

Reflections on the Success and Future of Eye Banking

Michael L. Nordlund, MD PhD, Townley Paton Award Recipient, 2017

I am truly honored and humbled to be included with the relatively short list of a previous awardees of the Paton Award; individuals whom I hold in high esteem and who are the fore fathers of not only modern eye banking, but also modern corneal transplantation. I have enjoyed my work with the Eye Bank Association of America (EBAA) over the last fifteen years. I first started as a member of the accreditation committee, then spent four years as co-chair of that committee. Subsequently I have served as a member of the medical advisory board and currently serve as its chair. For several years, I have also served on the board of directors of the EBAA. I can honestly say that my work with the EBAA during this time and my interactions with its many members, have been some of the most satisfying and rewarding aspects of my professional career. The EBAA is truly a role model association among associations and has been incredibly effective in its goal to promote and nurture the collaborative efforts of its constituents to advanced corneal transplantation and to restore sight. To demonstrate this success I'd like to provide a quick retrospective review of what has been accomplished. I think this review will be informative for not only younger physicians who have trained in the modern era, but also for those of us who've been in the trenches over the last couple of decades, to take a moment to reflect on the extent of what has been accomplished.

In the pre-eye banking era, the surgeon was directly responsible for all those procedures that we now consider to be traditional eye banking functions. These functions include recovery of the cornea, determination of donor eligibility, evaluation of the tissue, processing, storage, transportation and distribution of the tissue as well as all record keeping to maintain traceability. In modern eye banking. All of these steps are the purview of the eye bank. This transition has been relatively seamless and incredibly effective at providing better quality tissue and improving the reliability of tissue supply. The reason this system has worked so well is because of the close collaboration between the surgeons who use these tissues and the eye banks that prepare these tissues. There is a very close relationship between the supplier and the end user. Another reason that this model has been so successful is because of the hard

work of medical directors, surgeons who function as the eyes and ears of every other surgeon who receives tissues from a bank. Being a medical director is an awesome responsibility. While they do not recover tissues for other surgeons, they oversee the eye bank functions to ensure its quality. This model is similar to the two surgeon model often used in solid organ transplantation. In a kidney transplant one surgeon will harvest the kidney while contemporaneously a second surgeon prepares the donor to minimize the amount of time the kidney is removed from its blood supply. The medical director essentially serves as this as a second surgeon who oversees the recovery and processing of corneal tissues used by transplanting surgeons. So today, we have an eye banking system where surgeons can focus on patient care and eye banks reliably provide high quality tissue when its needed.

Eye banking has evolved even further, however. Over the last fifteen years, there has been a tremendous evolution in the management of corneal disease. When I finished my fellowship in 2001, we had one surgery for all patients with corneal disease. Penetrating keratoplasty was performed for both stromal and endothelial disease. Obviously this is not the case today. Today we have targeted therapies where we replace the endothelium when it's abnormal and the stroma when it's abnormal and this improved strategy requires markedly more processing of tissue by the eye bank. Thus, simultaneous to the tremendous innovation in corneal transplantation there has been an equally tremendous evolution in eye banking processing. Again, when I first got involved with the EBAA as an inspector for the accreditation committee, most eye banks looked the same. Some banks were small and some were large, but every bank was essentially the same and contained a specular microscope, a refrigerator for storing tissue and a laboratory hood for doing the excisions. Today many eye banks have entire clean rooms that rival our laser suites where highly trained technicians process tissue with microkeratomes and

Author Affiliation: Cincinnati Eye Institute, Blue Ash, OH

femtosecond lasers and use OCT machines to measure their results. Banks are also peeling Descemet's membrane and preloading it in injectors and some are now doing endothelial cell culture in preparation for the next wave of corneal transplantation. So there's been a tremendous amount of innovation that has occurred in corneal transplantation and in eye banking. In fact the reason surgeons have been able to evolve their surgical techniques so rapidly is because eye banks have been so willing to evolve their processing techniques. This innovation is the result of extensive collaboration between physicians seeking to improve surgery and eye bankers dedicated to providing surgeons the tissues they need. Maintaining quality of the tissue during the development of these new methods was a major focus of the EBAA. The approaches to solving the challenges to these new processing methods and methods to evaluate the quality of these newly processed tissues were discussed regularly at the biannual EBAA medical advisory board meetings as well as in casual conversations among eye bankers, physicians and medical directors. Much of this collaboration was cultivated by the EBAA which has for decades served the role of oversight in maintaining the quality of the tissue. It is this shared vision of quality that brings all of the EBAA constituents together. Surgeons want quality surgeries to improve patients outcomes. Eye bankers are committed to providing the quality tissue needed for quality outcomes. And the EBAA strives to promote and ensure quality through accreditation process and the medical standards. Through this collaboration and shared vision of quality we have arrived at our current iteration of modern transplantation where the surgeon can focus on surgery and patient care and the eye bank has a markedly increased role. And the EBAA continues to foster collaboration between surgeons and eye bankers and oversee the outcomes. The first three values of the EBAA's mission, vision and values are quality, collaboration and innovation. And it's this dedication to these attributes that has facilitated this marked advance in modern transplantation.

So, in summary, eye banking has undergone an impressive successful transformation. Where do we go from here and what's on the horizon? Unfortunately, I think there are some significant head winds and potential threats that could disrupt the fabric of what has made us successful. The impending changes of concern are increasing consolidation within eye banking and the transition to using endothelial cell culture.

Consolidation in healthcare is ubiquitous and has been a trend over the last decade. There has been consolidation of providers, consolidations of hospital into the healthcare systems, acquisition of providers by hospitals and healthcare

systems, consolidation of payers and we are now witnessing consolidation of a retail pharmacy and a payer with the announcement the intent for CVS to buy Aetna. Consolidation will likely continue and Deloitte projects that less than half of all health care systems today will exist in their current state in the near to intermediate future. Consolidation has impacted eye banking as well. Ten years ago there were about 100 banks nationally and we now have less than 80. Consolidation is occurring because there are significant benefits to consolidation. Standardization of processes can benefit providers and consumers. Consolidation also offers opportunities for cost sharing and improved profitability and possibly lower costs for consumers. And there's certainly market leverage, which is a primary driver of this change. In some cases consolidation provides for the survival of an entity which would otherwise fail. So yes there are benefits. However, there are disadvantages of consolidation as well. With marked consolidation, there is less competition and less diversity in the marketplace, which can result fewer people generating new ideas and thus innovation may suffer. There can also be increased separation between the end user and the supplier, which can disrupt the feedback loop that is so important in maintaining quality.

Even big successfully consolidated companies struggle with this risk to innovation. For example, big tech companies like Microsoft, Apple, and Google spend billions of dollars annually on internal innovation and yet they know that this effort is insufficient. In fact it is impossible for them to spend enough to compete with the thousands of entrepreneurs who are looking for the next new transformative innovation. These companies require lots of idea generators and they certainly can't employ them all and so they've come up with alternate strategies. Microsoft has a strategy called Bizspark, which is a business incubator for small start up companies with new ideas. Biz spark provides these start ups with resources and in exchange, Microsoft gets advanced knowledge of their ideas. Apple and Google purchase much of their innovation. In an eighteen month period in 2015-6, Apple acquired 24 different start up companies and Google acquired well over 50 in an attempt to maintain their competitive edge. So while it is difficult for market leaders to develop the needed innovation internally, there are effective ways to combat the reduced diversity that follows consolidation. These strategies, however, will not work in the eye banking community because eye banks do not have the capital to go out and buy lots of start ups and because there is no financial benefit to drive innovative people outside the industry trying to improve the world of corneal transplantation. So innovation in eye banking has

to come from within and with fewer people involved in the process, there could be a significant reduction in our innovative efforts and success.

As mentioned, consolidation can also increase the separation between the end user and the supplier and disrupt the feedback loop with unintended consequences. The American food system offers several good examples. It is a tremendously consolidated industry. Currently four companies control the bulk of a meat production, milk production is largely controlled by two different entities and four retailers control more than fifty percent of grocery sales and distribution and this is the market share before Amazon entered the market with purchase of Whole Foods. It has not always been this way. In the 1930's, approximately forty percent of Americans were involved in the production of food and today it's less than two percent. Again, there have been benefits to this consolidation. The stability of the food supply is better. There is more standardization. Consumers can walk into any grocery store and the food products offered are essentially the same. There are reduced costs to production so companies are making more and consumers may be paying less. Certainly there is more leverage for the companies that have survived. However, there are some unintended consequences as well because often the goals of these big companies aren't necessarily aligned with the goals of the end user. For example, when meat is processed at a very large scale, there are lots of scraps that get caught in the gears and the conveyor belts of the machines that process carcasses. The industry sees these scraps as lost profit and through innovation determined that these scraps could be processed differently and made into something useful. So currently they soak them in a very strong base to kill bacteria and breakdown all the connective tissue and grind it together to get a product called pink slime. According to the USDA, this is quality meat and it makes it into many processed meat products. Clearly it is not unsafe to eat, but it's also not very appetizing and its unlikely the product you are imagining when you are in the mood to cook something on the grill. So the companies idea of what is good and the consumer's idea of what is good is not always the same. This misalignment is not always recognized when there is separation of end user and supplier. There have been similar misalignments in the evolution of bread. Modern American bread has lost nearly all the qualities that makes bread wonderful. When bread production is centralized, it requires shipping product longer distances, which requires a prolonged shelf life. Unfortunately processes that prevent bread from becoming moldy or stale, negatively impact the characteristics that make old world bread so appetizing. Somehow, however, the food industry was able to convince

American consumers that the loss of hard crusts, flavor and variety was actually "wonderful" and we now have wonderfully soft, uniform and flavorless Wonderbread and its analogs. Similarly America lost its rich diversity of flavor and texture in beer. At the turn of the 20th century most towns had several local competing breweries, similar to the current situation in Germany. Through prohibition in the 1920's and subsequent consolidation of the beer industry, American consumers have been restricted for decades to a small handful of options ranging from Budweiser to Miller light. These beers in addition to lacking any real flavor are a tiny spectrum of the variety through out Europe and in America in the early 1900's. Thankfully, micro brewing has returned and options have exploded in the beer market. We are also seeing pushback in other food areas. Today consumers are much more aware of the benefits of buying locally sourced food and the number of farmers markets has increased dramatically over this last decade. In eye banking, we certainly want to avoid this drift in quality as we see increased consolidation and increased separation of end user and supplier.

The issues I have discussed, the separation of end user and supplier and reduction in innovation only become manifest problems if there is marked consolidation in the eye banking industry. Unfortunately, I do believe we're going to see increased and marked consolidation in the eye banking community. The impetus for this change comes from the advent of cell culture of endothelial cells to treat endothelial disease. The technique is expensive and will require significant investment and development, so like microkeratome or femtosecond processing, this service will likely be performed by a handful of banks. Early results suggest the treatment will be effective and markedly change the donor to recipient ratio. Currently, one donor can supply endothelial transplants for at most two patients. With culture of endothelial cells, one donor will likely supply enough cells for fifty to a hundred patients. Since more than half of all transplants performed are for endothelial disease, there will be a drop in need for donors of approximately fifty percent. Banks placing cultured cells will still get reimbursed for each placement and do well financially, but banks not performing cell culture will face a fifty percent reduction in placed tissue, and thus a tremendous reduction in revenue. Many small and medium banks could not survive in this environment. So I do think we're going to see increasing and tremendous consolidation, possibly down to a handful of banks nationally. In this scenario, there will clearly be a large disconnect between end user and supplier and physicians will have many fewer opportunities to participate in eye banking.

So how do physicians influence this transition. I believe it is now more important than ever that physicians maintain input in the process. We cannot stop consolidation, but we can certainly make sure that we influence how the transition occurs. From my perspective the best way to do this is to be involved with the Eye Bank Association of America. It is the parent organization that will continue to oversee these changes and its a place to have a voice. I also think it's important that physicians increase their involvement in their local eye banks by developing tighter relationships with their executive directors and administrative teams. Finally, like food, consider using locally sourced products when possible.

So, once again I would like to thank the EBAA for this recognition. I want to thank the EBAA professional staff for making my work with the EBAA over the last fifteen years so easy. I also want to thank my mentor and good friend, Ed Holland for introducing me to the EBAA and I want to thank my many physician and eye banking colleagues who have made my involvement in the EBAA so rewarding. Finally, I'd like to thank my wife, Lisa, my daughter Jessica and my son Michael, who put up with my absences for these and other professional meetings and who are truly the most rewarding and exciting part of my life. Thank you.