The French Health Products Safety Agency (Afssaps) is the national competent authority for tissue control in France. A pilot study gathering all French Eye banks was led from February to May 2005 with the view to validating the microbiological control feasibility and initiating a national control program.

Purpose:
A protocol was set up to test the microbiological control feasibility. The samples were sent to Afssaps and the results were compared with the ones obtained by the Eye banks. The main objective was to validate the microbiological control feasibility and to initiate a national control program.

METHODS

Samples Transport

459 samples of corneal media were sent to Afssaps from 20 Eye banks. 66% (303/459) of them were sent in their origin flask and 34% (156/459) were seeded on media received. All media received were analysed by Afssaps.

RESULTS

16/20 (80%) banks used a specific fungi medium with an inoculum of 50 l to 5 ml incubating from 5 to 30 days. 1 sample out of 459 negative (n°14) were found negative in Afssaps and positive in the banks. This was explained by the occurrence of antibiotics in the storage media and when the control is carried out by Afssaps at the same period of time, so that the corneas can be destroyed before graft when necessary.

Microbiological controls

Samples were analysed at Afssaps in a time schedule from 5/10/2007 to 31/3/2008. 46% (6/13) are aliquot of original flask. 63% of the positive tests (8/13) were sampling media (rate of contamination of the received storage media 1,7% (5/298) and 0 to 5 days after the banks' analyses. 3% of the results (13/459) were not compliant from the microbiological point of view and 2% (8/459) were analyzed came out to be not compliant during transport. 97% (446/459) of the media controlled were negative from a bacteriological and fungal point of view. Moreover gathering the results of these quality controls in the longterm will enable to standardize the methods to work out reference frames for control.

EXTERNAL QUALITY CONTROL

<table>
<thead>
<tr>
<th>Storage media</th>
<th>Inoculum</th>
<th>Incubation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original flask</td>
<td>5 ml</td>
<td>14 days</td>
</tr>
<tr>
<td>Original flask</td>
<td>1 ml</td>
<td>14 days</td>
</tr>
</tbody>
</table>

The control prepares the media according to the regulations in force at a +4°C temperature by (TEB 188/7 (XII/12)) for 12% being control media, 65% being storage media and 2% being deswelling media. The control procedures were carried out as described in the French Health Products Safety Agency (Afssaps) guidelines for the inspection and control of the corneal media received. The results are compared to the ones obtained by the Eye banks.

ACKNOWLEDGEMENTS

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DISCUSSION/CONCLUSION

A media showing a contradiction between Afssaps and Eye banks control would probably be necessary. To retain relevant control and be able to react before grafts (the case of a non-compliance fast destruction of the positive cornea) it is important to make blind controls and to use seed media samples to Afssaps within a maximum of 5 days after being analyzed by the bank. An improvement has been observed in 2008 compared with 2007 when 1% (3 of 303) of the results were not in time (within 5 days) and 98% (298/303) were identical results between Afssaps and Eye banks.

PERPECTIVES

Pertaining media corneal controls and modifying the current procedure by carrying out a random control of graft number. Feasibility study of endothelial cell density controls realized from September 2006 to September 2008 to be able to set up the external controls of the endothelial cell density.