

EBMT and latest EU regulations on personal data.

Individuals' privacy is a very important area for regulators and lawmakers in Europe. The European Union (EU) 95/46/EC directive regulating collection and storage of personal data is now becoming law in all EU countries. As EBMT is a Dutch organization, the introduction on September 1, 2002 of the new Dutch law based on the European directive has major implications for us. It is vital that we ensure that our procedures follow the law. There are a number of key points on safety of data and the integrity of the individual in the new law:

1. It differentiates between sensitive and non-sensitive personal data. All data on medical conditions, treatment, and outcome are regarded as sensitive so all data reported to the EBMT fall into this category.
2. The individual has the right to decide about the use of personal information. So individuals whose personal information is stored in any format must give their consent. Each centre is responsible for obtaining consent. We ask all centres reporting data to the EBMT, regardless of whether they (and the patients) are in or outside the EU, to certify that they have a procedure for obtaining patient consent and that they follow the EU regulations on data safety. It is important to note that the requirement for patient consent has nothing to do with the date when the patient was transplanted. The law covers new data, even on patients transplanted many years ago. So centres must obtain consent from old patients whose progress is being tracked and for whom follow-up data are reported. We are well aware that this will not be easy and can only ask that centres do their best to implement and follow correct procedures. The law does not cover data on deceased patients.
3. The data in the registry should be non-identifiable outside the treating centre. The EBMT registries will therefore no longer accept names of patients, although initials are acceptable. This may be a problem when trying to match new follow-ups to existing registrations. The following should therefore be taken into consideration. The EBMT registry has for many years been based on Unique Identification Codes (UIC) and all patients entered in the EBMT

megafire are given a UIC number. Centres can easily obtain UIC numbers if the data is entered through ProMISe. However, for patients reported through paper forms or through national registries, the centre may not know the UIC number. One way of solving this, even where the data is reported on paper, is for the centre to look at its own data through ProMISe and see which UICs EBMT has assigned to their registrations. If centres cannot use ProMISe, we will find other ways to communicate the UICs to them. It is also crucial that all registrations sent to the EBMT have a unique patient number (UPN) issued by the reporting centre. Centres must maintain a complete, updated UPN list to be accredited. These UPNs should never be changed. We hope that the combination of the UIC (issued by the EBMT) and the UPN (issued by the centre) will ensure registrations are properly identified, allowing patients' follow-up data to be matched to the original report without compromising the patients' right to a degree of anonymity.

4. The law requires each registry holder (the EBMT) to use safe procedures for storing, securing, backing up and transferring data. This is the EBMT's responsibility and procedures are already in place to ensure that this part of the law is followed. From the time of introduction of ProMISe, Ronald Brand has ensured, through encryption, that data is safe when entered on the EBMT database via the Internet.
5. The EU directive and Dutch law are particularly strict on the export of data outside the EU/European Economic Area (EEA). This is important for the EBMT, since many of its members are in countries outside the EU/EEA. More countries will become members of the EU in the next few years. Data are also exported from the EBMT megafire to outside the EU/EEA when an EBMT registry is outside the EU/EEA (such as the Solid Tumour Registry) or when an investigator on a certain study is outside the EU/EEA. The regulations also cover the export of data to the US. The EBMT has international collaborations with organisations such as the International Bone Marrow Transplant Registry. Many centres ask the EBMT to forward data to the IBMTR. To cover all these possibilities, patient consent forms should explicitly include consent to the export of data outside the EU/EEA.

The Registry Executive Committee of the EBMT has produced a sample consent form to help centres meet the law. The consent form and a EU regulation statement were sent to all member centres at the end of November. These documents are also available on <http://www.ebmt.org/4Registry/registry2.html#directive>.

Although ensuring adherence to the law will mean extra work if you are involved in reporting data to the EBMT, we have to remember that the law was developed in the individual's best interest to secure personal integrity. We therefore hope that centres will do everything that is needed to ensure that the EBMT's data reporting system meets the legal requirements. This way we can all continue to use EBMT data to study important issues, and thereby improve the results of stem cell transplantation in the future.

For the Registry Executive Committee

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