ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Concepts for Kidney Allocation

The Organ Procurement and Transplantation Network (OPTN) is seeking feedback regarding the use of two concepts in the allocation of deceased donor kidneys. Any feedback obtained will be used by the Kidney Transplantation Committee in its work to develop a revised kidney allocation system.

Instructions for Submitting Feedback

Key Dates

Release Date: February 16, 2011

Responses Due By: April 1, 2011

Issued by

United Network for Organ Sharing (UNOS) as the organization designated as the Organ Procurement and Transplantation Network (OPTN) by contract with the Health Resources and Services Administration (HRSA)

Purpose

UNOS is requesting feedback on concepts for possible incorporation into the allocation system for deceased donor kidneys. The targeted questions asked are intended to reveal gaps and highlight specific opportunities for action that will improve kidney allocation in the United States.

Feedback Requested

UNOS welcomes your feedback on all aspects of the document and the Kidney Transplantation Committee will consider all feedback submitted by the deadline. Please note that the concepts presented in this document are not formal policy. Rather, the Committee is asking for feedback on the general approach to allocation. Once that feedback is obtained, the Committee will send out a formal policy proposal which will discuss all of the details for how candidates will be "put in line" or "rank-ordered" within the allocation groups discussed in this document.

In addition to general comments, the Committee is asking for specific feedback on the following questions:

1. Are the specific objectives of the proposed allocation system for kidney transplantation appropriate? Are there other objectives that should be considered?
2. Is the methodology to achieve the specific objectives reasonable?
3. Do you agree that the medical qualifying criteria used to estimate post-transplant survival are objective and reasonable?
4. Do you agree that the concepts proposed (i.e., survival matching and age matching) provide more system flexibility than age matching alone?

Please consider and comment on the entire proposal. Do not feel limited to the focused questions. They simply point out key issues within the document that may specifically interest some readers.

How to Submit Feedback

The preferred method for submission is by e-mail to kidneypolicy@unos.org. Attachments are permitted in the following formats only: .pdf, .doc, .txt. Please note, e-mail addresses will not be shared with Committee members; only information contained in the subject line and body of the e-mail will be shared. Please do not include identifying information in the e-mail subject line, body or attachments as this information will not be removed prior to review.

For those without internet access, responses may be faxed to 804-782-4896 (attention: Kidney Transplantation Committee Liaison), or mailed to:

Attention: Kidney Transplantation Committee Liaison
United Network for Organ Sharing
700 N 4th Street
Richmond, VA 23219

The purpose of this document is to describe concepts under consideration by the Kidney Transplantation Committee for improving deceased donor kidney allocation in the United States. The concepts presented were developed in response to feedback provided by transplant professionals, patients, donor family members, and the general republic regarding organ allocation regarding limitations of the current allocation system. Such limitations include:

- higher than necessary discard rates of kidneys that could benefit candidates on the waiting list,
- variability in access to transplantation by candidate blood group and geographic location, and
- many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.

Specific objectives for a revised kidney allocation system include:

- Better approximate graft longevity and recipient longevity so that the potential survival of every transplanted organ can be realized within biological reason and acceptable levels of access for those on the waiting list.
    - Foster or promote graft survival of the kidney transplant for candidates with longest post-transplant survival who are likely to require additional transplants due to early age of ESRD.
    - Minimize loss of potential functioning years of deceased donor kidney grafts through improved matching of recipient and graft survival.
- Improve offer system efficiency and organ utilization through the introduction of a new scale for kidney quality, called the kidney donor profile index (KDPI).
- Make comprehensive data better available to patients and transplant programs to guide them in their renal replacement choices.
- Reduce differences in transplant access for populations described in the National Organ Transplant Act (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).

The Committee has learned that most stakeholders desire an allocation system that is straightforward and easy to understand. Stakeholders at a public forum in St. Louis in 2009 recommended approximated donor/recipient age matching as a straightforward approach to kidney allocation. Other stakeholders at that meeting recommended prioritizing kidneys from donors under the age of 35 to candidates under the age of 35 as a way to better match graft and recipient longevity. The Committee considered and modified these approaches to the concepts presented in this document which can be summarized as:

1. Utilizing a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process. The KPDI is a continuous scale for measuring kidney quality to estimate the potential function of a donated kidney if it were transplanted in to the average recipient.

2. Allocating the highest quality kidneys (KDPI 20% and below) to the candidates with the highest estimated post-transplant survival (EPTS). Such kidneys account for 20% of available kidneys at this time.

3. Allocating remaining kidneys (80%) such that candidates have highest priority who are within 15 years (older or younger) of the donor's age.

Background and Significance

As of March 21, 2010, 84,056 individuals were listed for kidney transplant. The demand for kidney transplant has steadily increased since the Organ Procurement and Transplantation Network (OPTN) began keeping records. However, the number of kidneys available from deceased donors has not kept pace with the increasing demand. The demand is projected to continue to grow given the increases in the number of Americans with end stage renal disease (ESRD) and chronic kidney disease (CKD).

In a perfect scenario, all who need a kidney transplant would receive one without delay. However, the shortage of deceased donor organs means that most candidates for kidney transplantation have to wait, oftentimes for years before receiving a transplant. Some transplant candidates do not survive long enough to receive a kidney from a deceased donor and die while on the waiting list. Other candidates are fortunate to receive a kidney from a living donor. While the number of living donor transplants has increased steadily over time, even with these additional kidneys, there is not enough supply to provide a transplant to all who need one.

Organ allocation is the process the OPTN uses to determine which transplant candidates are offered which organs. Each organ allocation system attempts to achieve different goals. For example, livers are allocated based on a candidate's chance of dying while waiting for a transplant. Those candidates at highest risk are transplanted ahead of candidates at lower risk. Lungs are allocated based on the candidate's chance of dying while waiting for a transplant and also on the chance of dying during the first year following transplant. In this way, the liver and lung allocation systems both attempt to minimize death on the waiting list. The lung allocation system is designed also to maximize survival in the first year after transplant. Kidneys are currently allocated based primarily on how long a candidate has been waiting. This is not how the Kidney allocation system was initially designed. Initially, allocation priority was heavily weighted based on closely a candidate 'matched' a kidney by tissue type testing. In the past, closer matching was necessary for acceptable results. With improvement in anti-rejection medications, the priority for tissue typing has been decreased greatly over the last several decades. While the current design of giving most of the priority based on waiting time may be perceived as "fair", it does not strive to minimize death on the waiting list nor promote maximize survival following transplant. It does not recognize that all candidates do not have the same ability to survive the wait. It does not attempt to match the characteristics of a donor's kidney to the candidate's characteristics to promote a long and healthy survival post-transplant. The system can be better and it can be designed to achieve more in the way of health and longevity than it currently does.

With the belief that the system can be improved, the Kidney Transplantation Committee, under direction from the OPTN Board of Directors, set out to design a new kidney allocation system. This process has taken almost six years to date and has involved hundreds of individuals including transplant professionals, transplant recipients, transplant candidates, donor family members, living donors, and members of the general public. In an effort to understand the current system's limitations and opportunities for improvement, the Committee held a series of public hearings, two public forums, gave many presentations to stakeholders, and reviewed hundreds of submitted comments.

During the public hearings, the Committee heard from the transplant community that the limitations of the current system include the following:

- high discard rates of kidneys (especially those from expanded criteria donors [ECD]) that could benefit candidates on the waiting list,
- variability in access to transplantation by blood group and geographic location, and
- many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.

From the feedback provided at the forums, the Committee learned that most people want a system that is straightforward and easy to understand. Some stakeholders specifically recommended approximate age matching as an easy to understand allocation approach for the Committee to investigate. The Committee's findings validated this recommendation. Therefore, one of the concepts presented in this document is an age matching component to allocation. The Committee also learned that while most people agree that extreme mismatches in kidney and recipient survival should be avoided (e.g., a kidney with an estimated 20 years of survival allocated to a person with an estimated survival of 6 months), that less stark mismatches (e.g., a kidney with an estimated 6 years of survival being allocated to a person with an estimated survival of 5 years) are acceptable and, in fact, desirable. The recipient of such a transplant may not have to return to dialysis before death, thereby improving the recipient's quality of life for the duration of his or her life. Based on the feedback provided throughout this process, the Committee developed the following goals for a new allocation system.

- Better approximate graft longevity and recipient longevity so that the potential survival of every transplanted organ can be realized within biological reason and acceptable levels of accessibility to those on the waiting list.
    - Foster or promote graft survival of the kidney transplant for candidates with longest post-transplant survival who are likely to require additional transplants due to early age of ESRD.
    - Minimize loss of potential functioning years of graft through improved matching of recipient and graft survival.
- Improve system efficiency and organ utilization through the introduction of kidney donor profile index (KDPI).
- Make comprehensive data better available to patients and transplant programs to guide them in their renal replacement choices.
- Reduce differences in transplant access for populations described in the National Organ Transplant Act (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).

In order to reach these goals, the Committee proposes:

1. Utilizing a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process. The KPDI is a continuous measure used to estimate the potential function of a donated kidney if it were transplanted in to the average recipient.

2. Allocating the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) than the donor are prioritized. This is a 30 year time span around each deceased donor's age.

3. Allocating some kidneys (20%) by the combination of the kidney donor profile index (KDPI) and candidate estimated post-transplant survival (EPTS).

Some may ask why the kidney allocation system needs to be changed right now. There are several reasons for updating the system at this time. One of the most important reasons for overhauling the system relates to the increasing trends in the demand for kidneys from deceased donors. The current system does not provide sufficient incentive to utilize all donor kidneys because those who are likely to benefit from some organs are not necessarily prioritized for that particular organ. There are only two classifications for deceased donor kidneys within the current allocation system: standard criteria donor (SCD) and expanded criteria donor (ECD). We know that the potential survival for these two classifications currently overlap, meaning that some ECD kidneys function better than some SCD kidneys. However, ECD kidneys are more likely to be discarded than SCD kidneys.

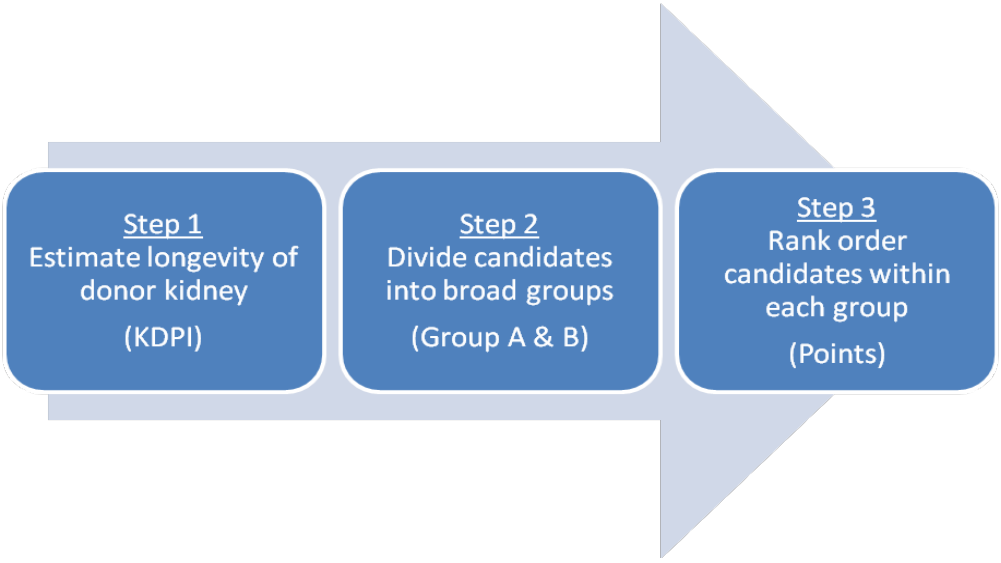
This policy development process has taken six years and a formal proposal is not expected to be circulated for public comment before fall 2011. The earliest possible time for consideration by the Board of Directors is June 2012. The OPTN is committed to developing and implementing a system that improves kidney allocation, better serves the nearly 90,000 individuals who are currently listed, and is prepared to serve the many individuals who will require kidney transplantation in the future.

While the improvements to the overall approach of the system (as described above) are important, updating the system now also has some other technical considerations. UNOS, as the OPTN contractor develops and maintains the computer system that matches organ donors and potential recipients and has done so since the inception of the OPTN in 1986. The national kidney allocation system has never been completely overhauled, rather, incremental changes to local and regional allocation systems have been added over time. Under the OPTN Final Rule, donation service areas (DSAs) are allowed to request variances to the national allocation system. The purpose of these variances is to test potential improvements to the national system on a smaller scale. The variances are to be time-limited and answer a research question, however, many of the kidney allocation variances have been operating for many years as a way to address some of the limitations of the national system. Thirty-nine out of the fifty-eight DSAs operate at least one variance or Alternative Local Unit (ALU) to the national allocation system which means that kidneys are not allocated uniformly across the country. Updating the system will allow us to recalibrate the system, eliminate local and regional variances to allocation and begin to study the outcome of a truly single national kidney allocation system.

Concepts Under Consideration

How would kidneys be allocated?

Organ allocation is the process of determining which candidates are offered which organs. For kidney allocation, this process would start based on the characteristics of the kidney. The estimated longevity of the kidney that is being donated creates the groups in which the candidates are first divided as to whether they will receive priority for that specific kidney. The two groups are also broken into divisions based on factors such as geographic location (i.e., local, regional, national), pediatric status, and degree of sensitization (i.e., difficulty matching with donors). Once the candidates are grouped (we will call them Group A and Group B from now on for clarity), they are rank ordered, or put in order in line, within that group by criteria such as time on dialysis (or with a GFR<20) and degree of sensitization (amount of antibodies against other people, called the CPRA or calculated panel reactive antibodies). The groups and the rankings are based on various criteria that we will review below.



The table below compares the current system groups to the proposed system groups.

Current System Groups	Proposed System Groups
• Kidneys meeting expanded criteria donor (ECD) thresholds are allocated first to candidates willing to accept these kidneys. • Kidneys not meeting ECD thresholds are allocated to all candidates on the waiting list as standard criteria donor (SCD) kidneys.	• Kidneys with a KDPI >20% are allocated first to candidates who are between 15 years older and 15 years younger than the donor. • Kidneys with a Donor Profile Index (KDPI) score <=20% are allocated first to candidates with the longest 20% estimated post-transplant survival (EPTS).

In this section, we describe the elements that are used to determine the groupings including the kidney donor profile index (KDPI) and the post-transplant survival calculation. We also describe the proposed allocation sequence and compare it to the current allocation sequence.

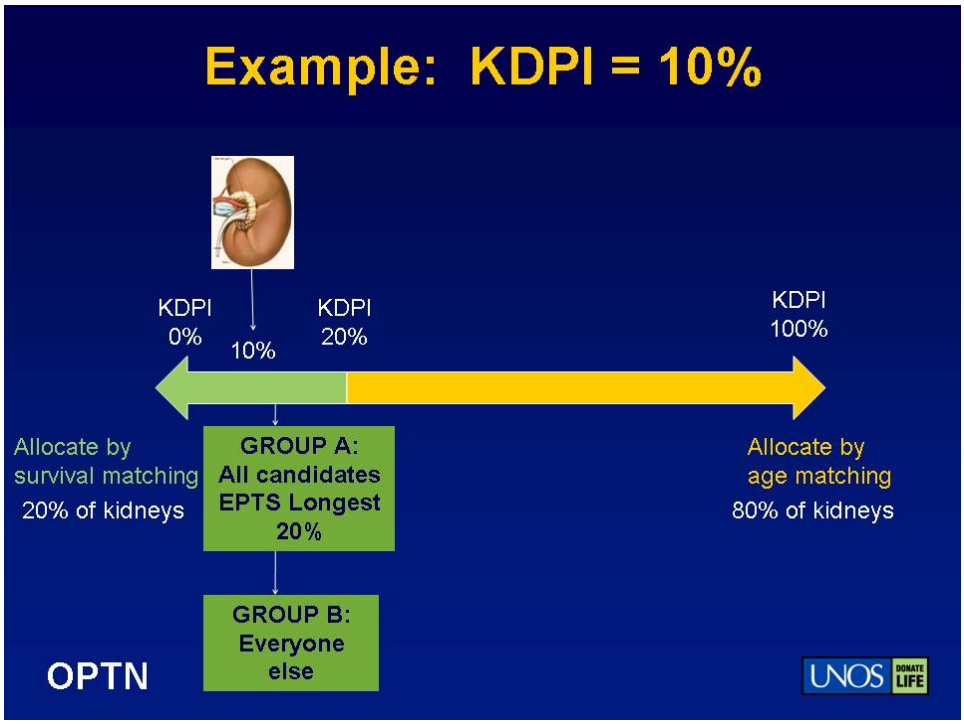
Kidney Donor Profile Index: How it may be used in a new allocation system.

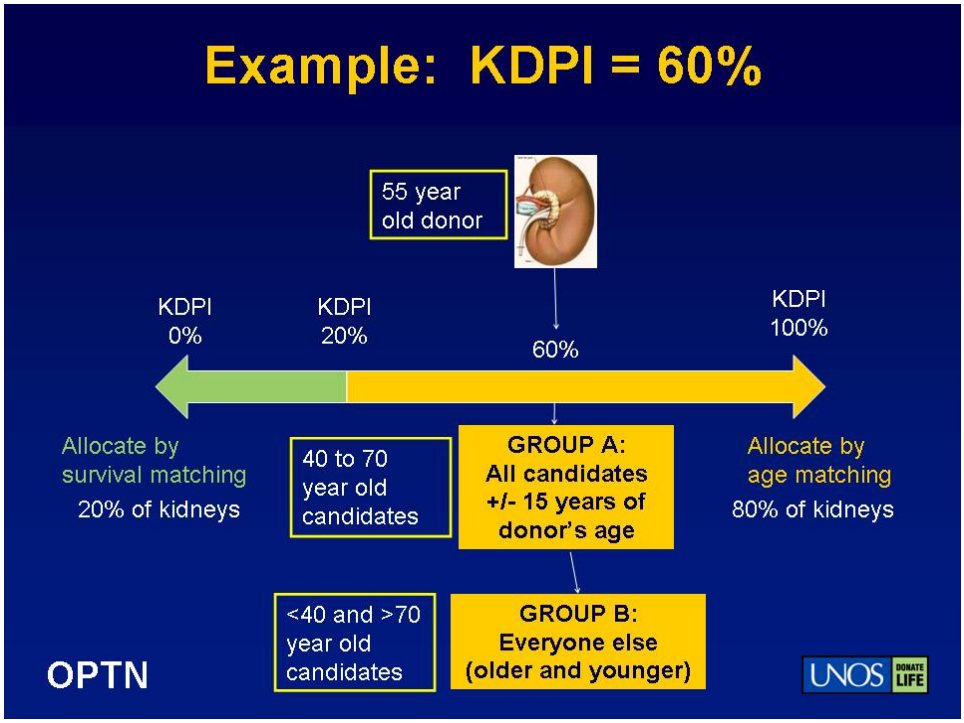
KDPI (Kidney Donor Profile Index) summarizes the risk of graft failure following kidney transplant by combining a variety of donor factors into a single number. The KDPI assumes the donated kidney is being transplanted into the 'average' recipient on the wait list based on the Rao, et al. paper[1]. Unlike the current system which classifies a kidney as either an SCD or an ECD, KDPI provides a continuous score. KDPI provides much more information for clinical decision making for transplant professionals and patients. KDPI is based on the following **donor characteristics (and *only* on donor characteristics)**:

- age
- race/ethnicity
- hypertension
- diabetes
- creatinine
- cerebrovascular cause of death
- height
- weight
- donor after cardiac death
- hepatitis c

At the time a kidney is offered, the Organ Procurement Organization already enters all of this information listed above into the computer system (DonorNet®), so a KDPI score can be easily generated. The KPDI score is calculated based on the donor information only, NOT on the candidate information. If the KDPI score is <=20% (kidneys with the predicted longest function), the donor's kidneys will first be offered to local candidates who have at least the 20% longest estimated post-transplant survival before being offered to all other candidates. If the KDPI score is >20%, the kidney is first offered to candidates who are between 15 years older and 15 years younger than the donor before being offered to all other candidates. The diagram below depicts both scenarios for two different kidneys.

[1] Rao PS, Schaubel DE, Guidinger MK, Andreoni KA, Wolfe RA, Merion RM, Port FK, Sung RS. A comprehensive risk quantification score for deceased donor kidneys: The kidney donor risk index (KDRI). Transplantation 2009; 88(2): 231-236.


Example: KDPI = 10%
KDPI 0%
10%
KDPI 20%
KDPI 100%
Allocate by survival matching
20% of kidneys
GROUP A: All candidates EPTS Longest 20%
Allocate by age matching
80% of kidneys
GROUP B: Everyone else
OPTN
UNOS DONATE LIFE


Example: KDPI = 60%
55 year old donor
KDPI 0%
KDPI 20%
60%
KDPI 100%
Allocate by survival matching
20% of kidneys
40 to 70 year old candidates
GROUP A: All candidates +/- 15 years of donor's age
Allocate by age matching
80% of kidneys
<40 and >70 year old candidates
GROUP B: Everyone else (older and younger)
OPTN
UNOS DONATE LIFE

Whether a candidate is in the first allocation group (which we will call Group A) or within the second allocation Group (which we will call Group B) depends on the medical characteristics of the donor kidney and the medical characteristics of the candidate. For example, if a donor kidney becomes available with a KDPI score of 35% (therefore, KDPI >20%), it will be allocated first to candidates within 15 years older or younger than the donor. Table 1 depicts how candidates would be grouped for three different donor kidneys with KDPI scores >20%. In these examples, no one candidate appears in Group A for all available kidneys. Rather, candidate priority changes based on the donor age in relationship to the candidate's age.

Table 1: For Kidneys with KDPI > 20% (Note, these are not the 20% longest functioning kidneys)

		Donor 1 Age: 34	**Donor 2 Age: 15**	**Donor 3 Age: 55**
Group A	**Age**	19 to 49	0 to 30	40 to 70
Group B	**Age**	<19 or >49	>30	<40 or >70
Candidates	**Age**	**GROUP**	**GROUP**	**GROUP**
Mary	30	A	A	B
David	60	B	B	A
Manuel	39	A	B	B
Sophia	21	A	A	B

If a donor kidney that becomes available with a KPDI score of <=20% (regardless of donor age), it will be first allocated to candidates with the longest estimated post-transplant survival of <=20% (Table 2).

Table 2: For Kidneys with KDPI <=20% (Note: the 20% predicted longest functioning kidneys)

		Donor X KDPI: 10%
Candidates	**Estimated Post-Transplant Survival (estimated percentile or "out of 100 candidates")**	**GROUP**
Mary	19%	A
David	75%	B
Manuel	27%	B
Sophia	12%	A

For both situations above (Table 1 and Table 2), if a kidney is not accepted for a candidate within Group A, the kidney will then be allocated to candidates in Group B.

Estimated Post-Transplant Survival (EPTS)

When a candidate is offered a kidney for transplant, the information available about the candidate at the time of the organ offer will be used to determine the candidate's estimated post-transplant survival (EPTS). The calculation for estimating post-transplant survival is based on four factors:

- candidate age,
- length of time on dialysis,
- any prior organ transplant, and
- diabetes status.

While no calculation will be able to predict life expectancy with 100% certainty, these four factors provide a reasonable estimate for identifying those candidates who have the longest possible estimated post-transplant survival (EPTS). The committee investigated other calculations, including life years from transplant (LYFT) which used additional factors but did not provide substantially greater predictive power.[2] Also, feedback from stakeholders, including organizations representing patients and transplant professionals, indicated that using more factors increases the complexity of the system to the point of confusion. The OPTN recently convened an Expert Panel to identify additional factors that could improve survival estimates in the future. The collection and evaluation of these factors will take considerable time, three or more years, but the OPTN will continue to work to improve organ allocation through better data collection.

Candidates who are in the top 20% for estimated post-transplant survival (EPTS) are not shut out of receiving organs from kidneys from donors with a KDPI >20%. When these candidates are within 15 years older or 15 years younger than the donor, they appear within Group A. As shown above in Tables 1 and 2, some candidates (Mary and Sophia above) will appear in Group A for kidneys from donors within 15 years older and younger, and from donors with a KDPI score <=20%. The opposite is also true as Candidates who appear in Group B for either quality of kidney may receive that kidney if no one in Group A is appropriate for that kidney or accepts that kidney offer.

The Allocation Sequence

The allocation sequence refers to the order in which kidneys are offered to candidates on the waiting list. In this section, we describe how the concepts of KDPI and EPTS and the groups/divisions described above come together to form the allocation sequence. ***The Committee has not yet finalized how candidates will be rank-ordered within each division.***

2 Wolfe RA, McCullough KP, Leichtman AB. Predictability of survival models for waiting list and transplant patients: calculating LYFT. Am J Transplant. 2009 Jul;9(7):1523-7.

The allocation sequence described below only includes those kidneys that are allocated to candidates listed for a solitary kidney (a kidney alone transplant without another organ transplant at the same time). Priority for candidates who are listed for a kidney-pancreas, kidney-heart, or kidney-liver transplant is not altered in this proposal. In 2008, 825 kidneys were transplanted with pancreata and 379 kidneys were transplanted with livers. The Pancreas Transplantation Committee is currently working to establish listing criteria for candidates awaiting simultaneous pancreas-kidney transplantation. The Liver and Intestinal Organ Transplantation Committee is working with the Kidney Transplantation Committee to establish listing criteria for candidates awaiting simultaneous liver-kidney transplantation.

The table below shows the high-level allocation sequence. A complete allocation sequence, with all of the divisions is included as Appendix A.

Current Allocation Sequence	**Proposed Allocation Sequence**
• Zero-antigen mismatches • Local prior living organ donor • Highly sensitized local • Payback debts • Local pediatric (donor age <35) • Local all candidates • Regional pediatric (donor age <35) • Regional all candidates • National pediatric (donor age <35) • National	• Group A zero-antigen mismatches • Local prior living organ donor • Local pediatric (donor age <35, this may change to KDPI range) • Local Group A • Group B zero antigen mismatches • Local Group B (All remaining local candidates) • Regional pediatric (donor age <35) • Regional Group A • Regional Group B (All remaining Regional Candidates) • National pediatric (donor age <35) • National Group A • National Group B (All remaining Candidates)

Rank-Ordering

The purpose of this proposal is to solicit feedback on the concepts of broad age matching for the majority of kidneys (80%) and survival matching for a small portion of kidneys (20%). As the next phase, the Committee will evaluate the current rank-ordering policies and determine if any changes need to be made. Those changes would be circulated for public comment at a later time. Briefly, we describe the way that candidates are rank-ordered in the current system. This description is only for the purpose of evaluating the results of the simulation modeling presented in the following section.

Within each category, candidates currently receive the following points:

- 1 point per year since listing (waiting time),
- 4 points if CPRA >=80%,
- 4 points if candidate is a prior living donor[3] (very few candidates are prior living organ donors), and
- 1 point for 1 DR HLA mismatch, 2 points for 0 DR HLA mismatch.

For purposes of the simulation modeling, the only changes that were incorporated into the rank-ordering within each category were the changes to waiting time (i.e. dialysis time in addition to wait time, as described below). None of the other point values described above were changed.

Currently, candidates accrue waiting time when they are placed on the list and have a GFR<=20% or are on dialysis. It will be proposed that the waiting time calculation be modified to allow for time to be back-dated to the most recent start of chronic maintenance dialysis if the candidate is listed after this date. If the candidate previously received a kidney transplant, the waiting time would be calculated from the point of the most recent initiation of dialysis. These changes were discussed publicly during the 2009 forum and were well supported at that time. This method of calculating waiting time has been tested since 2005 in several OPOs as a committee sponsored alternative system.

Supporting Evidence

[3] Candidates who are prior living organ donors receive 4 additional points for offers from regional or national donors. For local donors, these candidates are categorized ahead of all local candidates.

During the course of policy development, the Committee reviewed several forms of supporting evidence including:

- descriptive statistics regarding the past and current state of kidney allocation and transplantation in the United States (see Background and Significance);
- simulation modeling to determine the effects of potential future policy changes (Kidney-Pancreas Simulation Allocation Modeling [KPSAM]); and
- data from other recent allocation policy changes.

The thresholds for age (+/-15 years), KDPI (top 20%), and post-transplant survival (top 20%) in the proposed allocation system were determined based on recent information about the donor and candidate populations. The Committee realizes that the data available to estimate post-transplant survival (time on dialysis, candidate age, prior transplant, and diabetes status) are limited. One of the criticisms of the LYFT calculation was that with the current data available, it did not differentiate between medically similar candidates. The feedback from the public was that the LYFT calculation with its current limitations should not be used as the major determinant to allocate most kidneys at the current time. So the Committee decided to only use post-transplant survival as a measure of relative medical appropriateness for a small proportion of deceased donor organ allocation. In reviewing median survival for recipients from 2004-2007, the Committee determined that the top 20% of candidates had post-transplant survival that was the most discernible from other candidates (Figure 1). While the Committee acknowledges that the difference between a candidate in the 19th percentile and the 21st percentile will be marginal, it believes that this system offers the best compromise by only allocating a small portion of kidneys to these candidates, while allocating the majority of kidneys to all candidates based on age matching. The candidates on the margin of top 20% may move up or down based on other candidates added or removed from the list.

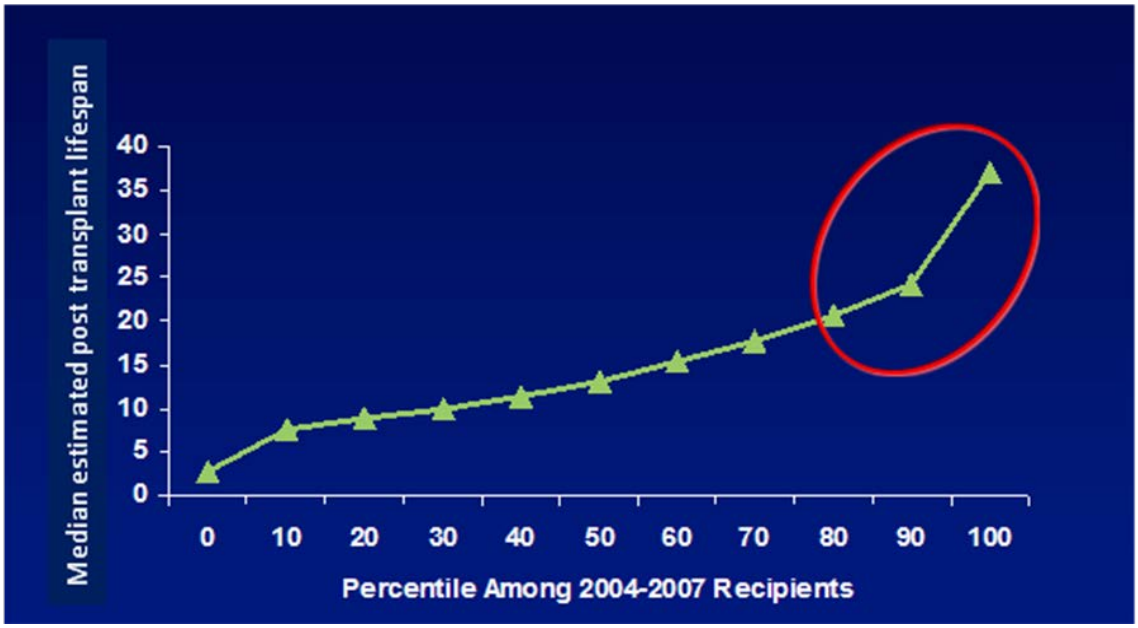


Figure 1: Distribution of projected median recipient life spans: 2004-2007. (Uses patient factors only) In this chart, a recipient with an estimated post-transplant survival of 25 years is roughly in the 90th percentile. A recipient with an estimated post-transplant survival of 13 years is roughly in the 50th percentile.

The Committee determined that the kidneys from donors with the longest predicted graft survival (a KDPI score <=20%) should be allocated first to candidates with the longest predicted post-transplant survival (an estimated post-transplant survival in the top 20th percentile) (Figure 2). Since the number of candidates far exceeds the number of donors, it is unlikely that any candidate in the top 20% would "jump to the top of the list" without significant ESRD time, since ESRD time will be a key factor in rank-ordering candidates within the Top 20% group. Participants at both prior forums voiced the concern that current candidates on the waiting list would perpetually be pushed back by candidates joining the waiting list. This concern was countered by a concern that there would be little possibility of a pre-emptive transplant, (i.e., a transplant before a candidate begins dialysis). To balance these competing concerns, the Committee retained the priority for local zero-antigen mismatched transplants and decided would continue to allow time accrual for listed candidates with a GFR< 20ml/min who are not yet on dialysis. So the possibility for a pre-emptive transplant remains for all candidates while ensuring that candidates who have been waiting are not continuously delayed by new candidates joining the waiting list. This allocation priority of the longest predicted functioning grafts to the candidates with the longest estimated post transplant survival (EPTS) was in direct response to a very frequently cited weakness in the current allocation policy: the allocation of organs with very long potential function to candidates with very short expected survival after transplantation, and vice versa.

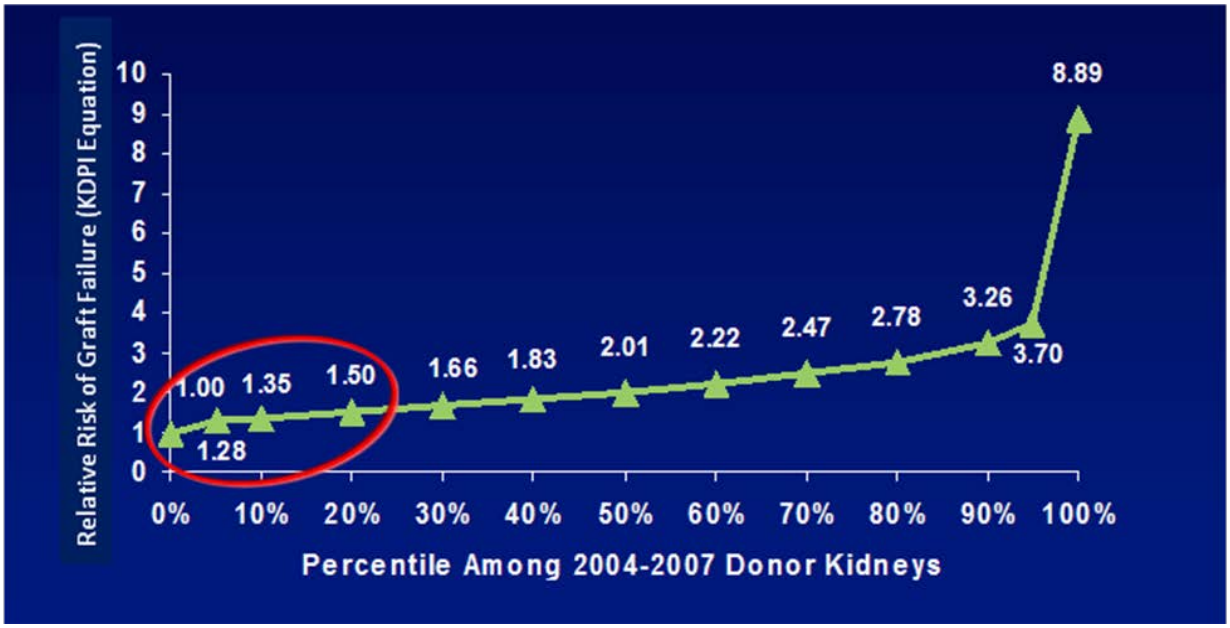


Figure 2: Distribution of relative risks for donor kidneys: 2004-2007. (Uses donor factors only). As an example, in this chart, kidneys in the 50th KDPI percentile have a relative risk of graft failure of 2.01.

The Committee reviewed the distributions of KDPI scores across donor ages and found that though donor age is an indicator of KDPI, there is still substantial overlap across the different age groups. Figure 3 shows how some donors between the ages of 50-54 have KDPI scores that overlap those of donors ages 25-29. Because of this overlap, with an age-based allocation system of +/-15 years, all candidates will still have opportunities to receive a kidney with an average KDPI.

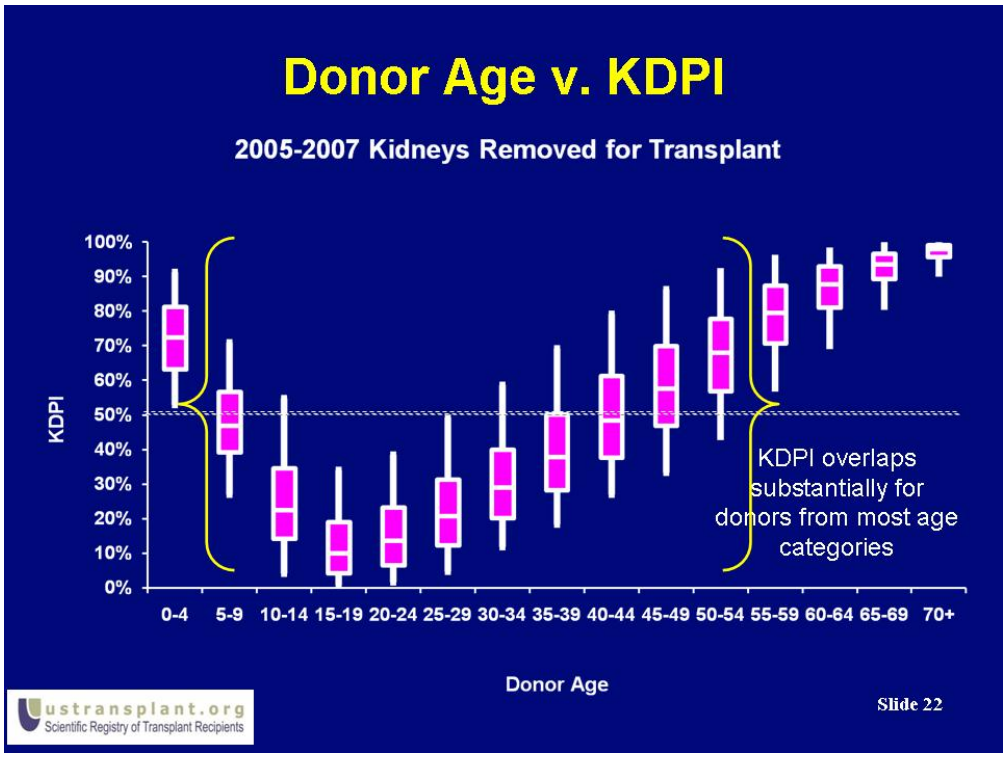


Figure 3: Donor age versus kidney donor profile index (KDPI). Based on kidneys removed for transplant 2005-2007.

When determining the age brackets to be used for kidney allocation, the Committee considered recipient ages within +/-10 years, +/-15 years, +/-20 years of the donor (Figure 4). The Committee selected +/- 15 years because the donor distribution is substantially younger than the candidate population. The +/-15 years allocation rule results in a broader distribution of donor organs available across the spectrum of candidates. As shown in Figure 4, the distribution of newly listed candidates in 2008 peaks around 60 years of age. The +/- 10 years system results in fewer donors available to candidates in their mid to late 30's, while the +/-20 years system results in a substantial increase in donors available to these younger candidates when compared to older candidates. The +/-15 years system smoothed out the distribution of organs available to candidates of all ages.

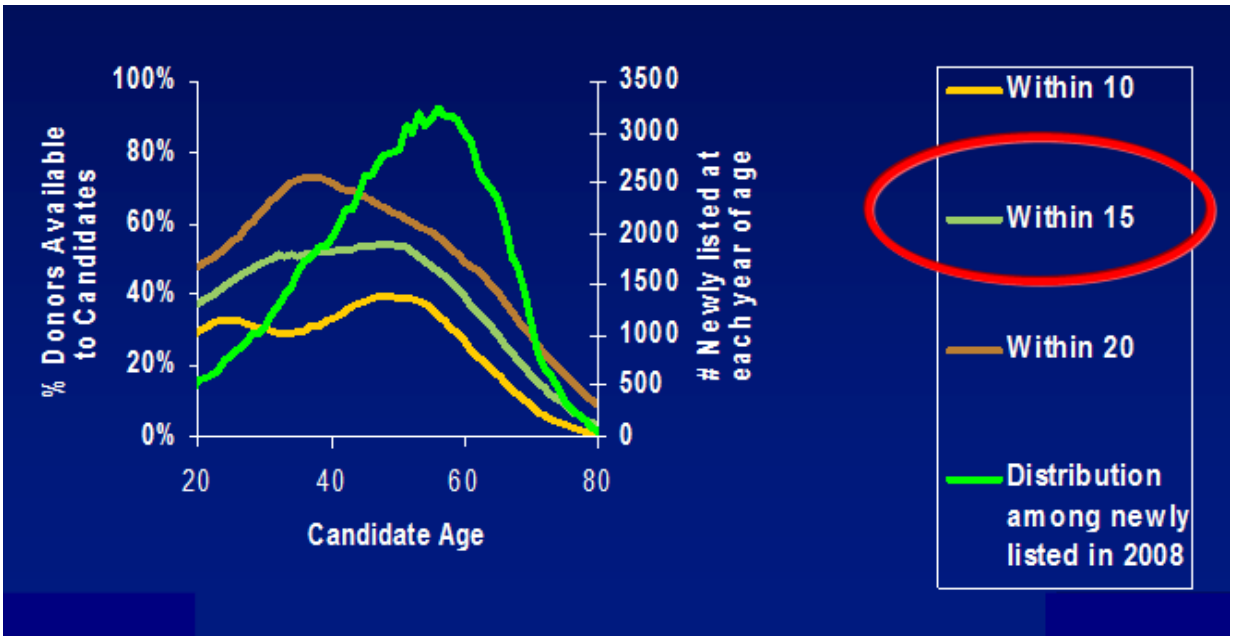


Figure 4: Candidates with priority if age is within 10, 15, or 20 years of donor age.

Predicting Future Changes

Over 41 different simulation runs were produced by the Scientific Registry of Transplant Recipients (SRTR) in response to requests from the Kidney Committee (Appendix B). The Committee presented the results of many of these runs at the two public forums. Previous versions can be reviewed at http://unos.org/kars.asp. Below, we present the results from the simulation runs of the proposed system and the baseline system.

- Baseline: Kidneys are allocated according to current allocation rules with the following exceptions. The rules for the A_2/A_2B kidneys into B candidates committee-sponsored allocation system are incorporated. Waiting time is recalculated not as the candidate's time since listing, but as the candidate's dialysis start date or the time point when the candidate's GFR <=20ml/min, whichever comes first. Paybacks are also eliminated in this run. This 'new baseline' is labeled Run 36 in the SRTR simulation data (Appendix B). These changes (from Simulation Run 35 in the detailed simulation data) reflect policy changes that the Committee have long considered as likely changes to the national allocation system and whose effects needed to be evaluated separately from the major concepts of age matching and survival matching.[4] Finally, this run allocated local simultaneous kidney-pancreas transplants according to the pancreas rules, not the kidney rules (i.e. "kidney follows pancreas"), in a manner similar to the allocation of simultaneous kidney-heart or kidney-liver transplants.

[4] To review the results of the baseline system to simulated results of the current kidney allocation rules, please see Appendix C.

- Proposed: Kidneys from donors within the top 20% for KDPI are allocated first to candidates with the longest 20% estimated post-transplant survival. Kidneys from donors with KDPI scores between 21% and 100% are first allocated to candidates within 15 years older and younger than the donor. For reference, the proposed system is abbreviated **(Top 20%, then +/-15 years)** throughout the document.

Please note that the rank-order of candidates within each of the groups mentioned above is based on the current national kidney allocation rules with the following exception: waiting time is calculated as either time on dialysis or time since listing with a GFR<=20ml/min, whichever is longer.

When comparing the proposed system to the baseline, the proposed system is expected to increase the total life span following transplant and total graft years of life. More specifically, the proposed allocation system is expected to result in an additional 15,223 years of life following transplant for recipients of one year's worth of deceased donor kidney transplants. If the fact that these recipients would have lived some time on dialysis even if they had not received transplants is accounted for, there are still 5,112 extra years in terms of the lifespan benefit due to kidney transplantation. Simulation modeling results, while useful, are not guarantees of future returns. In past validations, simulations have predicted the direction, and reasonably accurately predicted the magnitude of changes in patient outcomes due to policy changes. All of the simulation results presented in this document assume no changes in procurement, listing, and acceptance patterns. In addition to these assumptions, there is a certain amount of random variability in patient outcomes. When examining the evidence in this section, please keep these facts in mind, especially when evaluating small (e.g. one or two percentage point) changes in patient outcomes. For example, in the Table below, the number of transplant recipients is estimated to change from 10,974 to 10,930 a year, a decrease of 44 transplants. However, the number of transplant recipients are not statistically different, so this difference of 44 transplants is likely not real. In fact, the Committee is confident that the number of recipients will increase since acceptance patterns are highly likely to change with a new allocation policy, but the simulation system cannot predict this behavior change. Of the values below, all except for the number of transplant recipients are statistically different in the baseline as compared to the proposed system.

One way to evaluate the effectiveness of an allocation system is to examine the lifespan benefit per transplanted organ. In the baseline system, the average benefit is 4.9 years. In the proposed system, this average benefit increases to 5.4 years. This gain, while modest, is significant. Additionally, this metric does not reflect other benefits such as improved donor/recipient matching and improved system efficiency that would be achieved through the proposed system.

	Baseline (current 2009 rules + extras)	Proposed (Top 20%, then +/- 15)
Number of transplant recipients	10,974	10,930
Total lifespan after transplant	125,463	140,686
Total graft years of life	92,199	97,045
Total extra years*	54,197	59,309
Change in lifespan after transplant	(reference)	15,223
Change in graft years of life	(reference)	4,847
Change in extra years*	(reference)	5,112
Lifespan benefit per transplant	4.9	5.4

Table 3: Life years for baseline and proposed systems

Results of Baseline and Proposed Systems by Recipient Characteristics

The following graphs depict the percentage of kidneys allocated to candidates by race/ethnicity, blood type, diagnosis category, sensitization (PRA), and age as projected through KPSAM. Overall, major shifts in race/ethnicity, blood group, and degree of mismatch were not observed between the baseline and proposed systems.[5] A decrease in the proportion of transplants for candidates with diabetes was observed (from 31% to 26%), while an increase in the proportion of transplants for candidates with glomerulonephritis was observed (from 21% to 24%). The results do indicate a decrease in the proportion of transplants for highly sensitized candidates (i.e., those with a CPRA >=80%) using the current ranking system. The Kidney Transplantation Committee is working with the Histocompatibility Committee to identify strategies for improving transplantation opportunities for highly sensitized candidates.

[5] Gains in minority transplants were observed between the simulated results with current allocation rules when compared to the baseline. The inclusion of the A2/A2B and dialysis waiting time policies resulted in this gain. To review the results of the baseline system to simulated results of the current kidney allocation rules, please see Appendix C.

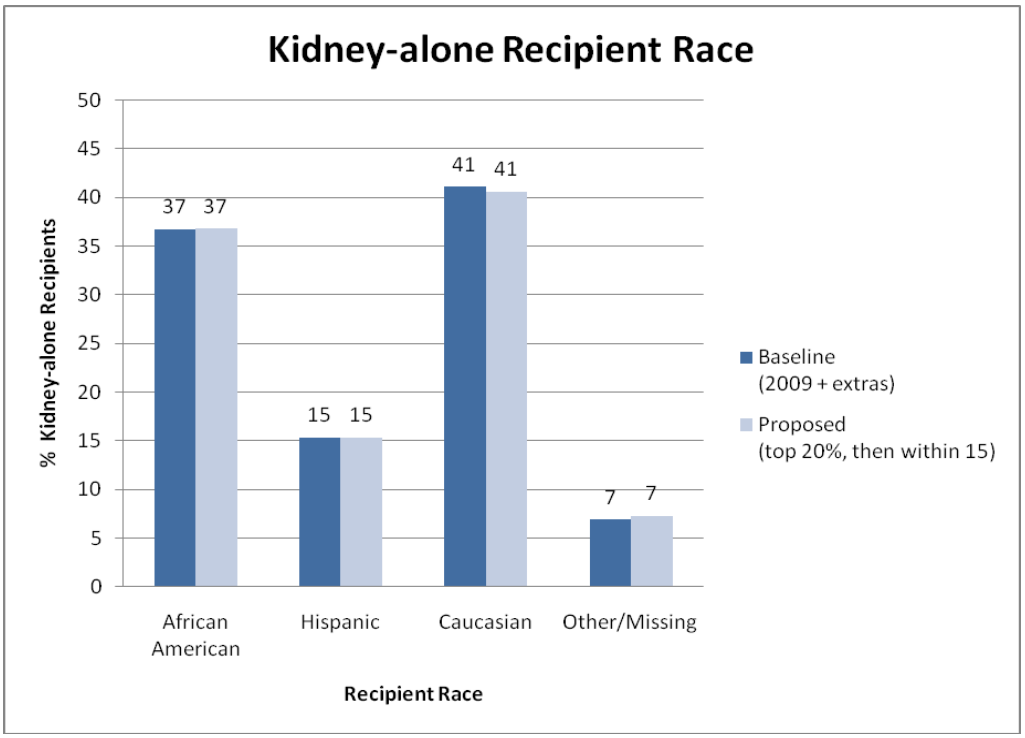


Figure 5: Projected percentage of kidney-alone recipients by race for the baseline and proposed systems

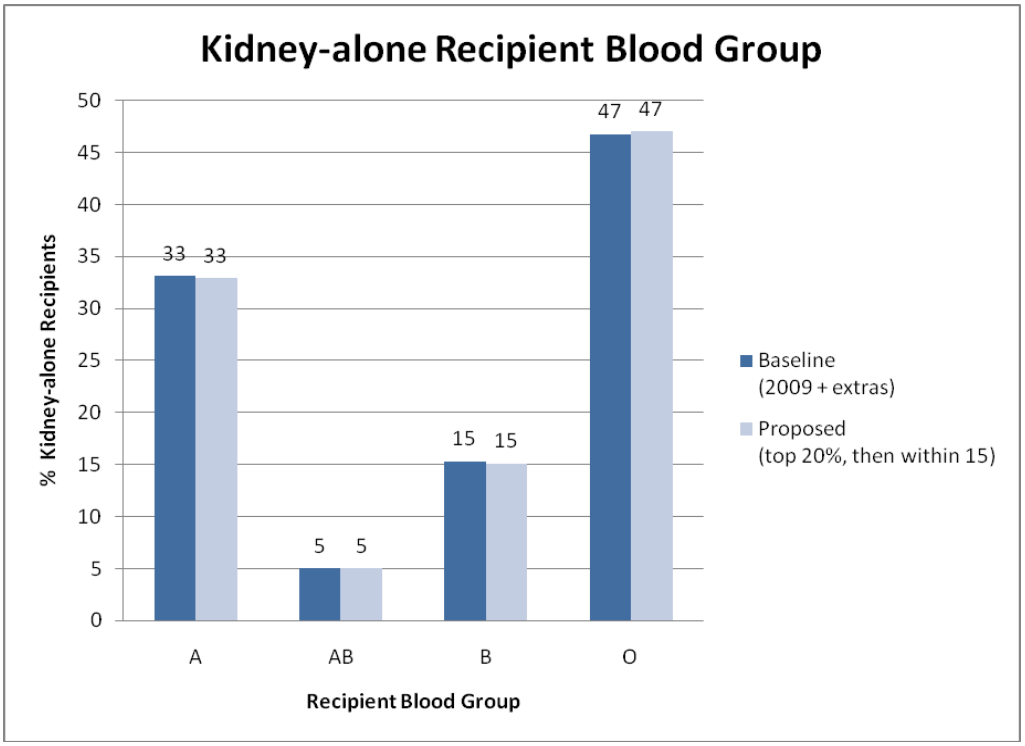


Figure 6: Projected percentage of kidney-alone recipients by blood group for the baseline and proposed systems

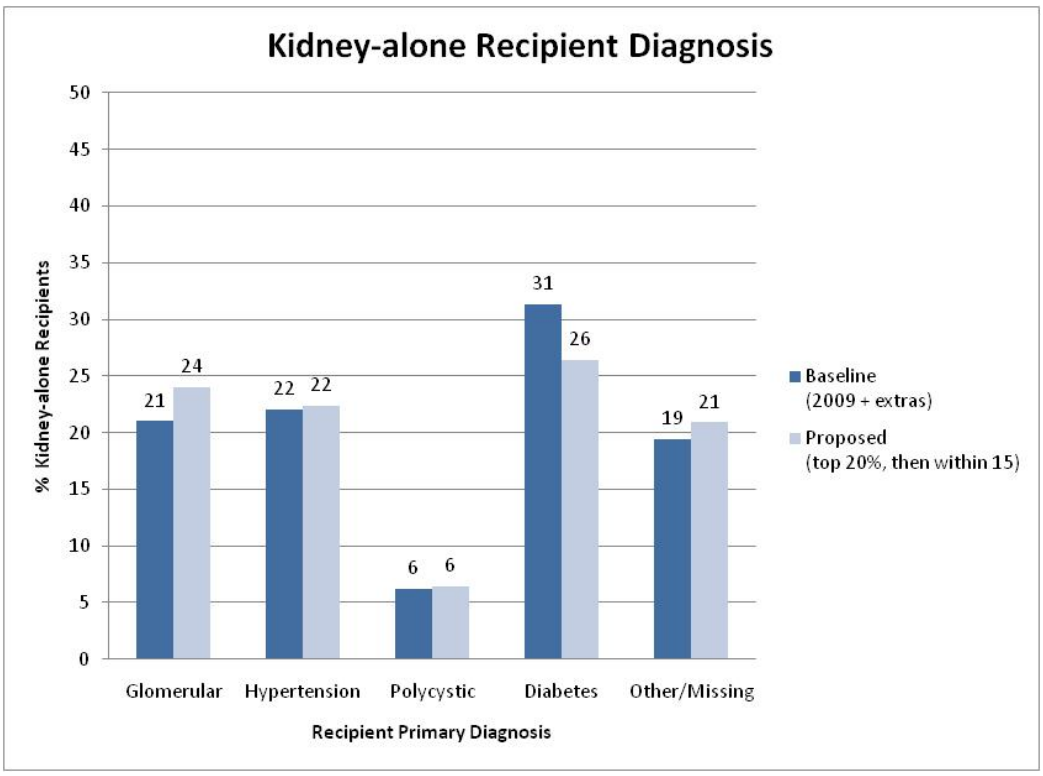


Figure 7: Projected percentage of kidney-alone recipients by primary diagnosis for the baseline and proposed systems

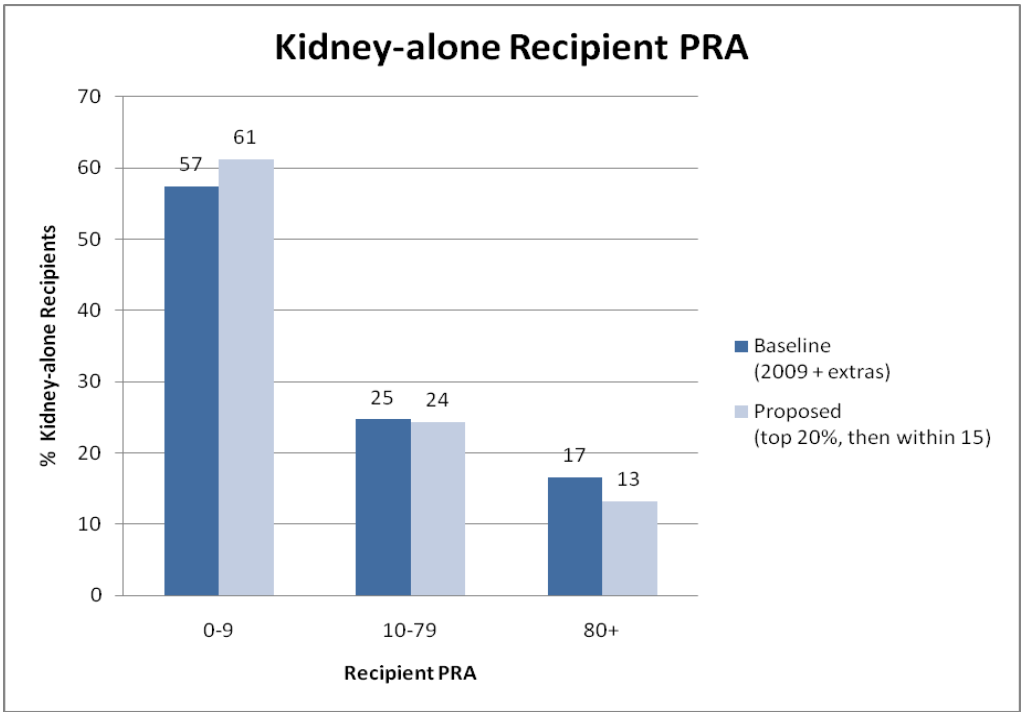


Figure 8: Projected percentage of kidney-alone recipients by sensitization level for the baseline and proposed systems

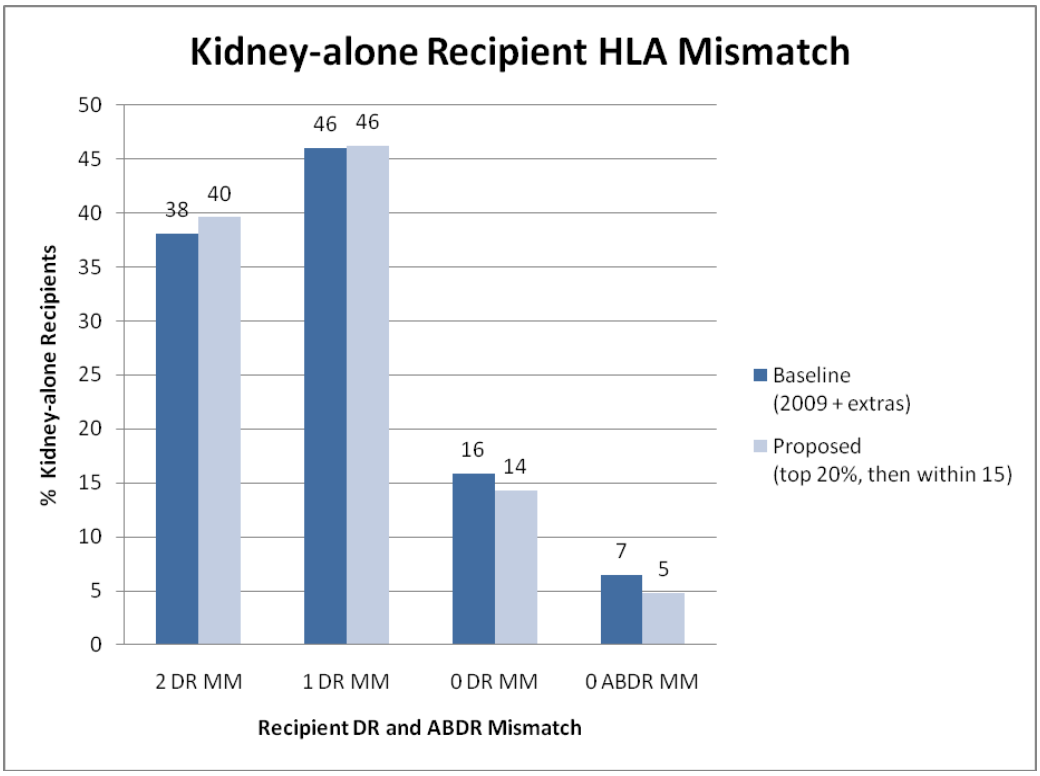


Figure 9: Projected percentage of kidney-alone recipients by degree of HLA mismatch for the baseline and proposed systems

Results of Baseline and Proposed Systems by Recipient Age

The most substantial changes in recipients are in the proportion of transplants by recipient age. These results were expected. Candidates in the top 20% in terms of post-transplant survival tend to be younger. In addition, the distribution of the current donor population is younger than the age distribution of the candidate population, so when candidates within 15 years of the donor age are prioritized, this tends to result in a younger population of recipients. If the donor population increases in age to mirror the general population, it is expected that the recipient age will also increase.

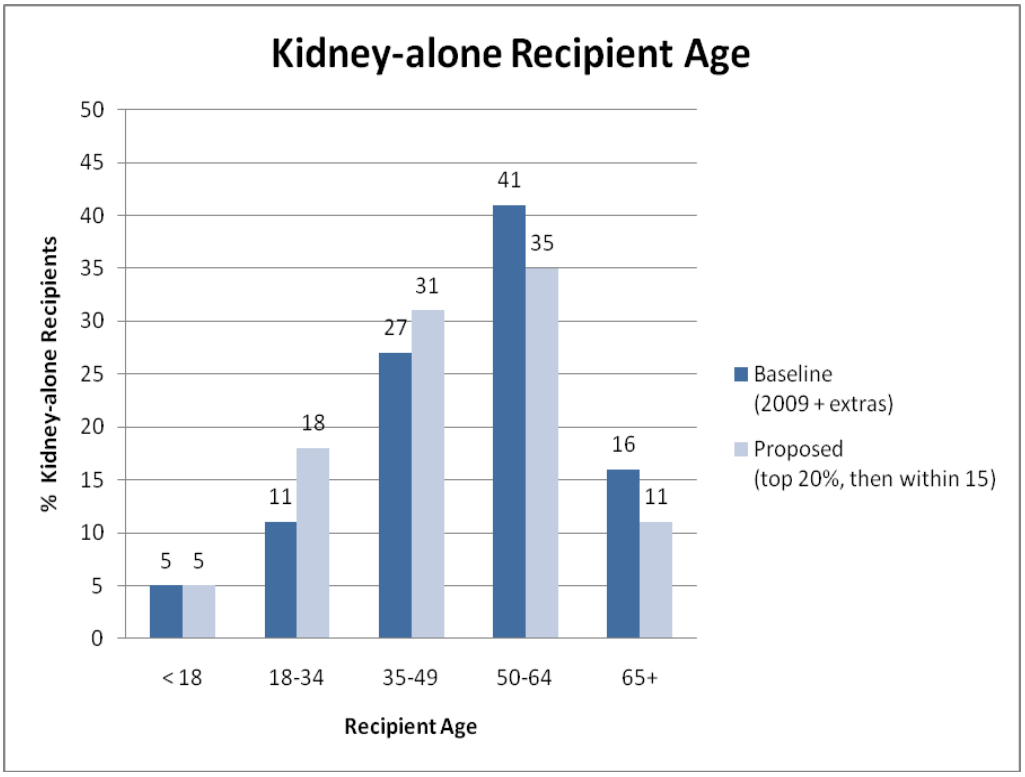


Figure 10: Projected percentage of kidney-alone recipients by age for the baseline and proposed systems

The percentage of transplants for pediatric candidates does not change because the Committee purposefully excluded any changes to the pediatric allocation system which is achieving its stated goals of expeditious transplant for pediatric candidates with kidneys from donors under the age of 35. As shown in Table 4, transplants for young adults (18 to 34) increased from 11% in the baseline system (current rules + extras) to 18% in the proposed system. Transplants also increase for candidates between the ages of 35 and 49 from 27% to 31%. Transplants for candidates between the ages of 50 and 64 decreased from 41% to 35%. Similarly, the transplants for candidates over the age of 65 decrease in the proposed system from 16% to 11%. The number of transplants for each category is presented below in Table 4. Again, we want to remind you that the KPSAM outcomes use the current estimated acceptance patterns that have come in existence under today's allocation policies and do not

predict any changes in transplants that may occur under a new allocation policy and likely changes in organ acceptance practices.

	Baseline (2009 + extras)	Proposed (top 20%, then within 15)	Change
< 18	508	524	16
18-34	1147	1873	726
35-49	2758	3168	410
50-64	4174	3516	-658
65+	1643	1122	-521

Table 4: Transplant counts by age group for one year of allocation under each system

In response to feedback that improving the age correlation between donors and recipients is an important goal of the system, the Committee examined the degree to which the proposed system improved age correlation compared to the baseline. The baseline system has a lower correlation (0.28) than the proposed system (0.50). This means that more recipients would receive organs from donors closer to their own ages (in this instance, within 15 years) in the proposed system than in the baseline system. Table 5 below depicts the donor/recipient age correlation for the baseline system. Green cells indicate the total percentage of transplants that are defined as closely age matched. Grey cells indicate transplants with a larger age differential. Peach cells are relatively closely matched in age. In the baseline system, 28.2% of transplants occurred between closely age matched donors and recipients.

Donor Age	Recipient Age					
	<18	18-34	35-49	50-64	65+	*All*
<18	1.2%	2.1%	3.5%	3.4%	0.9%	***11.0%***
18-34	3.3%	4.5%	8.7%	10.2%	3.1%	***29.9%***
35-49	0.4%	3.4%	9.0%	12.8%	4.1%	***29.8%***
50-64	0.0%	1.1%	5.0%	11.7%	6.1%	***23.9%***
65+	0.0%	0.1%	0.8%	2.7%	1.8%	***5.5%***
All	***5.0%***	***11.2%***	***27.0%***	***40.8%***	***16.1%***	***100%***

Table 5: Donor-recipient age matching for the baseline system.

Table 6 below depicts the donor/recipient age correlation for the proposed system. Again, green cells indicate the total percentage of transplants that are defined as closely age matched. Grey cells indicate transplants with a larger age differential. In the proposed system, 40.5% of transplants occurred between closely age matched donors and recipients.

Donor Age	Recipient Age					
	<18	18-34	35-49	50-64	65+	*All*
<18	1.3%	3.5%	3.3%	2.4%	0.7%	***11.1%***
18-34	3.5%	10.5%	9.8%	4.4%	1.4%	***29.6%***
35-49	0.3%	3.9%	12.9%	11.4%	1.3%	***29.7%***
50-64	0.0%	0.4%	4.8%	13.6%	5.3%	***24.1%***
65+	0.0%	0.1%	0.4%	2.7%	2.3%	***5.4%***
All	***5.1%***	***18.4%***	***31.0%***	***34.5%***	***11.0%***	***100%***

Table 6: Donor-recipient age matching for the proposed system.

It is clear that the proposed system results in more transplants between closely age matched donors and recipients. Some have expressed concern that an age matching system would result in a decreased benefit to older candidates who would receive organs primarily from older donors. However, when examined by age categories, it does not appear that recipients in one age category are harmed while another benefits in terms of the average number of life years gained during the first year following system implementation (Figure 11). These findings suggest that the longevity benefits experienced by current kidney recipients would continue to be experienced by future kidney recipients of all ages.

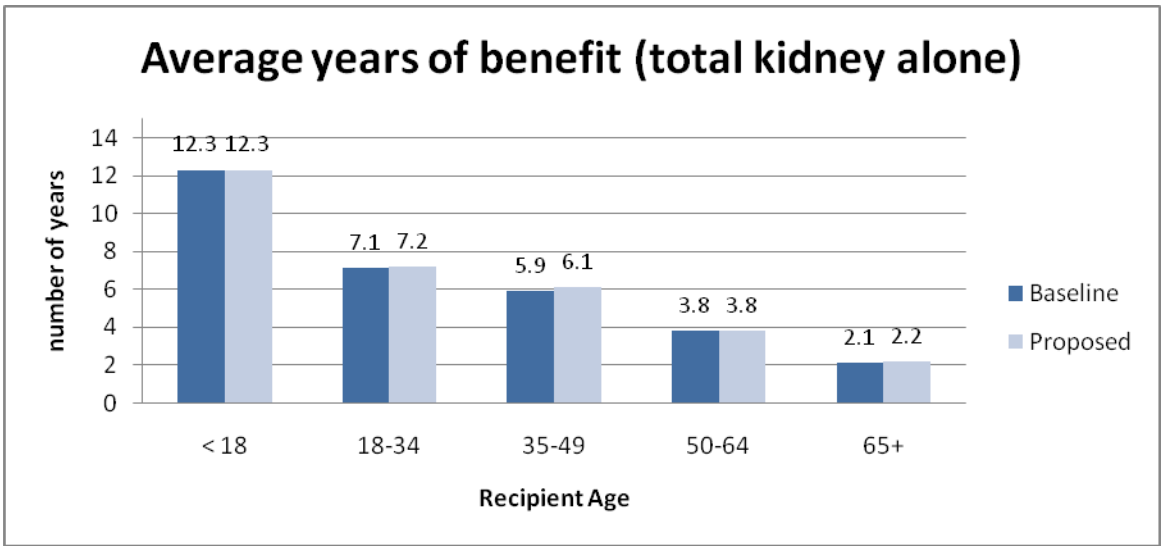


Figure 11: Average years of benefit for kidney-alone recipients.

While the years of benefit per recipient did not vary appreciably, the total benefit did decrease among the aggregate of recipients over the age of 50 due to the fact that this cohort received fewer transplants (Figure 12). The years of benefit increased more for the two younger adult group recipients (from 21 to 37 years, and from 37 to 44 years) than it decreased for the two older age group recipients (37 to 32 years and 10 to 7 years).

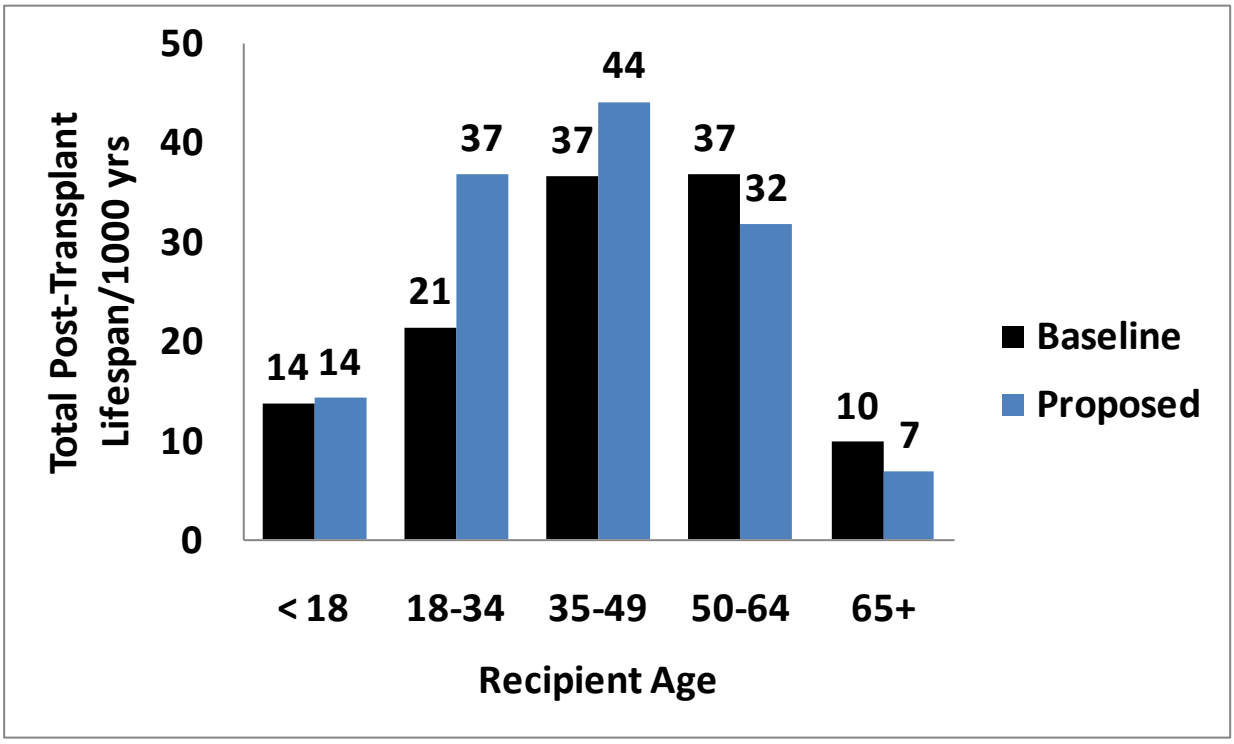


Figure 12: Overall benefit by age group, depicted as total post-transplant lifespan for recipients per 1000 years

In selecting a system based on age and survival matching, the Committee reviewed disease burden and expected survival for transplant recipients, dialysis patients, and the general US population. Individuals with ESRD (whether on dialysis or having received a transplant) have shorter life-expectancies than individuals without ESRD. However, the detriment to overall life expectancy is not evenly distributed. Individuals who develop ESRD earlier in life are much less likely to achieve a "normal" lifespan, that is, they die sooner than the average person or the person who develops ESRD at an older age. In Figure 13, an individual between the ages of 20-24 years without ESRD can expect to live an additional 56.9 years to about age 79 or so. With ESRD, that same individual could be expected to survive an additional 38.4 years with a transplant (about age 60.4), but only 14.9 years on dialysis (about age 36.9). Even with the best case scenario of a transplant, this individual is not expected to reach the lifespan of an individual who does not have ESRD.

The Committee weighed this information against the decrease in the number of transplants for older candidates under the proposed system. It does not believe that the proposed system unnecessarily favors the young. Rather, ***the proposed system provides better opportunities for all candidates to achieve as much of a normal lifespan as possible***. The survival matching component takes into account the fact that some candidates will need an organ that could potentially function for decades. The age matching component recognizes that not everyone waiting requires such long organ survival. The proposed concepts recognize both needs and attempts to allocate kidneys in a way that will allow individuals to achieve as much of a normal life span as possible.

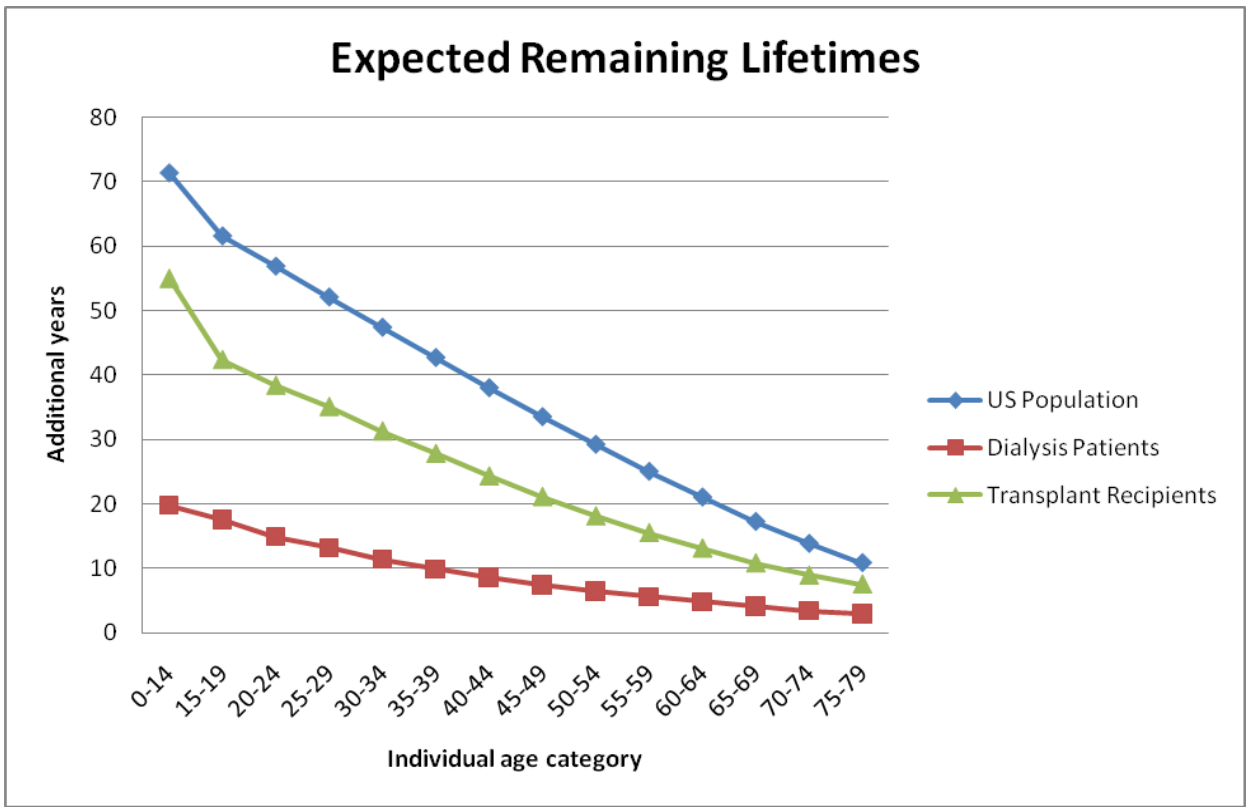


Figure 13: Expected remaining lifetimes for individuals with and without end stage renal disease[6]

The Committee also examined the historical changes in age distribution for kidney transplant recipients since 1990. Since 1990, the percentage of transplants for candidates in the young adult age category (18-34 years) has decreased from 30% to 13% and transplants for candidates between the ages of 35 and 49 decreased from 37% to 27%. Conversely, the proportion of transplants for candidates between

[6] *The data reported in Figure 8 have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government. Graph created from data available at* www.usrds.org/2009/pdf/V2_06_09.pdf

the ages of 50 and 64 has increased from 23% to 39%. The most substantial increase has been for candidates over the age of 65% which have experienced an increase from 3% to 15% (or roughly quintuple the proportion of transplants) during this time frame. The recent decrease in transplantation rates for the youngest adults is particularly noticeable, especially compared to pediatric candidates.

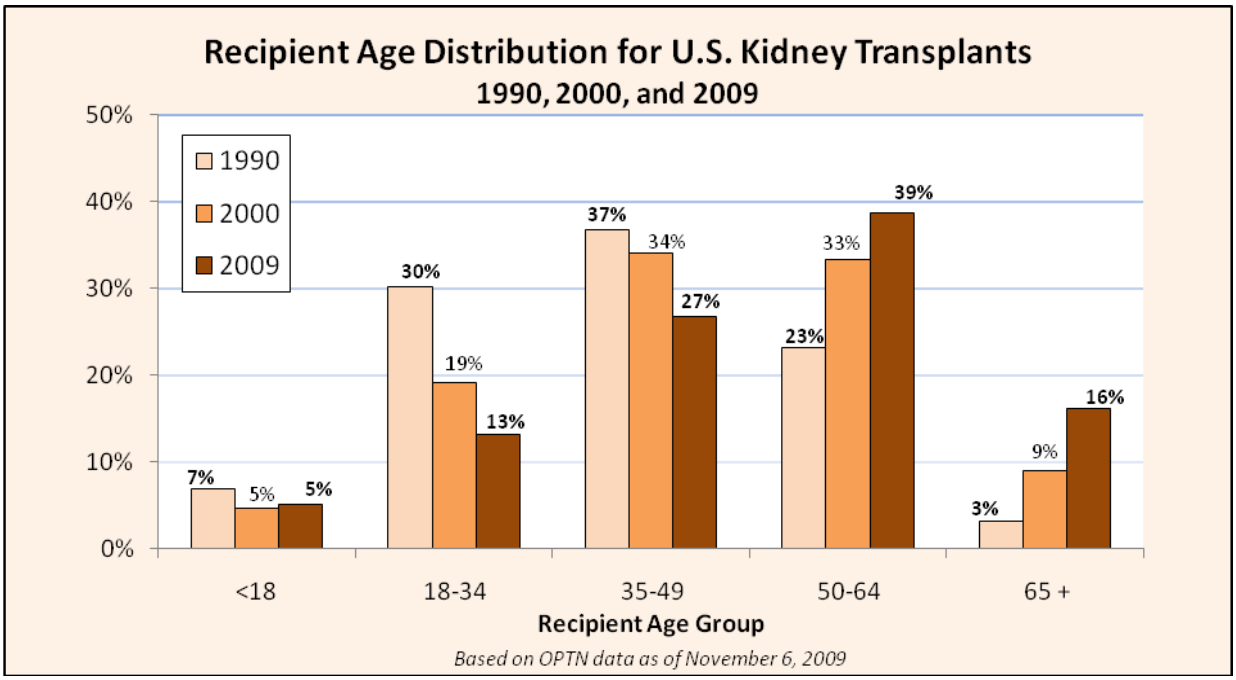


Figure 14: Recipient Age Distribution for U.S. Kidney Transplants in 1990, 2000, and 2009

While it is necessary and important to compare any proposed allocation system to the most recent results for the existing system, it is also important to understand the longitudinal changes that contributed to the results of the existing system. Therefore, the Committee examined the average of the results for the current kidney allocation system since 1990 and compared those results to the baseline and proposed systems (Figure 15). Upon comparison, the results for the proposed system most closely resemble the actual distribution of transplant recipients in 2000 shown in Figure 14.

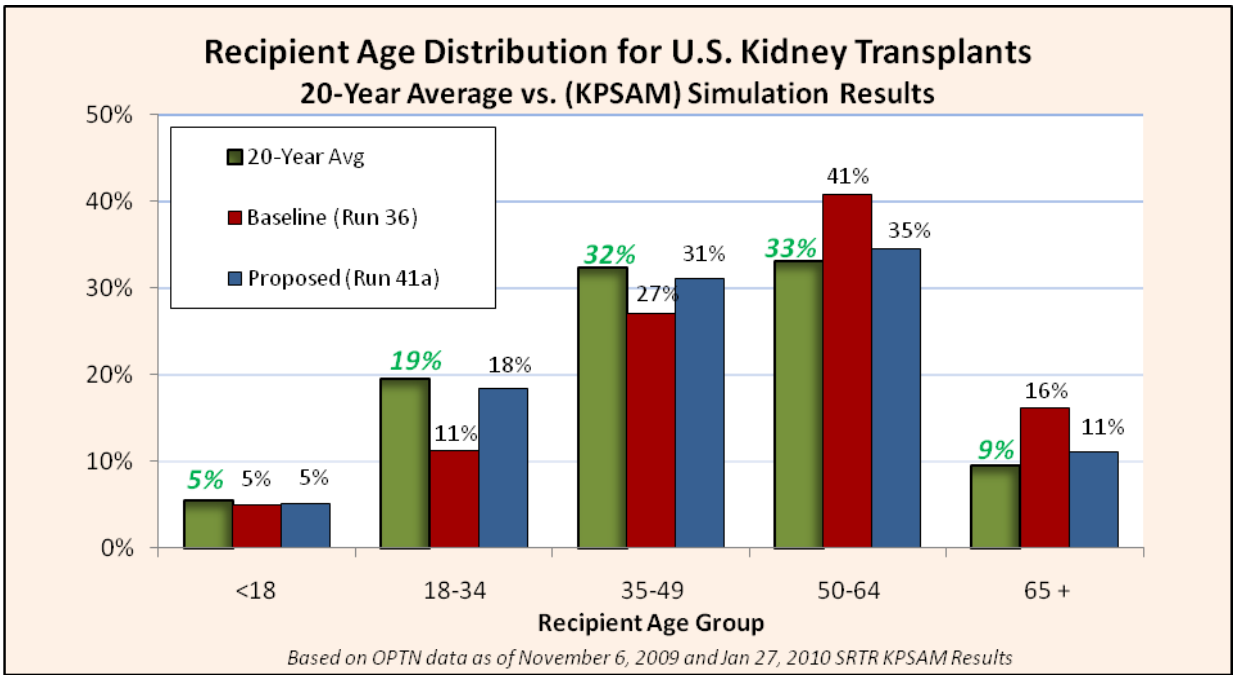


Figure 15: Recipient Age Distribution for U.S. Kidney Transplants (20 year actual average, baseline, and proposed)

Is there a potential for increasing the number of kidneys available to the allocation system?

The Committee reviewed the number of deceased donor kidneys recovered for transplant between 2005 and 2007 and found that there are a substantial number of kidneys discarded (Figure 16). Kidneys from donors over the age of 50 are more likely to be discarded than kidneys from donors under the age of 50. The Committee discussed this finding at length and agreed that at least some of these kidneys could have provided additional life years to candidates on the waiting list. The Committee discussed reasons why OPOs may be reluctant to procure some kidneys, and why transplant centers may be reluctant to accept some kidneys from older donors. Some of the reasons included system inefficiency; placement of these kidneys may take too long and place too much cold ischemic time on the organ. Additionally, since the current system is based primarily on waiting time, transplant centers may be turning down transplantable kidneys because once a candidate has reached the top of the list, they will continue to receive offers and a better kidney may be offered within a week or two. Other reasons may include reluctance on the part of transplant centers to potentially harm their overall outcomes by transplanting these kidneys, even though there are 'risk adjustment' models in place that should correct for different outcomes based on donor and recipient characteristics. The Center for Medicare and Medicaid Services (CMS) evaluates transplant programs based on expected versus observed outcomes,

and some transplant centers may be falsely assuming that using the older donors will harm their results and thus put them at risk of losing CMS reimbursement for kidney transplant services.[7]

Some members of the Committee remarked that an allocation based on age matching may reduce attempts by centers to improve their statistics by turning down viable ECD kidneys (higher KPDI kidneys) because the types of organs accepted for candidates would be more homogenized across donation service areas.

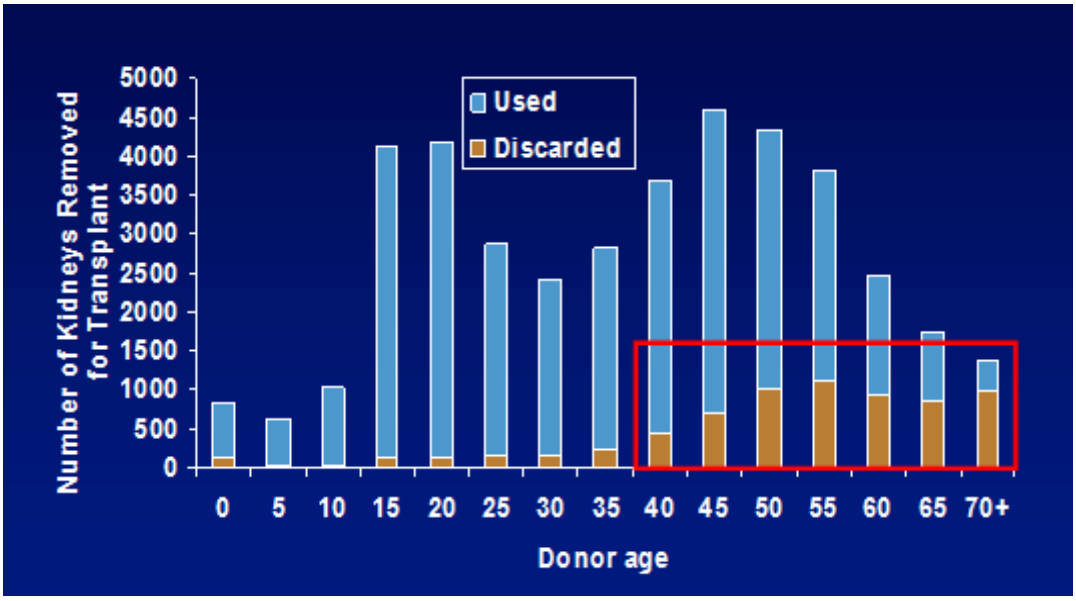


Figure 16: Kidneys used or discarded by donor age (2005-2007). The red box indicates that kidneys from older donors are more likely to be discarded than kidneys from younger donors.

To determine the effect that an age matching allocation system may have on the number of kidneys from older donors, the Committee also reviewed data from the Eurotransplant Seniors Programme (ESP). Eurotransplant is the international organization responsible for overseeing the organ transplantation network for Austria, Belgium, Croatia, Germany, Luxemburg, the Netherlands and Slovenia. In 1999, Eurotransplant instituted a set of policies referred to as the Eurotransplant Senior

[7] While it is true that kidneys from older donors tend to have the potential to function for shorter time than younger kidney donors, age is among the many factors used to calculate the expected survival rate in the Program Specific Reports used by CMS. Therefore, the expected survival rates for kidneys from older donors will also be lower. These expected rates are based on national data, which means that approximately half of the centers that transplant these types of kidneys actually improve their outcomes relative to what is expected. This in turn reduces these centers' chances of being labeled as having significantly lower recipient or graft survival than expected. The models used to calculate expected recipient and graft survival rates include many donor and recipient characteristics and undergo thorough review in order to compare the transplants at each center to similar transplants throughout the nation.

Program, which were designed to shorten the waiting time for elderly candidates by preferentially allocating organs from elderly donors (defined as >=65) to elderly candidates (also defined as >=65). Since the ESP was started in January 1999, Eurotransplant has seen a substantial increase in the number organs from donors >=65. A review of the Eurotransplant annual reports from 1997-2009 revealed a fourfold increase in the number of organs transplanted from donors in the >=65 age category from prior to implementation of ESP until 2008. The Committee predicts that increased utilization of older donor kidneys could be possible in the United States through this proposed allocation system.

Alternatives Considered

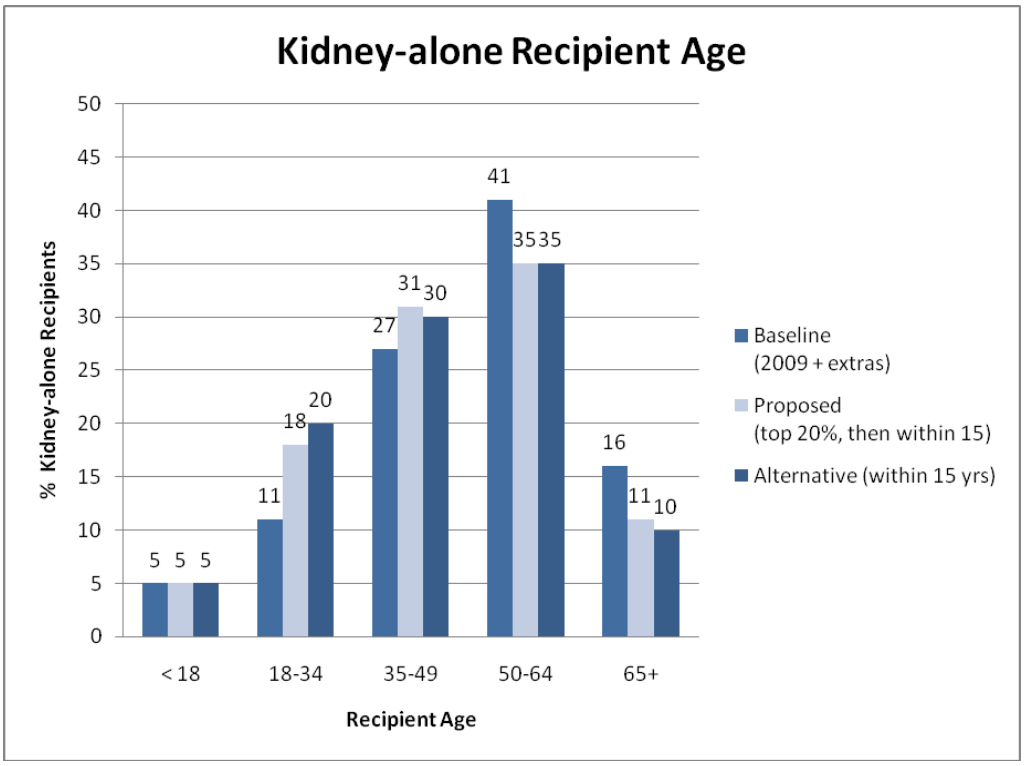
During the course of development, the Committee reviewed over 40 iterations of simulation models. While many of these runs were to test small, iterative changes, the Committee has studied and presented other major concepts. Other major concepts include life years from transplant (LYFT), and a system of categorizing and matching donor organs and candidates on the waiting list. Discussion of these alternatives may be found in historical documents on the OPTN and UNOS websites.

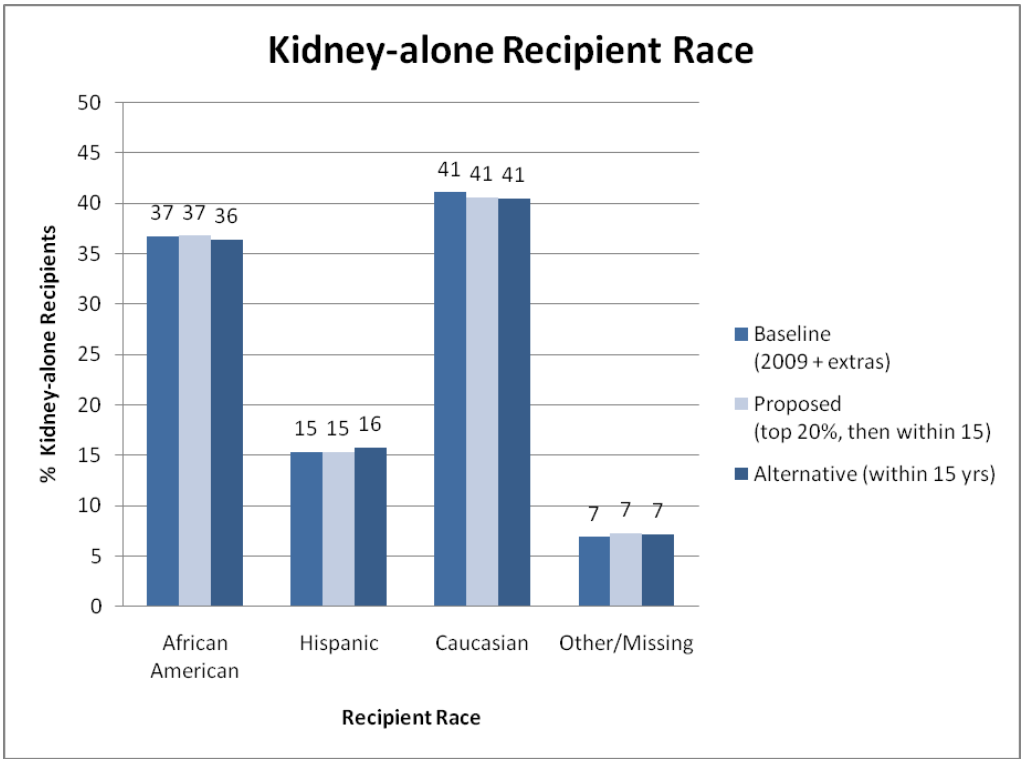
As an alternative to the age and survival matching concepts presented above, the Committee considered the alternative of basing an allocation system entirely on age matching. In this approach, all kidneys (regardless of KDPI) that are not allocated to pediatric candidates, multi-organ transplant candidates or zero-antigen mismatched candidates would be allocated first to candidates within 15 years younger and 15 years older than the donor.

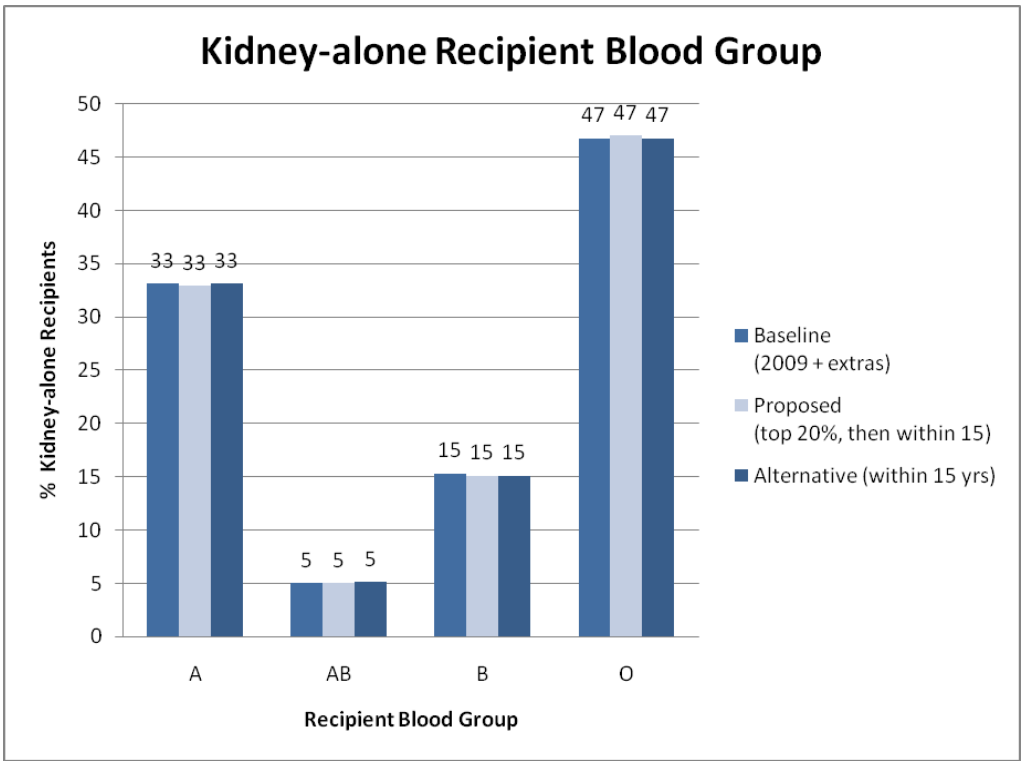
The results of this approach (identified as "Alternative") are very similar to the results of the proposed concepts (Table 7). This similarity makes intuitive sense because approximately 80% of kidneys are allocated according to age matching in the proposed system. When all kidneys are allocated by age matching, the results are very similar to the proposed system. The distribution of transplants by age, race, blood group, PRA, degree of HLA mismatch, and diagnosis, number of transplants did not vary more than 1% between the alternative and proposed systems. The overall lifespan benefit per transplant for the alternative is slightly higher than for the proposed (5.5 versus 5.4), though this difference may at least be partially attributed to a decreased projection in number of transplants (10,788 in earlier proposed allocation system versus 10,930 in this age matched system only) and is not significant.

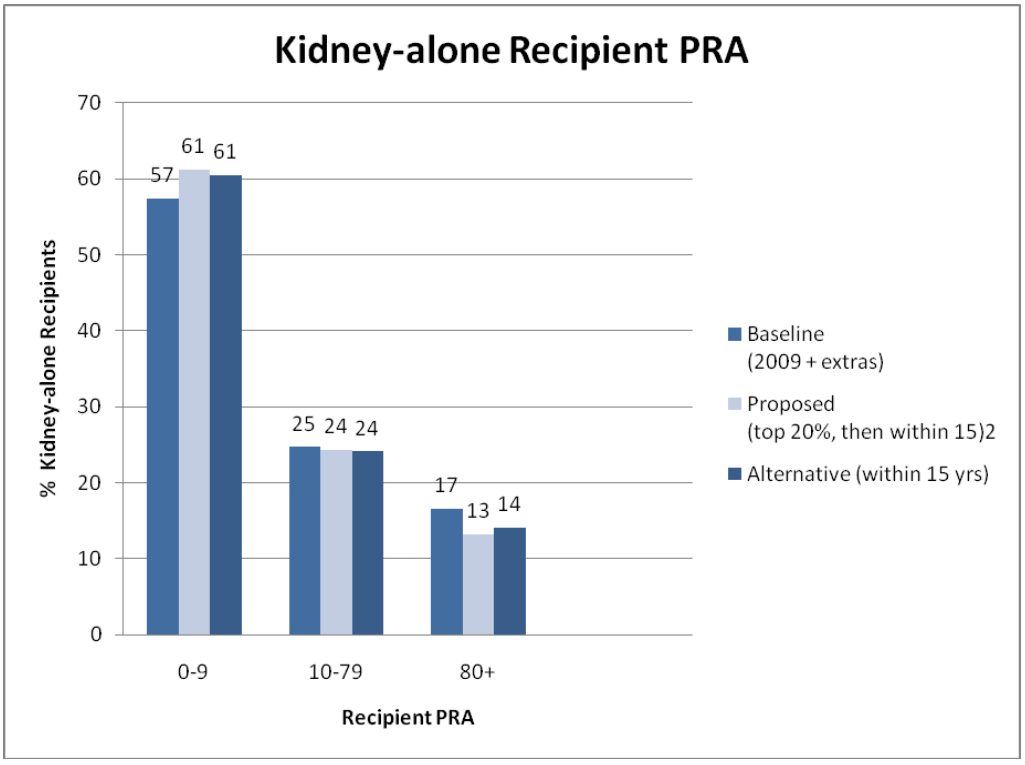
	Baseline: Current 2009 rules + extras	Proposed: Top 20%, then within 15 years	Alternative: Within 15 years
Number of transplant recipients	10,974	10,930	10,788
Total lifespan after transplant	125,463	140,686	139,508
Total graft years of life	92,199	97,045	95,910
Total extra years	54,197	59,309	58,965
Change in lifespan after transplant	(ref)	15,223	14,044
Change in graft years of life	(ref)	4,847	3,711
Change in extra years	(ref)	5,112	4,767
Lifespan benefit per transplant	4.9	5.4	5.5

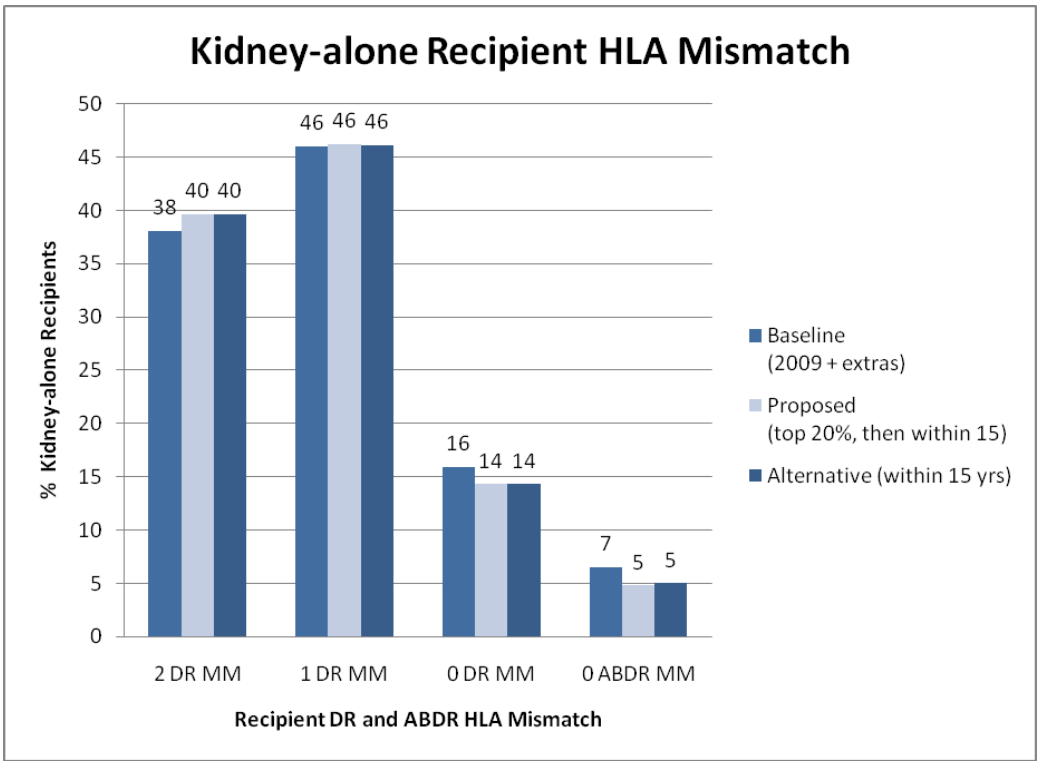
Table 7: Overview of results for baseline, proposed and alternative systems

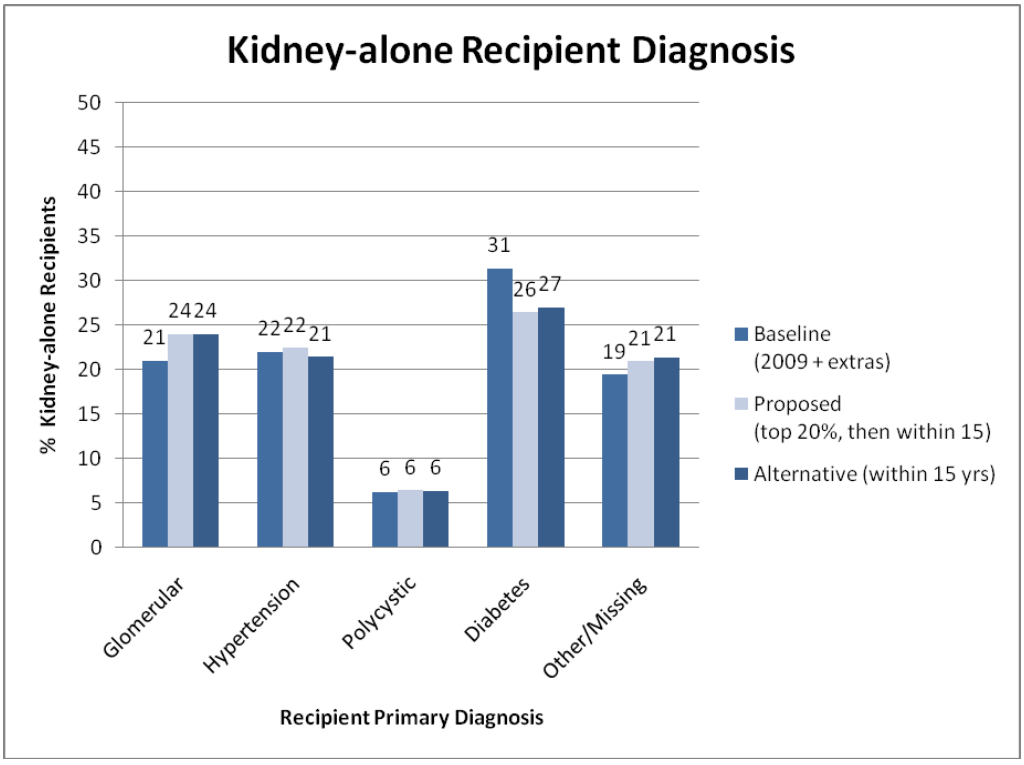

Kidney-alone Recipient Age
% Kidney-alone Recipients
50
45
40
35
30
25
20
15
10
5
0
5 5 5
11
18
20
27
31
30
41
35
35
16
11
10
< 18
18-34
35-49
50-64
65+
Recipient Age
Baseline (2009 + extras)
Proposed (top 20%, then within 15)
Alternative (within 15 yrs)


Kidney-alone Recipient Race
% Kidney-alone Recipients
50
45
40
35
30
25
20
15
10
5
0
37 37 36
15 15 16
41 41 41
7 7 7
African American
Hispanic
Caucasian
Other/Missing
Recipient Race
Baseline (2009 + extras)
Proposed (top 20%, then within 15)
Alternative (within 15 yrs)


Kidney-alone Recipient Blood Group
% Kidney-alone Recipients
50
45
40
35
30
25
20
15
10
5
0
33 33 33
5 5 5
15 15 15
47 47 47
A
AB
B
O
Recipient Blood Group
Baseline (2009 + extras)
Proposed (top 20%, then within 15)
Alternative (within 15 yrs)


Kidney-alone Recipient PRA
% Kidney-alone Recipients
70
60
50
40
30
20
10
0
57 61 61
25 24 24
17 13 14
0-9
10-79
80+
Recipient PRA
Baseline (2009 + extras)
Proposed (top 20%, then within 15)2
Alternative (within 15 yrs)


Kidney-alone Recipient HLA Mismatch
% Kidney-alone Recipients
50
45
40
35
30
25
20
15
10
5
0
38 40 40
46 46 46
16 14 14
7 5 5
2 DR MM
1 DR MM
0 DR MM
0 ABDR MM
Recipient DR and ABDR HLA Mismatch
Baseline (2009 + extras)
Proposed (top 20%, then within 15)
Alternative (within 15 yrs)


Kidney-alone Recipient Diagnosis
% Kidney-alone Recipients
50
45
40
35
30
25
20
15
10
5
0
21 24 24
22 22 21
6 6 6
31 26 27
19 21 21
Glomerular
Hypertension
Polycystic
Diabetes
Other/Missing
Recipient Primary Diagnosis
Baseline (2009 + extras)
Proposed (top 20%, then within 15)
Alternative (within 15 yrs)

Reasons for selecting the Proposed System over the Alternative System

While a system based entirely on age-matching is admittedly easier to explain than a system based partially on age-matching and partially on survival matching, the Committee does not believe that such an approach allows for as much flexibility in future policy development. As the field of transplantation advances, a system based entirely on age matching would not be nimble enough to incorporate new data or improved survival calculations without a complete system re-write. The Committee chose to present a system based on both age and survival matching because it provides more flexibility to respond to changes in waiting list demographics and donor characteristics.

Example 1: Data become available to improve survival estimates

While current data limitations do not permit the use of benefit matching for the allocation of all kidneys, there is the possibility that improvements in data collection over time will result in more robust estimates that could be used for allocation. In the proposed system, these calculations could be more easily incorporated (following appropriate policy development and public comment) because it would already include an element of survival matching. Additionally, if survival estimation improves over time, the proportion of kidneys allocated by survival matching (20% in the proposed system) could be increased incrementally over time. Conversely, if the results obtained through survival matching are not found to be acceptable, the proportion of kidneys allocated through this method could be decreased or even eliminated without an entire system overhaul.

Example 2: Donor distributions change

In an age matching system, the relationship of donor ages to candidate ages is important to ensure acceptable levels of access for all candidates. In a situation where the donor population is aging faster or slower than the candidate population, adjustments may be necessary to maintain these access levels. Both the proposed and alternative systems allow for this type of flexibility so that the donor age brackets (+/-15 years in the proposed systems) could be expanded or contracted.

System Flexibility and Variances

Due to the sheer size of the kidney transplant waiting list, the number of transplant centers involved in kidney transplantation, and the expected growth in demand for kidney transplant, the Committee feels strongly that any proposed kidney allocation system will need to be flexible in a way that the current system is not. Making changes to the current kidney allocation system is exceptionally difficult due to a number of factors including the number of variances employed at the donation service area (DSA) level and regional level. As a new system is implemented, these variances will need to be reviewed. Some of these variances will become part of the national allocation system because they have been tested and found to accomplish their stated objectives (e.g., 1) allocation of kidneys from A_2 and A_2B donors to blood type B candidates and 2) conversion of waiting time to GFR<=20ml/min or start of dialysis). Other variances may be potentially eliminated because they do not meet the standards of the OPTN Final Rule. Over the next several months, the Committee will begin to review current variances to national

allocation and identify which DSAs may have variances that will not be incorporated into the national system and do not meet the Final Rule standards.

By having one national kidney allocation system, the Committee believes that many of the inefficiencies to policy development and implementation can be reduced. Evaluating system changes currently is problematic because of the number of variances to allocation. Implementing system changes is also problematic because each variance has to be treated as a wholly separate allocation system.