eHealth Strategies

Country Brief: Bulgaria

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About the *eHealth Strategies* study

The eHealth Strategies study analyses policy development and planning, implementation measures as well as progress achieved with respect to national and regional eHealth solutions in EU and EEA Member States, with emphasis on barriers and enablers beyond technology. The focus is on infrastructure elements and selected solutions emphasised in the European eHealth Action Plan of 2004.

Disclaimer

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Reviewer

Lidia Georgieva

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Executive summary

Bulgaria has developed its own "National Strategy for eHealth Implementation", approved in March 2006 which is aligned with the EC eHealth Action Plan 2004. Leading on from this is the "Concept on E-health" which is planned for early 2011. The main goal of these eHealth strategies is to improve the quality, efficiency and effectiveness of the healthcare system through the development of ICT tools that will allow to better plan and control the health service delivery process. The strategy will be revised in accordance with the "e-Governance strategy" 2010-2015 and planned healthcare system reforms. Other related documents that precede the strategy are: the "National Strategy for Information society development" (2004, 2006) and the "E-Government Strategy (2002)"

In order to consider Bulgaria's position regarding eHealth interoperability objectives the following eHealth applications have been examined: the Ministry of Health (MoH) pilots in patient summaries and electronic health records, ePrescription, standards and telemedicine and the National Health Insurance Fund (NHIF) integrated IT system. In overview Bulgaria's situation is as follows:

Bulgaria has made strong progress toward implementing eHealth solutions in its service provision. At the national level the main actors are –the Ministry of Health (MoH) and the National Health Insurance Fund (NHIF). MoH has completed six pilot projects financed by the European Union and the national budget in various applications along the supply chain. NHIF has implemented two projects linking NHIF with health providers (hospitals, GPs and outpatient specialists).

Yet, there are significant challenges that need to be addressed as Bulgaria moves forward in implementing its eHealth agenda. While most of the pilot projects of the MoH were completed, they were not scaled up. There has not been a comprehensive assessment of the effectiveness of the pilot projects and none of them have been taken up into routine services. While the IT system of the NHIF is functioning, it is fragmented. It has two different solutions for each level of care – one for hospitals, one for specialists and GPs. These two solutions are not linked and as such, it is impossible to develop a patient record integrating all levels of health service. In addition, these solutions do not provide options for real time data collection and do not collect information on drugs.

Going forward, it will be essential to build on the achievements to date and take into consideration the lessons learned thus far. The challenges with the pilots thus far indicate that unless a pilot is implemented in the context of a larger scale up plan, its effectiveness will be limited. It will be essential to develop a comprehensive strategy with specific steps, timing and costing and implement it gradually as financing for each stage is secured thus building and integrating the existing infrastructure.

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1 Introduction to the report

1.1 Motivation of the eHealth Strategies study

Following the *Communication* of the European Commission (EC) on "eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area",[1] Member States of the European Union (EU) have committed themselves to develop and issue national roadmaps – national strategies and plans for the deployment of eHealth applications addressing policy actions identified in the European eHealth Action Plan.

The *2004 eHealth Action Plan* required the Commission to *regularly monitor* the state of the art in deployment of eHealth, the progress made in agreeing on and updating national eHealth Roadmaps, and to facilitate the exchange of good practices. Furthermore, in December 2006 the EU Competitiveness Council agreed to launch the *Lead Market Initiative*[2] as a new policy approach aiming at the creation of markets with high economic and social value, in which European companies could develop a globally leading role. Following this impetus, the Roadmap for implementation of the "eHealth Task Force Lead Market Initiative" also identified better coordination and exchange of good practices in eHealth as a way to reduce market fragmentation and lack of interoperability.[3]

On the more specific aspects of electronic health record (EHR) systems, the recent *EC Recommendation on cross-border interoperability of electronic health record systems* notes under "Monitoring and Evaluation", that "in order to ensure monitoring and evaluation of cross-border interoperability of electronic health record systems, Member States should: consider the possibilities for setting up a monitoring observatory for interoperability of electronic health record systems in the Community to monitor, benchmark and assess progress on technical and semantic interoperability for successful implementation of electronic health record systems." The present study certainly is a contribution to monitoring the progress made in establishing national/regional EHR systems in Member States. It also provides analytical information and support to current efforts by the European Large Scale Pilot (LSP) on cross-border Patient Summary and ePrescription services, the epSOS - European patients Smart Open Services - project.[4] With the involvement of almost all Member States, its goal is to define and implement a European wide standard for such applications at the interface between national health systems.

Earlier, in line with the requirement to "regularly monitor the state of the art in deployment of eHealth", the EC already funded a first project to map national eHealth strategies – the eHealth ERA "Towards the establishment of a European eHealth Research Area" (FP6 Coordination Action)[5] - and a project on "Good eHealth: Study on the exchange of good

[1] European Commission 2004
[2] European Commission 2007
[3] European Communities 2007
[4] European Patients Smart and Open Services (epSOS)
[5] eHealth Priorities and Strategies in European Countries 2007

practices in eHealth"[6] mapping good practices in Europe - both of which provided valuable input to the present *eHealth Strategies* work and its reports. Member States' representatives and eHealth stakeholders, e.g. in the context of the *i2010 Subgroup on eHealth* and the annual European High Level eHealth Conferences have underlined the importance of this work and the need to maintain it updated to continue to benefit from it.

This country report on Bulgaria summarises main findings and an assessment of progress made towards realising key objectives of the eHealth Action Plan. It presents lessons learned from the national eHealth programme, planning and implementation efforts and provides an outlook on future developments

1.2 Survey methodology

The key tool to collect this information from the correspondents was an online survey template containing six main sections:

A. National eHealth Strategy

B. eHealth Implementations

C. Legal and Regulatory Facilitators

D. Administrative and Process Support

E. Financing and Reimbursement Issues

F. Evaluation

Under each section, specific questions were formulated and combined with free text fields and drop-down menus. The drop-down menus were designed to capture dates and stages of development (planning/implementation/routine operation). In addition, drop-down menus were designed to limit the number of possible answering options, for example with regard to specific telemedicine services or issues included in a strategy document. The overall purpose was to assure as much consistency as reasonably possible when comparing developments in different countries, in spite of the well-know disparity of European national and regional health system structures and services.

Under Section B on eHealth implementation, questions regarding the following applications were formulated: existence and deployment of patient and healthcare provider identifiers, eCards, patient summary, ePrescription, standards as well as telemonitoring and telecare.

The data and information gathering followed a multi-stage approach. In order to create a *baseline* for the progress assessment, the empirica team filled in those parts of the respective questions dealing with the state of affairs about 3 to 4 years ago, thereby drawing on data from earlier eHealth ERA reports, case studies, etc. to the extent meaningfully possible. In the next step, national correspondents respectively partners from the study team filled in the template on recent developments in the healthcare sector of the corresponding country. These results were checked, further improved and validated by independent experts whenever possible.

[6] European Commission; Information Society and Media Directorate-General 2009

Progress of eHealth in Bulgaria is described in chapter 3 of this report in the respective thematic subsections. The graphical illustrations presented there deliberately focus on key items on the progress timeline and cannot reflect all activities undertaken.

This report was subjected to both an internal and an external quality review process. Nevertheless, the document may not fully reflect the real situation and the analysis may not be exhaustive due to focusing on European policy priorities as well as due to limited study resources, and the consequent need for preferentially describing certain activities over others. Also, the views of those who helped to collect, interpret and validate contents may have had an impact.

1.3 Outline

At the outset and as an introduction, the report provides in chapter 2 general background information on the *Bulgarian* healthcare system. It is concerned with the overall system setting, such as decision making bodies, healthcare service providers and health indicator data.

Chapter 3 presents the current situation of selected key eHealth developments based on detailed analyses of available documents and other information by national correspondents and data gathered by them through a well-structured online questionnaire. It touches on issues and challenges around eHealth policy activities, administrative and organisational structure, the deployment of selected eHealth applications, technical aspects of their implementation, legal and regulatory facilitators, financing and reimbursement issues, and finally evaluation results, plans, and activities

The report finishes with a short outlook.

2 Healthcare system setting

2.1 Country introduction[7]

The National Statistical Institute of Bulgaria estimates the country's population for 2009 at 7,606,000 people. Most of the population (71%) resides in urban areas. Life expectancy is 73.4 %[8].

The reforms in healthcare that began in 1989 transformed the centralised, tax-based system into a decentralised and pluralistic compulsory health insurance system, with employee contributions and contractual relationships between the National Health Insurance Fund (NHIF) as a purchaser and healthcare providers. The NHIF provides most of the funding through its 28 regional bodies (the regional health insurance funds), it finances the entire healthcare network for outpatient care, and since July 2000, it also finances contracted hospitals. Every Bulgarian citizen should be covered by the compulsory health insurance scheme and receive a basic benefits package of health services determined and reimbursed by the NHIF. Employees and employers pay an increasing, mandatory percentage of salaries, with the goal of gradually reducing state

[7] eUser 2005

[8] National Statistical Institute 2010

support of healthcare. Health care is provided in accordance with the National Framework Contract. Private insurers provide an alternative means of funding healthcare as well as those drugs and treatments that are restricted in the state health insurance package. Between 2002 and 2004, healthcare expenditures in the national budget increased from 3.8 percent to 4.3 percent, with the NHIF accounting for more than 60 percent of annual expenditures. In 2010, the healthcare budget amounts to 4.2% of GDP, or about 1.3 billion euro. Bulgaria has 361 medical doctors per 100,000 people, which is above the EU average of 321[9].

Medical staff in Bulgaria are trained to a very high standard, though hospitals and clinics in general may not have all the equipment and facilities we would find in Western Europe or in the USA. Despite this, standards of healthcare have improved dramatically since the post-communist restructure.

The box below summarises the key facts about the Bulgarian healthcare system:

Key facts about the Bulgarian healthcare system:[10]

Population: 7,606,000

Life expectancy at birth: 73.4 years

Healthcare expenditure as % of GDP: 9.1% (OECD 2007)

Public sector healthcare expenditure as % of total healthcare expenditure: 81.7% (OECD 2007)

2.2 Healthcare governance

Decision making bodies, responsibilities, sharing of power

The Ministry of Health (MoH) performs the state healthcare policy and implements the National Healthcare Strategy. The Ministry governs and administers 32 regional multi-profile hospitals for active care and 12 specialised University hospitals. The structure of the MoH comprises 28 regional Centres for Healthcare, a National Information centre and an Executive Agency of Pharmaceuticals.

The National Health Insurance Fund (NHIF) is regulated by the Health Insurance Act (1998), which introduced the mandatory health insurance and regulates supplementary health insurance in Bulgaria. It was founded on 15th March 1999 as an independent public institution separated from the structure of the social healthcare system and has its own bodies of management. The NHIF budget is separated from the state budget. The National Assembly votes on it on an annual basis. The NHIF Budget Act determines the amount of health insurance contribution[11].

[9] National Statistical Institute 2010

[10] Data from World Health Organization 2000; Health Consumer Powerhouse 2008; World Health Organization 2009

[11] National Health Insurance Fund 2009-10

The National Health Insurance Fund consists of a Central Office, 28 regional health insurance funds (RHIF) – one in each regional centre in the country, and 105 municipal offices.[12]

The Parliament is involved in developing national health policy and the Parliamentary Health Committee adopts health related legislation. The Parliament approves the budget of the NHIF together with the state budget, and, since recently, also approves the reports on the NHIF budget execution[13].

Healthcare service providers

The National Health Insurance Fund has direct contracts with medical institutions in order to provide medical services to patients who pay contributions to the fund - these services include general and specialist care at healthcare centres, hospital outpatient departments and at home, and also hospitalisation, prescription of medicines and dental care. Private insurers provide an alternative means of funding healthcare, they also offer drugs and treatments that are not so readily available with state health insurance[14].

From 1st July 2000 private individuals, or legal bodies, started carrying out outpatient care (with the exception of emergency care); this is very much like the organisation of health systems in other countries. The objective is to set into motion the existing economic instruments of competition, private undertaking and private property which will result in a better quality of service for insured persons and more successful management of the health establishment's resources.[15]

Clinical Pathways were introduced in 2001 as part of the National Framework Contract with the aim of improving the continuity and coordination of care across different disciplines and sectors by aiding the management of resources.

Clinical pathways could be viewed as algorithms, and describe the decisions to be made and the care to be provided for a given patient. Each clinical pathway signifies a series of predefined actions (diagnosis, admission, acute care, surgery, recovery, etc.) applied to patients in a health facility in order to ensure an expedient, effective and efficient treatment. All these actions are arranged in a specific sequence in time and are performed by the members of the medical team responsible– doctors, nurses, laboratory technicians, psychologists and other supporting staff.[16]

[12] National Health Insurance Fund 2009-10

[13] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

[14] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

[15] National Health Insurance Fund 2009-10

[16] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

Figure 1: Important features of primary healthcare organisation in Bulgaria[17]

Political/administrative unit responsible for primary healthcare	Ministry of Health and its 28 regional centres.
Consumer Choice	There is free choice of GP, but patients are only able to change their GP every six months.
Financing	Healthcare is financed by compulsory and Voluntary Health Insurance contributions, taxes, and formal and informal cost-sharing.
Public or private providers	GPs work in private practices, group practices and/or outpatient services. Many are contracted by the NHIF.
Gatekeeping function of the GP	All types of GP are gatekeepers by law, making referrals to inpatient and outpatient specialists. Patients may self-refer to specialists but pay 100% out of pocket. Women with children and pregnant women have direct access to paediatricians and gynaecologists. The number of patient referrals to specialists is limited for each GP. The number of referral cards is pre-defined on a monthly basis for every GP by the Regional Health Insurance Fund according to patient lists and the previous month's performance.
Integrating health: initiatives for coordination	Clinical Pathways aim at supporting clinical management as well as resource management, clinical audit as well as financial management and at improving the continuity and coordination of care across different disciplines and sectors

2.3 Recent reforms and priorities of health system/public health

Currently ongoing reforms in the health and social care systems

The reform of the healthcare system is one of the declared priorities of the Bulgarian government. The main focus is on optimisation of the number of hospital beds in the different regions and the implementation of eHealth.

Reforms are planned for the development of electronic healthcare in Bulgaria. Several areas have been identified and plans sketched. The areas chosen for development include: the introduction of electronic health cards, recently modified as electronic health records, on a nationwide scale, the introduction of software applications for real-time comprehensive processing, which includes electronic medical referrals; electronic prescriptions and other laboratory tests. With this in mind the government has set aside 3.5% of the healthcare budget specifically for the introduction of healthcare technologies[18].

The elaboration of a healthcare road map is in progress and based on the outcomes the long post pointed reform should start up at the end of 2010.

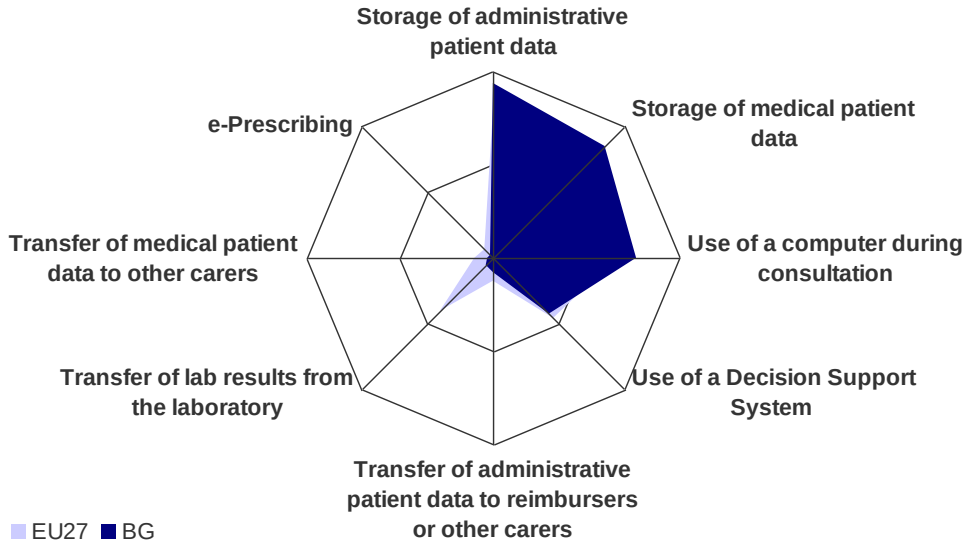
[17] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

[18] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

2.4 ICT use of general practitioners

This section provides a brief overview of relevant ICT related infrastructure and services data. It draws on earlier studies commissioned by the EC, notably the Indicators eHealth Study . Although the results of this study date from 2007 and may therefore not reflect latest changes, a more recent pan-European survey is not available[19].

Figure 2*[20]*: eHealth use by GPs in Bulgaria



Indicators: Compound indicators of eHealth use (cf. annex for more information), % values. Source: empirica, Pilot on eHealth Indicators, 2007.

Investment in the IT sector in Bulgaria has increased. The use of outpatient centres has increased and thanks to a World Bank donation, every GP now has a PC workstation. In 2003, the Ministry of Health, Ministry of Finance and the NHIF countersigned a roadmap for the incorporation of a diagnosis related group system (DRG). A pilot was created and implemented.[21]

Now there are a number of Information Systems for GPs in existence, which are in routine operation. One is “Hippocrates” (developed by Kontrax, a leading ICT firm in eHealth). It supports the primary medical care provided by GPs and the Diagnostic Consulting Medical Care Centres (DCMCs). It stores and maintains all relevant data obtained during the patient visits such as family anamnesis, illness history, examination results, diagnosis, prescribed therapy and medicines: creating a full patient medical record. The system generates all reports to the NHIF, reducing paper work and time for the physicians. It is used by 50% of the GPs in the country. A second system with similar

[19] ICT and eHealth use among General Practitioners in Europe 2007

[20] The notion of „compound indicator“ designates an indicator build from a set of other indicators/survey questions regarding the same topic. The compound indicator reflects an average calculated from different values. (see Annex) The final results of the study on eHealth Indicators are available at www.ehealth-indicators.eu.

[21] Georgieva L; Salchev P; Dimitrova S; Dimova A; Avdeeva O 2007

features is Aksiom (developed by ALIS) provides similar features for the GPs and DCMCs.

3 eHealth Strategies survey results

The following sections present the results of the eHealth Strategies country survey. In the first section, the eHealth policy actions undertaken in Bulgaria are presented. This is followed by a presentation of administrative and organisational measures taken. Section 3.3 presents results on key eHealth applications. Section 3.4 focuses on the technical side of eHealth, namely the role of patient and healthcare provider identifiers and the role of eCards. Legal and regulatory facilitators as well as financing and reimbursement issues are presented in the following chapters, 3.5 and 3.6. The report concludes with evaluation activities (3.7) in the country and an outlook (4.).

3.1 eHealth policy action

The eHealth strategies of EU and EEA countries are not always labelled as such. Some countries may indeed publish a policy document which refers to the ICT strategy in the healthcare sector. Other countries such as France and Germany have enshrined the central eHealth activities in legislation governing the healthcare sector. In Germany, the relevant law is the law on the modernisation of healthcare; in France the introduction of an electronic medical record is included in a law concerning social security.

Sometimes, also documents from domains such as eGovernment or Information Society strategies may contain provisions which concern eHealth. In cases where the healthcare system is decentralised, i.e. where power is delegated to the regional level, there may even be strategy documents regarding eHealth from regional authorities.

In the wake of the eHealth Action Plan, Bulgaria began to develop its own National strategy for eHealth implementation, approved in March 2006. It is aligned with the structure and content of the EC eHealth Action Plan.[22]

The main goal of the strategy is to transform the healthcare system so that it becomes convenient for citizens through implementation of ICT and establishes an information infrastructure for patient oriented healthcare services. Priority tasks are: the implementation of e-Cards, electronic health records, provision of on-line healthcare services and development of a modern ICT infrastructure and of Information Networks in the healthcare system.

The plan foresees a three stage implementation as follows:

Stage 1 (2007) – Development and Implementation of Clinical and Administrative information Systems for hospitals

Stage 2 (2010 – 2015) – Implementation of Electronic Medical Record, e-Cards, e-Prescriptions

Stage 3 (2017) – Implementation of Telemedicine and Telecare applications

[22] Министерство на здравеопазването [Ministry of Health] 2009

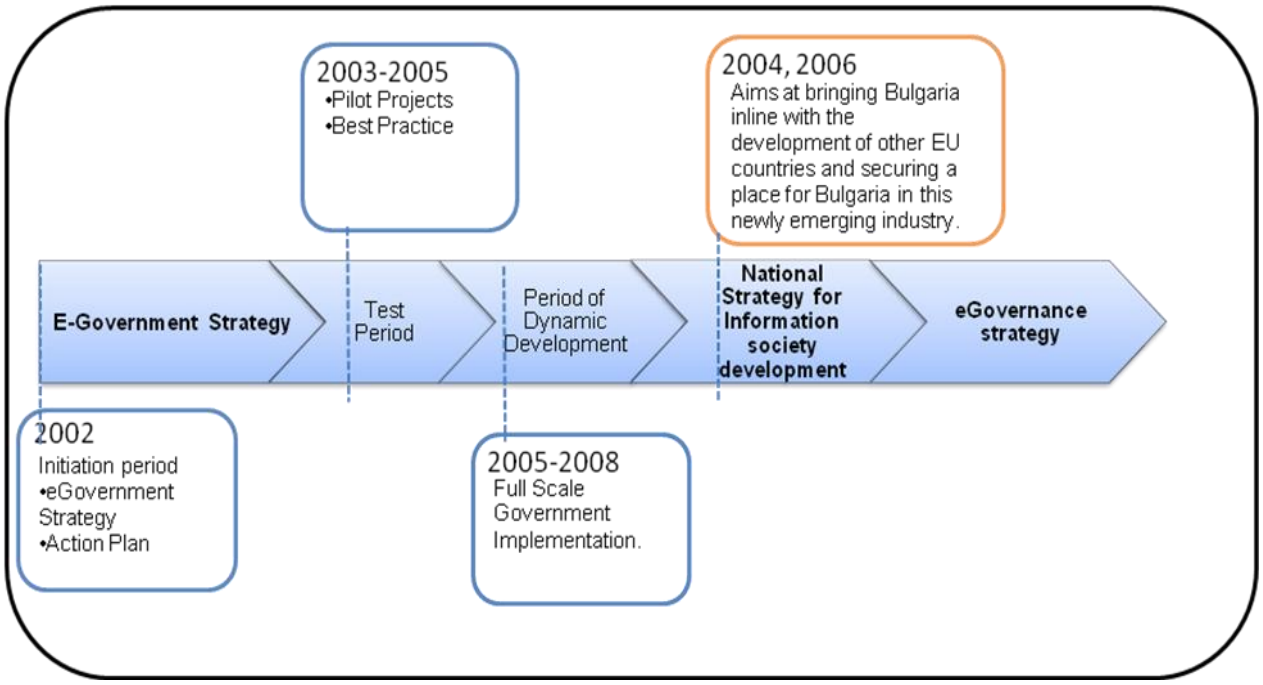
3.1.1 Current strategy/roadmap

The current strategy for eHealth in Bulgaria (2006) should be revised in accordance with the planned reform of the healthcare system and with the eGovernance strategy 2010-2015, currently available only in draft stage.

Important predecessor documents include:

- National Strategy for Information society development (2004, 2006)
- E-Government Strategy (2002)

Figure 3: Bulgarian Policy documents related to eHealth



3.2 Administrative and organisational structure

The Ministry is responsible for the implementation of the eHealth Strategy including organisation and coordination of the related activities, public procurement, creating and maintenance of the ICT infrastructure and data bases, establishment and implementation of standards. Until June 2010 there was a Directorate for eHealth within the structure of the Ministry which is now in the process of reorganisation, which won't affect the functions related to eHealth activities.

The National Information Centre at the Ministry of Health supports the implementation of the healthcare policy with various pieces of medical information including immunisations, prophylactics, and types of diseases by region and nationwide.

At the level of financing, the National Health Insurance Fund (NHIF) finances health related activities according to the National Framework Contract[23]. It maintains databases with information about GPs, hospitals, pharmacies and medical care providers. It is a member of the Netc@rds consortium and participates in the implementation of the European electronic health insurance card (eEHIC).

The dissemination work regarding eHealth in Bulgaria is organised through an NGO, the eHealth Bulgaria Foundation (NGO)[24]. This non-profit, non-governmental organisation was established with the purpose of boosting the development of e-Health on a national level as part of the electronic government of the Republic of Bulgaria. The main activities of the organisation are to organise conferences and seminars in eHealth and to promote eHealth applications.

Along with these organisations, there are also other organisations involved in the shaping of eHealth policy. These are:

1) The Bulgarian Medical Association[25]

It was created in 1901. The main tasks of the organisation are to guard the interests of physicians and their fees, to promote medical aid in the country and to contribute to the determination of the healthcare policy, including eHealth implementation. It maintains the Physician register in Bulgaria.

2) The Ministry of Transport, Information Technologies and Communication[26]

The Ministry is responsible for the Information Society development and for the e-Government implementation. It follows the directorate for e-Government.

3) Bulgarian Association for Patient Defense[27]

Its main role is to guarantee patient rights and to observe the quality of medical services provided throughout the country.

4) National GP Association[28]

It incorporates most of the GPs and aims to support them in improving their working conditions and the links to the National Health Insurance Fund.

5) ICT companies – KONTRAX, Gama Soft, Aksior

3.3 Deployment of eHealth applications

In this section currently ongoing activities with regard to the deployment of eHealth applications are presented. It is divided into four parts: the IT systems of the NHIF, of the

[23] Further information at: www.nhif.bg
[24] Further information at: www.ehealth-bg.org
[25] Further information at: http://www.blsbg.com
[26] Further information at: http://www.mtitc.government.bg/
[27] Further information at: www.patient.bg
[28] Further information at: www.nsoplb.org

Ministry of Health and of the service providers (hospitals, specialists, GPs, and pharmacies) and then a discussion of the technical aspects of implementation.

3.3.1 National Health Insurance Fund (NHIF) information systems

The NHIF system has two main modules: one for hospital data which was completed in 2002 and one for outpatient and drug data which was also completed in 2002. The two modules are not integrated yet and do not provide real time web-based services.

The hospital information system was developed over a two-year period from the inception of the NHIF in 2000 to 2002. It links all 420 hospitals in Bulgaria (both public and private) with the NHIF. This system was financed by the World Bank as a step toward implementing the diagnostically related groups in Bulgaria. It includes two main modules and collects ***patient*** and ***cost*** data:

Module 1: for planning and distribution of financial resources, which includes the fixed assets, budget, contract management, accounting, internal financial audit, and business analysis systems

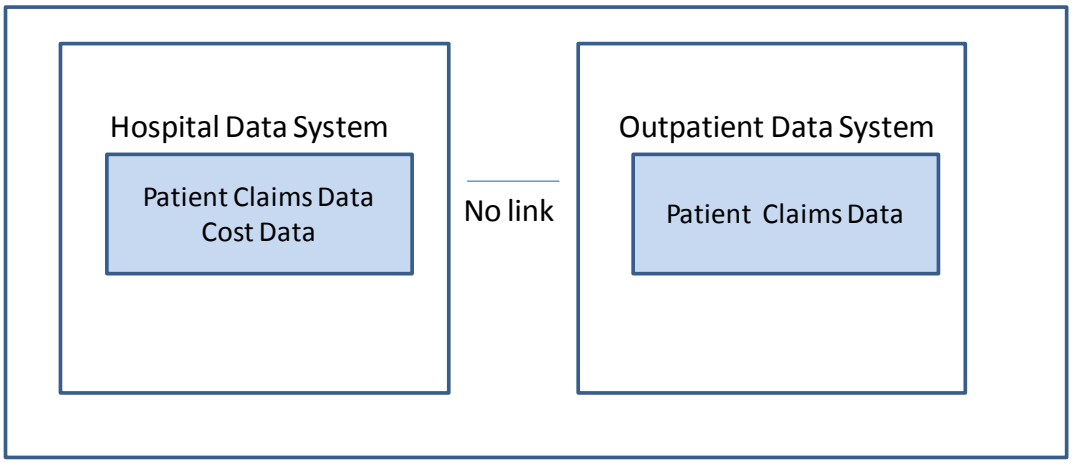
Module 2: for managing claims by medical service providers and pharmacies to reimburse their expenses: this covers claims management, objections and appeals, medical audit, quality assurance, national registers and regulatory standards.

The outpatient information system was completed in 2009. Its development and implementation is a part of *Bulgaria's Healthcare Reform Project*, financed by the World Bank. The intention of this system was to create an outpatient data information system and link it to the already existing hospital data to create an Integrated Information System for NHIF's main business processes: capturing contracts with medical service providers, processing payment requests from all these organisations (including validating the amounts they have claimed), and making the approved payments. However, the system was not linked to the hospital information system and the data at the NHIF remains fragmented with one database for hospital data and another database for outpatient and drug data.

The system maintains the registers of medical service providers and patients, and provides interfaces with external registers such as the National Revenue Agency.

The outpatient IT system has one module for patient data, i.e. for managing claims by medical service providers and pharmacies to reimburse their expenses: this covers claims management, objections and appeals, medical audit, quality assurance, national registers and regulatory standards. It does NOT collect data on costs and expenditures.

Figure 4: Data system planned integration



Reporting in neither of the hospital or outpatient system is real time yet. Service providers send monthly claims data reports to NHIF. These reports are processed manually and then entered into the data system. The system then verifies that healthcare services reported by doctors have actually been carried out: a real challenge involving more than 630 different types of named procedures and services. The data is used to prepare various reports and analysis for medical and financial controls. There are some standard reports and others are generated easily based on the specific analysis required

3.3.2 Ministry of Health Systems

3.3.2.1 Patient summary and electronic health record (EHR)

In this study, the epSOS project's definition[29] of a patient summary was used as a general guideline. There a patient summary is defined as a minimum set of a patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency, accident), but also in case of planned care (e.g. after a relocation, cross-organisational care path).

Lacking a standard definition, a patient's electronic health record (EHR) is here understood as an integrated or also interlinked (virtual) record of ALL his/her health-related data independent of when, where and by whom the data were recorded. In other words, it is an account of his diverse encounters with the health system as recorded in patient or medical records (EPR or EMR) maintained by various providers like GP, specialists, hospitals, laboratories, pharmacies etc. Such records may contain a patient summary as a subset. As of yet, fully-fledged EHR systems rarely exist, e.g. in regional health systems like Andalucia in Spain or Kronoberg in Sweden, or in HMOs (health maintenance organisations) like Kaiser Permanente in the USA.

It should be noted that in most policy documents reference is made simply to an "EHR" without any explanation of what is meant by it, thereby in reality even a single, basic electronic clinical record of a few recent health data may qualify. As a consequence, this section can only report on national activities connected to this wide variety of health-

[29] European Patients Smart Open Services

related records without being able to clearly pinpoint what (final) development stage is actually aimed for or has been reached so far.

The first project for EHR in Bulgaria was the development of a National Health Portal. Unfortunately, it is no longer operational but it is worth reviewing because it is the first such project in Bulgaria.

The National health portal was launched in March 2009 at www.zdravenportal.bg for all Bulgarian citizens. It was intended to provide up-to-date and accurate health information, registers of all health professionals, hospitals, pharmacies, medical services, health forms and others.

The health portal is integrated with the first electronic personal ambulatory books (eLAK) which were intended to be piloted with 40 000 state employees (representatives of different ministries, executive agencies, district administrations and municipalities) but for data confidentiality reasons, less than 1 000 employees filled in their data into the system although they received their eLAK for free from their employer, the Bulgarian government.

eLAK is a patient's personal health memory, a personal web-based health database which is available any time or place. It is a modern electronic version of the Bulgarian personal ambulatory book. In contrast to the traditional paper one, the electronic book also enables the storage of document copies such as prescriptions, immunisations, physicians' letters, X-rays, ECGs, NMRs and others.

eLAK also has an emergency record with information about one's blood group, allergies, chronic diseases, medications used and emergency contacts. The personal health record (PHR) is fully controlled by its user. Only the owner has access to the information stored there and he/she is the one who decides to whom and what information should be accessible: MD's, family members, pharmacists, etc.

Connection of the eLAK portal to hospital information and GP IT systems is still in progress.

3.3.3 Private Health Insurance Funds (PHIF) information systems

There are 21 registered PHIFs in Bulgaria. Only 3 of them are holding well developed electronic information systems.

The systems maintain:

- Register of medical service providers and pharmacies (contracted by the PHIF) to reimburse their expenses for medical services provided and drugs supplied.
- Register of patients (clients to the PHIF) for managing their claims.
- Register of the health insurance contracts.

The systems are linked to and provide information to the Financial Supervision Commission.

One of the PHIF has an electronic information system that is functioning in real time and collecting data on costs and expenditures.

3.3.4 ePrescription

In the framework of this study and following work in epSOS[30], ePrescription is understood as the process of the electronic transfer of a prescription by a healthcare provider to a pharmacy for retrieval of the drug by the patient. In this strict sense, only few European countries can claim to have implemented a fully operational ePrescription service.

ePrescription is on the political agenda for eHealth in Bulgaria and the first pilot for ePrescription took place in two villages linking 10 GPs with pharmacies. The pilot has not yet been scaled up.

3.3.5 Telemedicine

The use of telemedicine applications is recognised as beneficial to enable access to care from a distance and to reduce the number of GP visits or even inpatient admissions. Commission services define telemedicine as "the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location"31. In its recent communication on telemedicine for the benefit of patients, healthcare systems and society, the Commission re-emphasises the value of this technology for health system efficiency and the improvement of healthcare delivery[32].

Telemedicine applications in Bulgaria are currently limited in number. In existence is a Telemedicine system connecting an Obstetrics & Gynaecology hospital in Sofia with an Obstetrics & Gynaecology hospital in Pleven. This project has been in routine operation for the last two year now (starting in 2009).

In addition, a pilot project regarding telemonitoring of patients with chronic heart diseases is worth mentioning. It began as a pilot in 2005 and is located in the region of the town of Sepremvri and supports approximately 600 patients. The main technological partner engaged in this project was the former (until 2009) State Agency for ICT.

3.3.6 The role of eCards

In September 2007, Bulgaria started issuing its first electronic health cards as part of the pilot project launched by the Ministry of Health and the National Health Insurance Fund (NHIF) in February 2007. The project includes 1000 patients, 7 GP's and 4 pharmacies.

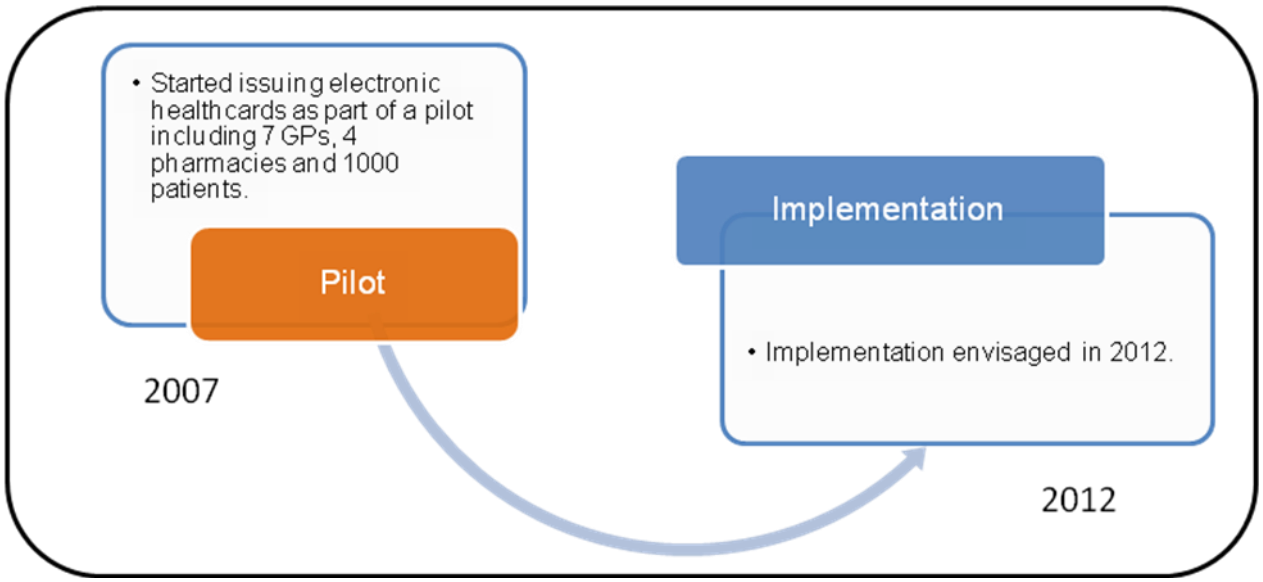
Each eHealth card is equipped with a microchip that stores data about the patient and the issuer, including the card number and a security certificate. With this information, the patient's insurance status and his/her assignment to a General Practitioner can be automatically checked. In addition, electronic prescriptions for medication covered by the Bulgarian Health Insurance Fund will be recorded on the chip. However, this functionality is only envisaged to be implemented by 2012.

[30] European Patients Smart Open Services

[31] Europe's Information Society

[32] European Commission 2008

Figure 5: eCards in Bulgaria



3.3.7 Service Provider Information Systems

3.3.7.1 Hospitals

The main objective of Hospital Information Systems (HIS) implementation is to improve patient services, to establish an effective management system optimising the use of resources, and to permanently upgrade the hospital information infrastructure. HIS support medical and administrative activities and are patient oriented. Today, e-business applications in hospitals support the following processes: patient admission, registration, primary care, hospitalisation and discharge, clinical pathways allocation, purchase and distribution of drugs and consumables, costs calculation, accounting and reporting, procurement management, personnel management, laboratory investigation, as well as general management and administration.

As a part of the Hospital Reform project financed with a World Bank loan, the government provided *free of charge* a software for reporting to link the hospital with the NHIF. Any upgrading to this software is a decision of each individual hospital as hospitals in Bulgaria are registered as corporations and the decisions about their IT systems are taken individually by their managers and boards of directors.

Although there has not been a thorough analysis of the functionality of HIS the following hospitals are considered to be success stories:

National Heart Hospital (2003)

National Cancer Hospital (2009)

University Heart Hospital " St. Ekaterina" (2007)

Military Medical Academy (2008)

Tokuda Hospital in Sofia (2008)

First Obstetrics & Gynecology Hospital " St. Sofia" (2006)

National Hematology Hospital (2009)

3.3.7.2 Outpatient services; GPs and specialists

GPs and specialists have software with administrative data for reporting to NHIF. The administrative reporting is based on the number of patients and referrals and as such cost data is not collected. In addition, the software does not include clinical data. Reporting takes place once a month via CDs and e-mails and there is no real time reporting option.

3.3.7.3 Pharmacies

Pharmacies also have software with administrative data for reporting to NHIF and limited clinical data. Reporting is also done monthly and not real time.

3.4 Technical aspects of implementation

A key prerequisite for the establishment of an eHealth infrastructure is the ability to uniquely identify citizens/patients and healthcare professionals. This part of the survey deals with identifiers and how they are stored. This section does not deal with the tokens through which identification can or will take place. One such possibility would be via an eCard. This topic is dealt with in the following section. The current section focuses solely on whether or not unique identifiers are in place in Bulgaria and for which purpose.

3.4.1 Unique identification of patients

Patients in Bulgaria are currently identified through the Personal Identification number, a citizen ID which is used in all personal oriented information systems such as the National Personal Information System, Taxation System, National Insurance System).

There are currently no plans to adopt a new system of identifiers specific to healthcare.

Data protection issues are addressed through PIN numbers for internet-based healthcare services in accordance with Personal Data Protection Act adopted in December 2001 and Access to Public Information Act adopted on 22nd June 2000.

3.4.2 Unique identification of healthcare professionals

The current healthcare professional identifier is a unified physician number, used in the register of physicians in Bulgaria. The register includes personal data about all physicians sorted by 28 geographical regions, but without information regarding their area of specialisation. There is no register of the medical nurses or other healthcare personnel.

3.4.3 Standards

Standards are not only crucial to enable interoperable exchange of meaningful information in the healthcare system; they also ensure secure access to patient records by healthcare providers and citizens. This study aims to identify, among other usage, standards related to the domain of health informatics, such as the SNOMED Clinical Terms or the LOINC terminology.

Standards currently used in Bulgaria are HL7, IHE, ICD 9, ICD 10, EN/ISO 13606. There is currently no usage of SNOMED CT. However, a translation of SNOMED CT into Bulgarian is envisaged for the year 2012

There are no nomenclatures of medicines (trade names) or of the medical consumables. The usage of the international codes of laboratory investigations (LOINC) is very limited – only 100 positions from 2000 – 6000 are used by the National Health Insurance Fund.

In general, interoperability between the various IT applications is very low. There is a Framework for Interoperability of ICT Applications in public administration (2008), which has to be applied and considered in all eHealth applications. This framework puts emphasis on the technical and organisational aspects of interoperability and recommends the use of standards to achieve it.

3.5 Legal and regulatory facilitators

Legal and regulatory issues are among the most challenging aspects of eHealth: privacy and confidentiality, liability and data-protection all need to be addressed in order to make eHealth applications possible. Rarely does a country have a coherent set of laws specifically designed to address eHealth. Instead, the eHealth phenomenon has to be addressed within the existing laws on professional liability, data protection etc.

Overall, an analysis of the current Bulgarian legal and regulatory framework shows that there is no consistent and comprehensive regulation for eHealth. In Bulgaria there are no specific provisions foreseen with regard to patient summaries, telemedicine or ePrescription. Where this does not pose immediate concrete problems with regard to the roll-out of the Electronic Medical Records or the use of Telemedicine, the current legal framework does conflict with the introduction of ePrescriptions.

Under the Human Medicine Act[33] and the Ordinance no. 4 on the Conditions and the Orders for Prescriptions and Issue of Medicinal Products the prescription of medical products should be made in writing through a by the Minister of Healthcare approved paper form[34]. Consequently the use of electronic prescriptions will not be possible as long as the Minister of Healthcare does not change this provision.

Even though no specific regulations on eHealth are thus yet available, the current legal framework does encompass a number of relevant normative acts:

[33] Human Medicine Act published in the State Gazette on 31 January 2007

[34] As published in the State Gazette on 15 January 2001

• E-Governance Act (2008) [35] and its 4 implementing Acts regulate the activities of administrative authorities when working with electronic documents through electronic means. The four implementing Acts include: the Ordinance for the Registers of the Information Objects and of the Electronic Services, the Ordinance for the Internal Circulation of Electronic Documents and Paper Documents in the Administrations, the Ordinance for the Electronic Administration Services and the Ordinance for the Certificates for Electronic Signatures in the Administrations. The two main consequences of this Law and its implementing Ordinances are that once a data set concerning an individual or a company comes into the possession of a public body, other public bodies cannot request the same data from this individual or company. On the contrary, they have to request it from the primary data administrator (article 2.1). Secondly, the Administrative services – also the ones in healthcare administration – will have to provide their services in an electronic way[36].

• Personal data protection Act (2002) [37] is Bulgarian's very similar transposition of the Directive 95/46/EC. It foresees that health data can only be processed under the conditions provided by law in article 5 (2). The law does not contain special rules for information and access rights of the patient. The general rules foreseen are also applicable to the collection of sensitive data.

• Act on Electronic signature and Documents (2001) transposing the EU Directive on a Community framework for electronic signatures (1999/93/EC) into Bulgarian law.

• Health Act (2004) [38] and the code of professional ethics of the Bulgarian Medical Association which describe the rights and duties of the healthcare providers and patients in Bulgaria. Concerning the Electronic Medical Record they provide that every physician should keep a medical record on each patient to whom he provides healthcare services. The medical record can – for now – still be kept on paper or in electronic form. This is however expected to change and to become mandatory in electronic form. What exactly the medical records should contain was regulated through an ordinance of the Ministry of Health of 2006, but since it was not well organised and contained gaps, revision is due.

3.5.1 Patient rights

In Bulgaria, patients have the right to gain insight into their medical record; the provider of electronic administrative services shall ensure the receivers unimpeded, direct and permanent access to set information[39]. The patient can request the deletion of parts of the record or oppose its creation[40]. Patients have the right to hide information from a doctor and to ex-ante contradict life-supporting measures in case of end of life care. In cases of emergency, patient consent to treatment is assumed to be given.

[35] Published in the State Gazette on 12 June 2007

[36] epractice.eu 2010

[37] Published in the State Gazette on 1 January 2002 and ammended numerous times.

[38] As published in the State Gazette issue nr. 70.

[39] Electronic Government Act June 2008, Obligation to provide information, Article 13.

[40] Electronic Government Act June 2008, Use of Electronic Administrative Services, Article 19.

It is the administrative service's obligation to collect, process and provide personal data and to not use it for any other purpose[41]. The Minister of State Administration and Administrative Reform is ensures the compliance with this act[42].

3.6 Financing and reimbursement issues

The financing of eHealth in Bulgaria is guaranteed through a variety of sources. Of this the national budget represents 2-3%, channeled through and contributed by healthcare funds.

Although within the EC structural funds there is no extra priority line for eHealth yet, there are some opportunities to apply to the programs "Administrative capacity" and "Human resources". Also, there are funding opportunities in other places, such as donations from the World Bank and the European Bank for Reconstruction and Development (EBRD).

At the moment, Bulgarian healthcare policy does not foresee a dedicated remuneration of healthcare professionals for use of IT applications.

3.7 Evaluation results/plans/activities

From a public policy perspective, evaluation is a key activity in the policy-cycle. It provides insights into the success or failure of a policy or project and leads to new policy goals and new methods of implementation. The need for evaluation of eHealth policies and projects has been stressed time and again by the EC, not least in order to further the spread of eHealth in the process of healthcare delivery.

The progress in eHealth was evaluated as part of the annual report E-Bulgaria, produced by the ARC Fund until 2006)[43]. The version of the report for 2009 is not published yet. The 2006 version did not concentrate on eHealth directly, but on the infrastructure and finances that would be necessary to have in place in order to support eHealth solutions. The report found that Bulgaria has established the public institutions that are necessary for the functioning of such a system, but that what is missing is the link between public institutions and private sector organisations. It was suggested that public resources for innovation development should be more securely connected to private and international co-financing follow stringent quality requirements. To do this it was acknowledged that a closer interconnection between the different national sector strategies and policies and the national innovation strategy and policy was needed[44].

There is no specific organisation yet specifically dedicated to the evaluation of eHealth.

[41] Electronic Government Act June 2008, Obligation to Collect, Process and Provide Personal Data, Article 16.

[42] Electronic Government Act June 2008, Article 59.

[43] Further information at : www.arcfund.net

[44] Eds. Petrov.M and Stefanov.R 2006

4 Outlook

In the near future, Bulgaria will be focusing on the following:

• To develop a National Integrated Healthcare Information System

• To extend the implementation of the National Health Portal with e-record for patients and e-Card implementation

• To update the National eHealth Strategy

• To elaborate an Act for eHealth

There is an initiative from the Parliamentary Commission for Healthcare to establish a working group with representatives of the Commission, the Ministry of Health, the Ministry for Transport and ITC and the National Health Insurance Fund with the task of evaluating the existing eHealth applications and to suggest updates in the eHealth Strategy and to prepare a draft of an eHealth Act for submission to the Parliament.

Summing up, one can say that although e-Prescriptions, Telecare and Telemonitoring are included in the eHealth Strategy, there are no projects in this field yet, with the exception of the above mentioned pilot projects in Telemedicine. The interoperability among the various eHealth applications is low. There is no unified nomenclature of prescribed medicines and medical consumables, which is certainly an obstacle to the further development of ePrescribing services. In addition, only limited funds for eHealth are available from the government or from the Structural funds.

5 List of abbreviations

BMA	Bulgarian Medical Association
DCMC	Diagnostic Consulting Medical Centre
DRG	Diagnosis Related Group
EC	European Commission
EEA	European Economic Area
EHR	Electronic Health Record
EMR	Electronic Medication Record
EPR	Electronic Patient Record
epSOS	European patients Smart Open Services
ERA	European Research Area
EU	European Union
GDP	Gross Domestic Product
GP	General Practitioner
HCP	Healthcare Provider
HIS	Hospital Information System
HL7	Health Level Seven International (authority on standards for interoperability)
HPC	Health Professional Card
ICT	Information and Communication Technology
ID	Identification (e.g. number, card or code)
IHTSDO	International Health Terminology Standards Development Organisation
IT	Information Technology
MTITC	Ministry of Transport, Information Technology and Communication
MoH	Ministry of Health
NHIF	National Health Insurance Fund
OECD	Organisation for Economic Co-operation and Development
PHS	Personal Health System
R&D	Research and Development
WHO	World Health Organization

6 Annex

6.1.1 Annex 1: Compound indicators of eHealth use by GPs

Compound indicator name	Component indicators	Computation
Overall eHealth use	Electronic storage of individual medical patient data Electronic storage of individual administrative patient data Use of a computer during consultation with the patient Use of a Decision Support System (DSS) Transfer of lab results from the laboratory Transfer of administrative patient data to reimbursers or other care providers Transfer of medical patient data to other care providers or professionals ePrescribing (transfer of prescription to pharmacy)	Average of component indicators
Electronic storage of individual medical patient data	A2a - Symptoms or the reasons for encounter A2c - Medical history A2c - Basic medical parameters such as allergies A2d - Vital signs measurement A2e - Diagnoses A2f - Medications A2g - Laboratory results A2h - Ordered examinations and results A2i - Radiological images A2j - Treatment outcomes	Average of component indicators
Electronic storage of individual administrative patient data	A1 - electronic storage of individual administrative patient	A1 value
Use of a computer during consultation with the patient	B2 - Computer use during consultation	B2 value
Use of a Decision Support System (DSS)	B3a - Availability of DSS for diagnosis B3b - Availability of DSS for prescribing	Average of component indicators
Transfer of lab results from the laboratory	D1e - Using electronic networks to transfer prescriptions electronically to dispensing pharmacists?	D1e value
Transfer of administrative patient data to reimbursers or other care providers	D1a - Using electronic networks to exchange of administrative data with other healthcare providers D1b - Using electronic networks to exchange of administrative data with reimbursing organisations	Average of component indicators
Transfer of medical patient data to other care providers or professionals	D1c - Using electronic networks to exchange medical data with other health care providers and professionals	D1c value
ePrescribing (transfer of prescription to pharmacy)	D1d - Using electronic networks to transfer prescriptions electronically to dispensing pharmacist	D1d value

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