INTERNATIONAL JOURNAL OF EYE BANKING

RESEARCH

Potential Adverse Effects on the Cornea Donor Pool in 2031

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ABSTRACT

PURPOSE: To evaluate the adequacy of the cornea donor pool in 2031.

METHODS: Cornea supply and utilization data were obtained from the Eye Bank Association of America's *2011 Eye Banking Statistical Report* and compared with population data projections from the US Census Bureau. The rate of utilization was extrapolated by linear best-fit analysis of the previous 5 years tissue utilization trends to estimate tissue needs in 2031. Similarly, the effects of hepatitis B, hepatitis C, and medical-social history on the donor pool can be projected.

RESULTS: The US population is expected to increase 16% over the next 20 years, but the rate of tissue utilization based on the last five years suggests the need for cornea tissue will increase nearly 133% in the next 20 years. If the trends from 2006 to 2011 continue over the next 20 years, the rate of donors testing positive for hepatitis B is projected to increase 275% and for hepatitis C, 241%, permanently eliminating them from the donor pool. In the same fashion, the number of patients eliminated from the donor pool because of medical-social history findings is estimated to increase 237% over the next 20 years.

CONCLUSIONS: The need for donor corneas over the next 20 years will increase proportionally much faster than the US population is growing. Potential donors eliminated because of hepatitis B and C and medical-social history are projected to increase as well. Public education programs, such as Donate Life America, which increase the number of consenting donors and mechanisms to enhance corneal preservation prior to surgery should be started now.

KEY WORDS: eye bank, corneal transplantation, hepatitis B, hepatitis C, eye donor

The first human corneal transplant was performed by Zirm in 1905.[1] Thirty-five years later, corneal transplants had become mainstream surgical procedures in the United States (US).[2,3] To help provide a supply of quality donor tissue for keratoplasty, the first eye bank, now the Eye Bank for Sight Restoration, was started in New York by R. Townley Paton in 1944.[4,5] To meet the growing demand across the US for corneal tissue for penetrating keratoplasty, more eye banks in different locations were started, and in 1961, the Eye Bank Association of America (EBAA) was founded by 10 initial member banks to help coordinate recovery and distribution efforts among eye banks.[6-8] The EBAA celebrated its 50th anniversary in 2011 with all 79 eye banks in the US as members.[9]

Fifty years ago, tissue was sporadically obtained, stored in a moist chamber in a refrigerator and used locally. Intermediate-term storage media allowed for longer death-to-surgery intervals to be accommodated, so tissue could be transported and used regionally or nationally, allowing for surplus tissue from one region to be used in another region where tissue was needed. As eye banks have increased their recovery efforts to provide more tissue, waiting times for keratoplasty in 2012 have decreased, and cornea surgery is frequently scheduled electively.[10] Tissue is now sent freely about the US, and surplus tissue from the United States is frequently utilized abroad. Both patients and surgeons now enjoy an abundance of quality tissue in our current circumstance.

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Author Disclosure: The authors report no conflicts of interest.

Fig 1. Cornea transplants using tissue from US eye banks

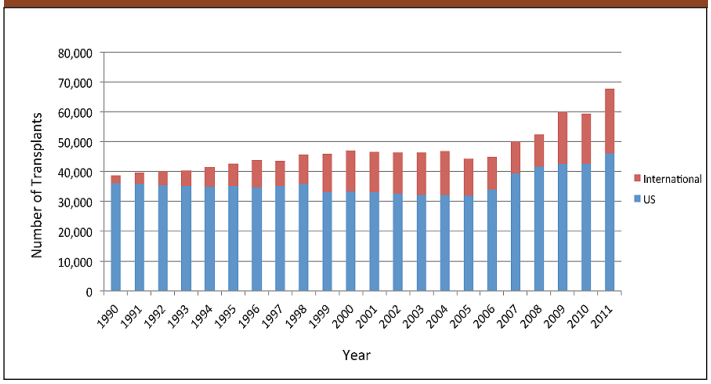


Fig. 1 shows the number of keratoplasty procedures increasing from 1990 to 2011.

Table 1. Domestic and international numbers of corneas used for keratoplasty

Date	US	International
1990	36,037	2725
1991	35,831	3684
1992	35,525	4448
1993	35,173	5042
1994	35,022	6517
1995	35,300	7440
1996	34,668	9043
1997	35,209	8283
1998	35,861	9718
1999	33,020	12,745
2000	33,260	13,689
2001	33,035	13,497
2002	32,559	13,881
2003	32,240	14,196
2004	32,106	14,735
2005	31,952	12,377
2006	33,962	11,073
2007	39,391	10,731
2008	41,652	10,835
2009	42,606	17,178
2010	42,642	16,629
2011	46,196	21,394

Table 1 shows the number of keratoplasty procedures from EBAA eye banks from 1990 to 2011.

In 1991, the EBAA started a statistical report of the numbers of corneas recovered and provided for surgery by eye banks in the EBAA. Figure 1 illustrates that the utilization of corneas produced by US eye banks has increased steadily from 1990 through 2011, except for a drop in 2005 and 2006.[11] Table 1, the data from which Figure 1 was compiled, shows a 45% increase in corneas used from 2005 to 2011.

In 2011, the last year for which data are available, 67,590 corneas were provided by EBAA eye banks.[11] The number of corneas exported abroad by US eye banks increased 93% from 11,073 in 2006 to 21,394 in 2011.[11] These figures suggest that the eye banking system in the United States today produces an adequate amount of cornea tissue to meet the demands of corneal surgeons in the United States and allows for a substantial amount of tissue to be exported for surgery in other countries.

So is there any reason to be concerned about the donor pool in the future? Many eye banks in the United States are looking for additional outlets to place their excess tissue. International use of US tissue is a buffer for excess tissue in the US, and frequently tissue that is not used in the US can be utilized abroad. Gratis or low-fee tissue placement does not cover the cost of recovery or processing, and eye banks have to maintain a balance between providing low- or no-fee tissue and generating sufficient processing fees to cover their operations. Although there exists an adequate tissue supply now, the industry should be alert for future threats to the donor supply that have the potential to upset the supply of tissue we enjoy today and potentially compromise care in the future. There should be no problem with tissue supply in the future as long as (1) tissue needs do not substantially increase, (2) the increase in the population in the future allows for tissue needs to be met, and (3) there are no adverse influences on the donor pool. The number of referrals eliminated from donation due to hepatitis B, hepatitis C, and medical-social history have risen dramatically in the last 5 years.[11] And although the surplus of tissue now produced by eye banks in the US might provide a buffer in the event of a short term tissue shortage, any changes in these parameters could adversely affect the donor pool 20 years in the future. If tissue parameters acceptable to surgeons, such as donor age,[12] cell count, preservation time,[13] etc., change in the future, the donor supply could contract or expand accordingly. With present usage methods, tissue exported internationally might theoretically be used in the United States if the tissue supply contracted, but a number of corneal surgeons around the world depend on the supply of corneal tissue from the United States for their patients.

Table 2. Population estimates

	2011	2030	% increase
World	6,984,895,594	8,259,167,105	18%
United States	312,780,968	363,584,435	16%
Kentucky	4,369,356	5,235,685	20%

Table 2 shows the current (2011) and projected (2030) populations of the world, the United States, and Kentucky, according to the US Census Bureau.

The purpose of this paper is to evaluate the tissue supply and tissue utilization in the United States now and 20 years from now. Using current population and cornea usage trends, we have tried to identify tissue needs in the future and potential impediments to meeting these needs. Using EBAA statistical data from 2006 to 2011, we are trying to identify trends which, if they progress unnoticed, may limit the supply of donor tissue in 2031. Using a linear best-fit curve analysis of data from the EBAA statistical reports from the last five years, we performed a theoretical analysis of the supply of donor tissue in 20 years.

METHODS

A comprehensive overview of tissue utilization in the United States can be found each year in the EBAA statistical report.[11] Future tissue availability depends on the donor pool, i.e., the population increasing at the same rate that corneas are being used and there being the same proportion of suitable donors in the population as exist now. If the cornea utilization curve goes up and there are fewer donors in the population, a shortage of tissue relative to what we enjoy today will be inevitable. In this paper, we consider the population predicted in 20 years, corneal utilization in 20 years, and the availability of suitable donors in the population. Such estimates as these assume that many variables such as birth rate, surgical patterns, and causes of corneal blindness will stay the same, which may or may not happen. They also assume donor consent, evaluation procedures, and eye bank funding mechanisms are similar in 2031 as now. However, we can make inferences from the data we have now on what the supply and demand of tissue might look like when today's "baby boomers" need their cornea transplants. More importantly, we can identify now how adverse effects trends on the donor pool that cause tissue to be judged unsuitable for transplant currently might change the availability of donor cornea tissue in 20 years if efforts are not made now to increase the number of useable surgical corneas recovered.

Table 3. Utilization of tissue in 2011

	United States	Kentucky
Total deaths	2,476,520	40,259
Total referrals	745,405	21,408
Eligible for surgery	170,388	--
Actual donors	57,835	489
Tissue recovered	101,533	--
Useable tissue	67,590	722
Death to cornea ratio	37:1	56:1

Table 3 compares the availability of corneal tissue in 2011 in Kentucky and the US to the number of deaths that occurred in these geographic locations.

The current and future population projections of the United States are available from the US Census Bureau's website. For this paper, we have used US census figures for the population of the United States and for one individual state (Kentucky) now and 20 years from now. The current population of the United States and Kentucky now and the population projected 20 years in the future are shown in Table 2. The number of deaths that result in one suitable donor cornea are shown in Table 3. The number of potential donors referred to eye banks in the United States from 2006 to 2011 are found in the EBAA's *2011 Eye Banking Statistical Report*. Statistics for Kentucky were obtained from both of the two eye banks that serve Kentucky (Table 3).

Cornea utilization figures in 2031 were calculated by charting the number of corneas produced by US eye banks from 2006 to 2011, then utilizing a best-fit linear analysis curve. This procedure averages the difference between each data point and produces a statistical best-fit line for the six data points (2006-2011). This curve is then extrapolated 20 years into the future to provide an estimate of the tissue need in 2031.

Similarly, the number of patients eliminated from the donor pool over the last five years from hepatitis B, hepatitis C and/or medical-social history were identified from the EBAA statistical report and plotted

Table 4. Limiting factors for corneal donation 2005-2011*

	2005	2006	2007	2008	2009	2010	2011
HIV	167 *(1)*	144 *(0.74)*	374 *(1.9)*	201 *(0.9)*	278 *(0.7)*	328 *(1.2)*	400 *(1.4)*
Hepatitis B	1,070 *(6.2)*	1335 *(6.8)*	2,304 *(11.3)*	3,558 *(14.9)*	4,254 *(11.3)*	4,488 *(15.7)*	4,261 *(14.5)*
Hepatitis C	929 *(5.4)*	1,050 *(5.4)*	1,006 *(5.0)*	1,587 *(6.6)*	1,942 *(5.1)*	2,697 *(9.4)*	2,637 (8.9)
Syphilis	121 (0.7)	168 *(0.9)*	219 *(1.1)*	269 *(1.1)*	256 *(0.7)*	271 *(0.9)*	347 *(1.2)*
Other serology	695 *(4.0)*	1,085 *(5.6)*	520 *(2.6)*	639 *(2.7)*	886 (2.3)	1,188 *(4.2)*	341 *(1.2)*
Medical-social history	3,630 *(23.1)*	3,445 *(17.6)*	3,787 *(18.8)*	6,508 *(27.1)*	8,425 *(22.1)*	8,212 *(22.8)*	8,450 (28.8)
Slit lamp	5,983 *(34.8)*	6,090 *(31.2)*	5,160 *(25.6)*	8,207 *(34.2)*	9,494 *(25.1)*	9,471 *(33.2)*	11,168 *(38)*
Specular	2,434 *(14.2)*	2,901 *(14.8)*	2,304 *(11.4)*	↗	↗	↗	↗
Other (eg transport/ storage)	611 *(3.6)*	2,367 *(13.5)*	2,683 *(13.3)*	2,314 *(9.7)*	3,083 *(8.2)*	–	–
TOTALS	17,192	20,066	20,180	23,974	28,771	28,541	29,407

*Numbers in italics indicate percentage of total usable corneas.

Table 4 shows the factors limiting corneal utilization from 2005 to 2011. Hepatitis B, hepatitis C, and medical-social history are three main factors that have adversely influenced the donor pool. Note, starting in 2008, the categories for donors eliminated due to slit lamp and specular were combined.

from 2006 to 2011 (Table 4). The best-fit linear analysis curve of these six data points was then projected 20 years forward to arrive at the estimated number of potential donors eliminated for hepatitis B, hepatitis C, and medical-social history review in 2031. Such extrapolations are subject to a number of variables, known or unknown at this time, which may alter the validity of these linear predictions. Statistical linear best-fit analysis of the available data points in 2006 to 2011 produced a curve with more conservative (lower) numbers for 2031 than an exponential best-fit curve analysis, and so was utilized in this analysis.

RESULTS

A. Tissue recovery. In the United States there were 2,476,520 deaths estimated in 2011. Out of this number, there were 745,405 referrals to eye banks for possible donation. From these referrals, 170,388 donors were eligible for surgical tissue and 57,835 were actual cornea donors. From these 57,835 donors, 101,533 corneas were recovered and 67,590 met EBAA medical standards criteria and were distributed for transplant. For every cornea distributed for transplant, more than 11 potential donor referrals on average were required. One donor cornea resulted from every 37 deaths in the United States, and if most donors had two eyes, that meant one successful donation resulted from every 74 deaths.

In 2011 in Kentucky, there were 40,259 total deaths reported overall. Of these, 21,408 occurred at a hospital and were referred for possible donation. One useable cornea resulted from every 56 deaths in Kentucky, meaning that fewer than one in 100 deaths resulted in a transplanted cornea. Of these referrals, tissue was recovered from 489 donors out of 21,408 referrals (2.2%).

For comparison, the EBAA Cornea Collaborative reported a 33% conversion rate. The Collaborative conversion rate was defined as transplant-eligible referrals/ transplant intended donors. Both the Kentucky experience and the Cornea Collaborative show there are a number of potential donors missed that never get into the system.

B. Tissue utilization. Tissue utilization patterns were relatively constant for 15 years from 1991 through 2005. Figure 1, the composite graph of corneal transplants utilizing tissue provided by EBAA eye banks, shows that since 2006 there has been a substantial uptick in tissue utilization. The current EBAA statistical report acknowledges a jump in corneal utilization in 2011 that is possibly due to one or more of the following: (1) a new collection format for eye bank statistics started in 2010, (2) an increase in endothelial keratoplasty and other lamellar procedures, and (3) the inclusion of long-term storage (glycerine preserved) tissue in the keratoplasty total number. Table 1 shows that the total number of corneas supplied by US eye

Fig 2. Keratoplasty procedures for 2031 predicted from 2006-2011 trend

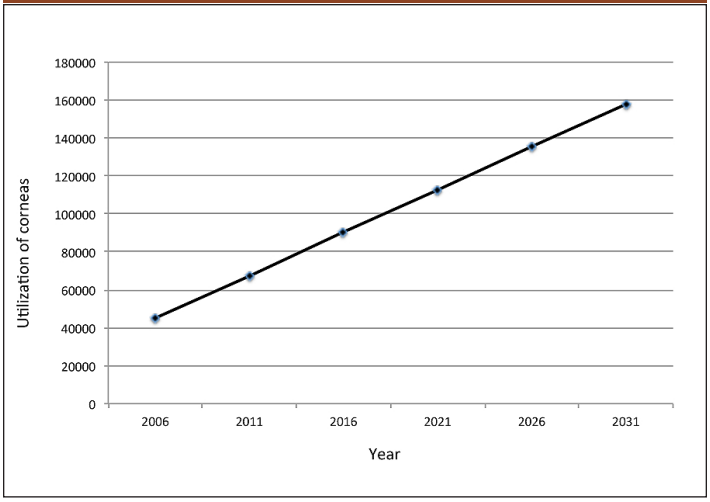


Fig. 2 shows the predicted number of keratoplasty procedures in 2031 extrapolated from the trend of 2006 to 2011.

banks used for keratoplasty increased 50% from 2006 to 2011. If this same pattern increase in utilization were to persist for the next 20 years, we would need almost 160,000 donor corneas to meet the needs of corneal surgeons in 2031 (Fig. 2). International use of tissue could also increase if foreign outlets start to pay competitive rates for tissue or US eye banks absorb the cost of providing low- or no-cost tissue. Surgeons could face increased competition for high-quality donor tissue in 2031. Conclusion 1 from the theoretical projection curve for utilization of tissue is that there will be an increase in the number of tissue requests in the next 20 years to a number significantly higher than in 2011.

C. World and US population projections. The world population in 2011, as seen in Table 2, is 6,984,895,594. Using data from the websites of the US Census Bureau (http://www.census.gov) and the Centers for Disease Control and Prevention (http://www.cdc.gov), we noted that the predicted population in 2030 is projected to grow to 8,259,167,705, an increase of 18% (Table 2). During this same 20-year period, the population of the United States is expected to increase only 16%. The birth rate in the United States is currently negative, and the population will increase slightly over the next 20 years because of immigration into the United States from developing countries.[14] So the future population increase of the United States will be relatively flat compared to the increase in tissue demand (18% vs. 140% in 20 years). Since the population growth curve will lag behind the tissue demand curve, if the current percentage of donors in the population remains the same, there will be less available tissue in 20 years than exists now. The ramifications of this change in supply and demand of tissue are unknown but suggest that the supply will be tighter in 20 years than it is now. Either the number of consents for donation as a percentage would have to increase, or the proportion of suitable donors in the population will have to rise significantly to meet tissue needs in 20 years. Conclusion 2 from these results is that the increased tissue needs in 2031 will not necessarily be met merely by the population increase in the United States in that same time period.

D. Factors limiting corneal utilization. Table 4 shows factors limiting corneal utilization from 2005 to 2011. There has been an increase in tissue that is ruled out because of hepatitis B, hepatitis C, and medical-social history over the last six years. Although the curves of the graphs in Figures 3, 4, and 5 show a plateau effect in 2011, the linear best-fit curve analysis of the last five years statistically was used to predict a 2031 value. We arbitrarily picked five years for statistical analysis, although variations in testing procedures and data collection have inevitable confounding effects on this theoretical model.

Figure 3 shows that donors who tested positive for hepatitis B increased in each year from 1,335 in 2006 to 4,261 in 2011. Extrapolating this five-year increase over the next 20 years (using a linear best-fit analysis curve to predict 2031 incidence) suggests that nearly 16,000 potential donors might test positive for hepatitis B in 2031 (Fig. 6). Donors ruled out from hepatitis C increased from 1,050 in 2006 to 2,637, or nearly 150%, in 2011 (Fig. 4). Donors ruled out because of hepatitis C would approach 9,000 in 2031 (Fig. 7).

Donors eliminated due to aspects of features in the medical-social history (e.g., prison incarceration, tattoos, intravenous [IV] drug use) increased from 3,445 in 2006 to 8,450 in 2011. The medical-social history, as it is utilized now, would account for over 28,000 donors ineligible to provide tissue because of adverse social history in their record (Fig. 8).

Not all patients eliminated due to medical-social history have features of high-risk behavior such as prison incarceration, tattoos, or IV drug use. But lifestyle markers such as these are among the reasons that potential donors are eliminated from the donor pool and are a potential cause of the rise in medical-social history incidents that parallels the rise in hepatitis B and hepatitis C infections. Conclusion 3 is that a significant threat to the donor pool looms from lifestyle issues such as IV drug use and other high-risk

Fig 3. Corneas declined due to hepatitis B

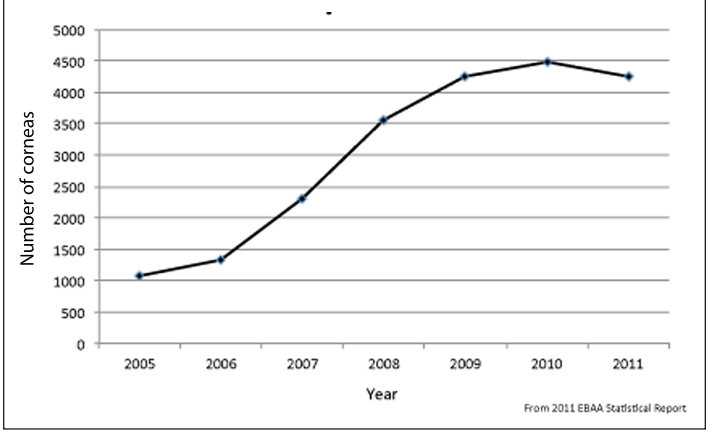


Fig 4. Corneas declined due to hepatitis C

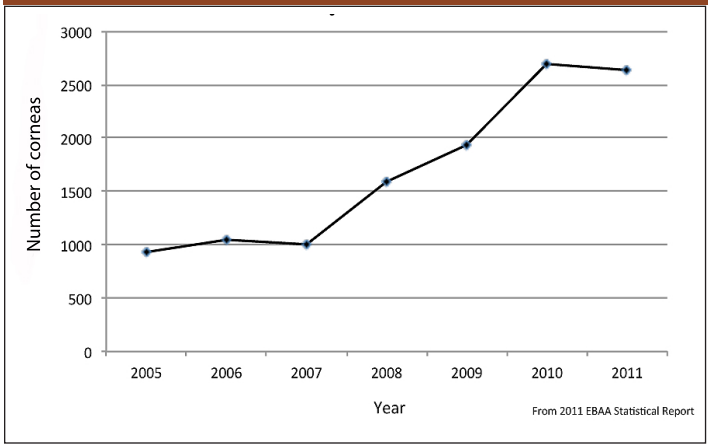


Fig 5. Corneas declined due to medical-social history

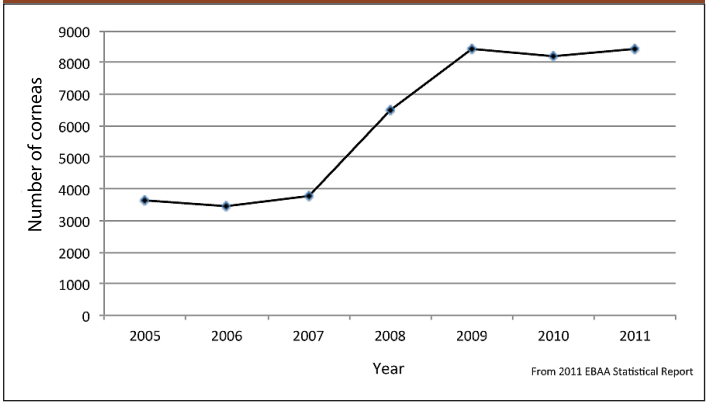


Fig. 3 shows the number of cornea donations ruled out due to hepatitis B from 2005 to 2011. Fig. 4 shows the number of cornea donations ruled out due to hepatitis C from 2005 to 2011. Fig. 5 shows the number of cornea donations ruled out due to medical-social history from 2005 to 2011.

behaviors that cause potential donors to be removed from the donor pool.

Some errors are unavoidable when making projections such as these from the data in the EBAA statistical reports. The statistical report lists donors ruled out by hepatitis B core antibody and hepatitis B surface antigen in separate categories, and some patients will test positive for both. Similarly, positive hepatitis C core antibody and nucleic acid tests (NAT) may both come from one donor. However, many eye banks use one test or the other, so for reporting trends, this paper utilizes all tests cumulatively in compiling each year's statistics. But if multiple tests from the same potential donor make the percentage of donors ruled out appear higher than it actually is, there is a counter tendency for eye banks to rule out donors not suitable for transplant as early as possible. Tissue might not be recovered at all if there is a history of "high-risk behavior." Even with the potential vagaries of this statistical data, social factors such as IV drug use, homosexual behavior, and tattoos have increased dramatically in the last five years. Although the number of corneas intended for transplants but discarded because of hepatitis B, hepatitis C, and medical-social history have plateaued, they are still at alarmingly high levels.

Even if the factors limiting corneal utilization are not as serious a problem in the future as the extrapolated statistical report data insinuate, the slope of the utilization of corneas curve is going up at a much faster rate than curve of the population of the US. The approaching intersection of these curves in the future suggest there should be relatively greater pressure on the supply of corneas, if the population (supply) remains unchanged and demand (utilization) continues to increase.

DISCUSSION

This paper looks at the increasingly rate of tissue that is ineligible for use, including that which is recovered and then discarded. Some tissue may be discarded because eye banks recover tissue as soon as it is available to facilitate placing the tissue in preservation medium, only to receive positive serologic results at a later time. The increase in discarded tissue may also be due to false-positive tests, or overlap of multiple tests performed by different organizations.

The most recently available CDC data in the United States shows a decrease in the incidence of hepatitis

Fig 6. Hepatitis B donors in 2030

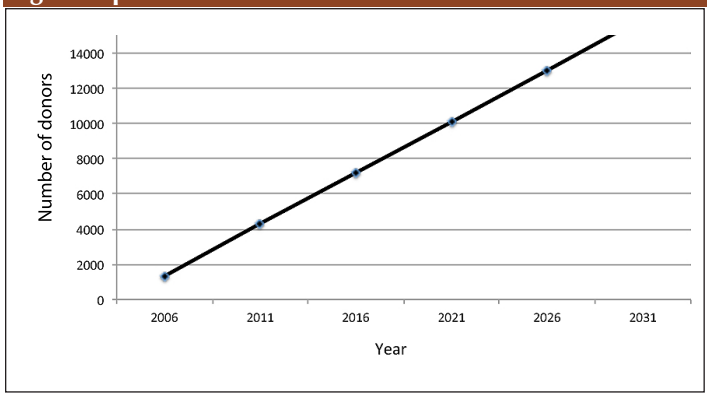


Fig 7. Hepatitis C donors in 2030

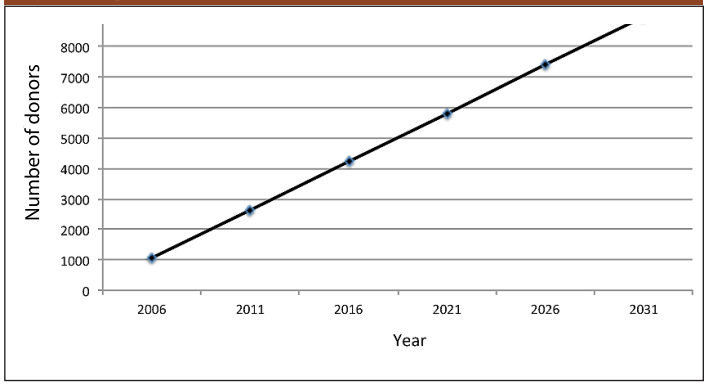


Fig 8. Medical-social history of donors in 2030

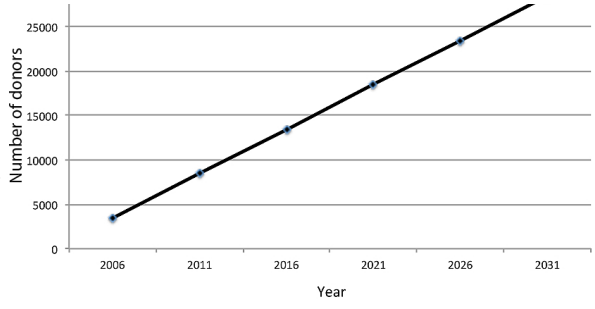


Fig. 6 shows the predicted number of donors who will be eliminated in 2031 due to hepatitis B based on extrapolation of the data in Fig. 3. Fig. 7 shows the predicted number of donors that will be eliminated in 2030 due to hepatitis C based on extrapolation of the data in Fig. 4. Fig. 8 shows the predicted number of donors that will be eliminated in 2031 due to medical-social history based on extrapolation of the data in Fig. 5.

B (Figure 9) and hepatitis C (Figure 10) in the United States.[15] Similarly, the incidence of HIV infection in the US was flat in the over 50 population age group from 2007 through 2010, the population group from which most donors come.[16] The disparity between the rising number of patients eliminated from the donor pool in the EBAA statistics and the decreasing hepatitis B and C numbers in the general population may point to a flaw in the EBAA statistical methodology, where referred deaths do not reflect the characteristics of the general population, or a flaw in the sampling techniques used to evaluate the incidence of the disease in the population. Extrapolation of the curves seen in the EBAA data (Figures 6 – 8) may falsely predict a dramatic increase in disease prevalence if the increase in numbers from 2006 to 2011 was due to a change in the way information was collected in the statistical report rather than an increase in the number of infected individuals in the population.

Reliable data for lifestyle markers like IV drug use are difficult to obtain. Multiple incidents in Kentucky, both objective and subjective, suggest that IV drug use has increased in the general population. Five out of the first eight deaths on the donor registry in 2012 in a small town in central Kentucky were under age 50, had a history of IV drug use, and were unsuitable for donation. [17]

While the US population data show a decrease in the incidence of hepatitis B and C and a flat curve for HIV, the increase in the number of cases eliminated in the EBAA data from 2006 to 2011 do not reflect this decrease. The EBAA data projections are based on extrapolating current trends n cornea usage, population data and donor demographics reported by US Eye Banks in the 2011 Eye Banking Statistical Report.

Although there are some confounding variables in this information, where patients may have more than one condition (hepatitis B, hepatitis C and a history of drug use), compilation of individual data may overestimate the problem. Lifestyle markers like IV drug use or tattoos are important because sharing needles may lead to the spread of blood borne pathogens. The extent of the problem may be more accurately surveyed at death, where every individual is evaluated, than by sampling the general population.

For economic reasons and to be good stewards of tissue, many eye banks identify unsuitable donors by family interview or medical history before efforts are

Fig 9. The incidence of hepatitis B decreased in the United States from 2001 to 2010

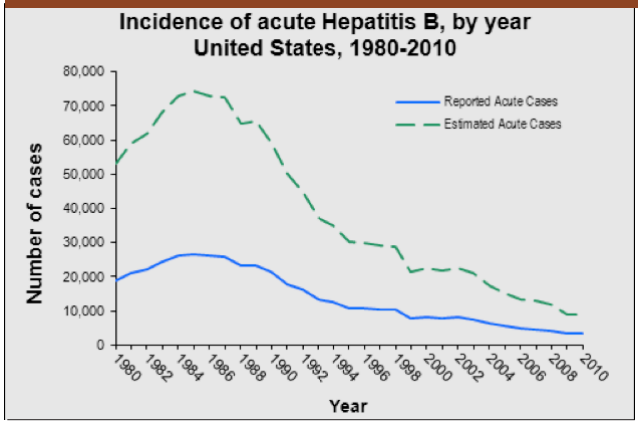
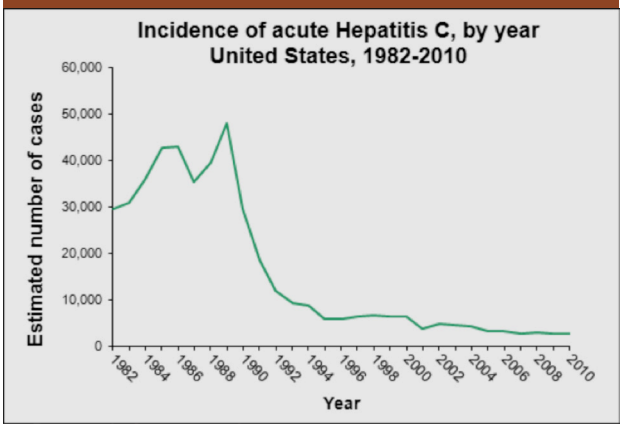


Fig 10. The incidence of hepatitis C decreased in the United States from 2001 to 2010



made to recover tissue to avoid the cost of retrieving unusable tissue whenever possible.

The information in the EBAA Statistical Report is only as good as the information sent in by the 79 member eye banks. But prudence dictates that threatening trends such as the increase in hepatitis B, hepatitis C and medical-social history noted 2006 – 2011 should be tracked until such time as they are no longer deemed to be significant.

If the projections drawn from these data are correct, an alarming number of donors will be unsuitable for transplant in the future. These projections are based on extrapolating current trends in cornea usage, population data, and donor demographics reported by US eye banks in the *2011 Eye Banking Statistical Report*. Although there are some confounding variables in this information, where patients may have more than one condition (hepatitis B, hepatitis C, *and* a history of drug use), compilation of individual data may overestimate the problem. For economic reasons and to be good stewards of the tissue, many eye banks identify unsuitable donors by family interview or medical history before efforts are made to recover the tissue to avoid the cost of retrieving unusable tissue whenever possible. The information in the EBAA Statistical report is only as good as the information sent in from the 79 member eye banks, but trends such as these in hepatitis B, hepatitis C, and medical-social history are hard to ignore.

Although we enjoy an excess of useable tissue in the US now, some attention to possible adversity in the future is prudent. For example, concern for prion disease has currently eliminated a segment of the population from becoming donors based on features in their history that were unknown at the time they lived abroad or consumed certain foods.[18,19] Data should be monitored yearly in the EBAA's statistical reports, and some attention to creative solutions that might mitigate a shrinking donor supply in the future would be prudent.

Possible solutions to alleviate some of this future stress on the donor pool are to (1) increase the corneal donation rate, (2) increase the time period for corneas to be used, (3) make certain that all donors ruled out are really unsuitable (i.e., patients with a history of drug use, previous ocular surgery, prison incarceration, or high risk behavior), and (4) find alternative sources of donor tissue such as an artificial cornea or glycerine-preserved corneas. The most cost-effective way of doing this now is to increase education on a national level to improve the consent rate in all states. Donate Life America is one such educational program that can increase donor awareness and potentially lead to more consenting donors and fewer missed transplantable corneas.

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