



EBMT AUDIT PROGRAMME 2007

I. Background

Data transmission from individual centres to EBMT registries has been based on mutual trust right from the start. This continues to be the basis for data transfer. However, verification of data is required today in many instances for scientific publications. Accreditation also depends on some control mechanisms. At the Annual Meeting in Vienna in 1996, the EBMT general assembly approved introducing an audit programme, which was successfully initiated in 1997. In 2003 the requirement to check for informed patient consent was added, to ensure compliance with EU directive (95/46/EC) regulating personal data.

II. Objectives

To ascertain the presence of an institutional unique patient number list (UPN list), verify consecutive case reporting and control accuracy of reported data, as compared to institutional medical records. To ensure compliance with EU directive (95/46/EC) regulating personal data.

III. Audit operations

EBMT members are subject to be audited once every three years. Ten institutions are first selected randomly. For each of these centres, a board or working party member near the institution is identified. The Principal Investigator is contacted and asked whether they accept the proposed Auditor. If the Principal Investigator perceives that there may be bias on the part of the selected auditor, they are given one week to request another auditor. Auditors are asked to sign a waiver stating that they have no political, financial, or other conflict of interest with the team to be audited and are then asked to contact the Principal Investigator directly to arrange a mutually convenient date for the audit to take place. This date should be immediately communicated to the Secretariat. Three weeks prior to the date of audit, the institution is notified of the 10 MED-A cases selected at random from among its contributions during the preceding five years. The audited institution in question is expected to have medical records, its UPN list, and all necessary supporting information gathered and available at the time of the audit for each of these ten cases.

a. Verification of consecutive reporting

Cases reported to the EBMT registries by the audited team for the previous year will be compared by the auditor to institutional records of all transplants performed to verify that all eligible cases were reported. The auditor will verify that records of the transplant programme confirm reporting of all cases and will confirm the conduct of a UPN list. The UPN list will be compared with the BMT activity survey submitted by the team for the two previous years.

b. Verification of accurate reporting

At the time of the audit, the auditor selects five of the ten available cases for detailed review. For these five cases, all MED-A items reported will be compared with data in the institutional medical record. Deficits and discrepancies are documented by question number and discrepancy, using a form-specific check list prepared by the EBMT audit committee and data office. The total number of allogeneic and autologous transplants performed in the last two years will be specifically noted and compared with the accreditation submission form.

c. Conformity with EU directive (95/46/EC) regulating personal data

As of 1 September 2002 all new patients and patients attending for follow-up treatment should be asked to give written consent to:

- Non-identifiable data on his/her transplant being reported to registries run by the EBMT
- Non-identifiable data being sent to registries situated outside the EU/EEA and to their use in EBMT studies outside of the EU/EEA

Centres are responsible for ensuring that the informed consent of every patient is obtained, prior to treatment. The new MED-AB forms include the question: Has the patient given consent for data submission to the EBMT? The MED-A form will be checked to confirm that consent has been obtained and a copy of the signed consent form should be made available to the auditor to check.

IV. **Assistance with the audit**

The data manager and/or transplant coordinator of the audited institution will function as an assistant to the auditor. The assistant locates information required in the medical record prior to the time of the on-site audit to expedite retrieval and verification by the auditor. The assistant also provides documentation of consecutive patients transplanted at the time of the audit.

V. **Analysis of audits.**

The auditor conducting the audit is responsible for preparing an analysis of the audit to include consideration of the following:

1. The presence of an institutional UPN list.
 2. Questionable or falsified reporting forms, i.e. reporting forms submitted to the EBMT describing patients who are not documented by a medical record.
 3. Misinterpretation of instructions or questions, such that incorrect answers are submitted.
 4. Discrepancies between data found in the medical record and the EBMT reporting form
 5. Failure to provide required follow-up
 6. Absence of adequate procedures for guaranteeing informed patient consent
- Audit analyses are done using a form provided by the Audit Committee. Analyses are submitted to the Audit Committee within 30 days of completing the audit..

VI. **Review of audits**

The audit committee will review each audit analysis and prepare an audit report to be sent to the audited institution and the Board within 30 days of receiving the audit analysis. This report may contain recommendations for important and local data management. Institutions that the Audit Committee considers suspect for fraud, biased reporting and/or serious deficiencies in data management are referred to the Board for further action.

VII. **Audit summaries**

The Audit Committee prepares an annual report of all audits for the Board and the general assembly meeting at the annual meeting.

VIII. **Consequences of fraudulent, non-consecutive and inaccurate reporting**

Institutions with serious deficiencies are referred to the Board for action. Instances in which fraud is suspected may result in additional requests for documentation and additional audits. If fraud is documented, the institution is denied further participation in EBMT activities and all data are removed from the EBMT database. In the event of failure to report consecutive cases, an institution is given 120 days to rectify the deficiency by reporting all omitted cases and is subject to re-audit in 12 months. Failure to remedy the deficiency results in suspension and removal of all data previously reported by the offending institution from the database and in suspension of EBMT membership. Serious inaccuracies in data reported to the EBMT are brought to the attention of the offending institution with recommendations for immediate action.