



NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

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**OPINION No. 60 OF THE
NATIONAL COUNCIL OF ETHICS
FOR THE LIFE SCIENCES**

**OPINION ON HEALTH INFORMATION AND
COMPUTER HEALTH RECORDS**

(September 2011)



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The National Council of Ethics for the Life Sciences, in the scope of its competences and by its own initiative, discussed ethics issues related to “Health Information”, the recording of that information on computerised means and the respective accesses and uses.

Consequently, it decided to approve the following **OPINION**.

I – General grounds on information and health information

- A.** A prior clarification on the concept and finality of information is needed. *Information* is understood to be a set of data and its processing, with the aim of knowing or understanding certain aspects or situations of the world and the action on them.
- B.** Information is fundamental in building knowledge and in any well-founded decision making that aims for a specific action. In a social and political perspective, information has implications in the exercise of citizenship. On the other hand, the perception of the information in question depends on the scientific, technological, artistic, cultural and social context, as well as that of those who interpret and use it.
- C.** Generally speaking, those who have access to quality and updated information in a timely way are able to make more enlightened and adequate decisions. The selection of the information and the optimisation of its use are of unquestionable relevance. In this context, information management is of vital importance in decision processes.
- D.** Knowledge uses and generates information. Health information is built in the context of a personal relationship with individuals, whether ill or healthy; it is set up and processed by health professionals and must be available and communicated to the person in question, as an essential tool to make a decision.
- E.** One of the most relevant aspects of health information is that, given its scientific and technical nature and its greater or lesser complexity, it requires specialised interpretation, to be given whenever requested.
- F.** The understanding of health information as a resource for oneself, as a tool for decision making, conforms with the respect for the person’s autonomy, the respect for their fellow citizens (family members or others), and also the responsibility of professionals in protecting that very information. The autonomy of a human being is indeed the ethical foundation of the duty of confidentiality and privacy protection.



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II – Specificities of access to health information

- a. Access to health information is permanently confronted with the respect for confidentiality (professional confidentiality) and with privacy protection of the holders (as it is acknowledged juridically in Law No. 46/2007, dated 24th August, in Law No. 67/98, dated 26th October, as well as in the constitution of the Commission for Access to Administrative Documents and the National Commission for Data Protection).
- b. The possibility of access to health information by its holder derives from the respect for the respective autonomy and it is a prerequisite for the exercise of informed, free and enlightened consent.
- c. Health information includes all type of available information and, directly or indirectly, connected to the health of a person, whether ill or healthy. It also includes information connected to recorded clinical data, results of analyses or other exams, data of family risk, clinical diagnoses, therapeutic or other interventions. The concept of health information is maintained after the person is deceased.
- d. Health information only pertains to the person from whom it was obtained, made into documents in the possession of health institutions or professionals, who are the custodians of such information.
- e. The access by the health services users to their data, by third parties authorised by them or even by those who demonstrate a “direct, personal and legitimate interest, sufficiently relevant according to the principle of proportionality” (Law No. 46/2007, dated 24th August), implies a communication that must be intermediated by a health professional if the applicant so requests or, preferably, consubstantiated in a specific and detailed report.
- f. In the cases in which the information obtained may be considered of sensitive nature, because it may affect third parties (family members or others), it should be subject to special protection. It is the case, for example, of genetic information, which is actually subjected to its own legislation (Law No. 12/2005, dated 26th January) and information on transmissible infectious diseases.

III – Assumptions on computer health records

- g. The set-up of digital records that implies dematerialisation of clinical files must, due to its importance, be weighed in function of the potential risks of breach of confidentiality or loss of privacy.
- h. The most relevant **advantages** of digital records are:



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- i.* Accessibility, by facilitating the continuity of care by several professionals in different institutions as long as there is interoperability between the systems;
 - ii.* Legibility, by avoiding handwriting that is difficult to read and reducing the margin of error in interpretation by the various interacting players;
 - iii.* Responsibility, by better controlling the exercise of each professional interacting in health care and the records they make;
 - iv.* Easier multidisciplinary approach by the various interacting health professionals and specialties;
 - v.* Global improvement of the care provided, thanks to support to the decision with integrated data access (norms of clinical guidance, emergency guides, bulletins on rare diseases and others, drug contraindications or interactions, bibliographical sources, therapeutic records, price lists and costs, lists of available exams and tests, reference centres or other specialised services, location of service providers of clinical and laboratory care);
 - vi.* Statistical control, with importance for information of scientific and social nature, namely epidemiological and public health;
 - vii.* Follow-up of expenditure and detection of deviations;
 - viii.* Cost reduction, by avoiding repeated or unnecessary exams, measures and interventions that are not indicated or even contraindicated and their complications, as well as paper or film prints of their results;
 - ix.* Clarification of recording procedures and the maintenance of computerised data;
 - x.* Information security, which is in many aspects greater than hard copy records, including relative to their loss, as long as the available and updated security measures are taken.
 - xi.* Anticipation in preventing or detecting errors, and respective signalling.
- i.** Among the most important **risks** of keeping computerised health data, one can anticipate the following:
- i.* Information leaks, through wrongful disclosure of whole data bases or deliberate intrusion by hackers on behalf of interested parties (for example, entities dealing with health risk assessment or for marketing actions);
 - ii.* Improper use of data for scientific research, with or without the identity of the respective holders;
 - iii.* Illegal transfer of information, without any respect for intellectual property or copyrights;
 - iv.* Breach of confidentiality of individual data, for illegal means or out of sheer curiosity, through security flaws which are difficult to prevent.



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IV – Sources of legal, regulatory and other scope

Article 35 of the Constitution of the Portuguese Republic – Use of ICT; Law No. 67/98, dated 26th October (Law of Personal Data Protection); Law No. 12/2005 (Law on personal genetic information and health information); Law No. 111/2009 (Statute of the Nurses' Association); Decree-Law No. 161/96 (Regulation on the Occupational Activity of Nurses); Regulation No. 14/2009 (Deontological Code of the Medical Association); Report on the right of access to health information of ARS Norte [*Northern Regional Health Administration*]; Opinion No. 20/2010 of the Ethics Commission for Health of ARS Norte.

V – It is the opinion of CNECV that:

1. One must seek strategies and promote actions for the development of a culture of ethical accountability, which respects the rights of the persons using health services.
2. Considering this culture of accountability, the different governing bodies of the health institutions must promote the training of their professionals regarding good practices of security, including the awareness of the respect for the nature of the health data of which they are guardians.
3. The programmes must bear the formal statement that the data bases are duly registered with the regulating entity (CNPD - National Commission for Data Protection).
4. The logic (programme) and physical (sever) separation of clinical data and identification data must be assured, thereby increasing security and ensuring the possibility of access, when properly authorised, to anonymised data for epidemiological and other researches.
5. An official health data base manager must be appointed in each institution, consulting room or organisation, whose identity is public, with duly regulated powers and accountability.
6. The norms on physical facilities and equipment, circuits, access, accomplishment and safeguarding of back-up copies must be defined in a clear way.
7. Those responsible for health data bases must keep a constant update of security measures and risk prevention, as well as mechanisms to check them.
8. Health data, being sensitive data pertaining to the person's intimacy, are reserved and subject to the duty of confidentiality.
9. At any moment of their relationship with health institutions or health professionals, any citizen has the right, including doing so in writing, that any specific clinical datum relative to themselves (as long as legal impositions based on Public Health reasons do not prevent it) be considered absolutely reserved and therefore barred from other accesses besides access by the professional to



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whom it was voluntarily transmitted. As such, the health professional or institution must, upon recording or as soon as possible, inform the person of such right.

10. Exceptionally, when the holder's consent cannot be obtained, the reserved data referred to in the previous number may be given to other health professionals when such is strictly necessary to safeguard the interest and health benefit of the holder. In any case, the right of the holder must be assured as to knowing who accessed their file and when.
11. Efficient measures of ICT techniques must be promoted that will lessen the problems indicated above, namely by creating automatic alerts during data processing and during their use.
12. The computer applications for clinical records must have mechanisms that (a) allow access to clinical data only to the health professionals with direct responsibility in assisting that person; and that, (b) in the case of undue access to a person's records, there is an alert as to the non-conformity of the intent, even though maintaining the possibility of access as long as a field is filled in supplying the reasons for access under those circumstances and the personal password is confirmed again.
13. The referred applications must have a field, associated to the clinical record of each holder, of exclusive access by the health professional i.e., where only its author can access, aimed at notes of personal nature, not usable as such in reports and similar documents.
14. One must try raise awareness of health professionals towards the notion that a computer can be an aid in the good relationship with patients and with other professionals and users of the services, and should therefore be used in a non-intrusive way, which does not harm the relation of empathy that must always exist between the health professional and the sick person.
15. The creation of the "Electronic Health Record", an ICT supra-structure that will permit the intercommunicability of data between health service providers, must be subject to special attention in the sense of identifying the issues of ethical nature relevant to its creation and functioning. In acknowledging the great advantages of this resource, one must expect that accesses are, in principle, only possible after consent by the respective holders of the data.

Auditions were carried out with the following entities:

- National Commission for Data Protection (CNPD) - Dr.^a Isabel Cruz;
- Health System Central Administration (ACSS) - Dr. Fernando Mota;
- National Commission for the Electronic Health Record (CNRSE) - Dr. Luís Campos, Dr. Rui Gomes, Dr.^a Ana Mirco, Dr.^a Elisabete Garcia, Dr. Manuel Sousa, Dr. João Faro Viana.

Lisbon, 27th September 2011



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The President,
Miguel Oliveira da Silva

The following Counsellors were rapporteurs

Rosalvo Almeida
Lucília Nunes
Jorge Sequeiros

Approved in plenary session on 27th September 2011 in which, besides the President, the following Counsellors were present:

Agostinho Almeida Santos
Ana Sofia Carvalho
Carolino Monteiro
Duarte Nuno Vieira
Isabel Santos
Jorge Novais
José Germano de Sousa
José Lebre de Freitas
Lúgia Amâncio
Lucília Nunes (rapportrice)
Maria de Sousa
Michel Renaud
Pedro Nunes
Rosalvo Almeida (rapporteur)