ORIGINAL ARTICLE

Projections in Donor Organs Available for Liver Transplantation in the United States: 2014-2025

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With the aging US population, demographic shifts, and obesity epidemic, there is potential for further exacerbation of the current liver donor shortage. We aimed to project the availability of liver grafts in the United States. We performed a secondary analysis of the Organ Procurement and Transplantation Network database of all adult donors from 2000 to 2012 and calculated the total number of donors available and transplanted donor livers stratified by age, race, and body mass index (BMI) group per year. We used National Health and Nutrition Examination Survey and Centers for Disease Control and Prevention historical data to stratify the general population by age, sex, race, and BMI. We then used US population age and race projections provided by the US Census Bureau and the Weldon Cooper Center for Public Service and made national and regional projections of available donors and donor liver utilization from 2014 to 2025. We performed sensitivity analyses and varied the rate of the rise in obesity, proportion of Hispanics, population growth, liver utilization rate, and donation after cardiac death (DCD) utilization. The projected adult population growth in the United States from 2014 to 2025 will be 7.1%. However, we project that there will be a 6.1% increase in the number of used liver grafts. There is marked regional heterogeneity in liver donor growth. Projections were significantly affected by changes in BMI, DCD utilization, and liver utilization rates but not by changes in the Hispanic proportion of the US population or changes in the overall population growth. Overall population growth will outpace the growth of available donor organs and thus potentially exacerbate the existing liver graft shortage. The projected growth in organs is highly heterogeneous across different United Network for Organ Sharing regions. Focused strategies to increase the liver donor pool are warranted. ***Liver Transpl 21:855-863, 2015***. **© 2015 AASLD.**

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Liver transplantation (LT) is a lifesaving therapy for patients with end-stage liver disease and hepatocellular carcinoma. Over the last decade, there has been a decrease in the availability of donor organs for deceased donor LT in the United States, and this has resulted in a plateau in the number of LTs performed.[1] The absolute number of organ donors has steadily increased over the years; however, there has not been a commensurate increase in the number of liver donors. The principal cause of this trend has been a decrease in the utilization of grafts, partially due to an increase in the number of graft discards.[2] This plateau has profound implications because the decrease in donor availability has exacerbated the disparity in the number of patients listed for LT and LTs performed.[3] This has resulted in prolonged waiting times for LT and higher rates of wait-list dropout due to patient death or a deteriorating medical condition.[4] More than 20% of patients listed for LT will drop off the wait list while they are awaiting LT.[5] Attempts to

Additional Supporting Information may be found in the online version of this article.

Abbreviations: BMI, body mass index; CDC, Centers for Disease Control and Prevention; DCD, donation after cardiac death; LT, liver transplantation; NHANES, National Health and Nutrition Examination Survey; UNOS, United Network for Organ Sharing.

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remedy this by increasing the donor pool by utilization of extended criteria donors [older donors, donors with fatty liver disease, and donation after cardiac death (DCD) donors] have resulted in inferior post-transplant outcomes and decreased utilization.[6,7] In addition, regulatory policy changes such as increased scrutiny of post-LT patient outcomes may have led transplant centers to become more risk-averse toward marginal grafts over time.[8]

The other reasons behind the decrease in liver donor utilization are multifactorial and include the aging population, the obesity epidemic, and the increased prevalence of diabetes.[2] The US population is expected to continue to age with projected demographic trends, and this will likely exacerbate the availability of donors.[9-11] Older donors can result in inferior graft outcomes, particularly in hepatitis C–positive recipients.[12]

Recent evidence suggests that the obesity and diabetes epidemics in the United States have plateaued in recent years; however, donor obesity and diabetes account for a large portion of the drop in liver utilization from 2004 to 2010.[2,13,14] The impact of obesity on donor utilization is largely a result of hepatic steatosis, with higher percentages of steatosis limiting the ability to conduct LT because of poor graft outcomes.[15] The correlation between obesity and liver steatosis is differential on the basis of race/ethnicity. For example, when one controls for the patient body mass index (BMI), African Americans have lower rates of significant hepatic steatosis than other subgroups, whereas Latinos have higher rates of significant steatosis.[16] Therefore, changes in the racial make-up of the US population will also affect donor organ availability over the next decade.

There are few data on the implications of demographic trends in the United States for the utilization of donors in the United States over the next decade. Although there is a common perception that organ availability is getting worse, there are few objective data to quantify expected organ availability. Therefore, we aimed to use data on expected demographic trends in the United States and past donor utilization to make projections of donor utilization for LT in the United States over the next decade. We hypothesize that liver donor availability will continue to disproportionately decrease because of demographic trends in the United States.

The study was approved by our institutional IRB.

PATIENTS AND METHODS

Data Sources

Historical Population Data

We used data from the Centers for Disease Control and Prevention (CDC) on total population statistics from 2000 to 2012, which were stratified by age, sex, and race. The race/ethnicity categories included white, black, Hispanic/Latino, and other.[17] Data from the US Census Bureau were used to obtain the population estimates by state from 2000 to 2012. We used 2 data sets from the US Census Bureau: (1) intercensal estimates of the resident population by 5-year age groups, sex, race, and Hispanic origin for states and the United States from April 1, 2000 to July 1, 2010 and (2) annual state resident population estimates for 6 race groups by age, sex, and Hispanic origin from April 1, 2010 to July 1, 2012. We then stratified these data by race, sex, and age group (18-34, 34-50, 50-64, and 65-84 years) and segregated them on the basis of the 11 regions established by United Network for Organ Sharing (UNOS). The 18- to 34-year-old age group of our models overlapped 2 age groups of the US Census Bureau data set from 2000 to 2010; consequently, the 18- to 34-year-old age group by region was estimated on the basis of the proportion of the remaining age groups by region (34-50, 50-64, and 65-84 years) of the total population of the 34- to 84-year-old age groups across all regions.[18]

Historical BMI Data

We used data from the National Health and Nutrition Examination Survey (NHANES) from 1999 to 2010 to stratify historical population data from the CDC by BMI, sex, and race.[19] The NHANES data had to be adjusted to match our modeling. For example, the race/ethnicity groups did not include "other." Given the overall obesity prevalence, the prevalence for non-Hispanic whites, non-Hispanic blacks, and Hispanics, and sample sizes of the relevant populations, we back-calculated what the prevalence of obesity would have to be for the "other" groups. Additionally, the NHANES reports data by the age groups of 20 to 39, 40 to 59, and 60+ years, but our model groups ages into 18 to 34, 34 to 50, 50 to 64, and 65 to 84 years. We imputed the obesity rates for the NHANES age groups and our predefined age groups.[19]

Donor Utilization Data

We performed a secondary analysis of the Organ Procurement and Transplantation Network database from 2000 to 2012. We determined the utilization rates of whole and split livers for all donors with at least 1 organ transplanted. We also calculated the utilization as a percentage of the overall population per year. We constructed utilization tables by year stratified by age groups, BMI (<30 or ≥ 30 kg/m^2), sex, and race/ethnicity.

Population Age, Sex, and Race Projections

Population projections in the United States for 2014 to 2025 were derived from the data from the US Census Bureau, which are stratified by age, sex, and race.[20] For the base case, we used the middle series projections.

State Population Projection

We used data from the University of Virginia's Weldon Cooper Center for Public Service on state population projections from 2010 to 2030 to estimate population projection for each UNOS region. The population projections were stratified by race, sex, and age group. Because population projections by state included information only for 2010, 2020, and 2030, the population projections from 2014 to 2019 and from 2021 to 2025 were estimated under the assumption of linear growth.[21]

Projection Development

We developed projections of donor availability from 2014 to 2025 by determining the US population–based rate of donation (donors transplanted/total population) per year and used the average donation rate from 2008 to 2012 stratified by age group (18-34, 34-50, 50-64, and 65-84 years old), race/ethnicity (white, black, Hispanic, and other), sex, and BMI (<30 or ≥ 30 kg/m^2). We then used the historic liver utilization rates (liver donors/total donors) to project future donor utilization. We used the average utilization from 2008 to 2012 and the best (2004) and worst (2012) liver utilization from 2000 to 2012 to conduct projections on liver donor availability. For regional projections, we used the historical regional rate of donation (donors transplanted/regional total population) per year and used the average donation rate from 2008 to 2012 to make regional projections on donor availability. All analyses were conducted with SAS (version 9.4; SAS Institute, Inc., Cary, NC), Mathcad (version 15.0; PTC, Needham, MA), and Microsoft Excel (version 2013; Microsoft Corp., Redmond, WA).

Sensitivity Analysis

We performed 4 separate sensitivity analyses; we varied the proportion of obese adults, proportion of Hispanic adults, and overall US adult population growth over the projection period, and we varied the change in the liver utilization rate over time. For the first sensitivity analysis, we varied the rate of BMI changes over the next decade. The ranges for the sensitivity analysis of BMI were derived from the average annual rate of increase in the US population BMI in the obese range (≥ 30 kg/m^2) from 1999 to 2010, which was approximately 0.75% per year.[19] The ranges for the sensitivity analysis for the proportion of Hispanic adults were obtained from US Census Bureau high and low race/ethnicity projections.[20] We chose to focus the sensitivity analysis on the proportion of US Hispanics because this population is projected to be the most dynamic in the United States over the coming decade with respect to other racial/ethnic groups.[20] For the overall population growth sensitivity analyses, we used the high and low population projections from the US Census Bureau data.[20] Because liver utilization has been decreasing over the last 7 years and there has not been a clear nadir in utilization, we conducted a sensitivity analysis and varied the rate of liver utilization. We calculated the average change in liver utilization from 2007 to 2012, which was a mean decrease of 0.72% per year. We then conducted our projections by increasing or decreasing the liver utilization by 0.72% per year from the 2012 rate. For the sensitivity analysis of DCD donor projections, we modeled liver utilization. There has been an increase in total DCD donors; however, there has been a decline in liver utilization from 2007 to 2012 of 3.94% per year. We modeled the average and increasing or decreasing utilization of livers from DCD donors by 3.94% from the 2012 rate. The overall DCD donation rate as a proportion of the population was averaged from 2008 to 2012.

Monte Carlo Simulation

We performed a Monte Carlo simulation in order to measure the combined impact of uncertainty in population projections, population BMI, donation rates, and utilization rates on projected donors. We defined each input variable as a distribution. The population projections were defined as normal distributions with the mean of the middle series projection and the standard deviation as one-quarter of the difference between the high and low projections. The fractions of the population with a BMI $>$ 30 kg/m^2 by age, sex, and race were defined as normal distributions with the means and 95% confidence intervals as reported in the NHANES study.[19] Donation and utilization rates were drawn from the annual empirical distributions of rates from 2000 to 2012. More details on the distributions used are in Supporting Text 1. We created projections with 10,000 Monte Carlo simulation iterations. The Monte Carlo simulation was executed with SimVoi (version 3.03; TreePlan Software, San Francisco, CA).

RESULTS

The historical trends in total donors and liver donor utilization are shown in Table 1. The number of cadaveric liver grafts used increased 49.3% from 2000 to 2006 and then slightly decreased 3.0% from 2006 to 2012. The proportion of liver grafts used per 100,000 US population plateaued in 2006 at 2.79/100,000 population and decreased since then 9.0% to 2.54/100,000 population in 2012. The utilization of livers from all donors has trended downward since 2004 from 87.92% to 81.72%% in 2012. The overall demographic trends of liver donors (race, age, and sex) did not change dramatically from 2000 to 2012 (data not shown). DCD liver utilization peaked in 2005 at 68.5%; however, there has been a steady decrease in recent years, with the 2012 liver utilization rate being 36.5%. The overall number of DCD liver donors has remained relatively stable, with 358 livers used in 2005 and in 2012, because of growth in overall DCD donation.

Figure 1 shows the utilized liver donor projections with the best (2004), worst (2012), and average liver utilization rates from 2008 to 2012. The worst liver utilization rates have been seen in recent years, and this is reflected in the projection curves. All the curves show a steady increase in the expected number of

TABLE 1. Total and Liver Cadaveric Donors and Utilization Liver Rates

Year	Number of Deceased Liver Donors	Deceased Liver Donors per 100,000 US Population	Total Number of Donors (All Organs)	Utilization (Deceased Liver Donors/Total Number of Donors), %
2000	4113	2.00	4966	82.82
2001	4251	2.04	5082	83.65
2002	4473	2.13	5250	85.20
2003	4863	2.29	5549	87.64
2004	5420	2.52	6165	87.92
2005	5869	2.70	6684	87.81
2006	6141	2.79	7035	87.29
2007	6095	2.74	7144	85.32
2008	5964	2.65	7096	84.05
2009	5942	2.61	7101	83.68
2010	5864	2.55	7093	82.67
2011	5963	2.57	7233	82.44
2012	5956	2.54	7288	81.72

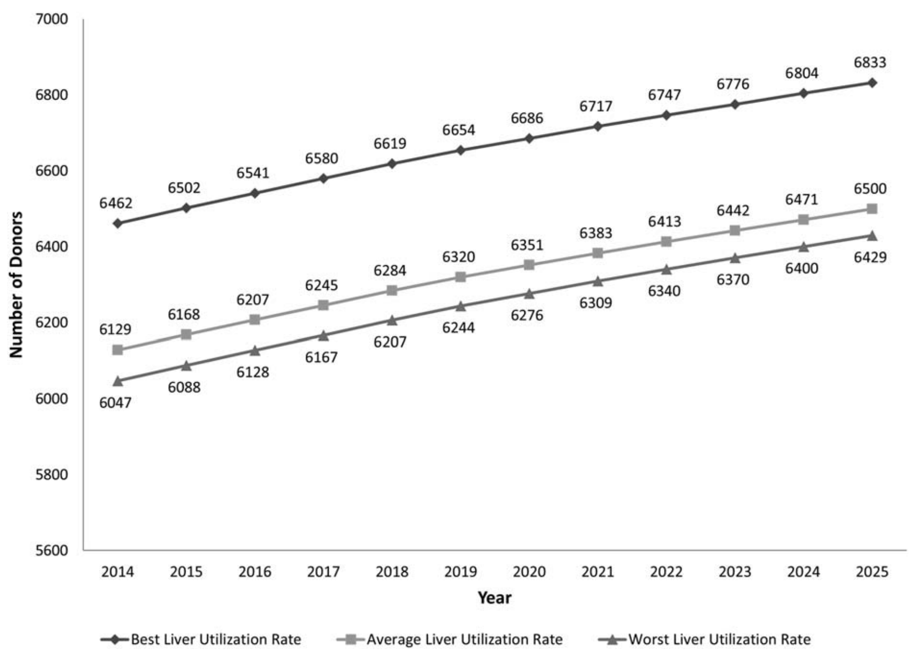

Figure 1. Projections of liver organ availability according to base-case and high-low liver utilization.

liver grafts available from 6129 (range, 6047-6462) in 2014 to 6500 (range, 6429-6833) in 2025.

Table 2 shows the projections in total adult US population growth versus projection in donor growth. The projected US population growth will consistently outstrip the growth in potential liver donors from 2014 to 2025. In total, the projected adult population growth (age, 18-75 years) in the United States from 2014 to 2025 will be 7.1%. This age range is considered acceptable at most centers in the United States for receiving LT. However, we project that there will be a 5.8% increase in the number of available donors and a 6.1% increase in the number of used liver grafts. The number of donors per 100,000 population will steadily drop over time, but the absolute number of donors will grow because of projected population growth.

The projections stratified by regions show differential projected growth of donors depending on the UNOS region, and they reflect regional changes in population growth (Table 3). The region with the most projected growth in liver donors is region 3 (10.8%), whereas region 10 is projected to have a decline in liver donors (−2.0%).

TABLE 2. Projected Population and Donor Growth From 2014 to 2025

Year	% Liver Donor Growth (Average)	Number of Livers	% Total Donor Growth	% Population Growth (18-75 Years Old)	Deceased Liver Donors per 100,000 US Population
2014	0.7	6129	0.7	0.9	2.57
2015	0.6	6168	0.6	0.8	2.56
2016	0.6	6207	0.6	0.8	2.56
2017	0.6	6245	0.6	0.8	2.55
2018	0.6	6284	0.6	0.8	2.54
2019	0.6	6320	0.5	0.6	2.54
2020	0.5	6351	0.5	0.6	2.53
2021	0.5	6383	0.5	0.6	2.52
2022	0.5	6413	0.4	0.6	2.51
2023	0.5	6442	0.4	0.3	2.51
2024	0.5	6471	0.4	0.4	2.50
2025	0.4	6500	0.4	0.4	2.49
Cumulative	6.1	+371	5.8	7.1	

TABLE 3. Liver Donor Projections by Region From 2014 to 2025

Year	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Region 8	Region 9	Region 10	Region 11
2014	177	829	1098	490	763	177	477	458	295	541	756
2015	178	833	1110	494	769	178	479	460	297	541	762
2016	178	837	1122	498	775	178	480	462	299	541	767
2017	178	840	1134	502	781	179	481	464	300	540	773
2018	178	843	1146	507	787	180	482	466	302	540	778
2019	179	846	1157	511	793	181	483	467	304	539	783
2020	179	849	1167	515	798	181	483	469	305	538	787
2021	179	852	1177	518	803	182	484	470	307	536	791
2022	178	854	1187	522	808	182	484	471	309	535	795
2023	178	856	1197	525	813	183	484	472	310	534	799
2024	178	858	1207	528	818	184	484	474	311	532	803
2025	178	860	1216	532	824	185	484	475	313	530	807
% change	0.4	3.7	10.8	8.6	7.9	4.3	1.5	3.7	6.1	−2.0	6.7

The results of the sensitivity analysis for BMI are shown in Fig. 2A. The results show that donor availability is sensitive to increases or decreases in the proportion of adults with a BMI > 30 kg/m^2, with a 6.2% range in projected liver donors. The results for the sensitivity analysis for changes in the Hispanic proportion of the US population are shown in Fig. 2B. Changes in the Hispanic population do not result in a dramatic change in the projected number of liver grafts, with a 0.62% range in projected liver donors. The impact of changes in total US population growth is shown in the sensitivity analysis in Fig. 2C. The availability of donors is also fairly insensitive to changes in these parameters, with a 1.4% range in projected liver donors. Figure 2D shows the sensitivity analysis of changes in the liver utilization rate over time. With this projection, the 2025 utilization would be 90.12% in the utilization growth scenario and 73.32% in the utilization decline scenario. The results show that liver donor availability is sensitive to utilization, with a 19.6% range at the end of the projection time period. The sensitivity analysis for DCD liver utilization is shown in Fig. 2E. The base case shows declining utilization of DCD livers under the assumption of a constant utilization rate. With increasing or decreasing utilization, mirroring trends from 2007 to 2012, we see marked changes in the available DCD liver donors, and they reflected the dramatic changes in utilization seen between 2007 and 2012.

The Monte Carlo simulation is shown in Fig. 3. Incorporating uncertainty in all the input projection variables, the projections using the Monte Carlo simulation are very similar to our base-case projections shown in Fig. 1.

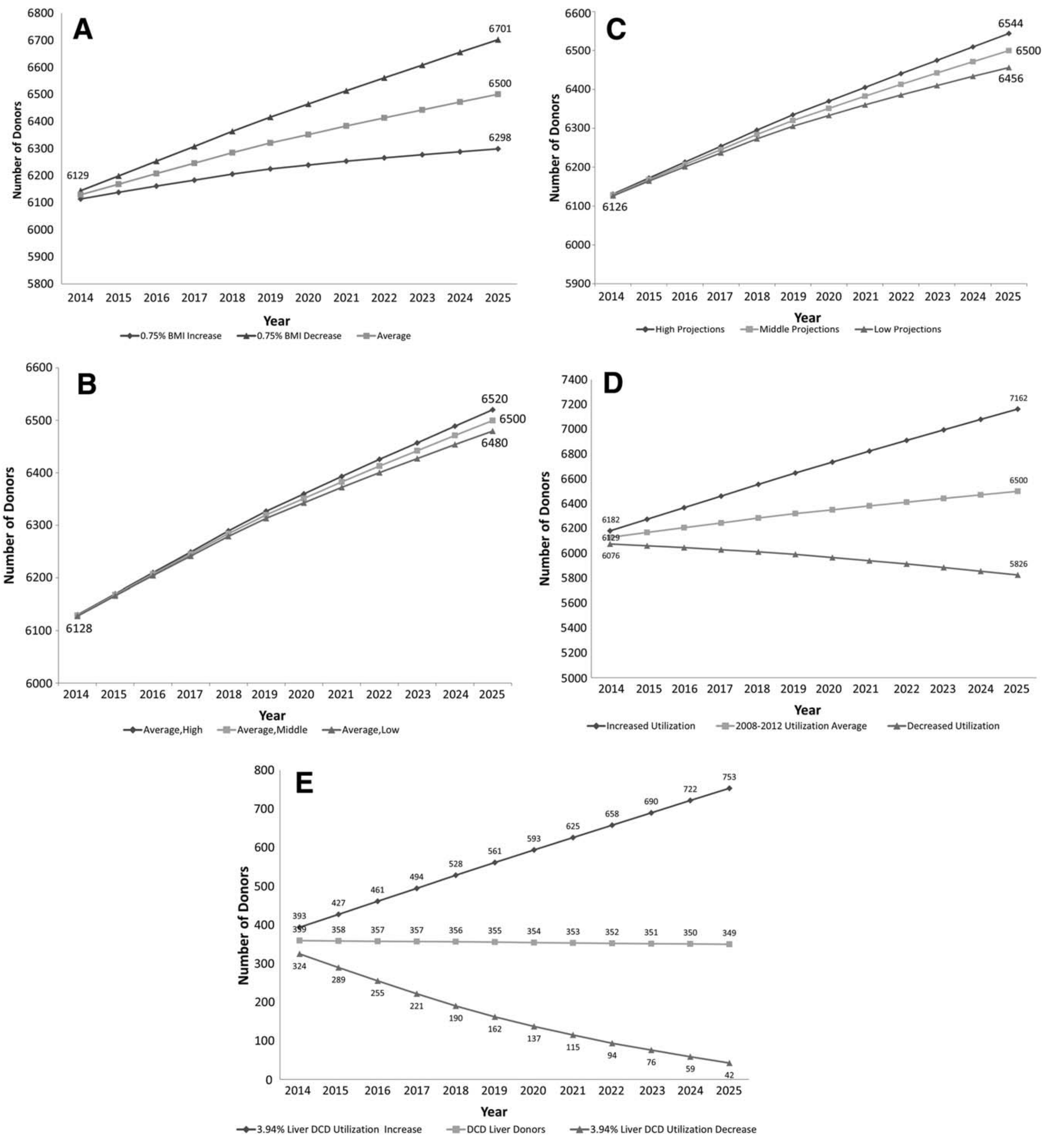

Figure 2. (A) BMI sensitivity analysis, (B) Hispanic population sensitivity analysis, (C) population growth sensitivity analysis, (D) liver utilization sensitivity analysis, and (E) DCD liver utilization sensitivity analysis.

DISCUSSION

LT remains the best lifesaving therapy for patients with end-stage liver disease and hepatocellular carcinoma; however, the ability to perform transplantation is limited by donor availability. Although there is a perception that donor availability will continue to worsen with future demographic changes in the US population, this has not been objectively studied. We found that although the donor population will increase over the next 12 years, general population growth will outstrip projected donor growth and thus potentially exacerbate the donor shortage and increase wait times for LT nationally. The projected discordance between population growth and liver

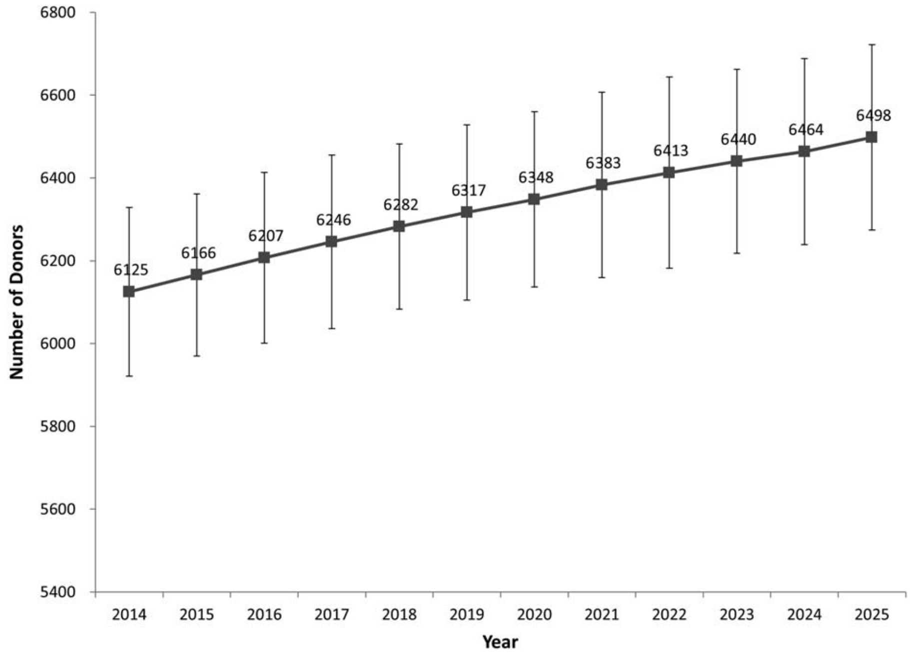

Figure 3. Monte Carlo simulation of liver organ availability.

donor growth is modest at 1%; however, the projections indicate that there is no relief in sight for the current donor shortage. There is wide regional variability in the projections. Although some regions (3, 4, and 5) are expected to have >7% growth in liver donors, regions 1, 6, and 10 are projected to have marginal or negative projected growth. There are profound implications for these regions that should be taken into account with future allocation policy and with any redistricting proposals that will be considered.

The sensitivity analyses showed that the projections were significantly affected by changes in BMI, liver, and DCD utilization rate but not by changes in the Hispanic proportion of the US population or changes in the overall population growth. Increases in the proportion of obese adults or decreases in liver utilization will further limit the availability of LTs. However, any intervention that can increase utilization will have a large impact on liver availability. For the DCD analysis, there is a wide projected range because of the marked changes in utilization in recent years.

Strategies to increase the donor pool are warranted to help alleviate the anticipated shortage in donors to decrease wait-list mortality. These include increasing donor enrollment and public awareness regarding organ donation,[22,23] optimizing the processes of organ retrieval and allocation,[24] and using technologies to increase the viability of organs with prolonged cold ischemia times and DCD donor organs.[25] In addition, regions with poor expected growth could implement more concerted efforts to increase the overall donation rate to help alleviate the projected shortages in their regions. Otherwise, we do not anticipate a major expansion in the utilization of DCD livers because of the inferior outcomes seen with these grafts, and our base case shows that the number of DCD livers transplanted will continue to steadily decline.[7] Expansion of living donor LT could also help alleviate the projected shortage; however, risks to donors remain a concern in the United States.[26,27] Broader regulatory changes that may lead to variance in risk aversion with respect to marginal grafts are more difficult to project; however, with the increased focus on outcomes and quality of care and links to reimbursement, we anticipate that risk aversion may worsen in the future.[28-30] In addition, there is uncertainty regarding the proportion of DCD donors in the future. Currently, DCD donors account for a small minority of organ donors; however, future increases would negatively affect liver graft availability.[2] We assumed maintenance of the current proportion of DCD donors in the future in our sensitivity analysis, but changes in utilization will markedly affect the number of DCD livers available. Any technologies to improve outcomes of transplanted DCD livers that lead to improved utilization could more than double the projected amount of livers available over the time period in this study.

Projecting the need for LT in the future is more uncertain because of the rapidly changing landscape of chronic hepatitis C and the emergence of nonalcoholic fatty liver disease. There is the possibility that the number of patients requiring transplantation will decrease, and this will partially alleviate the donor shortage despite our predictions. With new potent antiviral agents against hepatitis C under development and recently approved,[31] the need for LT in this population will likely diminish, although access to and the cost of these medications remain concerns.[32] However, nonalcoholic fatty liver disease–related cirrhosis and hepatocellular carcinoma have emerged as leading indications for LT, and continued growth may cause further expansion of the LT recipient wait list.[33,34] The results of our study must be contextualized with the need for organ transplants in the future, and further modeling of the demand side of LT in the coming years is warranted.

There are many strengths and weaknesses of our study. We compiled unique data elements from many sources to complete our projections, and thus, many of our input variables are dependent on single-source data. The projections of organ availability assume no major changes in donor availability or breakthroughs in procurement technologies that could dramatically increase liver utilization rates. We accounted for incremental changes that would affect liver utilization with our final sensitivity analysis, and we varied the utilization rate over time. A significant breakthrough resulting in major changes in utilization could significantly alter these projections. However, we do not anticipate approval and widespread adoption of new technologies during the relatively short time horizon of this study. In addition, BMI is an imperfect measure and has decreased validity in elderly populations, in part because of sarcopenic obesity.[35] Increased hepatic steatosis at lower BMIs in the elderly population may lead to lower than predicted availability of liver allografts. We also did not account for any other potential changes in public policy such as implied consent for donation that may increase the pool of donors available.[36]

In conclusion, we project further exacerbation of the donor shortage for LT over the next decade, with total population growth outstripping the growth in potential donors. There are marked and important regional differences in the projected growth that must be considered in regional planning and in allocation policy. Changes in the proportion of obese US adults over the next decade will significantly affect the number of available donors. This study can serve as an objective guide so that steps can be taken for future planning to help alleviate the mismatch between liver donors and recipients to prevent wait-list dropout.

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