IEO
European Institute of Oncology

Specific information on the Electronic Patient Dossier

Provision issued by the Italian Data Protection Authority No. 331 of 04/06/2015
Article 13 of EU Regulation 679/2016

Dear Sir/Madam,
we are contacting you because we wish to inform you about your patient dossier.

What is an electronic patient dossier?

It is an electronic tool created within the Institute. Its purpose is to collect information on your health in order to document your clinical history, with the intention of offering you a better, more effective, more efficient healthcare pathway. The Electronic Patient Dossier is not the same as the Electronic Health Records, in which the clinical history of a person is generated by different healthcare facilities.

What type of information is processed through the patient dossier?

Both general information (personal data, postal addresses, telephone numbers, images, etc.) and information concerning your health condition. This may be information provided by you, or acquired from health documents during check-ups and consultations. It is possible, subject to your specific consent, that data submitted under the current legislation of increased safeguarding may also be processed (healthcare services offered to people who are HIV-positive or using drugs, psychotropic substances or alcohol, women undergoing voluntary termination of pregnancy or who choose to give birth in anonymity, or those made pregnant during acts of sexual violence, paedophilia or by family counsellors).

How will the electronic patient dossier provide a better healthcare pathway?

Through:

• **Comprehensive, prompt access to clinical information for all the Institutes's professionals**, so that the Institute professionals involved in the clinical pathway have all clinical information acquired by the Institute at their disposal, irrespective of the department/area generating the information. Here is an example that perhaps might help clarify this concept: in a clinical pathway (including the various check ups over time) a patient is usually switched between a number of professionals working in different departments/areas: laboratory analysis, radiology, pathological anatomy, surgery, radiotherapy, oncology, etc.), each of which tends to work with a different IT application. Even within the same ward, the patient is monitored by several professionals; there is diversity in terms of role: doctors, nurses, and also in terms of the individual people: different doctors and nurses at different times. It can therefore be very useful for a practitioner, during the diagnostic stage or during an outpatient check-up, etc., to have an overview of the clinical picture in order to establish the best possible treatment plan, reduce the risk of errors, and avoid unnecessary repetition of tests already carried out. Without the patient dossier, the practitioner would only have access to the information supplied by the patient at that time, and whatever was recorded in relation to the clinical event for which the health service was requested. The idea of the ELECTRONIC PATIENT DOSSIER has arisen out of the need to enable this overview. It is a single computer area in which the information generated by the various applications used in the clinical process is merged.

• **Access to the patient dossier by the patient**
The Institute also envisages the possibility that you as a patient, with specific consent, can also access your dossier on the web. This will include reports of the healthcare services carried out: consultations, laboratory investigations and diagnostics, etc. In this way you can avoid returning to the Institute to collect those reports that are not always available at the same time as the procedure (laboratory analysis, pathological anatomy, radiology), and you will have constant, immediate availability of your documentation even in the event of loss of paper versions of reports. The choice of whether or not to access your dossier is optional and, if you choose to access, you may still receive paper copies.

How is your privacy safeguarded?

The **current legislation** on the protection of personal data, recognising the added value of such initiatives, makes it possible to set up a dossier within individual healthcare facilities, but with specific guarantees for the adequate protection of your information.

What are these guarantees?

1. Authorisation profiles to access the dossier that are consistent with the responsibilities of the job

Access to the dossier is currently granted to the following:
• healthcare practitioners providing healthcare for various reasons over time;
• healthcare practitioners acting as freelance professionals (also called intramoenia), or services outside their working hours using the outpatient and diagnostic facilities of the healthcare facility upon payment of a fee by the patient This option is valid only in the case of provision of services within a solvency system with a doctor's choice;
• administrative staff involved in various capacities in the clinical pathway, or who work in monitoring roles.

All persons who work at or for the Institute, carrying out formal duties, are required to comply with specific rules of behaviour, and may not communicate or disclose patient information to third parties not authorised by you or by law. The patient dossier may be consulted, in accordance with the General Authorisation of the Guarantor, if this is considered essential for the health protection of a third party or community (for example in the event of risk of outbreak of diseases in third parties due to the sharing of environments with the interested party).

2. Limitations of access, traceability, obscuration

In addition to the authorisation profile, additional security measures have been implemented:

2.1 Access for duration
Access to the patient dossier is automatically closed after 3 months from the last treatment.

2.2 Access due do necessity
It is possible that a practitioner may need to gain access after the dossier has been closed. By way of example: it is quite common for a patient to contact a doctor at the Institute by telephone for clinical-therapeutic advice regarding his/her condition, and this may take place after the period in which the doctor is allowed free access to the dossier. In such a case it would be detrimental to the patient and the doctor if full access to information was not possible. Therefore, access to the dossier will be provided by self-declaration of the reason by the practitioner, prior to identification.

2.3 Traceability of access and controls
All accesses to the dossier will be traced by storage of log files for 2 years. The Institute will also adopt a monitoring system, including retrospectively, randomly or resulting from an alarm deriving from alert systems on the legitimacy and lawfulness of access to the data contained in the dossier. You can enquire as to whether and for what purpose your dossier has been accessed at any time. The response must be provided within 15 days. If the procedures necessary for a detailed response to your request should present particular difficulties, you will be informed and the maximum deadline for the reply will then be 30 days.

2.4 Obscuration
Even if you consent to the creation of your patient dossier, you can decide to obscure some information or documents. This is similar to what takes place in the patient-doctor relationship, in which the former can decide not to inform the latter of some health events that concern them. As set out in the current legislation, the obscuration will be revocable over time and will take place such that access to practitioners for whom the patient has expressed such choice will automatically be denied (obscuring the obscuration: in practice a section/field will not appear in the dossier, with the wording: "document obscured by patient", and that document will simply not merge into the dossier). If obscuration is requested, the information or documents obscured will still be accessible to the practitioner/department who generated this information using the associated applications.

3. Rights of choice concerning the patient dossier

The following consents may be granted:

• **Whether to create the dossier**. Consent is optional and you can still seek treatment at the Institute without it.

• **Whether data subject to greater safeguarding is also merged into the dossier** (HIV, drug addiction, alcohol, sexual violence, voluntary termination of pregnancy, etc.). Consent is optional and you can still decide to have the patient dossier created without this type of information.

• **Whether you also decide to consult your dossier**. Consent is optional and you can still decide to have the patient dossier created without it. If you decide to consult your dossier, your direct identification data will be required by the Institute administration. You will then receive a confidential personal code that will enable access. All types of consent may be withdrawn at any time. If consent for the creation of the dossier is withdrawn, it will no longer usable by practitioners.

4. Additional security measures

Security measures have been set up to ensure the accuracy, integrity, continuity and usability of data. For technical details, please contact the following addresses.

Whom should you approach to assert your rights?

To exercise any of your rights in terms of access, amendment, cancellation, limitation, storage times, opposition, transferability of personal data, and particularly to:
• change your consent with regard to the dossier;
• exercise the right to obscuration of information/documents in the dossier;
• find out if and how the dossier has been accessed;
• understand the access criteria of the persons authorised to use the information contained in the dossier in greater detail, and find out what security measures are in place to ensure accuracy, integrity, continuity and usability of the data;
please contact the **Personal Data Protection Manager** directly, using the following contact details:
• Tel +39 02 57489285
• Email privacy@ieo.it / direzione.sanitaria@ieo.it
• PEC direzionesanitariaieo@pec.it

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For further clarification, or to exercise your rights regarding the protection of personal data, please contact the Personal Data Protection Manager:
T +39 02 57489285 M: direzione.sanitaria@ieo.it – privacy@ieo.it