

**Meeting Summary
Organ Transplant Work Group
Third Meeting, May 27, 2015
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215**

Work Group Member Attendees:

David Klassen, M.D.	Anne Weiland
Charles Alexander	Linda Ohler
David Leaser, M.D. (for Susan Ostovitz)	Daniel Schwartz, M.D.
Jessica Quintilian	Lori Brigham
Brigitte Sullivan	

Commission Staff Attendees:

Eileen Fleck, Chief, Acute Care Policy and Planning	Paul Parker, Director
Rebecca Goldman, Program Manager	Kathy Ruben, Health Policy Analyst

Other Attendees:

Dr. Allan Massie	Natasha Gill
Patricia Cameron	Spencer Wildonger

Introductions

Ms. Eileen Fleck opened the meeting, introduced herself, and asked the group members present and participating by phone to introduce themselves. After introductions, Ms. Rebecca Goldman noted that Mr. Charles Alexander and a representative for Ms. Susan Ostovitz were expected to call in to the meeting as well.

Review of meeting minutes

Ms. Goldman thanked those work group members who submitted changes for last January's meeting minutes. Dr. Daniel Schwartz requested two additional changes: on page 6, he noted that hospitals (not organ transplant programs) are required to report all deaths to OPOs; on page 8, he requested clarification on whether Maryland has a minimum volume requirement for pancreas transplantation. Ms. Goldman responded that currently COMAR 10.24.15 includes a minimum volume requirement of 12 transplants per year for pancreas transplant programs and that the group's recommendation was to change that current minimum volume requirement to "to be determined." She agreed to clarify this in the meeting minutes.

Review of meeting agenda

Ms. Goldman commented that the biggest challenge to the State Health Plan (SHP) update is dealing with the need projection for services and programs, and she wants to review the

need methodology and concerns raised. MHCC staff invited Ms. Brigitte Sullivan and staff from Johns Hopkins Hospital to present their own proposal regarding additional elements that could be incorporated. After that, she would like to review the general organization of other proposed changes, including reorganizing the policy section of the existing SHP chapter.

Discussion of the current need projection methodology in COMAR 10.24.15

To begin discussion, Ms. Goldman reviewed the sources of data used by MHCC staff to calculate projections in the existing need methodology. Data sources include the United Network for Organ Sharing (UNOS) for transplantation data, and population data from the Maryland Department of Planning, Weldon Cooper Center, and U.S. Census Bureau. MHCC recently received organ transplantation data from UNOS for 2014. She presented data on organ transplantation utilization by residents in the Donation Services Area (DSAs) that cover Maryland counties, one unit of analysis staff uses in the current methodology. Line graphs were presented that plot use for all organ transplants and living donation transplants from 2005-2014, as well as a table listing the change in the number of kidney and liver transplants year to year.

Ms. Goldman then reviewed the current methodology used to project the need for organ transplant programs. The projection is based on using three previous years of data to project three years into the future. Staff uses the aforementioned sources to calculate use rates for the populations of each of the DSAs for each type of organ transplants for the three most recent years of data available. The utilization projection is based on the average change in use rates for the previous three year period, which is applied to the aggregate use rate for the three year period, to project three years into the future, e.g., the use rates for 2010, 2011, and 2012 would be used to project use rates for 2015. Staff also adjusts for migration, which assumes the same rate of in-migration for the projected years and includes residents who out-migrate to other regions in the demand for the service in the DSA of origin. The need for new programs is then determined by subtracting the case volume in the most recent year from case volume for the projected year. If the result nets a number of cases over the threshold volume listed in the SHP, MHCC invites Certificate of Need (CON) applications for a particular service in a particular region.

Work group members have brought up some concerns with this methodology. First, the utilization of transplants is always driven by the supply, and there will always be demand for more organs than the number available. Due to this, organ transplantation is unique service among other regulated health care services. The next concern is the volatility of projections year to year. This results from projecting three years into the future using three years of data for services with relatively low volume, which can contribute to significant changes in use rates and inconsistent need projections. As an example, Ms. Goldman presented a table that displayed recent published need projections. The table summarized MHCC's last three published need projections. Ms. Goldman pointed out the year-to-year difference in liver transplant projections, which projected a need for a D.C. region liver transplant programs for the last two published projections. However, using UNOS data through 2013, preliminary calculations would conclude no need for a liver transplantation program in the D.C. area for 2016. Thus, MHCC would no longer be accepting applications for new development of that service. In the case of lung

transplants, in 2011, MHCC projected a need because of recent past growth. However, no need was projected in the subsequent publications.

Next, Ms. Goldman tested whether five years of data might produce a projection closer to actual volume. In order to do this, she modeled projections for resident use rates for the Maryland and Washington Regions using five years of utilization data, projecting five years into the future. Her calculations did not include migration trends. She compared the projection for resident utilization to actual resident utilization. She used this exercise to determine whether incorporating more years of data into the projections would result in closer projections to actual utilization. This exercise produced varied results by organ type. In some cases, the calculation produces a projection that is closer to actual utilization, but in other cases, the projection is farther from actual utilization. She also concluded that there is not a pattern, and future utilization will not necessarily follow historic trends. She pointed to the projections for one organ in which a spike in volume in 2009 resulted in a different projections for the five-year and three-year projections due to producing opposing trends. Ms. Brigitte Sullivan thinks this exemplified that large volumes produce a projected need for even larger volumes in the future. Because there were more transplants in 2012 and 2013, there's an even greater need projected in the latest calculation due to increasing volumes than had been projected in past years. She believes this is the reverse of what is intended.

Staff's ideas for revising the current need methodology and select policies affecting program approval

Ms. Goldman reported that Maryland is the only state she could find that publishes a need projection for organ transplantation programs. Other states release need projections for organ transplantation services based on data such as the rate of end-stage organ disease. Many also use program threshold volumes to determine whether a new program would be sustainable, in a similar way as Maryland. If MHCC updates the methodology in COMAR 10.24.15 and does not include a projection for need, it would remove one of the existing barriers to applying for a new organ transplantation program. If removed, MHCC would rely on existing program volume thresholds and add additional standards that would require an applicant to demonstrate the need for new services. The definition of need could include elements like improving access, decreasing disparity, or addressing existing quality issues at other programs. Ms. Fleck added that MHCC would also consider the impact of a new program on existing programs, a standard part of the CON review process. Ms. Goldman added that Staff would also consider adding a parameter that allows a new program to become established before any additional programs are approved, in order to avoid overdevelopment and allow a newly approved program to establish sustainable volumes. Ms. Fleck added that this would also provide time to evaluate the quality of new program.

Dr. David Leeser expressed concern that if MHCC limits development it could be accused of impeding fair competition. Ms. Fleck responded that the cardiac services SHP chapter contains similar language, which includes a provision that after a program is approved there will be a period of a few years before approving another cardiac surgery program in order to allow that new program to become established. That provision has existed for a while. Ms. Goldman

added that all of the changes that she is proposing are based on similar language included in other SHP chapters. Mr. Parker stated that he assumes that the MHCC, which has statutory authority to regulate certain facilities and services, has broad immunity from anti-trust concerns. While anti-competitive behavior by providers is a concern, he does not think that applies to MHCC regulation.

Ms. Brigham said that she understands the importance of projecting the need, but is having a hard time reconciling organ recovery volumes. Even if a need for 50 more transplants is projected, that does not increase the supply of organs. She also noted that the data currently available is a bit old, and it does not include the impact of the new liver allocation system and distribution. Additionally, the new kidney allocation system went into effect in December 2014, and data is just now available. She suggested incorporating the volume of organs recovered, but believes the new allocation systems should be considered in any analysis. Ms. Fleck stated that staff is aware of the changing policies, which are intended to address disparities to some extent. She explained that the challenge for staff is that MHCC is updating the SHP chapter now. The question is how to navigate having new national policies, while at the same time updating the SHP to include improvements and be more rational.

Ms. Brigham responded that staff should consider the number of organs recovered, look at whether the number is increasing, and if WRTC and LLF are recovering more organs. She believes that WRTC is exporting more organs nationally now due to new allocation policies. She is not sure if that is the case for Johns Hopkins and University of Maryland, but she questioned how it impacts regional utilization and need. Dr. Klassen said that broader sharing should work both ways. There is some data on the UNOS website that looks at kidney volumes over the last six months since the policy went into effect on a regional basis. Results appear to be mixed. Some regions have gone up. Some regions have gone down. Overall the number of kidneys is about the same. It is too early to say that there are any trends, but he would think that broader sharing is a wash in most parts of the country.

Ms. Goldman said that this discussion will help staff define access when they are revising the SHP. Ms. Fleck questioned whether it is an access issue if a patient is not getting an organ transplantation in their area of residence, but they are getting one in the neighboring area. She is not sure residents of Prince George's County who are traveling to the Maryland DSA have an access issue. Dr. Leaser suggested that the entire Eastern Shore is an area that has an access issue. Access to the initial transplant service is one thing, but access to the subsequent follow-up care should also be considered.

Anne Weiland recommended taking a step back and revisiting Ms. Brigham's point that organ recovery ought to be considered in the formula. She supports that and suggests considering this for every category of organs and living donations. Ms. Goldman asked whether we should project future recovery rates based on past recovery rates, similar to the question regarding past utilization. Ms. Brigham replied that Organ Procurement Organizations (OPOs) have to do that for their own budgets on a regular basis, even though hospitals may shut down. Though, she thought we may want to look at the number of transplantable organs, instead of all recovered organs. Ms. Weiland added that, because past events in certain years have impacted trend lines, it

might make sense to reset a trend line if a significant event takes place to alter organ transplant trends.

Ms. Sullivan agreed that looking at organ recovery is important. She is still concerned that the formula uses historical volumes and bases projections on what has been done in the past. Allocation policy changes, center closings, and other factors are not included. She suggested considering the actual number of patients who need a transplant, not just the number of transplants, so projections are not confined by those restrictions. She noted that even if an applicant is allowed to apply for a new program, MHCC does not automatically approve a program. The applicant still must prove how a program will improve the system. She believes that any of the options have limits, but there are ways to improve them.

At this time, Ms. Fleck sought to address some issues. First is the question of who is able to apply for a new program and at what time they are able to apply. She wanted to determine whether there should be a barrier to acceptance of CON applications, like the SHP chapter has now. She was concerned that the SHP does not currently have a good rule to determine when someone can apply for a CON. She wanted to discuss the issue. She thought it would be appropriate to consider historical trends to gauge the need for a new program. She noted that there are two things to consider. First, should there be a barrier? Second, what should the analysis include once someone has passed that barrier? While MHCC considers historical utilization when analyzing the need for a program, she wanted to know whether the CON process should include a strict rule that limits acceptance of applications. Alternatively, MHCC could allow applications and evaluate the application based on separate criteria.

Ms. Ohler asked whether the need assessment only considers the number of transplants that patients need. She asked about an assessment of the quality of current services. Ms. Fleck responded that staff seeks to look at multiple factors, including quality when assessing the need for a new program. Ms. Ohler asked what assessment might be made if there was a rapid decline in organ recovery rates in the service regions in the next two years and whether staff would project a need for another transplant program if rates of organ transplants were declining. Ms. Fleck replied that if fewer transplants were taking place, MHCC staff would be less inclined to agree that a new program is needed. While she believes utilization should be a primary consideration, she is trying to identify other factors that should be evaluated or that applicants should address to make a case that access is a problem. She asked whether MHCC should provide an opportunity through CON regulations for an applicant to make a case based on factors besides historical volume trends. She added that if work group members feel that the historical trend is the most important thing, and access is not issue, then she wants to know what criteria should be considered and the weight to assign different factors.

Ms. Ohler asked Ms. Fleck if she defines access as the distance a patient would have to drive to get the service, and whether driving from Washington, D.C. to the University of Maryland is an access issue. Ms. Fleck replied that for a specialized service like organ transplantation, MHCC states that a three-hour drive time is considered reasonable in the SHP chapter. Mr. Parker added that staff analysis of CON applications takes drive time and traffic congestion into account. Ms. Fleck added that other access issues could include language or

financial barriers. Ms. Ohler asked how staff assesses access barriers. Ms. Fleck responded that this could be included as criteria in regulations. For example, an applicant could demonstrate that it would take patients who are not served by existing programs. Ms. Ohler asked how staff would go about assessing policies of existing programs, in the CON process. Ms. Fleck responded that it might be challenging to address, but staff seeks to write standards that are specific and that give applicants clear direction in order to aid both the applicant and staff in determining whether a proposal meets a standard. She commented that she is interested in ideas regarding what work group members consider access issues, or do not consider access issues. Ms. Fleck used living donor programs, as an example. For example, if one region did not have a living donor program, staff might consider whether an access barrier exists. Ms. Goldman added that she believes there would be a heavy burden placed on an applicant seeking to justify a program based on access barriers.

Dr. Leeser, who was filling in for Ms. Susan Ostovitz, asked about the purpose of CON regulation. As head of the kidney transplant program at University of Maryland, he is interested in the goals MHCC is trying to accomplish through regulation. Ms. Fleck answered that the goal is to attain an efficient, cost effective health care system, a system that avoids waste and avoids new building for services that are underutilized with too much competition. MHCC also seeks to maintain high quality programs. MHCC is not interested in adding to the performance measurement system established by CMS for organ transplant programs. Instead, MHCC would use existing information and sources when considering new programs. Dr. Leeser commented that he believes that Maryland currently has a pretty efficient organ transplantation system, with two programs that control the vast majority of transplant services. If there is a fixed number of organs, there should not be consideration for adding a program. Ms. Fleck agreed that the emphasis was on cost-effectiveness and efficiency, but added that regulation intended to balance those principles with access and other issues. For example, Maryland could have one hospital for the whole state, but that wouldn't provide appropriate access to service for all Marylanders.

Ms. Goldman added that the current SHP chapter language puts up a barrier to opening new programs based on historical utilization, which would be fine if all patients who need services were getting them and everyone was served consistently and equally across the board. However, the need methodology might perpetuate past trends that have not been assessed or stymie new innovation in the field. Ms. Goldman commented that there may not be a need for a new program based on the number of historical transplants, but there may be a need for a new program for another reason. She is interested in knowing whether MHCC should open the application process. She is interested in either a better way to make need projections based on available information, or the group's feedback on not relying on need projections. Ms. Fleck added that the basis for identifying the need for a program could include program thresholds or quality issues.

Several members agreed that quality is an important factor. Ms. Ohler noted that SRTR has data on program quality that could be used to evaluate the need for a new program. Ms. Brigham added that UNOS has specific information about the performance of a transplant center. If a transplant center is performing poorly, it would be an indication that they are not serving the

community to the extent possible. Ms. Ohler added that CMS scrutiny could help to open the opportunity for another program. Dr. Schwartz explained CMS's regulatory requirement for one year graft and patient survival outcomes at CFR 42 482.82. He noted that the SRTR reports are a retrospective snapshot in time due to the data lag inherent in the SRTR reports. A program with a condition level deficiency faces a termination date. However, as defined in regulation (CFR 42 488.61), CMS works with these programs and many, if not most, improve their outcomes dramatically over time. He thinks that the group should be careful about relying on a single SRTR report rather than a performance review process. CMS sees circumstances where programs are struggling with their outcomes, then dramatically improves based on root cause analysis, peer review, and other actions during the review process. However, Dr. Schwartz added that if there was a program that voluntarily withdrew or was terminated from the Medicare program because of outcomes non-compliance, it may create a situation where Medicare beneficiaries would not be allowed to be transplanted in that program. He noted that it does not happen often, and it would only occur after a long period of outcomes non-compliance. Ms. Fleck asked Dr. Schwartz how much time a program has to improve, once they have been given a termination date by CMS. Dr. Schwartz responded that when a program has a conditional level of deficiency for outcomes, the most recent SRTR report has to show a non-compliance as well as one of the previous four SRTR reports. Programs could operate with borderline or below threshold CMS outcomes for a period of a few years. However, with outcomes non-compliance they get a termination date that is 210 days into the future. Most will apply for mitigating factors (488.61). Some programs will have made substantial improvements and present data showing that they would be back in compliance. Other programs may come back into compliance on the next SRTR report in 180 days. Others may be offered an opportunity (Systems Improvement Agreement (SIA) for another year of structured quality improvement. If they demonstrate improvement at the end of the SIA, they remain in the Medicare Program. It is a two or three year process of improvements. Most of the programs have been granted mitigating factors at the end because of improved outcomes.

Ms. Fleck asked the group members if they feel that they should base a quality criterion on decertification. Dr. Leeser suggested that MHCC leave certification to UNOS. Ms. Fleck clarified that the idea is to use decertification as a trigger to consider a new program, to wait until a program has essentially stopped operating, as opposed to considering a new program at a point where a program has been given a termination date. Dr. Schwartz added a point of clarification that CMS terminates Medicare certification. Without it, a program would not be allowed to transplant Medicare beneficiaries. Patients with other types of insurance could still receive a transplant. The program would also still be allocated organs by UNOS. Though, for kidneys, it would make a big difference because most patients who receive deceased donor organs are Medicare beneficiaries. Ms. Fleck thanked Dr. Schwartz for the explanation. Ms. Goldman reiterated that SHP and CON regulations do not address closing existing programs, except for newly approved programs with a condition to maintain minimum volume. In this case, a CMS decision could be the trigger, but MHCC is not judging existing programs that cease to take Medicare patients. MHCC would consider that potentially an access issue exists and a new program may be needed.

Ms. Ohler was unclear about when an applicant is able to apply for approval of a new program by the Commission. Ms. Fleck explained that a program would have to wait for MHCC to allow applications, which is one of the issues that wants the work group to consider. She asked, should MHCC make it easier to apply for a transplant program instead of relying on need projections primarily?

Mr. Parker commented that while it's easy to overthink the issue of market entry, the work group should address the entrée to the Commission. Right now, MHCC has a need projection, or a demand forecast, that explicitly accounts for transplant volume trends over time. It does not directly look at organ recovery and how many organs are available for transplant. With the different allocation systems and changes to those systems, it is hard to estimate how many transplants will occur based on organ recovery in a region because organs leave the areas where they are recovered. He noted that currently there is a demand forecast that is kind of a swinging door. It opens when a minimum net volume number is hit and allows applicants to approach the Commission. The next year, it may close, and the year after that it may open again. It has opened in recent years for some organs in some regions, and MHCC has not received applications. While Mr. Parker does not consider the year to year volatility necessarily a problem, others may be concerned about that.

Mr. Parker added that the corollaries to the need projection are the impact projection and threshold volumes. Instead of using the demand forecast as the way to give entrée to applicants, applicants could be allowed to approach the Commission at any time. He commented that currently the threshold volumes are low relative to the existing program volumes, and a new system could leave the door open based on high program volumes. Regardless, MHCC still has the task of determining whether the new program is a good idea. MHCC could find that an applicant will not really change the environment in a way that improves access or overcomes some disparity or equity problem in the current delivery system. MHCC may determine that existing providers are high quality programs and volumes are not high enough to justify a need for a new program, even though the forecast allows an application. He noted that Ms. Goldman's research indicated this is more in line with what other states do. Ms. Goldman has not found other states that make a similar utilization forecasts or use them to project a need for a specific number of organ transplant programs. Other states use volume thresholds as a trigger.

Ms. Weiland agreed that there should be objective criteria for applications, but that the methodology could be reconsidered. Ms. Brigham asked whether year-to-year fluctuations could be taken into account to establish a trend, maybe over a two year period. Two consecutive need projections would provide a little more information. Ms. Sullivan responded that she was concerned with the year-to-year volatility and the flaws in the need formula. The formula projects more transplants in 2016 than there were in 2012 through 2014, only because of increasing volumes at the University of Maryland and Hopkins during that time period. It also does not take into account the number of patients with end stage liver disease. Ms. Weiland added that it does not take into account the capacity of the existing programs and asked whether the Commission wanted to open the door for anybody to apply at any time.

Ms. Fleck confirmed that if existing programs are above the threshold, it would be part of determining whether to accept applications. For other types of organ transplants without thresholds listed in the SHP, MHCC would potentially accept those at any time. Ms. Weiland thinks that there are a number of objective criteria to look at besides volume, including wait times, number of patients on the wait list, organ allocation trends, and others. Those other factors should affect the equation, including capacity of the existing programs to absorb more transplant volume if organs were available. Ms. Fleck noticed some heads nodding among work group members, and she suggested that Ms. Sullivan give her presentation because staff at Johns Hopkins Hospital has some ideas about how to address these issues.

Presentation by the Johns Hopkins Hospital staff regarding the current need methodology and an alternative approach

Ms. Sullivan reminded work group members that they discussed the need methodology and some of its weaknesses at the last meeting in January, and introduced Dr. Allan Massie. Dr. Massie thanked the group and stated that he is an epidemiologist from Johns Hopkins who will be presenting slides that are explicitly built around the question of demand for organ transplantation. He explained that he would only address the question of latent demand for organ transplantation, which he attempted to quantify based on national registry data. He stated that MHCC currently uses a demand formula that is complicated and carries several flawed assumptions. One flaw is the assumption that the rate of end stage renal disease (ESRD) or end stage liver disease in a DSA is fully captured by the current number of transplants to residents of the DSA. If the current number of transplants to residents of a DSA is declining, then the formula calculates that need is declining, which may not be the case. The formula assumes that a new center will not change the proportion of patients in a DSA who travel outside of a DSA for a transplant, or ex-migrants. It also assumes that a new center will not change the proportion of patients who come from outside a DSA for transplant, or in-migrants. He added that MHCC's current assumptions are more reasonable for services addressing stroke, heart attack, cancer, or other diseases in which supply is not constrained in the way that it is for organ transplantation.

Dr. Massie was asked by the Department of Surgery to estimate latent demand for transplantation. He formed the following principles: Demand should be based on the cases of end stage renal disease or end stage liver disease, not necessarily the current transplant volume; ex-migrants from an OPO in excess of some baseline represent unmet local demand (not every single ex-migrant, but a large number of ex-migrants); the formula had to be clear, transparent, easy to deal with, and easy to calculate for MHCC with using a calculator or Excel; and demand is estimated independent of case mixture because white patients and patients with high socio-economic status have better access to transplants than others, but that is not a disparity that should be perpetuated by calculating demand based on case mixture.

Dr. Massie used national registry data for kidney transplant volume through 2013 and ESRD data from the USRDS registry through 2011, the most recent data available. He defined an ex-migrant transplant as a transplant outside of the DSA of residence. He conducted a linear regression with no constant term, or modeled a ratio of the number of ex-migrant transplants from a DSA based on the number of ESRD cases. Essentially, he modeled a ratio of ex-migrant

transplants to ESRD cases for residents based on national data. If observed ex-migrant kidney transplants were dramatically larger than predicted by the model based on national data, it would indicate latent demand for a new center. Dr. Massie presented a scatter plot graph. Dots on the graph represent DSAs; the larger dots represent LLF and WRTC regions. The x-axis shows the incident ESRD cases for the most recent year for which data is available. The y-axis represents the number of ex-migrant transplants. He noted the wide variation among DSAs, although the dots loosely cluster around the solid line that represents the national average rate of ex-migration. He observed that the rate of ex-migration in WRTC is three times the national average. Based on the national average and the number of incident ESRD cases in WRTC, he expected to see 43 ex-migrations. There were 123 observed. LLF is currently below the national average.

Ms. Fleck asked Dr. Massie if he looked at other dots that fall above the national average line to see if they were in areas in which people might have easy access to an adjacent DSA. She feels that is the situation in Maryland. It is not difficult to travel from D.C. to Maryland. She wondered if that plays a role in what happens in some of the other areas where residents live close to the border. Dr. Massie noted that there is always going to be some cross-migration, which is why he used a national average. He noted that there are six OPOs that stand out, but did not systematically compare them or know exactly where they are located, though he did check that they were spread out geographically across the country. He offered to look into that, but the data would not help determine how far away the nearest transplant center is to neighboring DSAs. Ms. Fleck asked if analysis on how far a transplant recipient lives to the transplant center would be possible. Dr. Massie responded that he believes he could use the zip code for ESRD cases from the USRDS dataset, but this work is based on the existing OPO-based formula. Ms. Brigham asked whether his analysis of people travelling outside of the WRTC service area includes northern Virginia, parts of Maryland, and D.C. Dr. Massie confirmed that it included all residents of WRTC based on zip code.

For end stage liver disease, Dr. Massie used the liver wait list registry as a denominator. He modeled ex-migrations as a proportion of all liver transplants, by DSA of residence. His analysis answers what proportion of residents who live in LLF, WRTC, and other DSAs in the country receive a transplant outside of their DSA of residence. He showed a regression with no constant term, the same mathematical calculation in for kidney, and modeled the ratio against the national average. The x-axis represents the number of liver transplants in 2013, the y-axis represents the number of ex-migrations, and the solid line represents the national average. There is more heterogeneity among DSAs for liver than for kidney, which is measured with an r-squared number included in the graph. The data indicates that the rate of migration for residents of the WRTC's DSA is more than twice the national average, not as extreme as kidney. There are 21.6 ex-migrations expected based on the national average and 49 observed. For residents of the LLF, the observed transplants are very close to the national mean.

His conclusions are based on the national average of ex-migration. WRTC has latent demand for an estimated 83 additional kidney transplants and 27 additional liver transplants per year. The rate of ex-migration in the LLF fell below the national average so this calculation

would predict no latent demand. Dr. Massie believes these estimates are conservative because they do not account for population growth or potential in-migration. A center that is more aggressive than the national average with regards to outreach for in-migration or living donation could capture additional demand. Dr. Massie invited questions about his presentation.

Discussion

Dr. Klassen asked how double listing factors into Dr. Massie's work. To Dr. Klassen, it seemed like ex-migration in a case of double-listing was probably driven by the wait time. He also wondered whether wait time was related to the number of centers in a given area. Dr. Massie addressed the first issue of double-listing at multiple centers. He did not look at the proportion of DSA residents who double-list at multiple centers or in multiple OPOs. He thought that it was likely that many of the recipients who are ex-migrating may have been listed at multiple places. He noted that it is possible that they were listed in the DSA of residence. Then, one could argue that if they were transplanted elsewhere, the local DSA was unable to meet their need. Regarding wait times, he did not look at the distribution of wait time. The difficulty is that wait time is driven partly by organ availability, but also by listing practices, multi-listing, and, particularly with liver, wait time is not a very good surrogate for supply. For kidney, the question of wait time better addresses supply. He thought it would be appropriate to look at the question of supply based on national averages. However, his presentation today was focused on demand.

Dr. Leiser asked if the 80 transplants Dr. Massie projects a need for in WRTC are being conducted in Maryland programs. Dr. Massie responded that he analyzed the DSA of residence to calculate need and did not look systematically to analyze in-migration. He assumed that many of the WRTC ex-migrants are being transplanted in the LLF, though some of them might be going to a program outside of the region.

Ms. Fleck asked if there is a specific way Dr. Massie would propose changing MHCC's regulations in order to incorporate this information. Dr. Massie responded he is an epidemiologist and not a policymaker, but that if the desire from the MHCC was for a need-based formula then he would recommend something similar to the formula that he presented. He would defer to policy makers if it is a decision about whether to move to something more demand-based or use another metric. Ms. Sullivan commented that she believes the current need formula could be improved and wanted to present this as an option. However, she is an advocate for not having a hard formula. She agrees with Ms. Brigham that the environment changes frequently, and it is difficult to project the intersection of demand and supply. She thinks the chapter should outline basic criteria that an applicant needs to demonstrate or meet, but it is questionable to have the door continually swinging back and forth.

Ms. Fleck asked whether there was consensus about how to handle accepting applications and when to accept them. Abandoning the projection could mean a wide open door. Ms. Goldman asked if anyone was opposed to that. Ms. Quintilian, a self-described outsider representing the National Kidney Foundation, commented that it leads to confusion when the door swings open one year and closes the next. She asked if there was a way to move to a broader approach instead of getting mired in the formula. Ms. Goldman replied that MHCC

would have other criteria regardless of using a need projection or not. She is interested in continuing to include the program threshold volume for existing programs before MHCC considers an application for a new program. This threshold is 50 for kidneys and 20 for other organs.

Dr. Leeser asked what the case would be if the MHCC received two applications, one from an applicant in Cumberland and one from an applicant in Ocean City. He is concerned that thresholds could prevent a new program from ever being allowed to apply. Ms. Fleck replied that if existing programs are below the threshold, MHCC would not consider applications. Dr. Leeser believes that if MHCC opens the door, anyone should be able to come at any time to apply for a program. Closing the application process based on a new program recently opening in the State of Maryland may create a situation in which a need is not being met somewhere else in the State. Demographics may change and the recently approved program may never reach the threshold. He commented that if MHCC is going to open the door, the door should remain open. MHCC should not shut off development throughout the entire state based on the creation of a new program.

Ms. Fleck thought it was important to keep in mind that the State does not appear to be particularly lacking in any area for a transplant program, in terms of programs and current volumes. The group previously discussed a drive time standard of three hours and the need for only a few programs in the State. The group also talked about separately considering the pediatric program in D.C. that has fewer than 30 kidney transplants and excluding that from the threshold volume metric. At this time, Maryland does not have a situation where the volumes would create a hindrance to applying for a new program. Dr. Lesser countered that he could see a situation where a new program is opened in Bethesda and another applicant wants to open up a program in Prince George's County. He concluded that someone in Prince George's County would not get a new program until that Bethesda program meets the threshold. He disagreed with that logic. Ms. Fleck responded that MHCC would not encourage applications if it has already been determined that MHCC will not approve a new program. However, she noted that if the work group agrees that there should be an ongoing opportunity to apply, staff should consider opening up the process.

Mr. Parker commented that some of Dr. Leeser's concerns could be dealt with procedurally. CON is not necessarily structured to be a first-come, first-served process. If MHCC adopts a new plan without a demand forecast or minimal volume requirements, MHCC could adopt a scheduled, announced review cycle for regions to address Dr. Leeser's Bethesda-Prince George's County example. If someone fails to present an application during a certain review cycle, it is their own fault because they have been given adequate notice that the opportunity existed for filing an application for a service within a region. Mr. Parker also concluded that there is strong consensus among the group regarding the importance of existing program volumes when regulating organ transplantation. MHCC wants programs to achieve some minimum volumes based on the understanding that that is a necessary part of obtaining good outcomes and proficiencies for transplant teams. If there is a review cycle and a new program is approved, there would be a period of time when MHCC would not approve another program on

order to give the new program a chance to ramp up its volume. Dr. Lesser expressed agreement with Mr. Parker's ideas.

Ms. Fleck said that staff had some other issues they wanted to cover at this meeting, but time was running short. She thought that it would be helpful to provide more specific proposals to the group for consideration. Group members could provide feedback on different approaches. Ms. Weiland thought that would be helpful and thanked Ms. Sullivan and Dr. Massie for the presentation. Mr. Parker noted that there is a meeting scheduled in July that is expected to be the last meeting for the work group. He suggested reserving the rest of the agenda items for the fourth meeting. Ms. Goldman thought that she could provide some additional information to the group via email. MHCC staff also requested that the work group members consider allotting an additional half-hour longer for the next meeting to ensure coverage of the full agenda. Ms. Fleck thanked everyone for attending and adjourned the meeting.