Discussion of 2021-1766

EARLY ASSESSMENT OF NATIONAL KIDNEY ALLOCATION POLICY CHANGE

**DR JE "BETSY" TUTTLE** (Greenville, NC): The authors discuss the new kidney allocation change that was put into effect in March of 2021, to make up for accidents of geography, as it were. The donor service areas and organ procurement organizations (OPOs) were determined arbitrarily in the 1970s and 1980s, based on geographical borders. And now, as with our thoracic colleagues, organs are going to be allocated in nautical miles from the donor facility; 250 miles.

 Theoretically, patients waiting for kidneys who are closest to the donor hospital would have the advantage, due to their proximity. This was based on Scientific Registry for Transplant Recipients (SRTR) modeling, which has been in existence since 1987.

 Unfortunately, the change was made abruptly without a study period, which is unprecedented. It also occurred in the middle of a national pandemic, while we were all otherwise occupied. The impact of the change was disruptive. Allocation of organs has been based on donor service areas and regions since the inception of the United Network for Organ Sharing (UNOS).

 Having said that, please note that the SRTR was developed in 1987 for research in policy. There was never a database determined to assess the quality of a transplant center. It has never been validated but has been used by CMS since the early 1990s and 2000s to publish program-specific reports and to judge transplant center quality. These reports are public and calls for cases are available to payers and CMS.

 We, like Charleston, have a large rural burden. We have a high prevalence of kidney failure; the fifth highest density of kidney failure in the country. In our 29 region, 29 county catchment area, are 10 of the poorest counties in the US. Two counties away from our transplant center, in Bertie County, the average median income for a family of 4 is $15,000. We also did not elect to expand Medicaid in North Carolina.

 This paper has shown that the number of organ offers has increased substantially, almost 20%, causing on‑call resources to increase in kind to fully evaluate these offers. Unfortunately, the number of organs from local donors for this center decreased, mitigating or disallowing the premise of this new allocation policy. The quality of kidneys received as a measure from the kidney donor profile index (KDPI) was lower than in previous allocation systems, with increased KDPI plus increased cold ischemia time due to travel. And lack of pulsatile profusion policy across different donor service areas has increased the rate of delayed graft function (DGF). This has short‑term graft implications in terms of loss and long‑term risk of chronic rejection and return to dialysis.

 There were good intentions behind all these changes. They were made, in part, to try and fairly distribute the limited resources to populations that were determined to be at-risk. However, the lack of foresight and preparation before launch has led to unintended consequences, not only for the operational and logistical systems, but increased financial burden for the program and the patient. The poorer population does not travel.

 Certainly, the OPOs were unprepared for this change and, in our center’s experience, still cling to the old ways of taking the organ back to the office before putting it on the road, or the logistically complicated system of putting it on a plane. Because the OPOs have no skin in the game for organ performance and are judged purely on the number of organs they place for intent to transplant, they have little or no incentive to change their practices. They are reimbursed on their cost report based on intent, not on performance in the recipient.

 Secondly, these changes were launched without a regional or national system to pump kidneys during transport, even across state lines. We all know that pumping kidneys during cold ischemia time can mitigate DGF and improve graft performance. In addition, the donor net system was developed in 2004 to allow recipient surgeons to primarily review donor offers, but none of us can do that any longer, due to the increased burden of organ offers, and we have hired intermediaries. While these are passed on to the cost report, this increases the total financial burden of transplantation. Certainly, an increase in the need for in‑house dialysis has increased the cost per case and increased the risk for the program and for the patients.

 I would ask the authors 2 things: One, has this changed your internal practice? Because now, as the transplant center, you assume the risk for taking some of these higher risk organs. Two, has this changed your immunosuppression protocol? And has that, in turn, led to increased cost for management of patients in the facility?

**DR JAYME E LOCKE** (Birmingham, AL): I should disclose that, on behalf of our patients, the University of Alabama sued the federal government, trying to prevent the implementation of this policy, and as a part of that, I provided an affidavit.

 In the context of an organ shortage crisis, efforts to maintain equity and access to lifesaving organs for transplantation have focused on establishing “rules of the game.” Published in the federal register, these rules provide rough guidelines for the Organ Procurement and Transplant Network, or OPTN, for developing allocation algorithms. The OPTN has contracted with UNOS to establish and implement allocation algorithms and logistics.

 To comply with the final rule, UNOS recently implemented a substantial change to the kidney allocation policy and, as highlighted by Dr Tuttle, did so in the middle of the COVID pandemic. The change focused on perceived geographic disparity. With rare exceptions, allocation proceeds in a rather ordinal fashion, such that kidneys are allocated locally first, then regionally, then nationally. UNOS purposed that donor service areas, or DSAs, were arbitrary boundaries and inherently an illegal way of defining "local," as the final rule states that allocation cannot occur based on accidents of geography. Curiously, UNOS replaced DSAs with a 250‑nautical mile circle around the donor hospital, with priority given to candidates closer to the hospital, a seemingly arbitrary accident of geography.

 Importantly, this redefining of "local" prioritized urban end‑stage patients over their rural counterparts, as most donor hospitals are in larger metropolitan areas. Moreover, the new system has increased the complexity of kidney allocation. For example, in the DSA system, the OPO worked with a median of 3 transplant centers to place kidneys for transplantation locally. Under the 250‑nautical mile system, they now work with a median of 32 transplant centers to place kidneys locally.

 Not surprisingly, and as demonstrated in this excellent study by Dr Rohan and colleagues, kidney cold ischemia time increased DGF. The increase in transplant center logistics for vetting offers increased substantially, along with associated cost. Importantly, Dr Rohan and colleagues maintained their kidney volumes by leveraging their aggressive center‑level organ offer acceptance practice and, as such, the quality of kidneys transplanted over the study period declined at their center. Only time will tell what that will do to their center‑level outcomes.

 The new 250‑nautical mile allocation policy could be called a cabal. Data provided from the current study certainly lends support to this assertion. The policy creates an equally arbitrary boundary, forced into a new allocation algorithm that was not supported by the majority of UNOS regions; a boundary that promotes the siphoning of the best kidneys from rural to urban candidates, a boundary that creates more cumbersome logistics resulting in longer cold ischemia times, worse graft outcomes and greater cost.

 Perhaps even more disturbing is that, before implementing the arbitrary 250‑nautical mile boundary, evidence abounded regarding geographic disparity within DSAs. In other words, redefining "local" was never going to solve the problem, and arbitrary boundaries do not correlate with the likelihood of transplantation. Transplant center organ offer acceptance practices do. In fact, there are disparities between transplant centers that are just 3 nautical miles apart.

 Bottom line, UNOS chased geography to solve inequity in access to transplantation that cannot be fixed by an allocation algorithm that does not account for disease burden, but rather, requires a comprehensive understanding of disease burden. Kidneys must go to areas that need them the most, and an assessment of transplant center organ offer acceptance practices must assure that when they are offered, the kidneys are accepted and actually transplanted.

 Moreover, chasing geography has increased cost and resulted in worse outcomes. Considering this, could the authors comment on the following: Should the Organ Procurement and Transplantation Network (OPTN) metrics for transplant centers include organ offer acceptance ratios? Do the authors think that inclusion of such a metric would level the playing field?

 There has been discussion of moving to a continuous redistribution model. Could the authors comment on the importance of accounting for disease burden to avoid exacerbating known disparity in this sort of model, and how their findings from the current study might be extrapolated to such a model?

 Finally, the number of transplantations in the US have increased. Some, particularly UNOS, will purport that this reflects the new allocation system. But as we know, allocation systems do not find organs; OPOs do. What is a true measure of the success of an allocation system is how efficient it is and what the discard rate is, however, we do not have those data yet.

 The authors highlight several inefficiencies in the new system that resulted in worse outcomes. Do they have any data on how these inefficiencies may have influenced their local kidney discard rate?

**DR DAVID LEESER** (Greenville, NC): The thing that concerns me about this study is that it is a single-center study that was a single-center OPO. So, if you are not competing with another center, obviously the number of local transplantations you are going to perform will decrease. When we implement a new system, there will be a huge shift right away, because we were at an equilibrium under the old system, and as soon as you change the system, that equilibrium is going to be shifted in very funny ways.

 At our own center, our creatinine levels have not increased, because that is what we chose. The authors chose more aggressive organs between the 2 time periods, which is why their creatinine levels were up. I think that it is way too soon to be starting to make wholesale changes. We are going to have to tweak things. Obviously, we are getting longer cold times on high KDPI, more risky kidneys, and we have got to do something to fix that. But at this same time, I am now starting to get organs from Richmond, which is not that far away from me. I am also getting organs from South Carolina, which may only be 3 or 4 hours away. We must look at the national numbers. There was no way we could continue with the boundaries we had, which were fixed based on a system that grew up around transplantation inception and was not well thought-out.

 This may not be a perfect system. In fact, I agree with many of the comments, but I think that we need to wait and see what happens. This is very early, and it is a single-center experience.

**DR DEBRA SUDAN** (Durham, NC): I must echo Dr Leeser's comments regarding the short timeframe in follow‑up. People have said that allocation of a scarce resource such as this is like redistributing deck chairs on the Titanic. There are just not enough organs out there to allocate to all patients.

 I am concerned the changes in selection have severely biased the outcomes of the study. The fact that you have used higher creatinine and longer cold ischemic times are concerning.

 My question to you is, overall, how has this affected the number of transplantations you have performed? I understand that your center has dramatically increased the number of transplantations based on the increased organ offers; is that not a benefit to the patients?

**DR ALAN KOFFRON** (Chattanooga, TN): At our center, we noticed an increased workload with more organ offers nightly. Staff and faculty are getting offers that ultimately come in late, with 10 to 12 hours of cold time on the clock, creating difficulty for a mid‑sized program to make a leap of faith and avoid primary non‑function and, obviously, clinical troubles downstream.

 My question for the authors is, have you pulled other centers’ personal data? Are we all like‑minded in thought? And, therefore, should we create a more multi‑center trial or review of this, because certainly, any allocation system will have centers that are doing better and centers that are not?

 Again, my feeling and that of my colleagues is that there are many offers, an incredible amount of offers, but fewer transplantations, because of the logistical bottlenecks.

**DR WILLIAM CHAPMAN** (St Louis, MO): We have been through similar allocation changes for liver transplantation that preceded the kidney allocation changes, and those were equally or maybe more contentious. During that process, the head of the Liver and Testing Committee said to me (and this was a person very much in favor of the allocation change), “I am not sure a broad distribution is going to make it better for the system, but it may make it equally bad for all.” First, I thought, that is kind of an incredulous idea, but now I think there is something behind it. Some centers think, for example, that in South Carolina they have it so great; that it is unfair.

 I would be interested in the author's thoughts on that and ask a question: Have you polled other centers? Are there places where the logistics are not a problem? They are a nightmare for us in Missouri, and I think they are a nightmare for most places. We have had to implement a call center, and the estimated cost will be a million dollars a year.

**DR JOSEPH K MELANCON** (Washington, DC): I think we would all agree that we need to do more pumping. I was wondering if you have spoken to your OPO and the OPOs in the area to see if there could be more agreement in pumping and transporting kidneys on pumps?

**DR WILLIAM CHAPMAN** (St Louis, MO): So that everyone understands the idea of pumping, it is meant to be beneficial, especially for marginal organs, including those that have long cold ischemia times. Traditionally, the OPO will pump organs if they are going to their local center. However, they will not pump organs that are going to be shipped out across OPO lines. So, you go to a broader distribution, and what happens? The kidneys do not get pumped. This is another one of the logistical areas that has made this problematic.

**DR VINAYAK S ROHAN** (Charleston, SC): To begin with, I will address the question of whether we have changed with the extra volume and how things are going, and have we changed our internal practice? We have had to change our call schedule for surgeons because it had become untenable. If you were taking 1 week of kidney calls, you would become a zombie by day 3. On average, there used to be 15 or 20 donor offers per night, with 15 hours of cold ischemia time for an organ coming from Kansas. So, there was no way these organs were usable. You would receive a call, then be up day‑in and day‑out.

 We changed the call schedule so that the surgeon is on call 1 night at a time, and someone else covers the next day, to help alleviate the strain of the workload. We had to change the call schedule for the call team, because their burden had become so great that we now have a call center within our institution, where they can decline calls which do not fit our metrics. Even for them, it reached the stage of doing shorter call schedules with more people taking calls simultaneously, because backup was necessary. Extra manpower was needed, so we ended up hiring more people to accommodate.

 Regarding the immunosuppression questions, we are a center that typically used both Simulect (basiliximab) and Thymoglobulin (anti‑thymocyte globulin) for immunosuppression. We did not believe in a "1-size‑fits‑all" approach, so we have gone to more time, because all organs have longer cold ischemia time for our Ardent policy, our higher antithymocyte antibody organs. We have used more Thymoglobulin in the last 3 years.

 I will address Dr Locke's question about the new criteria which may be considered for the organ, the performance evaluation of organ centers, including patients who are dying while on the waitlist, and the organ acceptance ratio. For our program, we have historically seen that our organ acceptance ratio has been beyond 2 standard deviations. If we made this part of the criteria, I am sure the organ acceptance ratio would increase, and more organs would be used. At the same time, it is going to be a new challenge. Nobody knows, especially for smaller and mid‑level programs with limited resources, who provide great service to the populations they serve; they may be hampered by the outcome issues. We must match the organ acceptance ratio with the right kind of organ performance ratio. The outcomes measures should be very clear regarding that.

 The continuous distribution, which is the next stage of organ allocation and may be changing from the 250‑nautical mile circle, is a new concept. Patients will be given points, like a liver system which has multiple features, such as medical urgency, wait time, chance of organ acceptance, as well as the way the organ is going to perform. Regarding your question about disparity, I am sure it will create new disparities, especially the concern that it could create disparities for patients with diabetes, because their outcomes are anticipated to be worse. So, they might be disadvantaged by this new system. Patients who are about 65 years old may also be disadvantaged by the system. Another key point of this new continuous distribution is that, on paper, it looks great; everybody gets a point. But this is pre‑organ procurement distribution, and once the mayhem begins, once the organ is procured and already has 16 hours of cold time, then what do you do? At that point you are scrambling. If arranged well, the pre‑organ system is a very nice system, where everyone has already agreed to take the organ before procurement, and all is well set up. It will be a new challenge, and it may bring in plenty of new questions to be answered.

 Regarding discard rate, what we presently have is a personal communication with a couple of OPOs. Their discard rate is up. One of the main reasons for discard rate is so‑called difficult‑to‑place organs, especially with long cold ischemia time. Other than the opportunity to review the discarded organs from an OPO, I felt that, out of nearly 100 organs that were discarded, 25 organs could have been used, if given to us at the right time.

 Regarding Dr Leeser's comment, that it is only a single-center study, and it is way too soon, I would agree. It is always way too soon, right? But it is also always the right time to ask the question, are we going in the right direction?

 I agree that, in a year or 2, we will know whether the system has leveled the playing field, and what the new challenges are. The challenges associated with the system are not going to go away. The calls are going to remain the same. The extra burden on the call team and how organs are distributed are going to remain the same. The median trend, cold ischemia time, (unless we change the policies and how the organs are redistributed, especially when the primary center declines the organ), will remain the same. To address that, we are accepting only higher creatinine organs, which is why that is skewed in our study. I do not think it is totally correct, because we have always been beyond 2 standard deviations for our organ acceptance rate for hard‑to‑place organs. So, we did not change our policy simply because, on March 15th, we changed the way the organs are allocated. We just stuck to our old organ acceptance criteria and followed up with that. But we also know the overall quality of organs we are receiving is much lower.

 To Dr Sudan's comment about number of transplantations performed, we have performed more transplantations during this period, and over the subsequent months. It is now December, and we have performed more transplantations than ever before. We can give some credit to the new allocation system, but in the last 3 months, we have gone back to the numbers we were at, pre‑allocation. So, that extra bonus has gone away. We are constantly performing more transplantations, and whether that is due purely to new allocations, it is difficult to say. According to the status key modeling, we are supposed to lose 150 organs. Well, thank God, we did not lose those.

 To the question on using other centers’ data, working with other centers in the region and collaborating on these metrics will allow us to have a much bigger impact and create many things to look forward to. I would be happy to work with other centers on this topic.

 As Dr Chapman said, allocation is a nightmare, unless the wait is allocated. The question of whether 250‑nautical miles is good is a different topic. Once in the system, it is equally bad for others. So, to change the nightmare, I think we must find a different way of allocating organs. Say you have 6 hours of poor time, during which there are multiple offers to different centers, so that everybody gets to evaluate before it is too late. At the end of the day, our response is not just to transplant more organs all over country. We were responsive for all those discarded organs, too.

 Regarding the question about pumping, the reason we have not been able to pump is that there are 6 pumps in South Carolina. With this number of donors, only a few kidneys are getting pumped. An interesting feature of the new allocation system is, if I were to accept a kidney today, I would get a reply from the pumper, asking if they can take the kidney out of the pump and put it in a box for me. I might be performing the operation tomorrow morning, but I still must go through the whole system, because they have many other kidneys sitting on the pump that are already 14‑hours out, and they want to allocate them to somebody.

 During the pandemic, our OPOs have lost so many people. There is a shortage of manpower, a shortage of pumps, and whether the kidney stays on pump in between is a big challenge.