Electronic Health Record (DES) Development and Implementation in Romania

Position Paper

Dr Sandra Alexiu
Dr Sergiu Chirilă
Dr Dan Doru Pletea
Dr Ciprian Vornicu
Dr Raluca Zoițanu

e-Health Working Group,
Romanian National Society of Family Medicine
[September 2014]

The Romanian National Society of Family Medicine (SNMF) supports the development, implementation and use of the patient Electronic Health Record in Romania (DES) and considers this project a normal development in the context of progress and increased use of health information systems.

At the same time, the Romanian National Society of Family Medicine is concerned about the lack of clear legislation regarding the creation, use and storage of DES. In this context, SNMF supports the adoption as soon as possible of the legal framework for the use of DES, which should contain:

- general information about the type of medical data, terminology, coding systems, permissiveness elements for cross-border use of data;

- regulations regarding the organization hosting the servers and owning the data from the patient Electronic Health Record;

- regulations regarding the explicit informed consent of the patient for the adequate protection of the right to privacy;

- regulations regarding the access, authentication, authorization and creation of patient Electronic Health Records;

- liability regulations regarding the use of patient Electronic Health Records, storage duration and other uses of the data in the patient Electronic Health Records;

- coordination of the patient Electronic Health Record with the Electronic Prescription System (SIPE) and the Electronic Health Insurance Card (CEAS) and the interoperability of these systems;

- logistic requirements for implementation and use, including minimum requirements;

- other rules of good practice;

- ensuring transparency regarding the costs of using patient Electronic Health Record.

DES must be accessed and data must be entered into DES in real time by all healthcare providers, both public and private. We consider it is absolutely necessary to standardize the software solutions used in the health system, so that the patient Electronic Health Records will be fully functional and used by all providers across the entire health system in Romania (family medicine practices, ambulatory care practices, diagnostic and treatment centers, medical centers, health centers, laboratories, public and private hospitals and other public and private health units) and pharmacies.

Finally, the Romanian National Society of Family Medicine considers it is essential to carry out a cost-effectiveness analysis and a feasibility study for DES, or to publish them if they already exist.

The patient Electronic Health Record becomes functional only when interoperability between healthcare providers is ensured, when they can access in real-time the relevant medical data, the patient's laboratory tests and their results, and when all these lead to the elimination of paper-based medical records.

Dr Sandra Alexiu
Dr Sergiu Chirilă
Dr Dan Doru Pletea
Dr Ciprian Vornicu
Dr Raluca Zoițanu
e-Health Working Group, Romanian National Society of Family Medicine

September 2014

The Romanian National Society of Family Doctors (SNMF) is the main professional association of family doctors in Romania. Established in 1990, the Society has 41 member organisations from each county, ensuring it is representative on a national level. Its main activity is improving family doctors' education and training through conferences, courses, workshops, dedicated working groups and other resources. SNMF also facilitates communication both between family doctors and with other members of the health system, acts as a voice for family doctors and their patients and represents family doctors in health policy matters.

SNMF is a WONCA Europe member since 1994 and has strong links with other professional and healthcare organisations in Europe.

Societatea Naţională de Medicina Familiei
Str. Ionel Perlea 10, sector 1, Bucureşti, Romania
Tel +40213154656
Fax +40213154656
Web: www.snmf.eu
E-mail: office@snmf.ro

Contents

Introduction

Through the press release[1] and ad[2] on 15 May 2014 the National Health Insurance House (CNAS) announced the completion of the Electronic Health Record project implementation, financed through a European Regional Development Fund (POS CCE) grant of approximately 19 million Euros. The announced project completion date is 24 May 2014.

The general objectives of the project are, according to CNAS, the increased efficiency of the health system in Romania, the increased assimilation, application and development of Information Technologies in health care, an enhanced interoperability among healthcare providers and among central bodies and an increased efficiency and quality of medical services provided to citizens. Regarding the latter objective, CNAS states in the press release that the system is geared primarily to the *reduction* (*sic!*) of time spent with the patient during a consultation, due to the reduction of time used for bureaucratic activities.

The press release also informs that CNAS completed the official promotion activities for the project, achieved through *lectures* in various medical conferences in the country, and also that until the date of the press release (15 May 2014) over 700,000 Electronic Health Records of Romanian patients were created.

Finally, in the press release CNAS also adds that both the content of DES and details about access were *discussed and approved* by a committee of representatives of physicians, hospitals, patients, Ministry of Health and CNAS in the analysis phase of the project.

The Romanian National Society of Family Medicine, through its e-Health Working Group, wishes to inform the public through this position paper about its official position on the subject of the Electronic Health Record project (DES).

Family doctors have proven in the past decade that they are in the vanguard of the computerization of the health system in Romania, representing the first segment of the system to widely adopt Information Technology since the introduction of the health reform in 1999.

In Romania, all family doctors have used computers since the first mandatory electronic reports to the County Health Insurance Houses (CJAS) in October 1999, going through the experiments – at first as pilot projects, then generalized – of all four versions of the Unique Integrated Information System (SIUI) and in the end adopting the online Electronic Prescription System introduced in 2012 by CNAS. The latter was adopted since the launch of the pilot project on July 1st, 2012 and until January 18th, 2013 by 96% of family physicians[3] and the percentage increased to 99.41% by mid-2013[4], according to press releases and reports issued by the National Health Insurance House. It should be noted that there are not any similar reports to analyze the use of electronic prescriptions by all the other health care providers under a contract with the CNAS, respectively ambulatory practices and hospitals.

Thus, we can say with confidence that the primary care segment, represented by family doctors, showed openness and interest to increase the efficiency and control of the health system through IT tools.

Analysis of the concept of Electronic Health Record

The Romanian National Society of Family Medicine recognizes the particular usefulness of the existence and appropriate use, in the entire healthcare system, of a patient's Electronic Health Record. The Unique Integrated Information System (SIUI), alongside the imminent implementation of DES certainly provide the necessary infrastructure to transform the health system currently based on traditionally written data (on paper) into a modern, fully computerized system, which could help health professionals in providing high quality medical services.

The benefits of using electronic systems for storing patient’s medical data can be evaluated in terms of clinical, organizational (healthcare providers) and social (public health policies, health insurance) benefits:

- The clinical benefits can be assessed particularly by evaluating the quality of care provided and patient safety. Although there are studies published internationally on this issue, we were unable to find any national scientific reports providing results and recommendations in this regard.

- From an organizational viewpoint, the existence of a unique nationwide system for keeping medical records of patients could provide some benefits. These may include: improved patient compliance (e.g. by raising patient awareness for preventive consultations and treatment monitoring), reducing the cost of the acquisition, completion and filing of consultation records, eliminating the need for data transmission and medical documents through various methods (e-mail, mail, patient), reducing the occurrence of medical errors that result from poor communication among healthcare providers.

- On a decisional level, the existence of a patient Electronic Health Record, when used according to a well-established legal framework that takes into account all the necessary aspects especially related to medical data confidentiality, could be an extremely important source of statistical medical data, thus facilitating the decision making process.

However, these potential benefits of a national system for collecting and storing patient health data may offer some disadvantages, which are absolutely necessary to be taken into account. Among them we would like to mention:

- Financial problems - represented by implementation, promotion and sustainability costs of such a system, through a long-term analysis.

- Decrease in revenue due to the time periods when the system is not functioning (an issue currently encountered with the Unique Integrated Information System, still not corrected).

- Costs related to training needs of healthcare personnel in the use of patient Electronic Health Records. These should be assessed because, in order to ensure efficient use and operation of DES and to guarantee correct data input, both training sessions and a system testing period are needed.

- Another concern may be the violation of patients' medical data security, this being, according to international studies[5,6], one of the main concerns expressed by patients.

In the present context, the European Union declared goals for e-Health[7] are:

- Improving health by providing all citizens, through e-Health tools, vital information,

- Improving access to healthcare and quality of health services through e-Health tools integration in health policy and coordinating the political, financial and technical strategies of Member States,

- Increasing efficiency of e-Health tools, through an increased ease of use and improved acceptance by involving health professionals and patients in the early stages of development, design and implementation of strategies,

The EU Member States' efforts focus on better collaboration among them for the mobility of information. Significant efforts are being made to harmonize the laws of the Member States in order to allow cross-border mobility of health data. Therefore, the development of a national EHR must take account of this trend. There are currently standards for interoperability between applications developed at the national level,

The European Union published in 2013 a guide regulating the minimum health data needed for the mobility of such data electronically, in accordance with Directive 2011/24/EU. This document contains important information on European legislation on patients' rights in the context of cross-border mobility of health data, e-Health networks, guidelines for data types and, of course, standards and protocols that must be followed to ensure the mobility of health data[8]. This document also provides precise specification of the sets of data that must be transmitted, both basic and extended, This document specifically governs the following aspects:

- The responsibility of Member States to take the necessary measures to ensure interoperability, both technical and semantic, of the data in Electronic Health Records;

- The possibility for Member States to freely choose how to implement HER systems, to use open standards for public health activities, to decide freely on adopting these standards in local legislation, to follow the guidelines when adopting local legislation (observing Directive 95/46/EC on the protection of personal data and the free movement of such data);

- The aim to achieve interoperability, represented by: providing support for ensuring of safe, high quality cross-border healthcare services in an emergency or in case of unforeseen events;

- The content of electronic health records, in terms of the information that must be contained;

- Standardization of terminology, either by mapping activities, transcoding or translation or by using coding standards (available in Annex B of the document cited);

- Although Member States may choose the technical way of implementing electronic health records, it must meet international standards approved for the mobility of health data;

- The Member States must ensure the security of personally identifiable health data transmission and processing and also keep logs of all cross-border transfers of data;

- The implementation of electronic health records in the Member States needs the allocation of a personal code for each citizen in order to identify the patient record in a unique way, the existence of electronic registries of healthcare professionals, regulated levels of authentication of citizens and health professionals;

- Creating a legal framework that allows interoperability;

- As electronic health records contain "sensitive personal data", Member States must ensure that security standards for the processing and storage of data comply with existing requirements. Member States must implement a management system for processing and storing data consent and authorization of later access to them;

- The need to apply measures of education, training and awareness raising of the benefits and necessity of interoperability.

The current situation

Through the amendments to the Law 95/2006 brought by the Government's Emergency Ordinance no. 2/2014 and no. 23/2014, the healthcare providers mentioned in article 29 paragraph 1 are "obliged to ensure the mobility conditions for electronic health data by using the patient's Electronic Health Record". Information about how to use and complete data in DES, according to paragraph 3, will be given in the rules for the application of the Law (norme metodologice). At the time of the issue of this position paper, no rules have yet been published for the application of the provisions relating to DES.

Currently, family medicine is the only segment of the health system in Romania fully computerized in terms of hardware and using 100% all systems required by decision makers (electronic prescribing, electronic reporting services for reimbursement). Other segments still resort mostly to traditional means regarding medical records. Despite requests made by the National Society of Family Medicine, the National Health Insurance House has not provided to date any data on the use of electronic prescribing in other areas of the health system. Although during the analysis and development of the Electronic Prescribing Information System, CNAS promised a rapid generalization on the use of the electronic prescription system by all prescribers in the health system, according to our observations it appears that the hospitals use electronic prescribing in a low percentage. Patients claim they do not receive prescriptions upon discharge and have to take extra steps to procure their much needed compensated medication after discharge. This situation exists despite the mandatory use of electronic prescription as of January 1, 2013, according to the Order of the Ministry of Health and CNAS no. 622/214 of June 14, 2012.

Moreover, the CNAS President assured the participants to the discussions that took place in May 2013, in the *Committee for the establishment of relevant medical data for DES*, that these situations will be addressed "right away", as the law already states that all healthcare providers must use the system. In September 2014 the issue is still not resolved. SNMF's e-Health group representatives asked again the CNAS management to ensure compliance to legislation and patient rights from all healthcare providers, offering also the IT solutions needed for this goal, but CNAS did not accept them[9].

On February 26, 2014, in the activity report of the CNAS president, it was noted that starting March 21, 2014 the Electronic Health Record will be tested for one month and after April 21, 2014 it will enter the production phase[10]. This statement is contradicted, however, by the CNAS address P/1769/12.03.2014 sent to the County Health Insurance Houses[11], which clearly states that the Electronic Health Record information system (the project name from Law 95/2006 is not used) has already gone through the stages of analysis, development and testing and, as of 20.03.2014, it goes effectively into the production phase.

In the same address, CNAS states that *family doctors* have the obligation "to ensure the mobility conditions for electronic health data by using DES, according to Article 29, paragraph (2) of Law 95/2006 as amended"[12]. This interpretation is inconsistent with the rules set out in Article 29, which refers not only to family physicians but to all healthcare providers in the health system – practices of family medicine and other specialists, diagnostic and treatment centers, medical centers, health centers, laboratories, and other public and private health facilities, public and private hospitals. The misinterpretation of the law can be seen, suggesting its application only to some healthcare providers. This can be considered a form of discrimination against family doctors. Inconsistencies between the documents and statements made by official representatives of CNAS can also be noted.

On April 4, 2014, the *SIUI-MF* application has been updated to version 4.0, which introduced the automatic download of health data in the Electronic Health Record[13]. To be noted that the SIUI-MF application is made available by CNAS to family doctors to report electronically for reimbursement of the medical services provided to patients. The update to version 4.0 was made without any prior detailed information given to health care providers and patients about the changes regarding the Electronic Health Records. The new version of SIUI-MF started to transfer health data into DES from April 7, 2014 automatically, without the application requiring the consent of the family doctor or of the patient who was receiving a free consultation according to the social health insurance plan. The application did not and is not currently giving the option to refuse health data transfer into DES. Going back to the previous version of the application was not possible because the other systems of CNAS such as the electronic prescription were not compatible with older versions of the SIUI-MF application. According to data provided by CNAS in the press release, until May 15, 2014, electronic health records of about 700,000 Romanian citizens have been created.[1]

As mentioned earlier, at the time of publication of this position paper, the rules for the application of the provisions of the law relating to DES as Article 29, paragraph 3 of Law 95/2006 requested were neither developed nor published. Therefore, we consider there is no legal basis for both requests from CNAS and CJAS to use DES and the automated data acquisition via the SIUI-MF version 4.0 application.

In the meetings of the *Committee for establishing the relevant medical data for DES,* which took place in May-June 2013, the representative of SNMF proposed CNAS to solve the existing problems (inconsistencies in the database of SIUI, breach of contractual obligations by other healthcare providers regarding electronic prescription and other provisions) and to carry out an analysis of the current situation regarding the IT hardware of hospitals, at least the University hospitals included in the DES project. According to our information, patient's reports and hand-written patient documents we receive, most hospitals and some clinics in ambulatory do not use computers, even in the context of the obligation set by law since 1 January 2013 to use electronic prescribing. Moreover, during the meeting of April 17, 2014, one of the reasons for the refusal from CNAS to implement the solutions given by SNMF was the lack of IT infrastructure of hospitals, of permanent Internet connections and dedicated staff, needed to report for reimbursement online, in real-time, the medical services provided.

International experience in the field of Electronic Health Records shows that a possible increase in efficiency due to the implementation of information systems does not correlate with a decrease in the overall cost of health systems[14] or a revenue growth for the health facilities implementing such systems, including family medicine practices. They, instead, face increased costs for implementation and the ongoing operation of such information systems.[15]

Studies based on international experience confirm that patients and doctors do not observe financial benefits through the implementation of these systems, and the only direct beneficiary of EHR implementation is the insurer, who achieves cost reduction, both administrative (the work of a large number of insurer employees is done more efficiently by the EHR) and through decreased reimbursement of the services required by patients (e.g. reducing diagnostic tests doubled or tripled when doctors had no easy access to the patient data and could not check patient requests).[16] A beneficial effect of introducing EHR in Romania will be observed if the funds saved are fully utilized in the health system.

The cost of developing and maintaining electronic health records should not be neglected. In Romania, the Electronic Health Record system (DES) was developed as a project with European Union funding worth approximately 19 million Euro. The administration costs of DES after this project is completed are not known to the authors, as on the CNAS website there is no budget impact analysis report for the DES project.

Until now, no information has been published on the costs arising from the acquisition, maintenance and use of computer systems needed for the implementation of DES. Also, there is no legislation to explicitly mention the institutions responsible for the security of the stored data.

Romanian experience of health system computerization has shown that since 2009, when the Unique Integrated Information System (SIUI) was introduced, there has been no increase in the revenue of family medicine practices which were computerized initially in a voluntary, then mandatory way, continuing in 2011 with the introduction of the electronic signatures and in late 2012 with the introduction of the electronic prescription. Instead, there was a significant and ongoing cost, both for hardware and related services - internet subscriptions, maintenance, training of employees - and supplies.

The unsatisfactory technical assistance offered by developers and Health Insurance Houses to the end users - health care providers and patients - and the lack of several functionalities of the systems announced by CNAS in the analysis and development stages of the projects have generated increased degrees of dissatisfaction of patients and medical personnel during testing and immediately after launch:

- As regards SIUI, the degree of dissatisfaction is kept at a high level to this date. This is also due to the fact that SIUI was announced by CNAS as the long overdue solution to eliminating multiple paper documents that patients had to show to demonstrate their status of insured patients.

- As regards the Information System for Electronic Prescribing, we will only mention the lack of the functionality which would assist the physician in prescribing, by warning of contraindications, side effects and dosages.

We believe that, also for the DES project, if CNAS maintains the current trend, family doctors will be among the only providers who will transfer medical data in good faith into DES. This data will not provide mobility of health data from all healthcare provider levels and DES will become a basic filing system for health data provided exclusively by the family doctor.

At the current stage of development there was no information disclosed about the cross-border transfer of data from DES and about the provision of cross-border e-Health services.

The Electronic Health Record system was released with no specific training and testing sessions for all health care providers involved in the completion and submission of data, and this issue can bring serious damage to the physical and mental integrity of patients, through the emergence of errors in the data contained by DES.

A number of sensitive issues, related to ethics and confidentiality, which have not been discussed in public until now by CNAS, despite repeated requests made by SNMF in writing[17], through the media[18] or in interventions in dedicated sessions at medical conferences[19], are related to the legislation necessary for the implementation and smooth functioning of DES.

The current legislation was created in a time when the health data entrusted by the patient to the doctor could reach a third party only by gaining access to the patient's paper chart, which was stored in a medical facility. In the context of computerization and remote access to confidential medical information, even kept behind highly secured computer barriers, we consider it is necessary to review the legislation and debate in a transparent, public way.

Recommendations

Given the above, the international experience and the Electronic Health Record situation in Romania, the National Family Medicine Society makes the following recommendations structured in three directions:

Legislation

A. We consider it is necessary to structure the legislative support for the operation of DES and to place the legislative projects in decisional transparency, accompanied by a broad public debate. The absence of the legal framework for the use of DES jeopardizes the doctor-patient relationship and creates the prerequisites of legal proceedings initiated by patients who believe that their explicit consent would be needed for transferring this very sensitive personal data. We also deem necessary the creation and the review or debate - where applicable – of the law on patients' and health care providers' rights, the review of legislation on access to health data, ethical standards, registration procedures for informed consent, responsibility for data input, consent for the creation of electronic health records, health data security and ownership of data and data management. These topics are also the subject of a study conducted by the European Commission - Directorate General for Health and Consumers, which aims to identify and examine national laws of the Member States and identify legal barriers to using electronic patient records at the national level and for the cross-border transfer of data within the EU. SNMF was consulted in February 2014 for this study.

B. We recommend specific legislation on the use of electronic documents. We believe that in the current context and taking into account the degree of computerization, it is necessary to review the legislation on the use and storage of medical records, updating it and to make the transition to a paperless medical system. These measures, possible with the proper implementation of DES, will lead to a more efficient manner in which medical services are provided, with a significantly improved communication between those involved and a decrease in the costs generated by the use of classical recording systems (referral notes, medical letters, discharge papers). The existence of the online Electronic Prescription system should lead to the elimination of compulsory use of printed prescriptions. The existence of the national Electronic Health Insurance Card should lead to the elimination of all forms of paper proof of insurance (paper pension coupons, employee certificate, fiscal certificate) to be presented to physicians and other healthcare providers. Similarly, the existence of Electronic Health Records should result in the removal of records, observation sheets, medical letters on paper. These issues, although logical, are not part of CNAS requirements and have not been translated into legislation. In the context of medical data filing required in both electronic and written paper form, specified in Law 95/1996, Article 131, there will certainly be resistance encountered from all practitioners, fully justified. This issue was stated by representatives of the Ministry of Health and hospitals at the Committee meetings.

C. We consider it is necessary to take into account the recommendations of the European Union related to cross-border health data mobility[7]. One of the main objectives related to health at EU level is to develop effective methods of providing cross-border healthcare. DES is a first step, allowing the realization of a national system of electronic exchange once its operation is regulated through legislation. To ensure mobility of health data it is necessary to comply with guidelines developed by the EU. As a result, we believe that it is absolutely necessary to standardize, improve or develop, where appropriate, how to record medical data in DES so that these specifications correspond to guidelines published by the EU. Such an approach would place Romania in a favorable position on implementing health systems in the EU, thus ensuring the quality of health care for any situation that may occur (accidents in another Member State, medical emergencies).

D. We consider it is essential to clearly establish all parties responsible for maintaining, securing and accessing the electronic records created, establishing clear property rights over them and the data contained therein. Currently, Law 95/2006 requires CNAS to ensure the organization and administration of the Health Insurance Electronic Platform (PIAS). There is no legal provision specified in the legislation on how CNAS will accomplish this. Also it should be noted that this approach (CNAS responsibility for DES) may be the wrong one, as the patient's Electronic Health Record system is mandatory to the whole health system (insured and uninsured patients, healthcare providers with and without a contract with CNAS for reimbursement of medical services provided to insured patients), and is not a specific tool for use in relation to CNAS.

E. We recommend the launch of a public discussion right away regarding the legislation on protection of specific personal data used in the patient Electronic Health Records. Although Romania has legislation regulating the use of personal data, it should be updated to respond to new situations that may be encountered by using EHR. Among these the most important are those aimed at clearly defining the requirements regarding informed consent of the patient, how the right to privacy is adequately protected and determining how to access DES in special cases.

F. We also recommend the setting of specific requirements of medical liability in connection with DES. They must address all those who are able to manipulate the data contained. We should clearly identify the entities (users, beneficiaries and technical support staff) which are authorized to add, delete or modify the data contained in the EHR. The legislation should also clearly set out how corrections can be made on the documents in the EHR. These are needed to transform DES in a medico-legal document, thereby ensuring the transition from the classic medical filing system (hospital patient paper file, consultation paper) to a modern, fast and efficient system of health data mobility.

G. We recommend close collaboration between CNAS and the Ministry of Health, so that the MoH can have access to anonymized data from DES for statistical purposes, in the interest of public health. This collaboration will lead to the reduction of bureaucracy for health care providers which currently report some statistic data to the Ministry of Health and the County Public Health Departments (DES).

Implementation

H. We recommend DES implementation to take place at all healthcare provider levels, whether or not under contract with the county health insurance house (CJAS), subordinated to CNAS. Although Law 95/2006 includes this requirement since 2014, the way in which compliance will be secured is not set. We make this recommendation because a significant number of patients turn to direct payment services outside the national health insurance system, sometimes almost exclusively. We consider that all relevant health data for the patient history must be present in the EHR to meet its purpose, no matter if diagnosis and treatment were conducted in the public or private sectors. This data must be entered in the EHR by the healthcare providers who produced it, and not to put further bureaucratic load on other providers, such as family doctors. Implementation of this recommendation will enhance the usefulness of DES for all parties involved, i.e. patients, doctors, CNAS, MS.

I. We recommend that the Electronic Health Record (DES) be developed together with the Electronic Health Insurance Card (CEAS) for the purpose of avoiding unnecessary duplication of information, taking into account the financial resources and time required for data entry. Authentication procedures for access to DES should take into account the timing of the implementation of CEAS and the technical arrangements regarding the electronic signatures of healthcare providers. Mistakes related to the doctor's registration number and electronic signatures should not be repeated, like the ones that appeared in the case of the electronic prescription system, which led to many complaints, expenses and unnecessary steps to solve the problems that were not foreseen by the project developers. Situations where design errors, downtime or delays in the response of the systems must be avoided, as they generate a major discomfort to patients or put their health at risk.

J. We recommend a major revision of the project regarding the implementation steps of DES. We believe it is necessary to stop the automatic data transfer into DES via the SIUI-MF application, which currently takes place without the existence of legal provisions or explicit informed consent of patients. We propose that the introduction of data into DES be carried in the first stage just by laboratories, imagistic units, pharmacies and hospitals (including maternity, ER and hospital ambulatory units), regardless of having or not having a contract with CJAS/CNAS, and family doctors only to have access in this first stage to reading this data and, depending on the patient's option, to be able to transfer data. This will eliminate the printed medical documents given by healthcare providers directly to patients, documents which are sometimes lost or which family doctors or nurses have to scan or enter manually, as appropriate, in the office software, in order to have an accurate and complete history of patient who was seen by other healthcare providers. Only after the successful completion of this first and crucial stage of the project we consider it will be necessary for family physicians to enter data considered relevant in these records already created and populated with data from other providers. To be noted that both laboratories and pharmacies have all the necessary equipment to transfer data into DES, thus in order to implement this recommendation all that is required is the will of CNAS and Ministry of Health.

Communication

K. We recommend that the initiators of DES should clarify the goals, objectives, costs and security of DES. A number of key issues have not been submitted to date by CNAS. We believe it is necessary to present the security guarantees and issues related to informed consent.

L. Regarding the acceptance and use of EHR, we recommend a study even at this point in the project development, together with an efficient awareness campaign about DES and the obligations and rights of Romanian citizens. There is the possibility that this form of national, centralized electronic health records will remain unused, most patients exercising their right to refuse to create their record for various personal reasons. Such a waste of funds should not be permitted in the Romanian health system and therefore we believe that these things should have been established before the project was started. The public has not been presented with an analysis made by CNAS to assess whether the people of Romania desire and will use such a system. Such an analysis could be performed by a public hearing procedure similar to the one initiated by SNMF and FNPMF on April 26, 2013 on the topic of prevention[20]. We believe that these steps should have been performed prior to the submission of the DES project by CNAS and obtaining EU funding, so that the project reflected the needs and desires of Romanian citizens.

M. We recommend the opinions and demands of patients and physicians, through their representative organizations, to be followed in the decision making process of establishing all aspects of the patient's electronic health record. We note with surprise that the objections of doctors and patients from the *Commission for establishing the relevant medical data for DES* concerning free access of any doctor to the *emergency health summary*, which comprises all chronic diseases, medications and hospitalizations in the last 6 months[21], were not taken into account. We believe that DES will not have any chance of success without a debate on health data security, data storage, ownership of the data, and especially the informed consent of the patient[22], risking to follow the path of failures already known in other countries that have minimized this step.

N. We recommend creating or publishing the report from the Health Technology Assessment process represented by DES, if it has previously been done by CNAS. The possibility of an unnecessary expense for a project that can be refused by the patients must be avoided, as there are examples with similar approaches in the UK's NHS[23]. We recommend taking these essential steps even at this time, before other projects and costs of further developments of DES indicated by CNAS will appear.

We believe that this method of implementing DES, together with the recommendations mentioned so far, would make it more useful to the entire health system and family doctors and patients in particular, really leading to the project objectives listed in the press release of 15 May. We believe that the benefit of patients and of the health system is minimal in the current version of DES, and current and possible future costs of the project have not been evaluated.

Conclusions

In conclusion, the implementation and current development of the Electronic Health Record (DES), without a specific legislative framework, violates the fundamental rights of patients. We consider it is necessary that the Romanian Government adopts the legislative framework for the operation of DES in the general context of the computerization of the health system.

In order to achieve this goal, DES must also ensure cross-border mobility of data so that data can be both accessed for information and completed, by healthcare providers in Romania as well as other EU countries.

The Romanian Government should make an analysis of the use of DES in the European insurance systems and assume the maintenance costs of DES.

The DES benefits should include lowered bureaucracy of health systems, including a reduction of the information stored on paper by switching to a paperless system. SNMF proposes that soon after the national implementation of DES, or simultaneously with it, paper records should not be used anymore in the offices of family physicians.

It is essential to standardize the existing software solutions in hospitals (including maternity units, the emergency room, hospital ambulatory units), laboratory units, imaging units, pharmacy, ambulatory clinics and solo practices both in the public and private sectors, to ensure the success of DES, through the participation of all these types of providers in sending medical data in DES easily. Only after taking these first basic steps, we believe that there may be integrated access from health professionals to patient data and DES can be considered functional.

Thus, we would like DES not to become just another project of computerization done by CNAS with European Union funding, successfully implemented only in family medicine, on the expense of family doctors and to the detriment of patients who need them but also the detriment of the doctor-patient trust relationship.

References

[1] Dosarul Electronic de Sănătate – Un pas important în debirocratizarea sistemului de sănătate, Comunicat de presă Casa Națională de Asigurări de Sănătate http://www.cnas.ro/post/type/local/dosarul-electronic-de-sanatate-un-pas-important-in-debirocratizarea-sistemului-de-sanatate.html

[2] Anunț de presă Finalizarea implementării proiectului Dosarului Electronic de Sănătate, Casa Națională de Asigurări de Sănătate, 15 mai 2014 http://www.snmf.ro/sites/default/files/anunt_de_presa_DES_15mai2014.JPG

[3] Comunicat de presă - Comunicat - 96% DIN MEDICII DE FAMILIE AU PRESCRIS REȚETE ELECTRONICE, 23 ianuarie 2013 http://www.cnas.ro/mass-media/comunicate-de-presa/comunicat-96-din-medicii-de-familie-au-prescris-re%C8%9Aete-electronice

[4] Raport al CNAS, 30 iulie 2013 - http://www.cnas.ro/media/pageFiles/RaportPE_30.07.2013.pdf

[5] Zurita L, Nohr C. Patient opinion: EHR assessment from the users perspective. Stud Health Technol Inform. 2004; 107(2):1333–1336

[6] Westin AF. Public attitudes toward electronic health records. Privacy and American Business. 2005; 12(2):1–6

[7] Comisia Europeană, Directoratul General Sanatate și Consumatori - Sănătate publică, eSănătate - http://ec.europa.eu/health/ehealth/policy/index_ro.htm

[8] eHealth Network, Guidelines on minimum/non-exhaustive paţient summary dataset for electronic exchange in accordance with the cross-border directive 2011/24/eu release 1, 19 November 2013, http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf

[9] Propuneri soluții sisteme informatice CNAS (SIUI, SIPE) – Societatea Națională de Medicină Familiei, aprilie 2014 - http://snmf.ro/sites/default/files/2014_04_17_SNMF_FNPMF_solutii_SIUI.pdf

[10] Bilanțul activității președintelui CNAS, dl. Cristian Bușoi, în perioada 17.06. 2013 – 26.02.2014, http://www.emedic.ro/Articole3/Bilantul-activitatii-presedintelui-CNAS-Cristian-Busoi-37.htm

[11] Adresa nr. P/1769/12.03.2014 CNAS către Casele de asigurări județene, http://www.cassam.ro/des17032014.pdf

[12] Adresa nr. P/1769/12.03.2014 CNAS către Casele de asigurări județene http://casmb.ro/Download/ANUNTURI_atach/20140318_adresa%20CNAS.PDF

[13] Versiune actualizată a aplicaţiei de raportare SIUI-MF pentru conectarea la DES, Casa Națională de Asigurări de Sănătate, aprilie 2014 http://siui.casan.ro/cnas/siui_4.0/versiuni

[14] Information Technology: Not a Cure for the High Cost of Health Care. Knowledge@Wharton, June 10, 2009 http://knowledge.wharton.upenn.edu/article.cfm?articleID=2260

[15] RWIF, GWUMC, and IHP Staff (2006). "Health Information Technology in the United States: The Information Base for Progress". Robert Wood Johnson Foundation, George Washington University Medical Center, and Institute for Health Policy.

---

[16] Evidence on the costs and benefits of health information technology. Congressional Budget Office, May 2008. http://www.cbo.gov/doc.cfm?index=9168

[17] Solicitare privind Dosarul Electronic de Sănătate – Societatea Națională de Medicină Familiei, iulie 2013, http://snmf.ro/sites/default/files/2013-07-03-SNMF-FNPMF-Notificare-CNAS-privind-solicitare-DES.pdf

[18] Medicii de familie și cooperarea instituțională au avut contribuții decisive la succesul rețetei electronice, Comunicat de presă – Societatea Națională de Medicină Familiei și Federația Națională a Patronatelor Medicilor de Familie
http://www.snmf.ro/sites/default/files/2014_04_10_SNMF_FNPMF_medicii_de_familie_contributie_decisiva_succes_reteta_electronica.pdf

[19] Sesiune dedicată Dosarului Electronic de Sănătate – Conferința Națională de Medicină Familiei 2014 - partea I, înregistrare video http://www.vimeo.com/amfb/des1

[20] Prevenția în sănătate – cine câștigă și cine pierde în sistemul de sănătate? - Sinteza audierii publice - http://www.snmf.ro/sites/default/files/Raport_sinteza_Audiere_public_Preventia_in_sanatate_23.05.2013.pdf

[21] Dosarul Electronic de Sănătate – Sumarul de urgență - http://www.des-cnas.ro/wps/portal/cnas/Dosarul-de-sanatate/Sumar-si-urgente

[22] „Datele noastre medicale, în pericol”, Curierul Național, 18 aprilie 2014 http://www.curierulnational.ro/Actualitate%20Companii/2014-04-18/Datele+noastre+medicale%2C+în+pericol

[23] NHS Connecting for Health, Wikipedia http://en.wikipedia.org/wiki/NHS_Connecting_for_Health