June 8, 2017

To the United States Office of Special Counsel regarding OSC File No. DI-14-3637 Phase 2:

I appreciate this opportunity to comment on the second phase report published by the Department of Veterans Affairs Office of Medical Investigation in response to my complaints. Again, I have identified numerous misrepresentations in their self-examination as they pertain to the National Surgery Office and National Transplant Program. The following information is offered as a rebuttal to the many inaccuracies I noted while researching their findings.

1) *"The contracted liver transplant surgeon and nephrologist have no association with the VA and experience in performing reviews" (phase 2, p. ii, para. 2).*

   In the interest of full disclosure, it would behoove the OMI to release the names of these individuals, their credentials, and their previous work history. The VA Transplant Centers (VATCs) have numerous associations with community based facilities and having this information for review would relieve any potential perceptions of bias.

2) *"Most VA facilities do not have the medical expertise to definitively determine whether a transplant procedure is indicated and, therefore, are not adequately positioned to authorize transplant procedures under the VCP" (phase 2, p. 8, para 2).*

   In the previous report the issue surrounding the use of the Veterans Choice Program (VCP) for transplant revolved around the ability to pay for organ procurement from a non-Veteran (phase 1, p. 9). "Although there are challenges relating to furnishing transplantation care under VCP…other contracting vehicles to pay for those costs are available". The phase 2 report on page 8 notes states, "However, most VA facilities do not have the medical expertise to definitively determine whether a transplant procedure is

indicated and, therefore, are not adequately positioned to authorize transplant procedures under the VCP" (para. 2). So, which one is it? VCP is not used because transplant centers will not accept our rates of reimbursement, or we don't have the expertise to send them to the community for an evaluation? The first argument is null and void since the report notes Medicare rates are offered and not accepted, yet, more than 70% of the local transplants in San Antonio are performed at Medicare costs. The second argument that we lack the expertise for referral is simply ridiculous. Many of the patients we send by VCP to the community are because we lack the expertise to care for them. Are they reviewed by the national office prior to referral? We also currently refer patients to a VATC because we think they need transplant, so don't we have the same expertise level to refer them to the community and seek an expert opinion? We also complained in phase 1 that we did not have the expertise to care for the post-transplant population, which your findings on page 10 of that report noted, "However, because the physicians caring for Veterans who had undergone liver transplantation had some training and experience in caring for these patients and because EXPERTISE was locally available from private medical providers in the San Antonio area, VA does not substantiate that a substantial and specific threat to public health existed" (p. 10). So, OMI agreed our providers have the experience to care for post-transplant patients (although the physician staff believe they don't) and we have experts available to us in the community. Is this not directly contradicting what the OMI has stated as a reason for not allowing us to refer to the community?

3) *"We do not substantiate a substantial and specific threat to public health in the manner in which VATCs use the body mass index (BMI) criterion in considering candidates for kidney transplantation therapy" (phase 2, p. iv, para. 1).*

The OMI and/or reviewer cite research from 2015 as blanket coverage in allowing VATCs to limit transplant services to Veterans. However, major research proves this limitation to be incorrect. This is supported by the fact that all three kidney transplant centers in San Antonio perform surgery on BMI's of 40 or less. The reason they do this is because RESEARCH proves that although there may be more complications, the patient is always better off with transplantation. According to Kalantar-Zadeh, von Visger, and Foster (2015), "In the long term and across all BMI ranges, there appear to be benefits of kidney transplantation as opposed to staying on dialysis therapy" (p. 2286). In fact, the same authors state, "we suggest that strict BMI threshold levels to withhold transplantation such as >35kg/m2 be revisited while other body composition metrics such as waist circumference and muscle mass assessments be added to current criteria. In-between patients across different BMI categories deserve equal chance of kidney transplantation" (p. 2286). Further research by Krishnan et. al and published in the *American Journal of Transplantation* note, "In summary, patients should not be denied transplantation based on their current BMI alone in the current era of intensive cardiovascular screening and potent immunosuppressive medications" (p. 2385). Obviously, this is supported by at least two of the six VATCs because they allow BMI's of 40 or less for transplant consideration (phase 2, p. iv). Since these centers are not in Texas, this reduces the Veterans chances at transplantation and poses a risk to public health.

Now, let's discuss access to care since the OMI continues to voice that BMI constraints etc. have no bearing on public health. Let's compare a few local kidney transplant centers versus the VATCs. Houston's current Scientific Registry of Transplant Recipients (SRTR) data reports they performed 12 kidney transplants, and have an expected 1 year survival of 100%. Their transplant rate is **8.3** per **100** people per year. Our local community centers have VERY different data sets. University Hospital during the same time performed 83 kidney transplants, and have an expected 1 year survival of 95.2%. Their transplant rate is **14** per **100** people per year, or close to double the amount the Houston VATC. Methodist Specialty Transplant Hospital during the same time performed 325 kidney transplants, and have an expected 1 year survival of 92.6%. Their transplant rate is **13.2** per **100** people per year. In comparison, another VATC is selected, like the Nashville, TN center. They performed 19 kidney transplants, and have an expected 1 year survival of 93.9%. Their transplant rate is **9.4** per **100** people per year.

When the OMI states there is not a threat to public health further investigation is warranted. Why is it local centers constantly outperform the VATCs when it comes to the number of people transplanted? One of the reasons is overly restrictive criteria, which every VA referring center is aware of in our health system.

4) *"We do not substantiate that VATCs apply inconsistent and overly restrictive eligibility criteria in evaluating candidates for liver and kidney transplants" (phase 2, p. 6, para. 3).*

OMI notes on page 10 and 11 of the phase 2 report that two patients were deemed not candidates by two VATCs because of cardiovascular risks that did not exist. In the report, they note the NSO should ensure the VA Tennessee Valley Health Care System

(Nashville)…review coronary artery disease as a relative contraindication for kidney transplantation therapy and take appropriate clinical educational and training action, if needed (phase 2, p. 7). The Portland VATC also declined the patient because they agreed with the Nashville VATC. The issue is that both patients faced EXTENSIVE wait times to be listed and receive their transplant, which is an absolute threat to public health. The only reason they (SAB) agreed to a review and subsequent 3rd evaluation, per a source that will remain anonymous but was a member of the transplant review board, was that I was a protected whistleblower already pursuing matters against the VATCs. Otherwise, they would not have considered this patient. OMI also noted in this report that cardiac stent placement in a pre-kidney transplant patient is not an absolute contraindication to listing. I agree. This statement was made because patients were denied LIVER transplant in the VA, specifically the Portland VATC (OIG Report 11-03671-207) because of the presence of a cardiac stent. The same patient was declined by the Pittsburgh VATC because of his kidney failure. The question surrounding cardiac stents and transplant is related to liver, not kidney services.

5) *"Overall, the reviewers found that the standard of care was met in 78 of the 80 cases…specifically, they found that the standard of care had been met in all 10 of the liver cases" (phase 2, p. 5, para. 4).*

Absolutely, unequivocally, false. Just one chart alone that was submitted was of a Veteran listed with the Houston VATC, and was refused transfer. The entire time he was here in our facility, in the ICU, we were told he was updated on the UNOS wait list. All of this is documented in his medical record. After Houston relented and accepted transfer, days later, the patient deteriorated quickly and subsequently died. I retrieved

information from their team that verified he was never updated on the UNOS wait list promised, and mandated. This Veteran died because of a VATC, and this evidence was submitted. Obviously, the standard of care was not met.

While on this topic of equal care their finding that the "VATC system works", let's now compare our nearest liver transplant center, the Houston VATC, with those in our local community. Their current Scientific Registry of Transplant Recipients (SRTR) data reports they performed 11 liver transplants, and have an expected 1 year survival of 76.3%. Their transplant rate is 28.4 per 100 people per year. Our local community centers have VERY different data and significant differences in outcomes. University Hospital during the same time performed 72 liver transplants, and have an expected 1 year survival of 88.4%. Their transplant rate is 41.8 per 100 people per year, or almost double the Houston VATC. Methodist Specialty Transplant Hospital during the same time performed 70 liver transplants, and have an expected 1 year survival of 91.5%. Their transplant rate is 63.7 per 100 people per year.

To say that VA patients, especially in Texas, have the same access to transplant care and the same QUALITY as those in the community is utterly false and incompetent to say the least. Sadly, this report demonstrates a far more sinister mechanism of self-preservation to the detriment of the patient.

6) *"During fiscal years 2014 and 2015, VA authorized and paid for 13 solid organ transplantations in the community" (phase 2, p. 8, para.3).*

This statement and accounting is very concerning. The OMI reports $26.8 million dollars were spent in the 13 solid organ transplants they performed in the community. Per Milliman and their *2014 U.S. Organ and Tissue Transplant Cost Estimates and*

Discussion report (http://www.milliman.com/uploadedFiles/insight/Research/health-rr/1938HDP_20141230.pdf), page 5, the most expensive procedure is an intestine transplant at $1.5 million. This includes pre-evaluation, surgery, 180 days' post care, medications, etc. Lung and heart are both less, at around $1 million or less. An examination of why 13 transplants totaled $26.8 million, well above national costs reports, is extremely concerning in regards to waste.

It is also noted that many of the VATCs perform transplants at non-VA centers, which would be considered community based transplant. It would be interesting to see these numbers as well for comparison to the national averages as mentioned above.

7) *"Although in our original report, we substantiated that communication problems did exist between San Antonio and Houston, we do not substantiate that any of the communication problems resulted in delays of care or caused a substantial and specific threat to public health" (phase 2, p. iii, para. 2).*

The complaint, as noted in phase 1, page ii, paragraph 3, notes, "Communication between referring and receiving centers is problematic and results in delays in care". Note, the complaint is not Houston alone, it is all VATCs! As I type this, we have waited over 4 weeks for a response from the Portland VATC regarding post-transplant results and medication adjustments. The Richmond VATC has the same issue, and the list goes on. This statement by the OMI obviously notes that they did not investigate the original complaint, and only focused on one center. And for the record, communication with the Houston VATC has improved slightly because of the ongoing investigation, but is still not to the level that is needed to provide safe care. Again, long distance transplant is not optimal.

Conclusion

In conclusion, more points could be made regarding this report and its short comings but I feel I have provided sufficient evidence to validate my concerns. However, I would like to focus on real world scenarios. A patient in Los Angeles was just approved for transplant at UCLA (community transplant) by VA funding because the wife contacted me and a report was broadcast in the LA Times. The wife also started a Facebook campaign where thousands of emails and calls were received by VA leadership in Washington, DC. The issue, as usual, is that they (VA) were trying to send this Veteran to Seattle, WA, or Madison, WI, for lung transplant. He has a wife and children, and they were not able to travel, live in hotel rooms, and wait months on end. Again, this Veteran, like so many I have cared for, had opted to have local transplant or die instead of destroying his family. Here is another example. We have a 44-year-old kidney patient, service connected, with numerous living donors. He is pre-emptive, not yet on dialysis. He has been trying since June 2016 to have local transplant. Again, his wife works full time as an NP and his children are in school. How does he travel for weeks, possibly months? How do they pay their bills? Who watches their children? Had he had access to local transplant his wife would still work, his children would still go to school, and he would receive his transplant with the support of his local family and community. Instead, he will probably end up with shunts in his arms, permanent disfigurement, and possibly death because of a lack of community resources.

While typing this report, I received a call from a patient in Dallas, Texas, who needs a bone marrow transplant but cannot travel to San Antonio, Texas with his support person. His wife, who has had a double lung transplant, needs to be at home near her physician staff and cannot spend weeks living in a hotel away from her own support mechanisms.

Sadly, these stories are numerous and repetitive. How many referring VA centers lack coordinators to even know to send these patients out for transplant to the VATCs? How many patients did the OMI contact and ask their opinion of the processes as they wait? I can provide media interview after interview that demonstrates the OMI and leadership of the NSO and VA are disconnected with Veterans and their specific needs for care. Think of your own situation, and would travel to another state, residence in a hotel etc. for weeks or months upend your home life? Could it be detrimental to the financial well-being of your family? Think of our recent liver transplant patients who spent 10 months or more in a medical center with their spouse at their bedside, losing their homes, cars, everything they saved and then the Veteran still died because of marginal care. Imagine being referred to a sub-par center where your outcomes were so significantly different from another that is in your own community. Imagine being cared for by referring centers who do not understand liver cancer criteria, cardiac assessments for kidney patients, etc.

Not once did the OMI contact any of the participants in this report, from STVHCS, after the initial interview. I continued to send emails with more evidence to OMI team members once they left San Antonio, and yet they never inquired about these things or asked further questions. Instead, every effort was made to justify the existence of the VATC programs.

Scientific data MUST be incorporated with common sense thinking and logic. This system is a travesty, and no amount of manufactured reports will hide the fact that this is a failed process.