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INFORMATION & COMMUNICATION TECHNOLOGY (ICT) IN THE HEALTHCARE SYSTEM¹

Introduction

The need to balance available resources and the quality of assistance offered is stimulating the development of eHealth or Online Healthcare, that is, the use of tools based on information and communication technology to support and promote the prevention, diagnosis, treatment and monitoring of diseases and the management of health and lifestyle. Online Healthcare contributes to the availability of essential information where and when it is necessary and is of growing importance since there has been an increase in the international circulation of citizens and number of patients. eHealth initiatives improve access to treatments, placing citizens at the centre of the healthcare system. It furthermore contributes to an increase in general efficiency and sustainability of the healthcare sector. This article is aimed at illustrating ICT in the Healthcare System and its usefulness for the general public as well as how it is developing at a European, National and territorial level. Reference has been made to publications, articles and experience related to this matter in the drafting thereof.

1. Presentation of a European context

The European Commission identified a series of actions aimed at offering better quality of healthcare assistance in all of Europe. The “Europe 2020 strate-

¹ The paragraphs of this document have been divided as follows: Alpi (paragraphs 1, 2, 3, 4, 5, 6, 7, 8, 9); Calvo (paragraphs 10, 11, 12); Alpi, Calvo (paragraph13).

gic plan”² is aimed at providing a contribution to the growth and dissemination of the benefits deriving from the digital era on a EC level by means of equipping all European citizens with secure online access to their medical records, with an elevated dissemination of computerised medical services by 2020, organising a minimum set of common data for the interoperability of patients’ records. From the latter, the 2011/24/UE Directive provides for the institution of a voluntary network, eHealth Network, which connects the national authorities responsible for healthcare assistance online, designated by the Member States. The aim of this network is to create conditions in which the continuity of care may be reinforced and access to a secure and high quality healthcare service at a EC level may be guaranteed.

2. Presentation of eHealth in Italy

These initiatives fit in with the general framework of modernising the relationship between the civil service and its citizens, which is provided for by the Italian digital agenda and which pursues various aims, including the “realisation of technological and immaterial infrastructure at the service of smart communities”, aimed at satisfying the growing demand for digital services in multiple sectors, including healthcare. The socio-demographic evolution of the population and the need to balance available resources and the quality of healthcare services have stimulated the definition of new ways to provide healthcare services which, first of all permits the clear traceability of a patient’s care from the first moment of interaction with the healthcare network. This is made possible by means of a system of integrated network services, which permits the control and systematic evaluation of various parameters³ in real time. The realisation of an integrated services system assumes noteworthy importance, especially within the framework of profound change and evolution in the NHS⁴, characterised by population that is more and more prevalently elderly and an assistance which is necessarily more centred on territorial services to face chronic illnesses. In this context, the application of

² Launched by the European Commission on 3 March 2010, it was aimed at tackling the particular economic trend and at supporting economic growth at a EC level and among the various initiatives, it provided for the organisation of a Digital Agenda for Europe which, organised by the European Commission, was made official on 19 May 2010.

³ Including clinical risk and diagnostic and therapeutic procedures, with particular reference to the quality of same, resources used, technology used and the level of satisfaction perceived by the citizen.

⁴ National Healthcare System

new technology is a valid opportunity to define better balancing, between the need for higher quality performance and a shrewd use of available resources.

Possible care envisaged for a citizen provides for the involvement of a General Practitioner (GP), a freely-chosen paediatrician, outpatient and hospital doctors and for a territorial level to manage the post-acute phase. The care provides for a patient's access to healthcare services via the general practitioner or freely-chosen paediatrician who, after having obtained the patient's signed consent to deal with his/her personal data, updates the patient summary contained in the patient's Electronic Healthcare File (EHF)⁵ itself or, where necessary, produce computerised sick leave certificates as well as electronic prescriptions. If provided for, the patient may have access to territorial services and hospitals through a Single Booking Centre (SBC)⁶.

The Electronic Healthcare File, updated continuously by persons caring for the patient within the framework of the National Healthcare Service (NHS), shall then contain all the patient's clinical information and collect the digital healthcare and socio-healthcare documents generated by the clinical events regarding the patient. This information supports the doctor's decisions, thereby guaranteeing a more effective and prompt diagnostic and therapeutic assistance, especially in emergencies. According to research carried out in 2013 of the ICT Observatory in Healthcare by the School of Management of Milan Polytechnic Institute, the total amount allocated to the digitalisation of the Italian Healthcare System was €1,23 billion, a reduction of 5% with respect to 2011. This amount equals 1,1% of the total public healthcare. The per capita expenditure in information technology is therefore €21 per inhabitant, an amount which is considerably lower than that of other European nations, like France and Great Britain, which have spent more than double that on the digitalisation of their healthcare systems.

According to the estimates of the Observatory, the €1,23 billion spent in Italy in 2012 was divided as follows between the various operators of the NHS: €895 million was spent by the healthcare companies, with a reduction equal to 2% with respect to 2011, which was already a reduction with respect to 2010; €280 million was spent by the Regions, with a reduction of 7% with respect to 2011; €54 million was spent by more than 47 000 General Practitioners, with a reduction of 24% with respect to 2011. In this context, the use of ICT solutions would lead to a total saving for healthcare structures estimated at approximately €68 billion a year (about €115 per capita), divided as follows: €3.000 million owing to discharges from hospitals made possible by the use of medical supporting technology in the

⁵ Referred to as *Fascicolo Sanitario Elettronico* (FSE) in Italian.

⁶ Referred to as *Centro Unificato Prenotazione* (CUP) in Italian.

territory and domiciliary care; €1.370 million savings in terms of time spent on medical and nursing activities by introducing the Electronic Healthcare File; €860 million thanks to the dematerialisation of reports and diagnostic imaging, which would reduce the waste associated with printing and time used to retrieve paper documents; €860 million thanks to the reduction in hospital admissions due to errors that could be avoided through the computerised management of medicines; €370 million thanks to reports delivered via internet so that desk operators may be used for activities of a higher added value; €160 million with online bookings of services; €150 million through the rationalisation of data centres in the territory and the progressive use of virtualisation techniques and lastly, €20 million for the reduction in the costs of printing medical records.

The economic savings for citizens, thanks to an improvement in service made possible by digital technology and supposing its complete adoption, would be estimated to be a total of approximately €7,6 billion (equal to about €130 per citizen), divided as follows: €4.600 million thanks to the downloading of clinical-medical documents via the internet; €2.200 for minor costs to be sustained with domiciliary care supported by Telemedicine solutions; €640 million for the use of service booking systems via internet and telephonically; €170 million with computerised systems for managing medicine.

3. EHF – Electronic Healthcare File

The aim of the Electronic Healthcare File is to provide doctors and more generally clinicians, an overall and unified view of the state of health of each citizen. It represents a point of information and clinical document collection and sharing concerning citizens, generated by the various operators in the Healthcare System. It contains health issues and summarised documents and is organised according to a patient-centric hierarchical structure, which permits navigation between clinical documents in different ways, based on the type of investigation⁷. The Electronic Healthcare File always refers to a single citizen in it. The referring time period is the whole life of the citizen. Furthermore, it is fundamental that a summary of the patient's case history, the Patient Summary, is contained in the EHF so that the necessary information can be used in an optimal manner. An important aspect

⁷ The main types of information collected and made available to a doctor and patient by the Electronic Healthcare File deal with the following situations: hospital admissions, outpatient specialisation, pharmaceutical services, residential assistance, home assistance, Emergency Room access.

to take into consideration is the privacy and protection of the personal data of citizens.

4. SBC – Single Booking Centre

Rapid access to assistance may be simplified by the presence of evolved systems of online healthcare, for the single booking of services through a Single Booking Centre⁸, which permits citizens to make a booking for healthcare services through various communication channels (company SBC of the LHA and Hospitals, pharmacies⁹, etc.), that favour access and reduce waiting times, by means of an integrated management of the appointments for booking.

5. Computerised sick leave certificates

The path for sending certificates certifying absence for health reasons envisages that an employee (public or private) contacts his/her doctor to request a sick leave certificate for his/her relative employer. The doctor then sends a computerised certificate to the NSSI¹⁰, which in turn, makes the sick leave certificate available to the employer through computerised means. The computerised transmission of sick leave certificates is done by both doctors employed by the NHS (hospital and district doctors) as well as doctors working under a convention with the NHS (general practitioners and outpatient specialists).

6. ePrescription – Electronic medical prescriptions

The Ministry of Health believes it is essential to develop ePrescriptions, especially considering the repercussions in terms of the clinical-welfare processes as a result thereof, including the increased ease of access to therapies, better mon-

⁸ SBC: an informed centralised system for booking.

⁹ A new type of pharmacy is emerging: the “*services pharmacy*”, meaning a facility where over and above medicine, a citizen can find a series of added, significant socio-healthcare services (bookings for outpatient specialised assistance at accredited public and private healthcare structures, payment of part of the expenses due by citizens, collection of the relative medical reports).

¹⁰ National Social Security Institute.

itoring and control of same, the increased capacity to prevent clinical errors, lower social costs. The transformation of paper prescriptions to electronic ones therefore becomes an obligatory passage in the automation of communication methods, both within the admission and treatment structures themselves as well as between general practitioners and freely chosen paediatricians and service providers. The adoption of digital formats thereby makes the exchange of information possible and automates the management methods of medical prescriptions. This aim, however, is not the only advantage derived from the adoption of electronic prescriptions. The possibility of controlling prescription appropriateness is an even more important element for the medical profession. In this context, electronic prescriptions contribute to making information on which clinical systems are based available, in support of decisions that improve the quality thereof and notably reduces risks for patients upon distribution. Furthermore, electronic prescriptions have the advantage of controlling costs more easily and accurately, certainly reducing the time usually needed with traditional systems for processing prescriptions. Sending computerised data regarding medical prescriptions substitutes paper prescriptions for all intents and purposes.

7. Telemedicine

Within the framework of implementing online healthcare services, the definition of the technical-organisational methods aimed at permitting socio-healthcare integration and supporting innovative forms of domiciliation, assumes great importance. Telemedicine services may, in this sense, represent an integral part of the structural and organisational redesigning of the assistance network of a country. Telemedicine may, in particular, contribute to improving the quality of healthcare assistance and permit the use of treatments, diagnostic services and long-distance medical advice, as well as constantly monitor vital parameters, in order to reduce the risk of complications in persons at risk of or affected by chronic illnesses. With particular reference to the aging population and the increase in the chronicity of illnesses, online healthcare may be synergetic to telemedicine operations in prevention. This may be useful especially for categories identified as being at risk, for example, when they are affected by cardiovascular illnesses. Even though these patients lead a normal life, they constantly have to monitor certain parameters in order to reduce the risk of complications. The interdisciplinary situation offered by online healthcare in this case, permits better service for the pa-

tient by means of quicker availability of information on his/her state of health, thereby permitting an increase in the quality and promptness of the doctor's decisions, which is particularly useful in emergency-urgent conditions. Telemedicine, which is one of the main fields of application of online healthcare, offers greatly significant potential, especially in terms of increasing equity in the access to socio-healthcare services in remote areas, thanks to the decentralisation and flexibility of the offer of service given and whose distribution is possible thanks to innovative forms of domiciliation. Telemedicine permits an optimal redistribution of human resources and technology between various aids, thereby covering the need for professional competence which is often lacking and assuring the continuity of assistance in the territory¹¹.

8. Territorial context

Various Italian regions have set up projects for the realisation of eHealth systems. Within the context of the Umbria Region, starting from 2011, the Local Health Authority ASL 4 of Terni¹² has been implementing the "Epidemiologic Concentrator" project, a computerised instrument for the management of territorial healthcare data of General Practitioners and District Health Centres. Epidemiological research models have been activated on the "Concentrator", which experimentally examine the illnesses having the widest socio-healthcare impact; it is possible to consult the inserted data online, so that the case history of each patient is accessible to all healthcare workers who treat that patient. Furthermore, the extracted data, which is made anonymous and grouped together, permits an improvement of the planning and management of the services offered. The electronic healthcare file in Terni Province is currently made up of 2 pillars: the Atl@nte project and the "Epidemiological Concentrator". Each day, GPs collect the clinical data of their patients using computerised methods in over 90% of the cases. The "Epidemiological Concentrator" project was created in August 2011 and gathers copies of the medical records of the patients, followed by the GPs, on

¹¹ Through the availability of teleconsulting services, telemedicine may offer valid support to urgent mobile services through the reorganisation of healthcare services and if necessary, by means of the use of long distance clinical resources, dislocated also directly on ambulances.

¹² ASL 4 of Terni, which includes all the province, provides assistance to approximately 232 thousand people, 202 thousand – those over the age of 14 – of which are entrusted to the care of 195 general practitioners (GPs) in the territory; since 01.01.2013, it has been inserted in ASL2 Umbria.

a computerised database system of the NHA. The transmission thereof is carried out in a bidirectional manner and in real time. Epidemiological research models with priorities have been activated on the “Concentrator”, which experimentally examine the illnesses having the widest socio-healthcare impact¹³. The designed computerised system responds to the needs of safety and data maintenance (data recovery), a repository of the essential information on each patient (patient summary) and a verification of the degree of accuracy of the data collection (individual audits of the GPs). The inserted data may be consulted online by GPs as well as continuity welfare doctors, emergency rooms and 118 emergency-urgency, so that the case history of each patient is accessible to all, also in the event of emergencies. On 30 June 2012, 170 GPs, who assist a total of 81,2% of the population over the age of 14, subscribed to the project. Thereafter “patient summaries” regarding 91,41% of the assisted population (95,19% over the age of 75) were sent to the system and made available: the updating of which is incumbent on the GP. When the “patient summary” is read by authorised healthcare workers, there is an automatic notification in the patient’s records within the computerised system of the GPs, with communication of possible medical action taken. Exchanged information, all of which is strictly authorised by the patient, deals with personal data, allergies/intolerances, active problems, ongoing medication and medical reports which the GP deems to be most relevant (various check-ups, blood pressure, etc.). This procedure may gradually be extended to the NHA’s outpatient specialists or hospital doctors who treat the patient. The systematic model adopted favours wide flexibility in the use thereof: in fact, it has been programmed so that the computerised sharing of medical records by GPs, which are merged in the “Territorial Functional Aggregation” (TFA) and the construction of the “Electronic Healthcare File” (EHF), is possible.

9. Lawfulness requirements when processing personal data in an EHF

An EHF is realised in two fundamental moments: on the one hand, there is the registration of a bulk of data and information and on the other, there is the sharing of this registered data amongst all the operators of the system justified in processing it. Taking into consideration the fact that this kind of infrastructure was subject to a wide range of criticism regarding the regulations protecting person-

¹³ Such as chronic bronchopneumonia, cardiac decompensation and diabetes mellitus.

al data and that there is no legislation referring to the EHF, the Watchdog for the protection of personal data intervened and outlined the guidelines in this matter. The holder of the processing must provide suitable information¹⁴ that establishes the prerequisite of lawfulness to the citizen beforehand.

In particular, the intention to establish an EHF that documents the patient's medical history in order to improve the treatment process must be highlighted, explaining that the data merged in the file refers to his/her past and/or current state of health.

Moreover, the information:

- must, in a simple manner, explain the opportunities that this advanced and innovative instrument offers to improve the procedures that guarantee the right to health and at the same time, the wide cognitive sphere that it may have;
- must inform the patient that his/her refusal shall have no consequences on his/her right to the requested treatment;
- must give a sufficient description on how the new digital instrument works;
- must indicate who, upon treating the patient, may have access to the EHF as well as the connected possibility of limiting which of these persons may consult it;
- must inform the patient of the circumstances where the File may be consulted, including without his/her consent, if it is essential to safeguard the health of a third party or the public in general¹⁵, whilst respecting the Watchdog's general authorisation;
- must highlight the circumstances in which the consent to consult the File by a certain person (eg: general practitioner or doctor of the ward where admission occurred) can be referred to his/her substitute;
- must provide the patient with the identification details of the holder/s of the processing of the personal data processed through the EHF;
- must inform the patient that he/she may in any moment exercise the right to access the data¹⁶.

10. Informed consent to the processing of data

The processing of the personal details of the EHF must fully respect the norms that regulate the protection of data¹⁷. It must therefore be subject to the pa-

¹⁴ Containing all the elements required by art. 13 of Legislative Decree no. 196 dated 30 June 2003.

¹⁵ Art. 76 of Legislative Decree no. 196 dated 30 June 2003.

¹⁶ In terms of art. 7 and subsections of the Code (compare point 5.1.3 hereafter).

¹⁷ Legislative Decree No. 196 dated 30 June 2003.

tient's free will, which through this consent, has the right to permit or not permit the establishment of his/her EHF, to merge the data regarding his/her current and/or previous state of health in it and to have the power to control by whom and what may be accessed in the file. These choices may be modified at any time. Thus, consent is the first prerequisite for the lawfulness of the processing thereof and is only validly given after adequate information has been received. The patient's consent to create his/her Electronic Healthcare File must be explicit, that is, unambiguously disclosed and therefore not by intuition or inferred from behaviour, not satisfying the criteria of silent consent. The refusal thereof must be of no consequence to the patient's possibility of using the requested and/or necessary medical service. Therefore, the patient's will to modular access to his/her EHF is expressed by means of:

- general consent, a preliminary and necessary element for the setting up of an Electronic Healthcare File;
- specific consent on both the information to be made visible or not as well as on the persons in the NHS that are treating the patient (eg. a GP, paediatrician, pharmacists), to be authorised to access the data in the EHF.

Any type of patient consent given may be revoked or modified in any moment. In the case of minors or persons under guardianship, consent may be given by a parent or guardian with a valid identity document.

A further guarantee for the patient is the right not to consent to the visibility of certain health information, regarding a single clinical event which may be merged in the EHF, to persons other than those who produced the data (obscuring) without the latter automatically being informed of the patient's choice ("obscuring of obscuring"). The "obscuring" of a clinical event may be revoked at any time. Persons in charge of the treatment may access the patient's data, except for cases of obscuring. When establishing the EHF and identifying the type of information which may also be reported thereafter, holders of the processing must respect the laws protecting the anonymity of the persons, including those protecting victims of sexual violence or paedophilia, persons tested HIV positive, persons who abuse drugs, psychotropic substances and alcohol, women who voluntarily interrupt a pregnancy or who decide to give birth anonymously as well as the services offered by family counsellors. This type of data is "private" ("obscured" by law) and may be made visible only upon the specific and explicit consent of the patient, in accordance with "the guidelines concerning the Electronic Healthcare File (EHF) and health dossier"¹⁸.

¹⁸ Approved by the Watchdog Authority for the protection of personal data dated 16 July 2009.

11. Exercise of a citizen's rights

Citizens must be guaranteed the possibility of exercising their rights set out in art. 7¹⁹, regarding personal data processed through the EHF, at any moment. These rights, including the right to access the data involving him/her and obtain communication thereof in an intelligible form, or rather the integration, updating or amendment thereof, may be exercised directly against the holder of the processing. Citizens must moreover be guaranteed easy consultation methods to their files as well as the possibility of extracting a copy thereof, if they wish to make it available to third parties.

Conclusion

The EHF is a new important instrument available to those operating in the health and hospital sector. Regarding the aim pursued by the EHF, citizens should be shown the usefulness of establishing and setting out a description regarding his/her healthcare information as completely as possible, in order to be able to offer better support not only to him/her but also to the healthcare system and to the doctor. In-depth knowledge of medical data, regarding the past as well, may in fact contribute to a more efficient identification of elements that are useful in evaluating the case. The situation regarding eHealth on a national territory level is even more specialised in terms of the maturity of regional computerised systems and with reference to the applicative solutions adopted. Regarding the territorial context in Terni province, just a year after the activation of the “epidemiological concentrator”, ASL 4²⁰ and the GPs have reached the goal of a centralised database which, strengthened by the data of the medical records of the doctors themselves, simplifies communication between various medical figures and guarantees the appropriateness, sustainability and effectiveness of the services provided. Digitalisation still hides criticality regarding computerised transmissions, digital documents, electronic prescriptions and online certificates²¹:

- documents are not digitally signed (the lack of a digital signature comparable to a traditional signature);

¹⁹ Legislative Decree no. 196 dated 30 June 2003.

²⁰ Forming part of ASL2 Umbria since 01.01.2013.

²¹ Position Paper March 2013 of the Italian Society of Telemedicine and eHealth (Giancarmine Russo, Secretary-General).

- lack of rules on the conservation of digital documents, which must absolutely be guaranteed for citizens and healthcare operators, who years later must have the certainty of tracing back to these same documents (problems of technological evolution, modification of document formats with the risk of inaccessibility);
- adequate information on the methods and purposes of processing has not yet been reached in the security and privacy system in order to obtain the patient's real conscious consent to the computerised transmission of his/her sensitive data.

One hopes that the access method to data with a username-password, which the law identified as being a weak method, permitted as an exception until December 2010, will be overtaken by a smartcard²² for doctors, so that digital signatures may become operational and there may be reliable authentication of healthcare, in order to maintain the relationship of trust and confidentiality which is at the basis of a relationship between a doctor and patient, intact.

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²² COS (Carta Operatore Sanitario) or Healthcare Operator Card, is currently active only for about a third of General Practitioners (18.000 out of 60.000 current doctors working under a convention).

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Summary

The need to balance available resources and the quality of assistance provided is stimulating the development of “eHealth” or “Online Healthcare”, or rather, the use of instruments based on information and communication technology to support and promote the prevention, diagnosis, treatment and monitoring of illnesses and the management of health and lifestyles.

Keywords: ITC, eHealth system, telemedicine, Italy