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European Eye Bank Association: Past, Present, and Future

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ABSTRACT

The European Eye Bank Association (EEBA) is a technical-scientific organisation for eye banks throughout Europe and beyond. Founded in 1989 with the simple objective of sharing information on eye banking, the Association is today the leading pan-national association in Europe dedicated to the advancement of eye banking and an authoritative reference point for eye banks that work according to quality standards. The Association establishes and maintains an agreed-upon set of medical and technical standards; promotes the collection of data on eye bank activities and processes; provides opportunities for the discussion of all aspects of eye banking practice, including eye donor selection and procurement, relevant research and development, education, and training in eye banking; and fosters links with national and international corneal transplant communities and relevant bodies. The introduction of a structured, focused Committee and a permanent Secretariat, and the development of an advanced website have enabled the Association to establish closer links and collaborative activities with key regulatory bodies. The Association has also provided a more constant exchange of clinical, scientific, and technical ideas and best practices with fellow professionals by means of annual meetings, the EEBA Directory and website, and a regular newsletter. The EEBA is committed to defining standards for eye banking and encouraging eye banks to maintain the highest possible standards for quality and safety. Through its Annual Meetings and the collection and exchange of detailed information from Member eye banks, the Association continues to speak with a confident and representative voice on eye banking in Europe.

KEYWORDS: corneal storage, corneal transplantation, eye banks, organ culture

Mission and Aims

The European Eye Bank Association (EEBA) is a technical-scientific organisation comprised of individual Members from more than 84 eye banks located in some 24 European countries. Founded with the simple objective of sharing information on eye banking, the Association is today the leading pan-national association in Europe dedicated to the advancement of eye banking (providing tissues and cells for treatment of eye diseases) and an authoritative reference point for eye banks that work according to quality standards.

The stated Mission of the Association is to help provide tissues and cells of optimum quality and safety for transplantation and treatment of eye diseases according to the highest medical and scientific standards. It makes them available to as many patients in need as possible in an ethical and humanitarian way, in accordance with the Declaration of Helsinki and applicable national and international laws and regulations.

To this end, the Association contributes to establishing a sufficient availability of tissues and cells for the treatment of eye diseases, works to develop and maintain professional standards for

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the practice of eye banking in Europe, establishes and maintains an agreed-upon set of EEBA Standards, promotes data collection on graft outcome to validate eye bank techniques, facilitates the interchange of information between eye banks, and provides opportunities for the discussion of all aspects of eye banking practice, including donor selection and procurement. The EEBA also encourages relevant research and development, provides informed comment to external agencies, fosters education and training in eye banking, maintains national and international links with corneal transplant communities and relevant bodies, and makes knowledge in the field of eye banking available to any person for the general good of society.

Background

The first meeting of the EEBA took place in Århus, Denmark, in 1989. The handful of people present, invited by Professor Niels Ehlers, could not have known how the organisation would develop—only that there was much to learn and share about eye banking. At that time, those invited to the meeting were all working with organ cultures and evaluating the corneal endothelium by light microscopy, having learnt such techniques in Århus from Niels Ehlers and his co-worker Steffen Sperling, who introduced the organ culture technique in Europe.¹

Although the intention of Ehlers was to have a pure brain-storming session, many of those attending took the opportunity to present their state-of-the-art work for discussion. The meeting was held in a classroom in the ophthalmology clinic of the university hospital. The participants arrived on Friday evening, engaged in presentations and discussions on Saturday morning, and were treated to a good lunch with "smørrebrød" and to dinner at Ehlers' home served by his wife Lise on Saturday night. On Sunday morning, everyone returned to the classroom for further discussions. This simple arrangement would long serve as the format for subsequent EEBA meetings.

After some drinks on Saturday evening, it was decided that a European Eye Bank Association would be established with Niels Ehlers as President and Liesbeth Pels as Secretary. The small group of founders formed themselves into a Committee and promised to meet each year to share their knowledge to improve eye banking. They vowed to keep the meeting as informal as possible, with the final scientific programme composed on Friday evening on the basis of those present. However, because of the growing interest in these meetings, the latter idea could not be sustained for long.

Those present at the first EEBA meeting totalled fewer than 20. A year later in Bristol, England, the group had doubled in size to 40, and the following year in Noordwijk, Netherlands, to about 80. An alternative meeting room had to be found at the last minute, and microphones were needed for this large number of suddenly appearing colleagues. The first of many adaptations and changes followed during the growth of the organisation. However, this original open-minded approach to sharing eyebanking knowledge and techniques is surely one of the reasons

why the EEBA has managed to grow and become a successful organisation.

Whilst a relative informality has continued to be a key characteristic of the EEBA, developments in the regulation of tissue banking in the European Union (EU) member states²⁻⁴ meant that the Association needed to revise its objectives, rules, and finances. Therefore, in September 2002, the EEBA Committee met for the first time between annual meetings to be briefed on and discuss new developments prior to the regular annual meeting. At that time, it was decided that a part-time Secretariat would be established and hosted at the Veneto Eye Bank Foundation in Venice, Italy. The Association's rules were subsequently revised and expanded to define clearly the Association's aims, Membership, administration, composition, and terms of office of its Executive Committee, Special Interest Groups (SIGs), Minimum Standards, the Annual Business and Scientific Meeting, and the Annual Directory, amongst other topics.

Logo

At the seventh annual EEBA Meeting, in Budapest, Hungary, a design contest was held to create a logo for EEBA as part of an initiative arranged by the local organizer. However, according to the opinion of the Logo Committee, none of the submissions could be compared with the logo that had been used one year earlier in 1994 by the local organizer, Carles Viader, for the sixth annual EEBA Meeting in Palma de Mallorca, Spain. According to Viader, his logo was inspired by Joan Miro, the famous Spanish and Catalan painter, sculptor, and ceramicist, who spent some of his working life in Mallorca (Fig. 1).

Who designed the logo? Anna Viader Soler, the daughter of Carles Viader, who at that time was a student of architecture in Barcelona, Spain, came up with the design. She graciously agreed

that it could be used as the official EEBA logo, along with the lettering and writing of the name of the Association.

Standards

The EEBA maintains a set of recommendations relat-



ing to the medical assessment of donors and contraindications to transplantation of ocular tissues ("Minimum Medical Standards").⁵ These Standards are subjected to a formal annual review by the Medical SIG but may be reviewed more frequently should the need arise. The review takes into account current professional guidance ⁶ and clinical practice as well as relevant national and international regulations. Recommendations from the Medical SIG for amendments and/or additions in the light of changing standards and practices are submitted to the EEBA Committee for approval.

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Table 1 – Responding Eye Banks*											
Parameter	1991	1993	1995	1997	1999	2001	2003	2005	2007	2009	2010
No. of banks	19	34	50	70	75	65	83	54	66	69	70
No. of countries	11	14	22	22	22	21	20	19	19	20	20
No. of corneas processed	11,530	18,594	22,722	27,713	32,497	36,567	41,709	28,634	32,080	28,270	33,760

^{*}Biennial data are shown. For 2010, figures include the latest available data.

In addition, the EEBA has established a series of "Technical Guidelines for Eye Banking," which define the minimally accepted standards of quality and safety for the procurement, retrieval, processing, storage, and evaluation of corneal and scleral tissue for transplant. These standards are subject to periodic review by the Technical Guidelines SIG, and any proposals for changes must be submitted to the EEBA Committee for approval.

In 2010, a Stem Cell Cultures SIG was established to monitor developments in the area of epithelial stem cells. The first EEBA recommendations for stem cell cultures were published in 2012.⁸

Members of the EEBA must agree to any changes in the standards approved by the Committee at a business meeting of the Association. At least 21 Members must be present, and two-thirds of those voting must be in favour of the change before it is fully implemented.

Directory

Details concerning technical aspects of European eye banks, along with a yearly overview of their activities, have been collected and presented since 1991 in the form of an Annual Directory, published in time for the annual meeting. Unfortunately, not all banks submit annual data, and therefore some analyses do not include all the statistics from all of the European banks (Table 1). Univ 11

Table 2 shows the differently sized banks, arbitrarily divided according to their activity, which is expressed as the number of corneas issued per year.

The increase in the percentage of corneas evaluated as being unsuitable for transplantation over the period 1991–2009 (Table 3) can be attributed to the more stringent quality and safety standards and regulations with regard to donor screening, serologi-

Table 2 – Number of Differently Sized Banks*											
Corneas issued per year	1991	1993	1995	1997	1999	2001	2003	2005	2007	2009	2010
< 50	3	4	10	11	11	4	5	5	4	6	7
50–99	4	7	7	18	20	16	19	13	15	7	5
100–499	8	17	21	29	33	37	50	26	38	36	36
500–1000	2	4	7	7	4	5	6	7	4	11	14
> 1000	2	2	3	3	4	4	4	3	4	4	8

^{*}Biennial data are shown. For 2010, figures include the latest available data.

Table 3 — Corneas Discarded/Unsuitable for Transplantation*											
Parameter	1991	1993	1995	1997	1999	2001	2003	2005	2007	2009	2010
Corneas unsuitable for transplantation (%)	39	41	39	42	45	48	48	44	47	51	39
Positive serology (including inadequate blood samples or dubious or incomplete test results) (%)	3.8	5.4	5.4	7.5	6.1	6.2	9.1	7.6	11.9	9.4	9.0
Contamination rates (organ culture) (%)	2.1	3.1	3.5	3.1	3.4	3.8	4.4	4.1	3.4	3.3	3.5

^{*}Biennial data are shown. For 2010, figures include the latest available data.

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cal and microbiological testing, and corneal evaluation criteria (e.g., minimal endothelial cell density accepted). The drop in the percentage of discarded corneas in 2010 owes much to the development of new posterior lamellar techniques, which allow eye banks to supply surgeons with corneas that would have previously been unacceptable for penetrating keratoplasty.

Organ culture remains the preferred routine storage method in Europe. In 2010, organ culture was used by 77% of banks and hypothermic storage by 14%, whilst the remaining percentage used both methods. The advantage of organ culture storage is that the endothelium can be inspected at different stages in the storage process. Endothelial cell density (ECD) is checked not only at the time of preservation but also prior to the surgery, so any potential unexpectedly high ECD loss during culture is detected before the tissue is used (organ culture acts as a "stress" test for donor corneas). As shown in Table 4, a major reason for tissue discard in 2010 was problems with morphology, which can be better detected with organ culture.

Another difference from cold storage is the rate of contamination detected in an eye bank, which is always higher in organ culture banks. The reason for this is obvious: unlike hypothermic storage, microbes multiply in organ culture, revealing themselves by a change in color or by turbidity of the medium, or they are detected with routinely performed microbiology tests. The minimum criteria for donor selection are those laid down by the EEBA, although many member eye banks apply additional donor criteria and contraindications.

The Association is committed to encouraging banks to produce standard operating procedures. It also encourages putting into action a quality management system based on the principles

Table 4 – Corneas Not Transplanted in 2010							
Reason for cornea not being	(%)						
Medical history	2.8						
Serology	8.4						
Microbiology	Bacteria	1.7					
	Multiresistant bacteria	0					
	Fungi	0.3					
	Multiresistant fungi	0					
	Combination of bacteria and fungi	0.4					
	Not specified	1.0					
	Suspected	0.1					
	Total microbiology	3.5					
Morphology		19.5					
Other or unknown reasons		4.0					

Table 5 – Quality Management						
Management measure	2010					
Standard operating procedures	64 (2)					
Quality manual	58 (7)					
ISO 9001-2000 certification	22					
Other certification	11 (12)					
Quality and technical summary	57 (4)					

Numbers in parentheses indicate those in preparation at the time.

of good medical practice that are in accord with the requirements laid down by national authorities responsible for the accreditation, designation, authorisation, and licensing of tissue establishments in compliance with the EU directives. Table 5 shows the number of quality management measures in place, or in preparation, in European banks in 2010.

Membership

Individuals who wish to become EEBA Members are expected to share the aims of the Association and abide by the EEBA rules. Membership is on an individual basis (Ordinary Member), and each Member is required to pay an annual subscription fee to receive EEBA benefits: a registration fee discount for the EEBA Annual Meeting; inclusion in the EBAA Annual Directory (provided data are delivered in time); a personal copy of the EEBA newsletter; access to training opportunities; and right of entry to the Members-only section of the website.

One Ordinary Member from each eye bank is identified as the Corresponding Member, who assumes the responsibility of returning data annually to compile the Directory. Failure to return data by the specified deadline may result in that eye bank not being listed in the Directory.

Any Ordinary Member may, upon retirement, request to become a Retired Member. Retired members need not pay the annual subscription but have all of the privileges of Ordinary Membership.

Any Member may recommend for Honorary Membership any person of distinction who has contributed outstandingly to the aims of the Association. Proposals for Honorary Members are discussed and voted on by the Committee. Honorary Members need not pay the annual subscription, but they have all of the privileges of Ordinary Membership.

The Committee may invite the President-Chair of a non-European eye banking organisation to become an Invited Member for the duration of his or her post. Invited Members need not pay the annual subscription, but they have all of the privileges of Ordinary Membership and may at the discretion of the Committee receive financial support to attend the Annual or Committee meeting.

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Successes

The evolving regulatory landscape in the field of tissues and cells-in particular the implementation of the European "directive on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells" (Directive 2004/23/ EC2) and associated technical directives—meant that the EEBA needed to change to provide more effective and timely information and advice to its membership. The introduction of a more structured and focused Committee, a permanent Secretariat, and a dedicated website has enabled the Association to meet the challenges put before it. It has built closer links and collaborative activities with key regulatory bodies and continues to provide a steady exchange of clinical, scientific, and technical ideas and best practices with fellow professionals by means of its Annual Meetings, the EEBA Directory, the EEBA website, and a regular newsletter. In 2010, an EEBA information booklet describing the aims and activities of the Association was published and distributed to more than 300 European ophthalmic surgeons, researchers, and other health professionals connected with eye banking to increase awareness of eye banking and the activities of the Association.

The EEBA seeks to make eye banking in Europe more efficient and safer and has established its standing as a recognized and respected pan-European association, acknowledged by the World Health Organization (WHO), the European Commission, the European Association of Tissue Banks, and the Eye Bank Association of America. In addition, the European Commission Health and Consumer Protection Directorate-General (Directorate C-Public Health and Risk Assessment, C6-Health Measures) and the WHO Expert Committee on Biological Standardization have consulted the Association for its expert opinions. It was also invited to attend the Council of Europe meeting of the group of specialists on quality assurance for organs, tissues, and cells (SP-S-QA Committee). The EEBA is participating in the EU-funded project Vigilance and Surveillance of Substances of Human Origin and plays a leading role in the Eye Bank Technical Advisory Group formed by the International Council for Commonality in Blood Banking Automation to develop an international nomenclature for ocular tissue, with representatives Diego Ponzin (Venice) and John Armitage (Bristol) as chair working in collaboration with colleagues from all of the other major eye banking associations (Eye Bank Association of America, Eye Bank Association of Australia and New Zealand, Eye Bank Association of India, and the Pan-American Association of Eye Banks). The EEBA is regularly invited to give presentations or run courses on eye banking at key international meetings, including those organised by EuCornea, European Association of Tissue Banks, European Association for Vision and Eye Research, European Society of Ophthalmology, and American Academy of Ophthalmology.

Future

Serving a population of 738 million people¹² and with the need for donor tissues and cells for ocular surgery in Europe still not being fully met by European eye banks, EEBA will continue to play a positive and leading role in promoting greater availability of tissues and cells for the treatment of eye diseases through the constant exchange of clinical, scientific, and technical ideas, and best practice.

In addition, EEBA increasingly seeks to support the advancement of new treatments for diseases affecting the cornea and associated forms of ocular surface damage (e.g., serum and amniotic membrane drops, epithelial stem cells, gene therapies). In recent years, we have seen that the connection between corneal surgeons and eye banks has strengthened as new posterior lamellar techniques have become the preferred methods for treating corneal endothelial disease. Also, an increasing number of banks has started preparing lamellar grafts in the eye bank laboratory, thereby moving parts of modern corneal surgery from the operating theatre to the laminar airflow bench in the bank. In 2010, some 18 EEBA Member eye banks reported precutting tissue for lamellar grafting (in contrast to only six in 2009). Continued exchange of knowledge among banks on optimizing these techniques and reporting data on precut grafts to the Directory are crucial to ensure the best results for our prospective patients.

In the future, EEBA will seek to encourage the publication of results from national quality control registers and actively give its full support, as a founding member, to achieving the key objectives of the fledgling Global Alliance of Eye Bank Associations, which EEBA believes are essential for the future of eye banking: (1) sharing best practices and guidelines; (2) sharing information on scientific meetings/conferences/workshops; (3) establishing a worldwide registry of eye banks; (4) developing and promoting global coding, traceability efforts, and biovigilance systems for ocular tissue; and (5) providing global advocacy for eye donation and eye banking.

Conclusions

In Zagreb, Croatia, on Jan. 18-19, 2013, the Association will celebrate its 25th consecutive Annual Meeting, which together with the yearly collection and exchange of detailed information from member eye banks in the EEBA Directory, amounts to a significant track record. Thus, EEBA can rightly claim to speak with a confident voice on eye banking in Europe. As a scientific group, the EEBA remains committed to defining and upholding minimum standards and to encouraging banks to produce standard operating procedures as required by the relevant authorities in each country.

The continued support of its Membership is essential in maintaining and enhancing the Association's strong reputation. All medical, scientific, and technical colleagues working in the field of eye banking (tissues and cells for treatment of eye diseases) are invited to join the Association (see www.europeaneyebanks.org for details).

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