's Health (CoIA) established in January 2011. One of the ten recommendations set by the Commission encourages "Innovation through information and communication technologies (ICT) for accountability". The International Telecommunication Union along with the World Health Organization and the Innovation WorkingGroup have been partners in supporting this recommendation and have as a result produced a report (2012) that reviews each of the ten CoIA recommendations, highlighting the contributions ICT applications can provide in their implementation. This material was also used as an input for question 14-3/2.



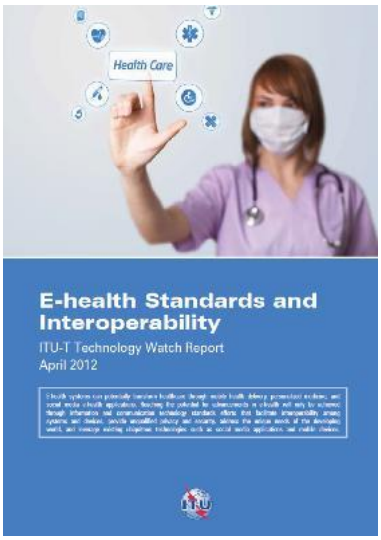
The CoIA has also initiated the WHO world survey specifically dedicated to this topic in 2013 which led to the publication of the report of the results: eHealth and innovation in women's and children's health: A baseline review.

To be complete, let's mention that ITU had produced other reports previously, targeted mainly to developing countries which still provide today valuable inputs. The previous question 14-2/2, studied during the period 2006-2010, led to the publication of the report : Mobile eHealth solutions for Developing Countries which highlights the role of mobile telecommunication technology in health care by offering at a distance the medical

consultation and administration of patient treatment. It provides input on what is Mobile Health, how to use Clinical Decision Support Software and Traffic Control System for Medical Information Network, Models of Wireless Access and Connectivity, etc…and provides a number of examples from developed and developing countries.

Two reports have furthermore been commissioned by ITU to. P. S. Ramkumar (India) in 2011: Telehealth in India provides a comprehensive analysis matched against 16 criteria (e.g. coverage, portability, interoperability, usability, training etc..) of real-life application scenarios d covering over 26 Tele-Health initiatives from a mix of private, government and NGO managed care delivery organizations across India. The second report, Scaling eHealth Services in step with ICT Transformation**, focuses on the importance to** understand which eHealth services can be deployed immediately with available infrastructure and which additional services can be added, as the infrastructure is transformed according to the needs and constraints of the target demographics. It presents a methodology of study of the **ICT requirements of a complex health care system** in terms of its activities, transactions and nature of information exchanges, and map their computing and communication needs at the point of care to existing technology standards

4.8.3 Report on eHealth standards and interoperability (2012)



This report has been written at the request of ITU by Dr. Laura DeNardis of American University in Washington, DC, expert on Internet governance and ICT standards. It was released in 2012 and provides a snapshot of the statute of standards and interoperability at the time while considering current and future needs such as mHealth, personalized medicine or use of social media and Web 2.0 applications. It provides a description of the achievements of some standardisation organizations /initiatives (including EpSOS or Continua but excluding others like IHE and many others) but is mainly meant to promote ITU activities. The telemedicine roadmap report (2006) already mentioned was from that perspective far more comprehensive. It includes a good glossary and could still certainly be used as one of the main reference materials by ongoing related initiatives.

The report proposes five high level standards prerequisites necessary for achieving the promise of eHealth: Emphasizing greater interoperability, increasing coordination over global eHealth standardization, ensuring privacy and security, reducing the standardization gap in the developing world, and leveraging existing technologies like mobile devices and social media applications.

The report provides a good introduction to the issue and its strategic importance for a public not acquainted with interoperability issues, mentions European initiatives such as Epsos but is incomplete and already partially outdated.

Some European States such as Holland (Nictiz) (ICT- standards in health- a practical overview 2012) and Ireland (Overview of Healthcare Interoperability Standards, July 2013) have also produced reports that ambition to provide a global overview of the issue of standardization in the healthcare sector, although each from a somewhat different perspective. The report produced by Nictiz was produced with the purpose to increase knowledge and awareness of a large number of Dutch stakeholders. Although it was never translated in English and needs to be updated, it could certainly be used as a starting point to build the one-shop standards information point requested by many.

A recent report (October 2016) published by the Alliance for Internet of Things Innovation (AIOTI), initiated by the European Commission in 2015, provides a global overview of the main players currently involved in standardization.

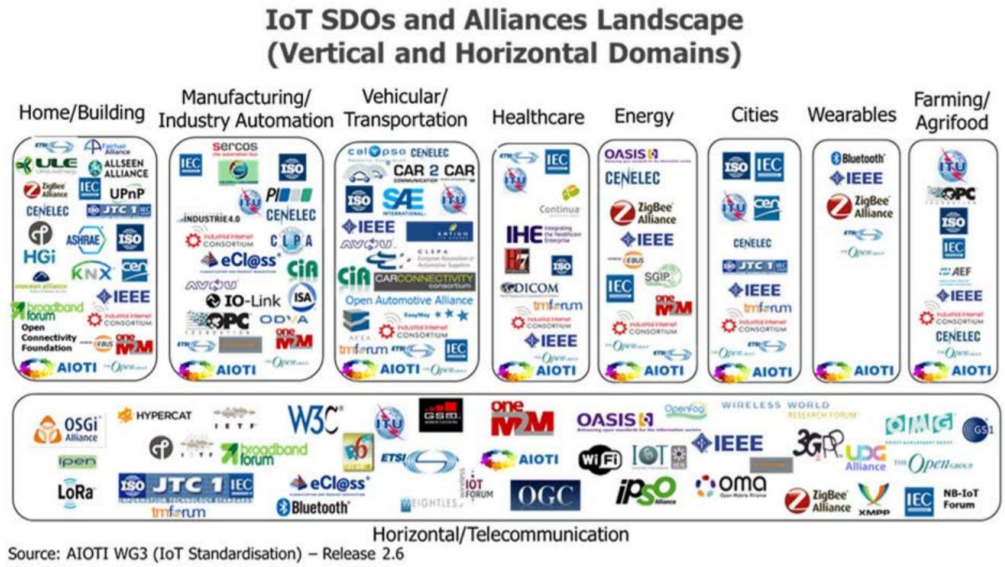


Figure 18: Internet of Things- SDOs and Alliances landscape

4.8.4 Discussion paper: filling the gap: legal and regulatory challenges of Mobile health (mHealth) in Europe (September 2014)

This report, already mentioned earlier in this document, has been written at the request of ITU by Prof. Lucien Rapp, Professor at the University of Toulouse1-Capitole, Associate Professor, HEC (Hautes Etudes Commerciales), Paris. The document claims that currently applicable rules in Europe are either non-existent or extremely inadequate, which might mean that they do not account for or, at least do not appropriately account for, the specific requirements for the development of mHealth. Furthermore European institutional and legal landscape is described as too fragmented with a European regulatory framework for mHealth which appears to be lagging behind that of competing regions (North America or Japan). The author provides a summary of legal issues and their possible solutions with regard to the three notions of medical devices, medical information and medical practice.

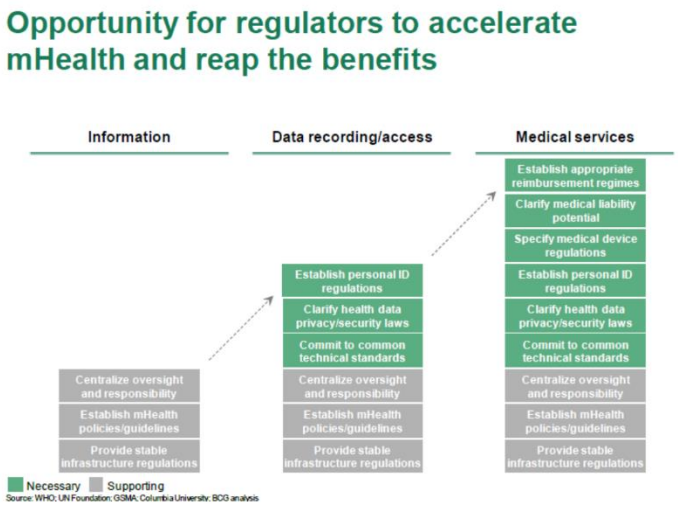


Figure 19 : Necessary and supporting elements to support mHealth and reap the benefits

It advocates the need for MS to:

- create a statement of **currently used services or practices** and a list of the different sectors of activity concerned;
- share their respective experiences, and particularly legal challenges, that arise from the development of these new uses and any solutions found for them; and
- adopt a shared legal framework, harmonized if possible;
- reflect on shared initiatives, such as, for example, the **implementation of a single control structure**, specifically intended to coordinate all of the efforts led by medical or pharmaceutical practitioners, mobile electronic communication network operators, manufacturers (from medical device or mobile terminal manufacturers to software designers), content aggregators, insurers and welfare agencies, to develop mHealth.

It also proposes to take advantage of the experience and solutions developed in other sectors, notably the aviation sector with guideline and structure like the Joint Aviation Requirements (JAR) and Joint Airworthiness Authority (JAA) -before the creation in 2003 of the EASA (European Authority on Aviation Safety)- whose purpose was to minimize problems rose by standard certifications and to facilitate the movement of aeronautical products. The author also suggests the creation of a European office specialized in mHealth which is considered as a powerful tool to unlock the full potential of mHealth, encourage innovation in healthcare in Europe and stimulate new deployment on the market.

4.8.5 eHealth Standardization Coordination Group (eHSCG)

Following a workshop on eHealth standardization in eHealth organized in May 2003 by ITU-T (Telecommunications) and ITU-D (Development) which brought together the major players in eHealth standardization, it has been decided to create a **eHealth Standardization Coordination Group (eHSCG).** This group is composed of representatives of the major SDOs ((ITU-T, ITU-D, ISO TC215, CEN TC251, IEEE 11073, HL7, DICOM, OASIS International Health Consortium, GS1 and WHO).

- The original terms of reference for the group was to serve as an overarching coordination group in the area of eHealth standardization, such as **serving primarily as a technical, rather than regulatory group**, to help promote cooperation among various standards development groups doing work in eHealth, to discourage duplicative standards efforts, and to provide a repository of information identifying current eHealth standards and work. Original terms of reference also included the guidance for standards implementation and case studies and special consideration for the requirements of developing countries (case studies).

Considering the absence of publicly available materials which could demonstrate a proactive activity, It seems clear that eHSG has actually not succeeded to play the technical coordination role it intended to play in 2003. On the ITU website, a list of standards and the support standards developed is available but the list does not seem to be regularly updated and is currently very much outdated. The initiative seems thus be "dormant".

4.9 eHealth Technical Advisory Group-eHTAG (internal to WHO)

WHO has also decided to create in 2013 an **eHealth Technical Advisory Group**. The overall purpose here is to support the work of the WHO by advising, within its scope of expertise, on aspects of policy, standardization, planning, priority setting, resource mobilization, collaboration and partnership building, evidence building and **evaluation of eHealth activities in the Organization**.

The selection of members for technical advisory groups is conducted based on the principles of adequate international and technical distribution of expertise, global representation of different trends of thought, approaches and practical experience, as well as interdisciplinary balance. 18 members (4 for Europe) have thus been selected to assist WHO Regional and Headquarters staff office.

The first meeting took place in December 2013 in Geneva. Follow-up meetings were foreseen by teleconference but no public report is available concerning its activity. eTAG decided to form six working groups based on the WHO's major ongoing themes in eHealth and reflect on possible new approaches and opportunities. Cross-cutting areas of eHealth were identified, such as improving the development of standards and interoperability, enhancing eHealth awareness among leaders and in the workforce, developing evaluation and performance indicators for eHealth programmes, and leveraging the impact of other health programmes through the use of mHealth. For each working group, a number of challenges/issues had been identified. They are reproduced here as they indicate the concrete directions the organization wanted to take in the following years.

Group 1: National eHealth Strategies and Planning: Suggestions included **highlighting success stories and sharing experiences**, providing interactive technical tools, identifying local support, leveraging national research and education networks (NRENs) and other supporting bodies, establishing links between countries and ensuring coordination between WHO and other partners.

Group 2: eHealth Initiatives: Many eHealth initiatives are currently being implemented through collaborative efforts with the ITU, WHO collaborating centres, and other partners in MS. The objective is to pursue partnerships and develop joint initiatives to support eHealth implementation in countries. Challenges in eHealth initiative implementation include ***fragmentation of initiatives due often to uncoordinated work and the lack of national eHealth strategies and standards***. Focus should be to facilitate eHealth implementation based on health priorities in MS, consistent with their national strategies.

Group 3: Standards and Interoperability: The challenges that this area faces include determining the framework for use of standards and policies for their adoption. The focus for 2014-2015

includes **introducing the WHO handbook on standards and providing strategic guidance** to countries. The future opportunities for WHO could include establishing a **common gateway for accessing standards**, developing a **checklist for standards adoption**, working with standards development organizations for improving access to standards, **identifying and promoting successful case studies** and facilitating a policy dialogue on national coordination structures for implementation.

Group 4: Evidence and Surveys: Challenges include the need for increased MS' participation and commitment in completing surveys, the development of national observatories, and improved data collection methods. The group had suggested that the third global survey could focus on Universal Health Coverage (UHC) and that's what has actually been done. It is also important to note that **lack of continuity and capacity at the national level for updating country eHealth status poses a problem for data accuracy and completeness**. It was proposed that WHO consider using WHO country offices where feasible, to inform and guide the survey process.

Group 5: eLearning and Innovation: Challenges include the lack of eLearning policies in countries, the need for capacity building at the country level, and availability of content in suitable formats.

Other areas to be addressed include the need to improve infrastructure and delivery mechanisms, foster collaboration with multiple partners, and develop human and financial resources.

Group 6: Capacity building and Networking: Currently there are a number of initiatives linked to WHO that support capacity building and networking in eHealth. Challenges include the lack of access to infrastructure, the need to improve coordination of public-private partnerships, effective collaboration with non-health stakeholders, fostering government support for eHealth solutions, and promoting eHealth literacy among policymakers.

4.10 WHO-ITU joint programme on mHealth for noncommunicable diseases (ncds) toolkit: the "be he@lthy be mobile" initiative.

Launched in October 2012, this collaboration between WHO and the ITU was developed to provide low- and middle income countries (LMICs) with a specific support to address their burden of Non-communicable diseases (NCDs) using mHealth. Among all the initiatives launched by ITU/WHO, this is certainly the one which is the most operational.

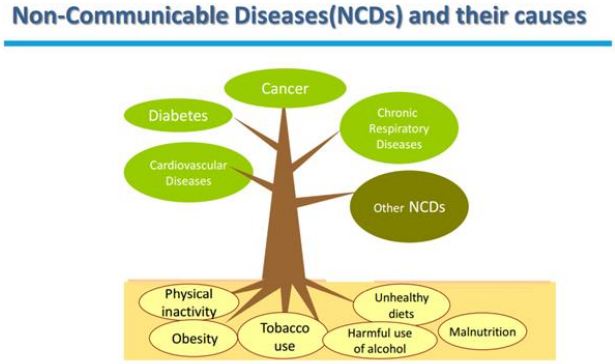


Figure 20 : Non-Communicable Diseases and their causes

According to the initiative, low and middle-income countries are particularly affected by NCDs, bearing approximately 75% of the global deaths (estimated at 38 million deaths each year). NCDs include cancers, diabetes, heart and lung diseases and represent 68% of global deaths annually with close to 40% being premature. The estimated cumulative

loss in economic output due to NCDs in developing countries is US$7 trillion for 2011-2025, according to a Harvard University study

The objectives of the initiative are the following ones:

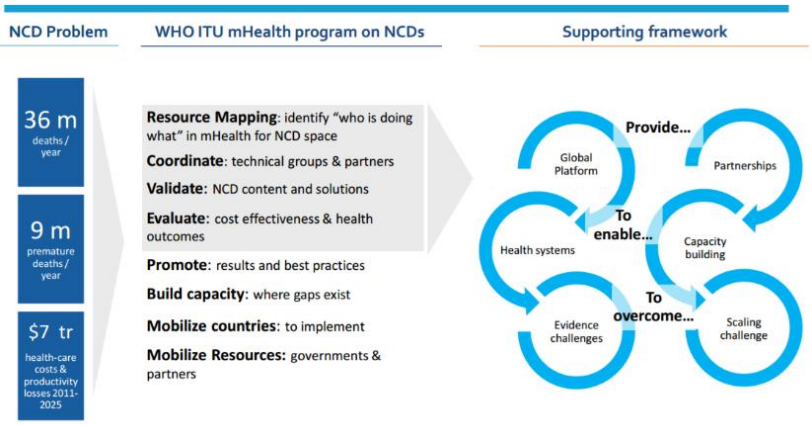


Figure 21 : WHO ITU supporting framework for NCDs

- Create global, regional and country level platforms in achieving NCD goals through technology.
- Develop cost effective, sustainable and scalable mobile NCD projects.
- Strengthen the capacity of local stakeholders towards optimal and efficient use of available resources.
- Validate the use of mobile NCD projects for results, quality assurance and cost/effectiveness and to share best practices.

Be He@lthy Be Mobile considers that the fact that the number of subscriptions to mobile phone programmes is now superior to the world population provides a unique opportunity to go beyond the usual "pilot projects" approach and opt from the start for a rapid wide scale deployment in phases.

Eight countries have proposed efforts to improve health through the use of mobile phones in 2012 for the project 4 years duration (2013-2016): **Costa Rica, India, Norway, the Philippines, Senegal, Tunisia, the United Kingdom, and Zambia**. Generally, each country project begins with a pilot phase. Based on the results, adjustments are made and the program is expanded. **Egypt** has decided to join the initiative in 2016, relying on its own resources. Over 40 additional countries have approached Be He@lthy Be Mobile with requests to launch projects.

A country selects its intervention by identifying its priorities from criteria such as: 1. Weight of disease burden for a specific NCD or risk factor on the population 2. Disease priority in the national health agenda 3. Existing technology that they would like to be refined through the initiative 4. Desire for a rapid implementation (SMS) or a longer project (building a tailored Smart- phone app or a full mobile platform for example for screening and treatment).

After identifying its priorities, a country can then pick solutions from the WHO/ITU mHealth program's "juke-box" of possible approaches. These have been selected from evidence collected from all over the world. Overall coordination is carried out by a Be

He@lthy Be Mobile Steering Committee made up of high-level officials of ITU and WHO. Staff from the two agencies makes up a small secretariat that provides day-to-day and background support to countries proposing and carrying out projects.

There are three broad areas of intervention: prevention, treatment and enforcement. These cover treating patients already suffering from an NCD such as diabetes or cancer, reducing population exposure to risk factors for later developing an NCD (e.g. poor diet and no exercise, which contribute to heart disease and cancers), and helping governments enforce national policy on NCDs. This last category can include not only helping lower national targets for NCDs, but also other areas such as reducing counterfeit cancer drugs using a mobile scanner and bar code to determine a drug packet's authenticity.

Most (but not all) of the implementations to-date have been focusing mainly **on prevention** using mainly mobile phones and some kind of interactivity.

Here is a summary of the main mHealth services considered by the initiative:

	DESCRIPTION	**EXAMPLES**
mWELLNESS	SMS tips and Smartphone apps for monitoring and increasing physical activity and diet.	a) Smartphone app which allows the user to scan health content of a food in a supermarket and using the traffic light system for foods find healthier replacements b) Messages to inform, encourage and track physical exercise or diet programme.
mDIABETES	Use of mobile phones to track a patient's blood sugar/insulin levels, remind them to take their insulin, and give advice on dietary changes to stabilize condition. Can also be used as a preventative measure by informing people about lifestyle choices which increase their risk of developing diabetes.	a) Diabetic has a Smartphone app which tracks their blood sugar in a graph, helping them control fluctuations and reduce damage. b) Pre-diabetic receives tips on healthy cooking, lowering their tendency towards developing diabetes. E.g. gestational diabetes could easily be prevented or better managed reducing IMR/MMR.
mCESSATION	Mobile-based support for tobacco users who want to quit. Toll-free SMS and mobile quitline. Smokers receive encouragement, support and advice on coping with quitting.	The programme provides an ongoing algorithm based messages to the user to help them quit based on a target date, with added interventions for eg. Smoker is craving a cigarette at 7am. They send an SMS with a key word, "CRAVE", to a toll-free number. Seconds later they receive a reply SMS telling them what is making

		them crave the cigarette and how to stop it. Result: smoker is less likely to have the cigarette, helping them avoid cigarettes for the rest of the day.
mTRAINING	Mobile based support for health workers and teachers to include training on prevention and control.	Mobile phones and internet used to train health workers, social workers, care providers, parents, teachers and also patients (for self care) in lieu of structured training.
mSURVEILLANCE	2-way SMS system for enforcing smoke-free zones.	An individual enters a smoke-free zone and receives a text informing them that the zone is smoke-free. They are also able to report people seen breaking this ban within the zone.
mSMOKEFREE	Using a mobile-based device to track smoke levels in bars/restaurants/public spaces and register them, so that asthmatics, families with young children, etc. can avoid areas with high smoke levels.	A device developed by CERN which attaches onto a Smartphone and measures the density of smoke particles in the air in a bar.
mILLICIT / (also called mTRAC)	Mobiles are used to register serial numbers for cancer and other NCD drugs (already used for HIV, TB, malaria), tracking deliveries and avoiding counterfeits.	Bar code is scanned or alphanumeric code is sent via SMS to a number which verifies the code's authenticity or looks at stock and supply.
mSCREENING	Online and mobile platform to screen entire populations for existing NCD conditions and to monitor their treatment.	Fully integrated technology into the primary health care system allows patients and doctors to track and manage their conditions and plug in relevant interventions including schedule appointments, consult online etc.
mSURVEILLANCE	Mobile house to house questionnaires/surveys to monitor NCD risk behaviours in individuals.	A surveyor keys in responses to survey questions and these are aggregated and analysed in real time.

mTobacco cessation is by far the service which has received first priority as it has been selected by 4 countries: Costa Rica (2013), Senegal (2014), India (2015) and Egypt (2016).

mDiabetes has been chosen by Senegal (2014) and Tunisia (2016) and Egypt (2016).

mCervical cancer has been selected by Zambia (2016)

As for the 2 European partners, Norway has prioritized ***mCOPD*** (2013) while UK has selected **mHypertension** (2016).

Each interested country receives a "**mHealth for NCDs Tool-box**", assembled by the project's staff which includes:

1. **Best Practices**: such as "best apps for NCDs", case study series, literature review, projects database, etc.

2. **Content:** including database of validated content and Community Health Workers (CHWs) eLearning materials and professional development curricula for NCD prevention and treatment.

3. **Technology solutions and platforms:** including available validated m-apps and service delivery platforms that are preferably open, standardized, secured and modular that can be reused by countries for NCD prevention and treatment.

4. **Deployment Strategies and Business models:** This can include the development of materials such as "mHealth Standard Operating Procedures (SOPs), marketing strategies and sustainable business models.

5. **Policies:** that induces an enabling environment for scalable and sustainable mHealth services.

6. **Monitoring, Evaluation and Evidence:** including evaluation methodologies and mHealth for NCD impact assessments.

Only Norway, Costa Rica and Senegal have been able to start their project during the first two years. Most of the other implementations have only begun quite recently.

The initial four years of the program focused on those 8 countries was supposed to end in October 2016 with a budget of roughly US$9 million but only US$5,3 million had been levied leaving a gap of US$4.7 million. The project had anticipated a much higher financial involvement from the sporting goods and telecom industries. Due to late start however, only US$1.9 million had been spent end of 2015 leaving a surplus of US$3,4 million for 2016+.

	2013	2014	2015	2016+	4year+ total	Funding gap 2013-2016
Pharmaceutical IFPMA, GSK, Novartis and Sanofi	$104,895	$150,000	$648,006	$750,000	**$1,652,901**	**$347,099**
Health insurance/ wellness Bupa	$150,000	$350,000	$500,000	$1,000,000	**$2,000,000**	-
Sporting goods	-	-	-	-	-	**$2,000,000**
Telecoms/ technology Verizon	$71,429	-	$71,429	-	**$142,858**	**$1,857,142**
Bilaterals/ foundations African Development Bank, WHO, WDF, Norway	-	$140,959	$545,354	$830,000	**$1,516,313**	**$483,687**
All Sectors	**$326,324**	**$640,959**	**$1,764,789**	**$2,580,000**	**$5,312,072**	**$4,687,928**

Figure 22 : Funding of the Be He@lthy Be Mobile initiative

Each participating country is requested to show its support by contributing to the program. In developed nations this is usually project financing. In developing countries where self-financing is impossible, countries are expected to offer political support and in-kind contributions, via partnership with local telecoms for example. This display of commitment is designed to

ensure that the mHealth interventions have sufficient resources to make them sustainable after the WHO-ITU program ceases its involvement in country activities.

Financial contributors to date include **pharmaceutical firms** (such as GSK, Novartis, and Sanofi); **health-insurance**/wellness corporations (Bupa); **Telecom company** (Verizon) **regional organizations** (African Development Bank, Asian Development Bank) and **Norway**. Academic institutions (Oxford University, Cambridge University's Judge Business School, the University of Southern California) and civil-society health organizations (The NCD Alliance) have offered in-kind contribution.

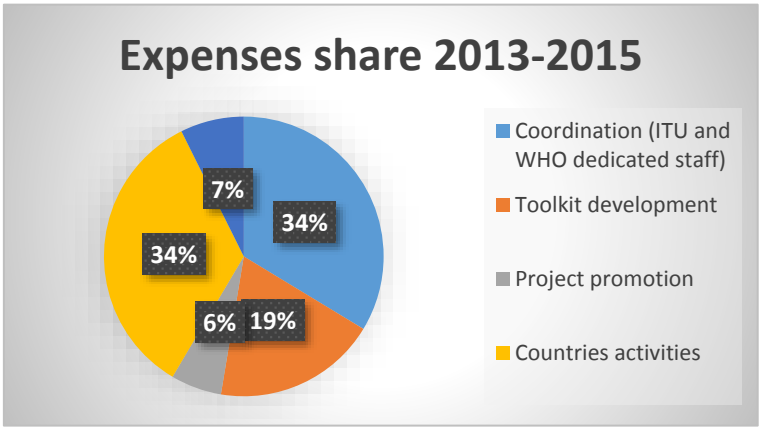


Figure 23 : Expense share of the Be He@lthy Be Mobile initiative

With only 34% of expenses allocated to in-countries activities, the majority of the resources available have been used to support coordination costs and the development of the toolkit. Even for the countries which started early, the amount invested remains relatively modest (approx.. US$ 165.000 e.g. for Costa Rica and Senegal.

The methodology of the projects involves outcome-based systems to monitor progress and measure impact. Individual country projects are to be evaluated using mobile technology that will feed into national information systems and central monitoring across the eight countries. **WHO is indeed very keen to see the initiative strengthening domestic monitoring systems**. In line with WHO guidelines third party evaluations of the global and country projects are foreseen. Interim evaluations have already taken place for the early starters. **Monitoring and evaluation** is considered as a service per se.

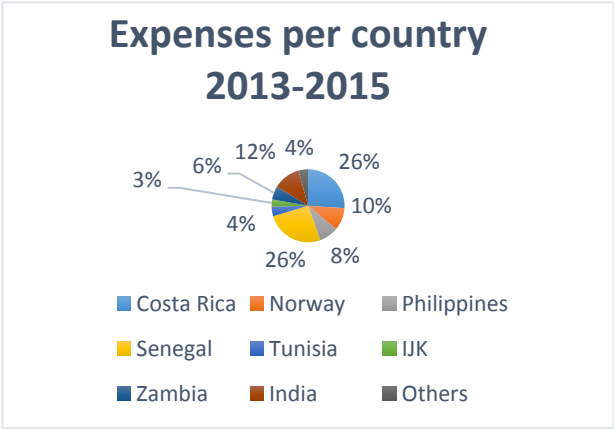


Figure 24: Be He@lthy Be Mobile: Expense per country (2013-2015)

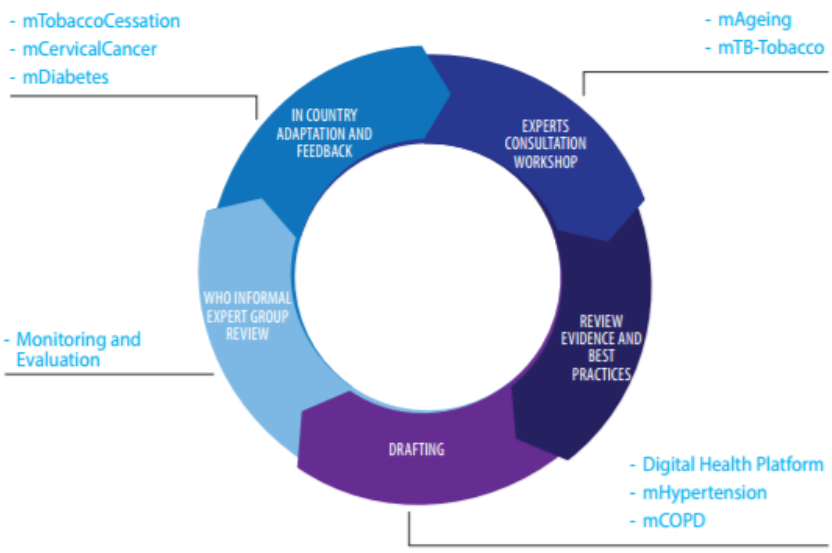


Figure 25 : Be He@lthy Be Mobile: current status of mHealth services

At the end of the four years WHO/ITU had foreseen to go through their normative processes and ensure that the mHealth interventions scaled through this project are standardized for the world (ITU study group process/WHO guidelines process). Handbooks for each mobile intervention are thus to be developed by the Secretariat with the support of an informal advisory expert panel for each theme together with academic and technology partners. These documents contain business and technology rules and operation guides, as well as content for the specific disease intervention. Considering the late start in a number of countries, it seems clear that all the guidelines will not be produced in 2017. Even if no supplementary resources are not identified, it will take at least a couple of supplementary years to gain and monitor experience in the targeted countries. The graph above shows the status (2016) of a number of those guidelines. The future direction (extension, budget, number of countries…) of the initiative still needs to be clarified.

4.11 WHO classifications in support of eHealth

The health classifications developed by WHO are de facto the ones which are widely used around the world. They have been developed with the key objective to support the monitoring and evaluation of health systems and therefore also to allow comparisons between these systems; they can be considered as the main WHO contribution to health data standardization.

Aiming at monitoring the incidence and prevalence of diseases and other health problems of population group, the International Classification of Diseases (ICD) is presented by WHO as the standard diagnostic tool for epidemiology, health management, and clinical purposes. This includes, providing a picture of the general health situation of countries and populations.

Figure 26: WHO family of International Classifications

Many countries have been introducing "pay for performance" schemes, focusing in particular on hospital care, with the objective to incentivize health actors to improve quality of care, follow best practice and to a certain extent contain costs.

It became then necessary to classify patients in homogeneous clinical groups while being able to compare the resources used for their treatment. WHO ICD classifications are thus instrumental for this purpose but many countries have adapted them in order to make them fit to the specific features of each national system, leading thus to a number of derived classifications.

ICD (and other related classifications) coding has thus remained unchallenged for a long time while the work related to this coding was confined to a somewhat closed ecosystem.

The development of eHealth is largely challenging this legacy. The perspective of an intensive use of artificial intelligence in healthcare together with the many expected other benefits of semantic interoperability require to consider the "coding" of health data from a wider angle and to take into consideration not only of the statistician "coder" but also the practitioner and the patient.

Until recently WHO was considering that its classification systems were adapted to deal with all the purposes, including clinical practice, that eHealth can ambition to support. Contrarily to clinical terminologies, it is however widely recognized today that WHO classifications have not been built to support clinical practice.

The Recommendation ITU-T H.860 (2014), *Multimedia eHealth data exchange services: data schema and supporting services,* for example, which specifies a common health schema applicable to a wide range of health systems, refers exclusively to WHO ICD for diagnostics and complaints, AMA CPT for procedures and LOINC for clinical observation. No reference is made to clinical terminologies such as e.g. SNOMED CT.

Since a few years however, WHO has been increasingly aware of the importance to establish formal relationships (mapping) between its classifications and clinical terminologies developed out of its direct control such as SNOMED-CT and has thus somewhat facilitated this process.

Since 2012, the SNOMED International/WHO collaboration covers all WHO classifications. WHO is however not part of the Joint Initiative Council which organizes the collaboration between 8 different Standard Development organizations (SDOs). The collaboration between WHO and SNOMED International is thus from that perspective a more "ad hoc" one.

The SNOMED CT to ICD-10 map and link to ICD-O is now released twice a year by SNOMED-CT and since the July 31 2015 release, an algorithmic approach has been used in the completion of the map and Algorithms have been incorporated into the mapping tool for the July 31 2016 release. SNOMED International also publishes a map between the SNOMED CT International General/Family Practice subset (GP/FP subset) and the International Classification of Primary Care, 2nd Edition (ICPC-2). The GP/FP subset focuses on two semantic data types commonly used in general/family practice electronic health records: Reasons For Encounter (RFEs) and Health Issues.

As far as ICD-11 is concerned, the need to establish those links is clearly established as stated by the WHO answer to the report it commissioned to an independent panel to obtain a view of current progress on contents and process of the revision:

"*Objective 3: The ICD revision established solid linkages with terminologies such as SNOMEDCT; and has developed computerized infrastructure for editing and sharing including webbased tools such as iCAT, ICD Browser, Mapping Tool, Coding Tool (electronic index) and others which are freely available to stakeholders. A computer assisted Multi-Lingual ICD Tool has been created for all languages making use of previous ICD translations, with available linguistic tools to enable digital translations in all languages with a priority on WHO official languages."*

On its website, WHO also states that: "ICD-11 is built for an electronic environment, facilitating the classification of information in electronic health records, with technology assistance including coding tools, browsers, and different web services, focusing on ease of use and improved specificity and consistency of the coded data. ICD-11 has a focus on interoperability and consistency with other information products (e.g. SNOMED-CT for clinical recording) (….)".

Concretely, the work performed by IHTSDO related to ICD-11 is to ensure there is content alignment so that there can be a linkage, and this is resulting in new content in SNOMED CT where it is clinically valid. The WHO effort to drive for ICD-11 has been originally mainly motivated by the need to manage diagnostic information in different ICT-tools.

Given all the numerous current changes at WHO, both personnel wise and approach to ICD-11, IHTSDO priority is now on a map between SNOMED CT and ICD-11 MMS (Mortality and Morbidity Statistics) which is due for release in 2018. The work of SNOMED International in this effort will feed in to the field testing being undertaken by WHO of the ICD-11 MMS as additional quality assurance. SNOMED International Member countries will be participating in the mapping activity being undertaken by SNOMED International.

This initial approach is being adopted as a short term solution to provide a linkage until WHO and SNOMED International have time and resources to work together on managing a linkage to the ICD-11 Foundation layer in a more systematic way.

WHO had taken a number of other initiatives to try to answer to the new pressing harmonisation requests such as e.g. the need for a unified nomenclature system for medical devices that could be used globally. An informal information session gathering all stakeholders took place in March 2011; in 2008, a previous meeting had concluded that "the end product, that is the "single" or "consolidated" nomenclature system, should be managed by WHO". However, the March 2011 meeting which agreed on the need to build a UDI (unique Device identification) rather assigns to WHO a facilitation role in the process. A number of follow-up meetings were foreseen but the initiative was then in fine mainly developed by GS1 with the active support of a number of official agencies. WHO plays also a relatively passive role in the current strategic discussions surrounding the safe identification of drugs and its structuring concepts associated with the implementation of the standard ISO IDMP (Identification of Medicinal Products) although the Uppsala Monitoring WHO Collaborating Center and WHO Geneva have been associated to the talks and WHO Geneva has offered to shelter the algorithm which can produce the central identifier.

4.12 WHO collaborating centers and NGOs.

WHO collaborating centres

WHO has selected a number of collaborating centres for eHealth, telemedicine and health informatics around the world that help WHO to fulfil its eHealth's mandate. Two of those centres are located in Europe (Norway and Switzerland). One of the recent recommendations of the report produced by WHO Europe is to make more use of those centres.

The Designated institutions include:

- Asian Pacific Ubiquitous Health Care Research Centre, University of New South Wales (UNSW)

➢ Key focus is on developing ***models and indicators for the assessment of eHealth/mHealth*** in improving access to and quality of healthcare delivery and mHealth applications for ageing and chronic care; the approval of the status of WHOCC (WHO collaborating centre) was granted after UNSW-Australia completed WHO projects on eHealth and mHealth in Asia Pacific countries (India, China, Vietnam, Philippines, PNG, Bangladesh and Nepal) since 2006.

- Centro de Relações Internacionais em Saúde (CRIS), Fundação Oswaldo Cruz (FIOCRUZ)

➢ Role of technical support to MS in implementing the Rio Political Declaration (RPD) on Social Determinants of Health (SDH). To Support the WHO ***ePORTUGUESe Programme*** and upon request, to support MS to strengthen disease surveillance, prevention and control.

- Center for Health Statistics and Information (CHSI), Ministry of Health of the People's Republic of China

➢ Terms of reference are quite overwhelming but focus mainly on sharing implementation experiences and best practices, supporting knowledge sharing on information system development and informatics to MS and contributing to technical interoperability challenges.

- Norwegian Centre Telemedicine, University of Hospital of North Norway

➢ Proposed contribution is providing advice and consultancy on best practices in national settings, identifying and developing an evidence base on the use of telemedicine and eHealth for improving access to and quality of health service delivery, and enhancing performance of health service providers, supporting/facilitating/developing e-learning programs as a means for health system capacity building.

- Département d'imagerie et des sciences de l'information médicale, Hôpitaux Universitaires de Genève

➢ Terms of collaboration include: development of an ***eHealth and telemedicine impact evaluation framework***, increase capacity building for health information systems standardization and interoperability, remote education and support of Health care professionals (and production of training materials), convergence between patient care and public health.

- Centers for Disease Control and Prevention (CDC), The Center for Global Health, Division of Global Health Protection, Global Health Security Branch, Systems and Planning Team:

➢ Key focus is on supporting informatics efforts pertaining to Integrated Disease Surveillance and Response (IDSR) framework in national programs participating within Africa. The CDC is also meant to provide input for minimum data standards for routine ***disease surveillance systems*** and collaborate to an annual scientific event.

WHO has also established official relations with the following **Nongovernmental Organizations (NGOs)** which are officially invited to take part in the meetings of the World Health Assembly and other WHO HQ and Regional Offices official meetings and events and thus contribute to work on eHealth policy and eHealth strategy implementation. The projects implemented by those organization are however mostly independent from WHO but contribute directly to some of the priority objectives put forward by WHO.

- International Medical Informatics Association (IMIA)

The International Medical Informatics Association is an independent organization established under Swiss law in 1989. As an 'association of associations' bridging the world of health and biomedical informatics, IMIA membership consists primarily of Member Societies, Institutional (Academic and Corporate) and Affiliate Members, and Honorary Fellows.

IMIA has been deploying and evaluating the impact of ***a large telemedicine and distance education network in Sub-Saharan Africa***. The project called RAFT (Réseau en Afrique Francophone pour la Télémédecine- (http://raft.network) started in 2003 in Mali and Mauritania. It aims at using simple and robust informatics tools, adapted to local conditions, to ease communication, collaboration and remote training of healthcare professionals. It is now active in 20 French speaking countries in Africa. Content originally only available in French has been progressively extended from 2008 onwards to English, Spanish and Portuguese thanks in the two latter cases to interest in Bolivia and Angola.

The core activity of the RAFT is the webcasting of interactive courses targeted to physicians and other care professionals, the topics being proposed by the partners of the network. Courses are webcast every week, freely available, and followed by hundreds of professionals who can interact directly with the teacher. 70% of these courses are now produced and webcast by experts in Africa. A bandwidth of 30 kbits/second, the speed of an analogic modem, is sufficient, and enables the participation from remote hospitals or even cybercafés.

The network is currently organized and run by more than 40 national coordinators throughout Africa, and by a coordination team based in Geneva. In each of the partner countries, the RAFT activities are supervised by the focal point, a medical authority (usually a

university professor) that links the project to the national governmental bodies (ministry of health, ministry of education). A local medical coordinator (a junior physician) and a technical coordinator take care of the day-to-day operations, including communication with the care professionals, identification of training needs, technical training and support of the various sites within the country. The program has been developed in partnership with the Université Numérique Francophone Mondiale (UNFM)

Other activities of the RAFT network include medical tele-expertise, tele-ultrasonography, and collaborative development of educational on-line material.

- International Society for Telemedicine and eHealth (ISfTEH)

ISfTEH mission statement is to facilitate the international dissemination of knowledge and experience in ***Telemedicine*** and eHealth and to provide access to recognized experts in the field worldwide. Members include organizations representing telemedicine/eHealth in their particular countries and their affiliates, institutional members such as governmental and non-governmental academic institutions and commercial organizations such as manufacturers, distributors and telemedicine service providers.

ISfTEH works through online forums, offline discussions and collaboration, but also through face-to-face meetings or sessions and presentations at events like the annual ISfTeH International Conference and the annual Med-e-Tel meeting.

ISfTEH has established a number of Working Groups (16 to date) which focus on a specific medical discipline or application (e.g. teledentistry, teleopthalmolgy or collaborative Care Team in Open Source). They can also be a group of members with a same profession or activity (e.g. junior doctors, students). Or they can have yet another topical focus (e.g. eHealth Economics, Social Media).

Finally ISfTEH has also produced online concrete education material such as the Telemedicine Training Outline which provides a practical working knowledge of Telemedicine and competence in the ethical use of Telemedicine and Tele-education.

- Health On the Net Foundation (HON).

The role of HON has already been described under section 4.6 (Governance of health internet and certification of health content).

5. Synthetic categorization of WHO outputs

Action plan (AP)
Country Profiles (CP)
Knowledge sharing/best practices (KBP)
Report (RE)
Reports with recommendations (REC)
Terms of reference or specification (TOR)
Toolkit/Guideline (TKG)

Document name and URL	Decsription	Year	Scope	Topic	Type	Target
Working document. eHealth solutions in the African Region: current context and perspectives	Africa WHO Regional Office work plan	2010	Global		AP	Africa
Strategy and plan of action on eHealth for Americas 2012-2017	Americas WHO Regional Office Work Plan	2011	Global		AP	Americas
Strategy and action plan (2014-2020) for South East Asia	South East Asia WHO Regional Office Work Plan	2014	Global		AP	South East Asia
Countries profiles (2005)	Atlas of eHealth Country profiles (Survey 2015)	2006	Global		CP	WORLD
Global Observatory for eHealth series - Volume 1	Atlas of eHealth Country profiles (Survey 2009)	2011	Global		CP	WORLD
Atlas of eHealth country profiles 2013: eHealth and innovation in women's and children's health:	Atlas of eHealth Country profiles (Survey 2013)	2014	Global		CP	Developing countries
eHealth country profiles (2015)	Atlas of eHealth Country profiles (Survey 2015)	2015	Global		CP	WORLD
ePORTUGUESe Initiative	Knowledge and Best Practice sharing between 8 Portugese speaking language	2005	Global		KBP	Portugese speaking countries
Question 14-2/2 Mobile eHealth solutions for Developing Countries	ITU-D Case studies report describing mobile health solutions implemented by Low or Middle Income countries	2010	Thematic	mHealth	KBP	Developing countries
Directory of policies (2015)	Ehealth Directory of country policies based on survey (2015) data	2015	Global		KBP	WORLD
eHealth Conversations: Using Information Management, Dialogue, and Knowledge Exchange to Move Toward Universal Access to Health	Insights from experts who contributed with knowledge and reflections on the present and the future of eHealth in the Americas	2016	Global		KBP	Americas
eHealth tools and services: Needs of the MS	Preliminary report based on results of the 2005 survey	2006	Global		RE	WORLD
Building Foundations for eHealth: Progress of MS	Final Report and recommendations based on the findings of the 2005 survey.	2007	Global		REC	WOLRD

Building Foundations for eHealth in Europe	Report and recommendations based on the findings of the 2005 survey (Europe).	2008	Global		REC	Europe
Global Observatory for eHealth series - Volume 3 : mHealth	mHealth: New horizons for health through mobile technologies: Based on the findings of the 2009 survey	2011	Thematic	mHealth	REC	WORLD
Global Observatory for eHealth series - Volume 2 : Telemedicine	Telemedicine – Opportunities and developments in MS : : Based on the findings of the 2009 survey	2011	Thematic	Telemedicine	REC	WORLD
Global Observatory for eHealth series - Volume 6 : Management of patient information	Management of patient information: Trends and challenges in MS : Based on the findings of the 2009 survey	2012	Thematic	EHR	REC	WORLD
Global Observatory for eHealth series - Volume 5 : Legal frameworks for eHealth	Legal frameworks for eHealth: Based on the findings of the 2009 survey	2012	Thematic	Legal	REC	WORLD
Global Observatory for eHealth series - Volume 4 : Safety and security on the Internet	Safety and security on the Internet: challenges and advances in MS : Based on the findings of the 2009 survey	2012	Thematic	Security	REC	WORLD
Report of the first WHO forum on health data standardization and interoperability	Recommendations on standards development and use	2012	Thematic	Standards	REC	WORLD
ICT for Improving Information and Accountability for Women's and ChIldren's health	ITU-D Recommednations (Developing countries)	2012	Thematic	MCH	REC	Developing countries
Report on eHealth standards and interoperability	Report (sole author) on status of eHealth standards	2012	Thematic	Standards	REC	WORLD
eHealth and innovation in women's and children's health: A baseline review	Based on the findings of the 2013 survey of CoIA countries by the WHO Global Observatory for eHealth	2014	Thematic	MCH	REC	Developing countries
Discussion paper on Legal and Regulatory Challenges of Mobile Health (mHealth) in Europe	Report (sole author) on legal obstacles to mHealth in Europe	2014	Thematic	Legal/ mHealth	REC	Europe
Second WHO Forum on eHealth Standardization and Interoperability	Recommendations on standards development and use	2014	Thematic	Standards	REC	WORLD

Global diffusion of eHealth: Making universal health coverage achievable	Report of the third global survey on eHealth (2015)	2016	Global		REC	WORLD
From innovation to implementation:eHealth in the WHO European Region	Regional Report on eHealth in Europe based on the findings of the 2015 survey of European countries	2016	Global		REC	Europe
Breaking the barriers to implementation	Regional Report on eHealth based on findings of the 2015 survey for Americas	2016	Global		REC	Americas
National eHealth Strategy Toolkit	High level guideline to support National eHealth Stetegy development (ITU/WHO)	2012	Global		TKG	WORLD
Compendium of innovative health technologies for low-resource settings (2013)	Assistive devices eHealth solutions Medical devices	2013	Thematic	Devices	TKG	Developing countries
QUESTION 14-3/2 Information and Telecommunications/ICTs for EHealth	ITU-D Guidelines for Implementation of eHealth in Developing countries and lessons learnt	2014	Global		TKG	Developing countries
Question 28/16 (Multimedia Framework for eHealth Applications)	ITU Terms of reference Multimedia Framework for eHealth Applications	2003	Thematic	Standards	TOR	WORLD
Recommendation ITU-T H.860	Multimedia eHealth data exchange services: data schema and supporting services- specification	2014	Thematic	Standards	TOR	WORLD
Technical Paper ITU-T FSTP-RTM (2006), Roadmap for Telemedicine:	ITU-T Specifications/Guideline for Telemedicne development	2006	Thematic	Telemedicine/Standards	TOR/TKD	WORLD
Technical Paper ITU-T HSTP-H810	ITU Guideline standard (Personal Health Alliance)	2014	Thematic	Standards	TOR/TKD	WORLD

6. Preliminary conclusions:

As a UN worldwide organization, WHO has been relatively slow in integrating concretely the eHealth perspective and challenge Its coordination ambitions have so far been limited by a number of factors among which one can note:

- The complex governance and limited structural financial and human resources of the organization;
- The "worldwide" focus of the organization which requires to take into consideration very different needs, situations and constraints;
- The existence of numerous more focused regional or sub-regional other initiatives which have put WHO in a reactive rather than proactive situation.
- The complexity at stake and the highly transformational impact of eHealth on most of the public health domains.

WHO positioning has therefore been to act more as global "add-on" facilitator than as a formal coordinator. This is also the result of the discussions which took place within the World Health Assembly where some of the more influential MS opposed the idea to see WHO playing a normative/regulating role.

WHO has assigned itself a specific role in reducing the gap between developed and developing countries. Many of the eHealth related initiatives launched try indeed to increase awareness, collect best practice, support policy and propose methodological tools which can be useful for countries where resources remain scarce and which do not benefit from the support of other organizations. Specific emphasis put on questions such as universal access to care, innovative prevention strategies or training of healthcare professionals are also part of that rationale. From that perspective, WHO is thus filling an important gap.

In the paragraphs below, the objectives set forward by WHO himself are briefly commented:

Collect and synthesize good practices and facilitate access to knowledge: Through its Global eHealth observatory, WHO has invested heavily in the organization of 3 world surveys. Considering the variety of situations, elaborating a survey which covers the full range of eHealth dimensions is extremely challenging, WHO has however made the most of the information collected with the publication of global and thematic reports (the 6 thematic volumes) and in some cases of specific regional reports. Portal allows also to have access to Members Country Profile (2015) and to national eHealth digitally documented resources. The initiative has thus the potential to increase awareness and share knowledge at world level.

The use of surveys to collect and diffuse information suffers however many limitations:

- There is a clear "survey fatigue" in a number of countries where the same questions are being investigated by a number of a-organizations and actors with as a result a limited investment and sometimes validation from MS.
- Surveys provide snapshots but fail to capture evolving situations. Information is thus quickly outdated.
- The eHealth domains evolve permanently, creating constantly new needs and questions. The need to rely on a solid basic but evolving information framework is thus essential in order to make the information "actionable".

Surveys have often been built without taking into consideration information already available through other channels.

With eHealth becoming high on the political agenda of many countries, there is thus a real need to find alternative solutions to collect and diffuse meaningful information related to the fundamentals of an eHealth national strategy.

Support capacity building and policy Support: The national strategy eHealth toolkit produced with the support of ITU is the main policy support material produced to date. The document provides a very useful methodological approach, based on in depth analysis of success stories, to the development of a national eHealth strategy. The use of document is however facing a paradox: The toolkit seems to suffer from a deficit of diffusion/ownership in countries which could make the wider use of it (where the minimum prerequisites in term of availability of resources and basic infrastructure are met) while it is more widely promoted in less advanced countries but many countries lack the expertise and experience to make effective use of the tool. In Europe, more efforts should be done to reference and promote this very useful document.

As for developing countries, WHO and ITU have tried to reduce somewhat the complexity, to take into consideration the infrastructure available in developing countries and make the best of the opportunities offered by mHealth: the *mHealth for NCDs Tool-box* is thus an answer to adapt policy support and tools to the reality and needs of developing countries.

Support to regional action plans: the WHO regional offices can also play a catalyst role depending on the motivation of its members and the existence or not of other initiatives. The "leadership" of WHO can thus somewhat vary from region to region. South America and South East Asia for example have both established a pluri-annual relatively detailed eHealth action plan with the support of WHO regional office. In Europe, given the role played by the European Union, the WHO Regional Office has rather decided to act as a bridge between EU and non EU countries by producing specific reports outlining the European eHealth reality through the information collected through the surveys and focusing on specific issues such as the legal barriers to mHealth. Through this flexible role of its Regional Offices, WHO remains thus in a position to support an active cross-fertilization between regions

Policy recommendations: WHO governance instances, and notably the World Health Assembly, have issued a number of high level global and specific recommendations together with a number of follow-up actions which have been described earlier in the document. Of particular relevance for Europe are the recommendations listed in the report published in December 2016 called "from innovation to implementation". The report synthetizes a number of high level recommendations but makes also explicit references to initiatives and materials developed in Europe such as ***the Refined eHealth European Interoperability Framework*** and recommends the ***introduction of a quality management system for interoperability testing***, a set of appropriate testing tools and quality label and certification processes. In line with one of the key recommendations of the discussion paper on mHealth published in 2014, it also encourages MS to ***establish an entity responsible for the regulatory oversight of mHealth applications***. It also considers that further detailed legislation surrounding ***the use of national electronic health records*** should be further developed and harmonized by MS and that specific attention should be the use of social

media. WHO Europe states that it will intensify ***open and active partnerships*** with the European Commission, Organisation for Economic Co-operation and Development, World Bank, nongovernmental organizations and other international stakeholders engaged in developing and promoting eHealth.

Support education and knowledge sharing through e-learning:. The educational modules proposed by the health academia are mainly supporting the diffusion of key educational messages of primary importance from a public health point of view. They have their own "awareness" rationale and value but can barely be associated per se with the development of eHealth in a specific country. The initiatives taken by WHO related to the remote training of healthcare professionals are of limited scope as they target priority topics related to the work of UN agencies. WHO has up to now not taken the decision to act as broker or facilitator to quality e-learning programmes such as "massive open online course" (MOOC) organized today by a number of credible organizations and institutions.

As mentioned earlier, IMIA, one of the NGO in official partnership with WHO, has however implemented a large scale MOOC project called RAFT. The initiative ePORTUGUESe has also to some extent contributed to the diffusion of eHealth related resources in Portuguese speaking countries.

Collaborate with other organizations of the United Nations system and stakeholders to **develop and adopt eHealth standards:** Most of the initiatives taken by WHO to date have rather targeted ad hoc facilitation and awareness than development and adoption of standards. There is no evidence of recent activity of the eHSCG (eHealth standard coordination group) which thus seem not to play any real- be it passive- role of coordination between SDOs. The forum on health data standardization organized by WHO/ITU in 2012 has certainly contributed to increase global awareness of the importance of the issue and has led to the elaboration of a number of high level principles but most of the foreseen follow-up actions have not really materialized. ITU has indeed developed a number of standards covering a number of issues also relevant for eHealth but its original contribution to eHealth standards stricto sensu is rather limited as it covers mainly the incorporation of the standards developed by the Personal Health Alliance (ex Continua Health Alliance). The Recommendation ITU-T H.860 (2014), *Multimedia eHealth data exchange services: data schema and supporting services* may appear as a an attempt to provide a first answer to the follow-up action "identify and provide a **core set of minimum standards**" but this standard seems by many aspects already largely outdated and is not used as a reference by most advanced countries. Two important objectives set forward in 2012, namely: to facilitate a **mechanism to provide free and open access** to existing standards **and host a 'gateway' on eHealth standardization and interoperability** to serve as a single source of information for MS and other stakeholders have not materialized. The other objectives, such as setting interoperability goals, helping to build policies for data sharing, providing support to countries in decision-making on standards technical or providing support for implementation of standards do not seem to have yet been rooted in dedicated initiatives.

As for the objective to help unify data and setting standards for coding and data sharing across countries, WHO has positioned itself more as a SDO or as a facilitator than as a coordinator although it is increasingly aware of the importance to create the conditions of a

global ecosystem as shown by the willingness to establish "structural" linkages with terminologies such as SNOMED-CT.

WHO does not however seem to be in a position today to play a leadership role and on this aspect and, as for the others, rather tries to bring the perspective and voice of developing countries.

Be he@lthy be mobile is the first real experiment with direct operational impact launched by WHO/ITU. While the conditions of developing countries are very much at the core of the initiative, the portfolio of mHealth services at stake is relatively extended and can also be of interest for developed countries. A mix of developed and developing countries is indeed seen as important in order to obtain wide validation and facilitate knowledge sharing. The future guidelines associated to specific pathology/issue, when accompanied by appropriate technical support, have the potential to convince a number of countries to embark on the eHealh journey as shown by the important number of countries have expressed their interest to join the initiative. Originally foreseen for a period 4 years ending in 2016, the project will most probably be further extended as many implementations have only begun recently. It remains however very fragile with a funding which currently mainly relies on participation from the private sector and which has for now not been up to the expectations.

Impact indicators and (e)Health monitoring: The reinforcement of health information systems and the capacity to develop indicators which are fed by objective and qualitative data is a WHO priority. When describing the three initial scenario, the national strategy eHealth toolkit refers to the capacity of a (e)Health system to produce the data necessary for the monitoring and evaluation of the health system. The same toolkit insists in part 3 (evaluation and monitoring) on the necessity to rely on "results based management". The toolkit proposes a number of high level examples of quality outputs and outcomes indicators classified by stakeholders and describes how to make them measurable. The Be he@lthy be mobile initiative is also proposing a dedicated evaluation and monitoring module for mHealth. Those tools are a first interesting step but in order to make substantial progress, it is essential that key indicators are defined, described and maintained through a sustained coordinated approach, in close collaboration with organizations such as OECD which have already invested and produced a guideline on the issue. One of the recommendations of WHO Europe is to use the ***WHO European Health Information Initiative*** to support this objective. The ultimate objective should also be to go beyond eHealth outcome indicators and to investigate more ambitious impact assessment (such as contribution to health system quality or efficiency and impact on morbidity or mortality). This was already stressed in the WHA66.24. resolution which was approved by the World Health Assembly in 2013.

As an overall preliminary conclusion and considering current situation and needs, it appears that there is a limited immediate added value for the eHN to invest further in a structural collaboration with WHO. However, the governance and materials adopted by the eHN together with the knowledge accumulated might certainly provide valuable inputs to support the global objectives pursued by WHO. Given the acute need to accelerate knowledge diffusion, to develop common referentials and support wider interoperability, communication channels could certainly be improved. The recommendations proposed here below support that statement.

One of the messages for me is that WHO don't appear to work well with other global eHealth actors. Is that intended to come across? If so, this might be good reason for a recommendation about convergence 9e.g. over ICD110

the focus is on WHO helping the eHN but there is plenty of scope for eHN to contribute to the work of WHO - could we not propose this?

7. Recommendations and possible actions to be undertaken

On the base of the general assessment performed, a number of follow-up actions are suggested. Some can be implemented on a short or medium term basis without major new investment while others will require new formal decision and collaborating mechanisms to deliver concrete outputs.

General short-term recommendation to the eHealth Network:

- Improve **visibility and accessibility** to main key resources already developed by WHO and OECD. Many resources, such as the **national eHealth strategy toolkit**, with a potential high added value for policy support and the development and monitoring of national eHealth action plans are insufficiently known, used or maintained.

Those resources should be:

- Categorized and indexed in such a way that they can easily be retrieved and evaluated quickly against purposes. This deliverable can be seen as a first step in this direction.
- Cross-referenced between organizations and thus submitted to a formal submission process between organizations.
- Documented -when appropriate- using the structure/template proposed by the Refined European Interoperability Framework (ReEIF)[7].
- Promoted adequately, after approval of the eHN, through the adequate European web-portals.

- Actively **use WHO European regional office** to act **as a go-between EU and non EU countries in Europe** in the dissemination of key resources produced by the eHN.

This echoes in particular WHO Europe recommendation to "act as a **knowledge broker for development of best practices** for eHealth and innovation within a European context (2016). "

[7] http://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf: six levels are defined: Legal and regulatory, policy, care process, information, applications and IT infrastructure.

- Consider to promote and reuse elements and lessons learnt of the **Be He@lthy Be Mobile** initiative which have an added value for the MS of the eHN.

Although the initiative is relatively recent and focus in priority on Low or Middle Income Countries, it conveys a number of services and tools which could prove very valuable for EU MS. The **Millicit service** for example use mobiles to register serial numbers for cancer and other NCD drugs, tracking deliveries and avoiding counterfeits. Even if the problem is by far less acute than in other regions of the world, there has been a recent increase in the prevalence of counterfeit medicines even in developed countries. Most counterfeit branded pharmaceuticals include indeed innovative treatments for severe diseases (antic-cancers, heart diseases, anti-cholesterol and antihypertensive drugs, psychological disorders and infections) whereas before, counterfeit had more to do with lifestyle drugs such as erectile dysfunction.

General short-term recommendation to WHO :

- Intensify ***open and active partnerships*** with the European Commission, Organisation for Economic Co-operation and Development, World Bank, nongovernmental organizations and other international stakeholders.

Extend your partnerships to all actors actively engaged in developing and promoting eHealth, with the aim of leveraging the collective strengths of each in providing harmonized support to MS and also capture lessons learnt from EU and non EU countries.

Commitment to align WHO classification systems, and in particular ICD11, with clinical terminology such as SNOMED-CT currently adopted by numerous MS should be reasserted and reinforced.

Valuable work performed by official WHO current partners such as IMIA (e-learning) could be better promoted while other valuable similar initiatives could be identified and diffused.

Medium term recommendations to WHO and the eHealth Network related to telemedicine and mHealth:

- Consolidate and use all **valuable information collected on Telemedicine**

Due to its worldwide mandate, telemedicine has been a key focus for WHO/ITU from 2005 onwards. The telemedicine roadmap report (2006) produced by ITU-T is today outdated but could still be used as reference material for a number of aspects together with the volume 2 of the eHealth series "Telemedicine: opportunities and developments in MS: report on the second global survey on eHealth, 2009". The telemedicine training kit developed by one of the WHO NGO official partner, the International Society for Telemedicine and eHealth (ISfTEH) would also benefit from a wider

diffusion in Europe. WHO has also collected interesting evidence from telemedicine implementation projects all around the globe and which, if consolidated, could contribute to a better knowledge of telemedicine outcomes and benefits and therefore contributes to a wider adoption in Europe.

The European Commission has also taken a number of initiatives and has funded a number of coordination and implementation projects[8] which involved an important number of European regions. It published in 2012 a staff working document on the applicability of the existing EU legal framework to telemedicine services while more recently the eHealth Stakeholder Group (March 2014) has produced a report of on implementing the Digital Agenda for Europe Key Action 13/2 'Telemedicine'

Information present in those different reports and projects have intrinsic value but semantic referential, lessons learnt and recommendations set forward could be integrated in a common framework in order to guarantee progressive alignment of concepts, consistency in the recommendations and early identification of best practices.

Telemedicine and mHealth are furthermore closely connected topics which should not be separated artificially when considering consolidation.

Longer term recommendations which require new formal collaborating mechanisms between the eHealth Network, WHO and OECD.

Towards a permanent structure to evaluate National eHealth Strategies:

- **Establish a reference database for monitoring implementation of National eHealth strategy and plan**.

The use of surveys to collect information from National contact points encounters important limits, especially in a rapidly evolving sector. Effective transfer of knowledge requires the necessity to rely on quality and validated information which is regularly updated and accessible though the web. Today, in the European Union, several country profiles with different sets of data, different dates and different validation methods are accessible through the internet.

Surveys will probably always be necessary in order to address some urgent or specific questions but resources and energy should now be allocated to the creation of a referral database which should first concentrate on monitoring key enabling eHealth building blocks and progressively be extended to the use of services. If surveys are still to be conducted, **preliminary consultations between organizations** concerning timing, content and indicators need to take place.

8 See for example Renewing Heath, United4Health, Momentum

The consolidated structured database through its advanced search capabilities would offer extremely valuable information to a variety of key stakeholders, and first of all for public decision-makers in opposition to the current "snapshot" and rather static situation.

As a first step, on the base of the existing initiatives, a **canvas of the minimum set of data[9] (and their context of use) to be provided by each country should be established**. The eHN with the support of the JAsEHN and WHO Europe could be instrumental in this perspective.

A governance mechanism to define the rules necessary for the selection of the data, their update, validation and publication will need to be established with the support of all participating organizations.

The fulfilment of the referral eHealth database (and its updating mechanisms) should also rely on the suggestions of its members.

A link with the key consolidated policy recommendations of major international organizations (in original language and English) should allow to monitor their overall progress in this respect.

Finally, the creation of **a permanently maintained reference eHealth glossary**, objective put forward by the SG 16 of ITU-T, would certainly contribute to increase understanding and comparability.

Towards a common validated referential of eHealth outcome and impact indicators

- **Identify and/or develop and validate a set of core eHealth outcome and impact indicators.**

Some important work has already been accomplished, notably by OECD, but still needs to be further explored and consolidated.

The proposal made by WHO Europe in its 2016 report "from innovation to implementation" to work under the umbrella of the WHO European Health Information Initiative created in 2015 and of which 21 EU MS are now members, to "build capacity for implementing and managing eHealth as a national strategic asset and to further its role in reforming national health information landscapes" is certainly very supportive of this objective. Although links are said to have been established with the OECD and the European Commission, the fulfilment of this objective will require a dedicated shared workplan and associated resources.

Once evaluated as sufficiently robust by a representative official panel to be created , those indicators should be actively promoted and used by Individual States. They should also then be used to measure the deployment and use of services to be progressively included in the referral eHealth permanent database.

9 The first set of data could be focused first on essential infrastructure and infostructure components while providing being able to categorize the overall context (role of public/private actors, overall connectivity etc..)

Towards a common inventory of existing and emerging standards

- **Host a 'gateway' on eHealth standardization and interoperability** to serve as a single source of information for MS and other stakeholders.

No international organization seems today in a position to coordinate the **identification, production and validation of standards related to eHealth**. With rapidly evolving technology and needs and multi-sectoral aspects at stake, this is more than ever a moving and complex target. Priority should therefore first go to an effective global monitoring of existing and emerging standards actually implemented in such a way that it is accessible to a variety of stakeholders. A number of MS and international organizations have all conducted at some point of time their own situation analysis. The information here again is however quickly outdated and is not necessarily widely available.

The centralized documentation of the standards used accompanied by implementation guidelines and use cases is a preliminary condition for future alignment and harmonization. It should also allow taking conservatory measures in order to avoid major harmful divergences between SDOs. Information concerning effective use of those standards would be provided by the reference eHealth database which could also then de facto play an active information and dissemination role.

Preliminary work already performed by Nictiz (Holland) and Ireland could here be used as inputs while links need to be established with the European Multi Stakeholder Platform on ICT Standardisation and the Joint Initiative on SDO Global Health Informatics Standardization.

This echoes the global recommendations made by the 2 sessions of the WHO forum on eHealth standardization and interoperability (2012 and 2014) listed under section 4.7 and one of the 4 follow-up recommendations proposed by the 2016 WHO Europe report "from innovation to implementation".

One of the 2012 recommendations, namely to "*facilitate a mechanism to provide free and open access to existing standards to MS through an innovative financing mechanism*" should receive regained attention.

- Consider to include objectives associated to the implementation of current recommendations in the updated Multi Annual Workplan (MWP) 2018-2021

Given the important challenges at stake, an updated MWP supported by a new JOINT ACTION could have as one of its key focuses to work with the OECD, WHO and other selected organizations on the practical implementation of the current recommendations, once approved by the eHealth Network.