Biovigilance reporting: technical errors

M.J. Happel-van 't Veer, P.Y. Zijlker-Jansen, J.C. Wiersum-Osselton, A.G. Bokhorst
TRIP National Hemovigilance and Biovigilance office

Introduction

TRIP has collected reports of (serious) adverse reactions and events related to quality or safety of human tissues or cells since 2006. Submitted biovigilance reports (2007-2013) were analysed with regard to technical errors, according to the TRIP definition.

TRIP definition of technical errors:

All cases where the technical equipment or materials used for procurement, testing, processing, storage, transportation or application of human tissues or cells was defective.

Case

16 embryos of 5 couples lost due to failing controller of cryopreservation device. Alarm did not go off, no fail-safe system.
Actions: Motherboard replaced, fail-safe alarm added, maintenance doubled, in-house technician, emergency protocol adapted.

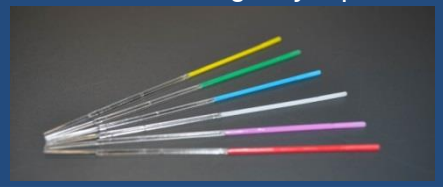

Table 1. Technical errors subdivided by tissue type, 2007-2013

Tissue or cell type	Number of reports	Serious event
Bone	1	0
Cartilage	3	2
Ocular tissue	3	3
Hematopoietic stem cells	14	11
Gametes, embryos and gonadal tissue	31	18
Other tissues and cells	2	2
Total	**54**	**36**

Table 2. Types of technical errors and results, 2007-2013

Description technical error	Number of reports	Loss of tissues / cells	Possible loss of quality
Incorrect/defective collection, processing and storage material	33	24	9
Failing/malfunctioning cryopreservation equipment	12	6	6
Failing/malfunctioning of other critical equipment	9	5	4
Total	**54**	**35**	**19**

Conclusion

Technical errors were the subject of 16% of reported adverse events in the period 2007-2013. They led to avoidable loss or (potential) loss of quality of the tissues or cells. Based on these adverse events several recommendations for preventing or minimising damage from technical errors were made in the annual TRIP Biovigilance Reports.

TRIP recommendations 2007-2013

1. The introduction of new techniques or transplant procedures should be based on a standard operating procedure after careful guidance and training of staff in order to prevent avoidable adverse events.
2. Particular alertness is advised after maintenance or repair of essential equipment. The recommissioning should be laid down in a standard operating procedure.
3. Adverse events concerning leakage of units of recipient-specific and potentially irreplaceable hematopoietic stem cells should be reported in order to gain insight into the extent of this problem.
4. Validated transportation conditions are necessary for assuring the quality of transported tissues or cells. If validation of these processes has not been performed this should be undertaken.
5. Essential equipment like transportation boxes, incubators, cryopreservation devices and storage devices needs an adequate fail-safe alarm system to prevent quality loss or avoidable loss of tissues or cells in case of breakdown. Cryopreservation equipment should also be monitored during the cryopreservation run.
6. In case of difficulties in preparing a cornea with a microkeratome in a transplanting institution a rejected cornea can be ordered to use as testing material.