Charter for an Ethic of Medical Informatics

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The French User's Club of the International Classification of Primary Care, an association affiliated with the WICC (Wonca International Classification Committee), and better known under the name CISP Club, has met annually since 1998. As an ongoing result of these reunions, the present document has been written by Bruno Seys (GP in Brussels), Madeleine Favre (GP in Paris) and Michel De Jonghe (GP in Tournai) and edited by Marc Jamoulle (GP in Charleroi).

We, members of the CISP Club, a group of healthcare professionals and informaticians, experts in the treatment and processing of medical information, herein express

- our desire to preserve a meaningful therapeutic relationship with our patients
- our desire to promote the intelligent and ethical use of information technology when working with and managing electronic health records
- our desire to call to the attention of our colleagues the potential problems posed by the future of electronic health records
- a persistant worry about the effects of political or corporate intrusions into the principles of medical secrecy and the private lives of citizens
- our dismay about the increasing interest in the use of personal medical information as a financial object and potential profit center
- our awareness that many healthcare professionals are unsure of the procedures for following disparate or unreliable technical specifications or recommandations concerning personal medical information
- our anxiety about the potential consequences of a careless usage of information technology by healthcare providers when working with patients' medical records
- our uneasiness in the face of mounting pressure on medical practitioners to disrespect their patient's rights to information and privacy.
- Our worry about the prevailing lax attitude being shown for the ongoing integrity of personal medical data

We further believe it vital that we affirm our commitment to three basic ethical principles that we believe must guide and govern the processing of all personal medical information:

- Respect of individual privacy
- Confidentiality of the doctor/patient relationship
- Patient consent

These three principles are developed and defended by several universally respected sources:

- **1. Fundamental References**
    - 1.The Helsinki Declaration, 1964
    - 2.AMM: Lisbon Declaration, 1981
    - 3.GEE: Ethical Aspects of the Use of Personal Medical Data in the Information Society, 1999

- **2. International Treaties:**
    - 1.The Universal Declaration of Human Rights, 10 December 1948. Art 12.
    - 2.The European Convention on Human Rights: the Preservation and Protection of Fundamental Liberties Art 8-1
    - 3.The European Charter of Fundamental Rights, art 3 & 8.

- **3. Belgian national texts:**
    - « Recommendations on the establishment and maintenance of medical databases containing nominative data » Council of the National Order of Doctors (Belgium), Bulletin of the National Council, #97 p.6 (Ref: A097008)

- **4.Academic works:**
    - 1. Chevalier S., Ethics and Informatics, The Protection of Electronic Medical Data.2003
      (Other resources are noted in the bibliography at the end of this document.)

After much reflection, we draw the following conclusions:

- **1: Concerning the Patient**
    - 1.He is owner of his medical records and confers stewardship of these records to healthcare professionals. He can at any time, consult, modify, or suppress information contained therein.
    - 2.He has the right of confidentiality over his medical information.
    - 3.He can demand that certain personal medical information be neither noted nor divulged.
    - 4.He acknowledges the existence and consents to the use of his personal medical information.
    - 5.He is a full partner in his personal healthcare.
    - 6.He has the right to understanding the meaning of information pertinent to his health.

- **2: Concerning the Healthcare Professional**
    - 1.He is responsible for the integrity of all patient information received.
    - 2.He is the guarantor of the confidentiality of this information.
    - 3.He respects the reluctance a patient may express toward recording or divulging personal medical data.
    - 4.He informs the patient of the possible uses of personal medical information.
    - 5.He respects the patient's active role in his/her own healthcare and accordingly, will release any personal medical information when requested to do so by the patient.
    - 6.He will respect the patient's request to not include sensitive information.

- **3: Concerning the electronic health record administrator**
    - 1.He is responsible to both the healthcare provider and the patient concerning the use made of personal medical data.
    - 2.He is sworn to professional secrecy.
    - 3.He is able to guarantee that confidentiality always takes precedence over technical performance or ease-of-use.
    - 4.He can demonstrate to the healthcare provider that the confidentiality principle is respected, both in everyday interactions and in backend technical operations.
    - 5.He is obliged to respect patient desires about the non-recording or nondivulgation of personal medical data.
    - 6.He is the conceptor of the consent form that the healthcare provider submits to the patient.
    - 7.He is obliged to provide the healthcare provider with means of informing the patient of the results when new personal medical information has been generated or processed.
    - 8.The processes by which original personal medical information is destroyed shall be explicitly respected and recorded.

- **Chapter 4: Other Intermediaries**
    - 1.He respects the roles and obligations of the actors described in the preceeding paragraphs.
    - 2.He respects the venerable principles of reciprocal doctor/patient confidence and confidentiality

embodied in healthcare philosophy over the centuries since Hippocrates.

In Conclusion We recognize that the health information process is complex. We fully acknowledge the need for continuing medical research, are convinced of its role in improving the quality of healthcare.
We also believe that medical informatics will play a crucial role in delivering improved healthcare in the years to come, and that the sharing of personal information and medical data can be an important tool in improving efficacity and equity of healthcare.
We believe strongly that each practitioner must work in the environment of his choice.
Accordingly, we ask all our colleagues in the healthcare community to exercise the highest levels of critical judgement when confronted with new situations arising from the digitalisation and sharing of patient healthcare information.
We call on all healthcare professionals to act conscientiously whenever confronted with the non-respect of the issues concerning patient medical data
integrity and confidentiality described in the preceeding paragraphs of this charter.

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Bibliography 1.World Medical Association Declaration of Helsinki.
Ethical principles for medical research involving Human Subjects. WMA General Assembly . Helsinki, Finland, June 1964, and amended by the last revision (Tokyo)
2004
2.World Medical Association Declaration on the Rights of the Patient
Adopted by the 34th World Medical Assembly Lisbon, Portugal, September/October
1981 and amended by the 47th General Assembly Bali, Indonesia, September 1995.
3. Findings by the European Community Committee of Ethics and Technology: Ethical
Aspects of Use of9ij0-yt7 Personal Health Data in the Information Society n°13; 30 july1999.
4. Déclaration Universelle des Droits de l'homme. Nations Unies.10 décembre 1948 .
5. Convention européenne des droits de l'homme : Convention de sauvegarde des Droits de l'Homme et des Libertés fondamentales (1950) telle qu'amendée par le Protocole n°11 (1998)
6. Charte européenne des droits fondamentaux de l'Union européenne. UE, Parlement européen. Office des publications officielles des Communautés européennes. JOCE C 364/1 du 18/12/2000 22p et 1 p – JOCE C 007/8 du

11/01/2001 (rectificatif).
7. Recommandations relatives à la tenue de bases de données médicales contenant des données nominatives ou identifiables, Conseil national de l'Ordre de médecins (Belgique), Bulletin du Conseil National, n°97 p. 6 (doc : A097008).
8. Chevalier S. Ethique et informatique, la protection des données médicales informatisées.
[Thèse de doctorat en médecine] Faculté de Médecine Jacques Lisfranc. Saint-Etienne, France. Année universitaire 2002- 2003 ; 57 pp.
9. The world medical association declaration on ethical considerations regarding health databases. WMA General Assembly, Washington 2002.
10. Convention for the protection of Human Rights and Dignity of the human Being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine. Oviedo 04 04 1997.
11. Directive 95/46/CE du parlement européen et du conseil relative à la protection des personnes physiques à l'égard du traitement des données à caractère personnel et à la libre circulation de ces données. Journal officiel des communautés européennes. n°1 281/ 31-38.
12. Assemblée fédérale de la confédération suisse: Loi fédérale sur la protection des données (LPD). 19 juin 1992.
13. Manifeste pour la défense de la confidentialité et du secret médical. Madrid: Juin 2003.
14. Décret pris pour l'application des chapitres Ier à IV et VII de la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés. version consolidée au 30 avril 2002. Chapitre II. Formalités préalables à la mise en oeuvre de traitements de données personnelles de santé à des fins d'évaluation ou d'analyse statistique des pratiques et des activités de soins et de prévention. Décret n°78-774 du 17 juillet 1978 (publié le 23 juillet 1978)
15. Décret no 99-919 du 27 octobre 1999 pris pour l'application du chapitre V ter de la loi no 78-17 du 6 janvier 1978 modifiée relative à l'informatique, aux fichiers et aux libertés et relatif aux traitements de données personnelles de santé à des fins d'évaluation ou d'analyse des pratiques et activités de soins et de prévention.
16. Le nouveau dispositif de notification anonymisée des maladies infectieuses à
déclaration obligatoire. Circulaire DGS/SD5C/SD6A n° 2003/60 ; 10/02/2003
17. Récolte et exploitation de données médicales. Conseil national de l'Ordre de médecins (Belgique). Avis du 16 juillet 2005. , consulté le 5 octobre 2005
18. Jonathan M. MANN: Santé publique: éthique et droit de la personne. Congrès de la Société française de santé publique. 1998

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