



Archiving Medical files within a Hospital

Setting the scene.

[Context]

- Hospitals are, by law, obliged to store patient files. Electronic files are preferred, but this comes with specific practical problems:
 - What has to be stored?
 - For how long?
 - By whom?
 - Where?
- Privacy, patient rights and specific legal requirements for patient files have to be taken into account when setting up medical archiving

[Overview]

- Medical archiving: what?
- The legal framework.
- Storage of patient files: what, how, how long and where?
- Safe storage: security requirements.
- Ownership.

[Medical archiving: what?]

- Medical archiving = the storage of medical data onto electronic devices with the purpose of long-term preservation
 - can be active or dead files
 - can be originals or duplicates
 - can contain written text, images, test results,...

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[The legal framework]

- Law on hospitals and royal decrees on medical file and nursing file
 - Law on hospitals August, 7th 1987
 - Royal Decree on the general minimal conditions to the medical file May, 3rd 1999
 - Royal Decree on the general minimal conditions to the nursing file December, 28th 2006
- Law on patient rights (August, 22nd 2002)
- Law on data protection (December, 8th 1992)
- Soft law such as
 - Advices and recommendations from Belgian Privacy Commission and European Article 29 Working Party
 - Advices from the National Council of the Medical Association
 - Advices from the Commission on telematics
 - Security standards such as ISO / TC 215 WG4 Health Informatics

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Storage of patient files: What?

- Every patient has a right to a carefully organised and safely stored patient file from his medical practitioner(s)
 - The hospital is required to keep two files for each patient:
 - Medical file = representation of the medical tests, diagnosis and treatment
 - eg: test results from radiology, advice of consulted oncologist, evolution of the disease
 - Nursing file = representation of the nursing process
 - eg: description of the patients' way of life, prescribed medication, expected results, list of planned care
- ⇒ For each file a minimum dataset is specified in Royal Decree
- ⇒ Medical file + nursing file = patient file
- General purpose = to guarantee continuity of care and allow a quality control in case of conflict

Storage of patient files: How long?

- It is required, by law, to store
 - the medical file “for at least 30 years in the hospital”
(art 1§3 KB 3/05/99)
 - the nursing file “for at least 20 years in the hospital”
(art 1§3 KB 28/12/06)
- However... it is advisable to store the full patient file for 30 years
 - due to possible civil liabilities with regard to the file
(art 2262bis Civil Code)
 - due to medical deontology
(art 46 Code Geneeskundige Plichtenleer)

Storage of patient files: How?

Electronically or on paper?

- Storage in electronic format is allowed and for the files of those patients who have left the hospital department preferred.
- Central storage is advised per hospital or at least per department.
- Continuity of care and therefore permanent accessibility is the key requirement for medical archives
 - Note! Storage in electronic format does not change the duty of practitioners to conscientiously feed the files
 - Note! Permanent accessibility ≠ permanent access

Storage of patient files: Where?

In the hospital?

- According to the literal phrasing by the Royal Decrees: *in* the hospital
- However, advices from
 - the National Council of the Medical Association
 - On “Storage of medical data trough a commercial firm” (16/01/1999)
 - On “Storage of medical hospital data” (21/04/01)
 - the Commission for Telematics (advisory commission set up by the Minister)
 - Advice nr. 7 on “Long term storage of patient files by hospitals” (18/06/02)

do not object storage outside the hospital as long as the patient rights and other requirements by the Law on Hospitals continue to be met.

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Safe Storage: security requirements

- In case of archiving by an external partner, the archiving party will act as “processor” and the hospital will remain “controller”.
- The Data Protection Act (art 16 DPA) and several soft law instruments impose security obligations onto the controller.
- The controller can shift (some of) these obligations onto the processor on contractual basis.

Safe storage: security requirements

- For the security of every medical archive 3 key words should be kept in mind:
 - **Integrity:** the processed information must remain accurate and non-authorized modifications must be prevented
 - **Confidentiality:** restricted access and use
 - **Availability:** the processed data must be readily accessible and usable for duly authorized users; effective back up and recovery mechanisms must be in place in order to secure the content of the processing

Safe storage: security requirements

- These 3 key words can lead to the following examples:
 - Appropriate logging and tracing mechanisms
 - Use of two-factor authentication and modular access rights
 - Use of encryption
 - Effective back-up and recovery mechanisms
 - Use of technical mechanisms to ensure data integrity and authenticity
 - Use of technical mechanisms for assured delivery
 - Use of unique and meaningless identifiers
 - Appropriate solutions in case of failure
 - ...

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[Ownership]

- Ownership of medical files does not exist.
 - “Ownership” = a property right = absolute disposition (art 544/522 Civil Code)
 - There is no absolute disposition of a medical file nor by a practitioner, nor by the patient, the hospital or the archiving party
 - e.g. the practitioner is not allowed to share the data without any reason – he has to take into account his professional secrecy
 - e.g. the patient can’t physically dispose of the file

[Ownership]

- ⇒ Question to ask is: “who can have access to which file or which part of a file on what moment”
- Responsibility about access rights / access restrictions depends on
 - Delineation of the controller – processor roles in accordance with the DPA
 - Law on Hospitals determines that the head of practitioners and the head of the nursing department are responsible for taking the “necessary initiatives” with regards to respectively the medical file and the nursing file

[Conclusion]

- Medical Archiving outside the hospital in cooperation with an external (commercial) party is allowed on the conditions that:
 - the purposes of the patient files (continuity and control) are guaranteed to continue to be met
 - the proper security mechanisms are imposed
 - the right of access and restrictions thereto are carefully translated into the automated application
- The hospital will remain responsible, being controller.

Questions and contact

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