

Ways to go about clinical data management

The Health Unit ULSS (Unità Locale Socio Sanitaria) no. 8 in Asolo (Veneto Region, Italy), in order to address the appropriate and advanced management of archived data, has created a Clinical Data Repository, through the digital recording of clinical case files to replace the original, enabling online consultation of more than six million case files. The digital clinical case file meets the requirements of current regulations concerning digital substitution of the original. Although the digital product could replace the original, all the paper-based clinical case files have been preserved in a central archive; our evaluation of current experiences with long-term preservation of digital data is that it does not provide adequate security.

Objectives

In the last three years the Health Unit ULSS no. 8 in Asolo has laid a solid foundation for intensive and widespread use of digital technologies in different domains, both clinical and administrative, with the aim of putting online services such as medical reports, e-learning, PACS (Picture Archiving and Communication System), online reservations, statement of account for suppliers, medicine flow, etc.), in order to work progressively without paper.

Experiences

A project for the creation of a new data system, which started in 2004, is taking place in this context. First we created a new unique archive, which replaced 27 peripheral archives; it was created outside the hospital and involved complex logistics; in fact, the hospital is integrated in the structural and operating context of the Service Centre for Logistics of ULSS. All the documents, both clinical and administrative, have been collected in the central archive and catalogued by an ICT system that makes it possible to know their location at any time, thanks to the technological management of their traceability.

The paper archive of six million case files from 1905 to 2006 has been reproduced in a Digital Clinical Repository (DCR), putting online all the clinical information about admissions (without limiting the access to different hospital ward case files, using a security system comprising a smartcard and a password; in addition, every search leaves a trace within the system that identifies the person who executed the operation). Every case file is controlled by the archivist who arranges it and scans it. The digitisation process is carried out according to current regulations regarding digital substitution of the original, and is concluded by a comparative verification between analogue and digital image undertaken by the person responsible for preservation, who affixes a digital signature to each new original.

The characteristics of the process for digital substitution of the original are defined by the CNIPA resolution dated 19 February 2004 no. 11 and by the Code for digital administration (D. Lgs. 82/2005, in particular articles 22, 23, 43 and 44).

All the data and images of DCR feed into a clinical data repository, which also regularly takes information produced by different clinical and diagnostic clinical areas for current patients (medicine prescription and administration, clinical reports, radiological PACS-RIS, etc.), for whom an individual 'medical digital dossier' (which will become the electronic clinical folder) is used.

Reference regulations and sectorial experiences

The subject of case file preservation is regulated by DPR 128/69 and 225/74, by DPCM 27.6.1986 and by L. 675/1996 (privacy law). Several Health and Hospital units are currently facing critical issues, both old and new, with this type of document. For example, we could mention the Istituto Oncologico Europeo di Milan, the Hospital of Bolzano, the Hospital of Niguarda in Milan and others.

Interesting information can be found in the following reports:

Angiuli, A. and Caputi, Jambrenghi V., (ed.), (2005), *Commentario al Codice dei beni culturali e del paesaggio*, Torino.

Archivi sanitari: il futuro del nostro passato: atti del convegno di studio, Conference Proceedings, Trento, 31 October 2004.

Bonfiglio Dosio, G. (2005), *Primi passi nel mondo degli archivi. Temi e testi per la formazione archivistica di primo livello* (Second revised and extended edition), CLEUP, Padova.

Bonfiglio Dosio, G., *Archivi Journal*, edited by ANAI (Associazione Nazionale Archivisti Italiani).

Guercio, M., (2002), *Archivistica informatica. I documenti in ambiente digitale*, Ed. Carocci, Third reprint.

Archivi & Computer (SI) Journal, Quarterly, Director Roberto Cerri, Direction Maria Guercio, c/o Archivio Storico Comunale, San Miniato (PI).

Lodolini, E., (2005), *Archivistica: principi e problemi*, 12 edn, F. Angeli.

Lodolini, E., (2006), *Storia dell'archivistica italiana dall'antichità al XX secolo*, F. Angeli.

Ministero per i Beni e le Attività Culturali (MiBAC), (ed.), (2001), *Medicina e ospedali, memoria e futuro. Aspetti e problemi degli archivi sanitari*. Napoli 20, 21/12/1996.

Vitali, S., (2004), *Passato in digitale. Le fonti dello storico nell'era del computer*, B. Mondadori.

Zacchè, G., (2002), (ed.,) *Lo scarto. Teoria, prassi e normativa*, Archilab.

Open issues

The creation of the Digital Clinical Repository must address a series of open issues concerning the long-term preservation of digital data.

In our experience, three important critical issues have emerged:

- at present there is a contradiction between the regulations concerning digital substitution of the original, which guarantees the integrity and authenticity of the document in the course of time, and the traditional regulations, which have always required the everlasting preservation of the paper document. Nowadays, two-fold preservation, digital and paper, is compulsory; this does not permit disposal of the original paper document, even if it is no longer readable;
- the need for the preservation of clinical digital memories should rely on appropriate solutions that make it possible to preserve them for at least as long as the time foreseen by the current regulations on temporary preservation of medical documents (10-12 years);
- the application of digital technologies in the medical domain raises a number of questions, from the ability of organisational structures to meet the technical-operational consequences resulting from digital innovation, to the need to design and develop a data management system that is increasingly integrated with medical and general services.

These issues were addressed during the International Symposium promoted by the Asolo Health Unit on 29 September 2006; in particular, we discussed the integrity of documents, the respect for security measures, readability over time, and the conformity of the documents with the use of the digital signature.

The Health Unit ULSS no. 8 in Asolo has an active work group on clinical data management, composed of:

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