Kidney disease mitigation, Home dialysis and transplantation - Options for a way out of a deepening crisis for people with kidney disease in the USVI

Scope of the problem:

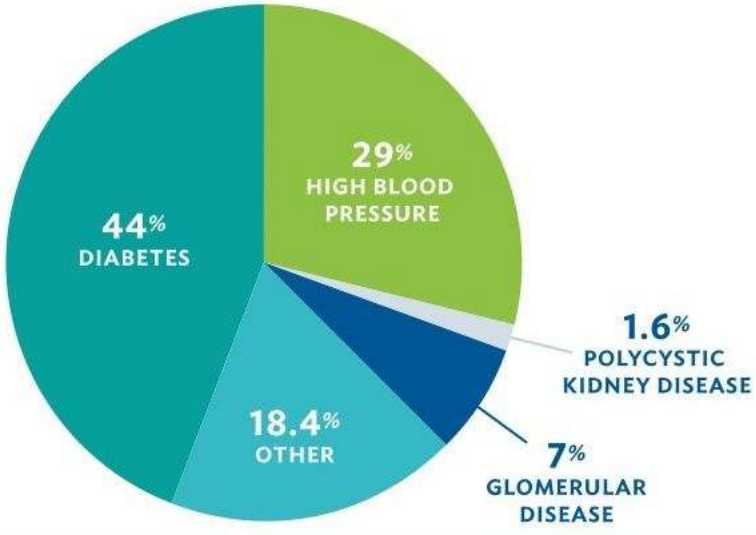
- Kidney disease affects probably every family on the USVI to some degree. In mainland USA, about one out of every 13 people with African heritage is expected to develop end-stage kidney failure (ESKD) during their lifetime. In the Caribbean including the USVI, the number is even higher. It is about one out of every 10 people. The higher occurrence of ESKD in the Caribbean has recently been attributed to a specific Caribbean form of kidney disease named “Mesoamerican nephropathy”, but its cause is yet to be established.

I shall limit this presentation to covering chronic kidney disease.

Chronic kidney disease (CKD) is common and affects probably one in 6 people here in the USVI. While most people with CKD will not require dialysis during their lifetime, it tends to decrease their life expectancy depending on the severity of the CKD. CKD is staged based on the body’s progressive inability to eliminate waste products with the urine. Most people with CKD will have mild to moderate kidney dysfunction at stage 3 CKD and progress over years to decades to CKD stage 4 and this is typically not associated with any abnormal bodily sensations. CKD stage 4 tends to progress to ESKD (= CKD stage 5) within 2 years and this still may be associated with few or no abnormal bodily sensations. Dialysis or kidney transplantation becomes necessary to avoid life-ending derangements of the body fluids or otherwise uncontrollable body sensations. Repair of failing kidneys is not possible since the alterations occur with chronic progressive scarring and destruction of the kidney architecture. Early detection and intervention to slow disease progression and even avoid future need for dialysis can be very successful and should be aimed for in people at risk for CKD.

Risk factors are diabetes, hypertension, obesity, ageing, African heritage, living in the Caribbean, COVID19, consumption of toxic substances like NSAIDS, certain herbs and plants like aloe vera and carambola

Most frequent causes of CKD leading to need for dialysis:



Source: Fresenius Medical Care

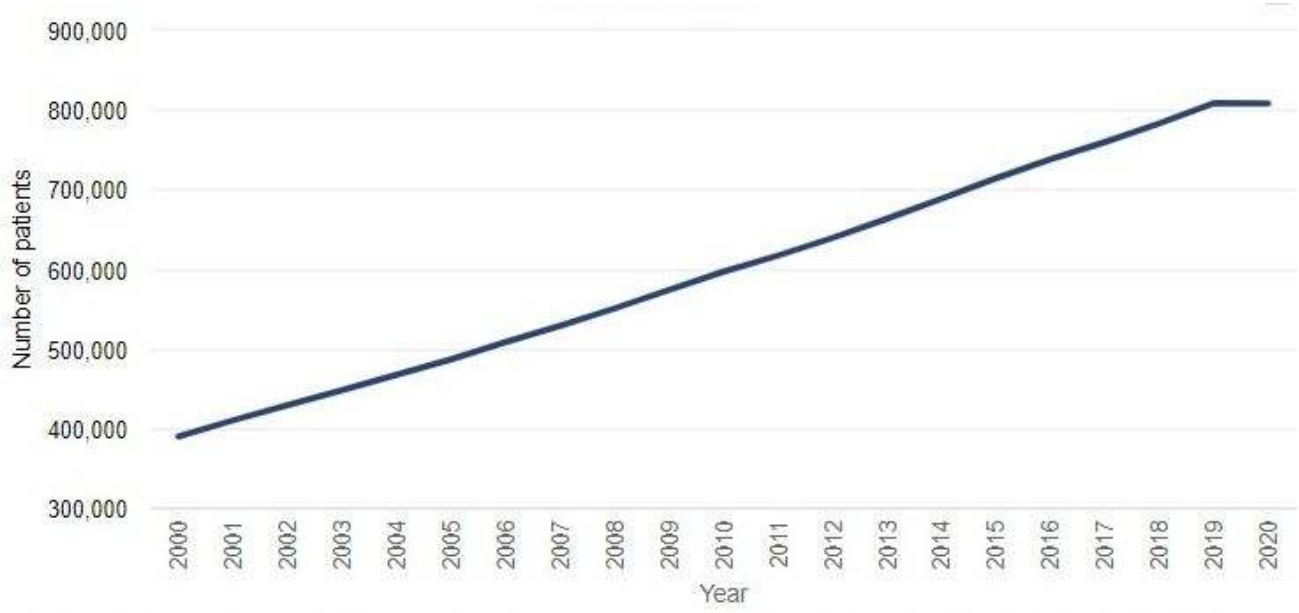
- About 250 Virgin Islanders are currently requiring chronic outpatient dialysis services to allow their survival after permanent kidney failure. Another 20-40 patients are off island, unable to return to their homes in the USVI for lack of suitable outpatient dialysis chairs.

- Patients from St John and Water Island have no dialysis options on their islands and have to commute three times weekly to receive 4 hourly dialysis sessions on St Thomas during the productive hours of the day.

- People with End Stage Kidney Disease in the USVI are far less likely to obtain a kidney transplant. This is particularly grave for younger people who would stand to gain most in additional lifetime and quality of life. Treatment with a kidney transplant at any age offers more than twice the remaining lifetime compared to dialysis. People with a transplant are also much more likely to remain employed and active in their community, enjoy their life and experience less treatment complications over all.

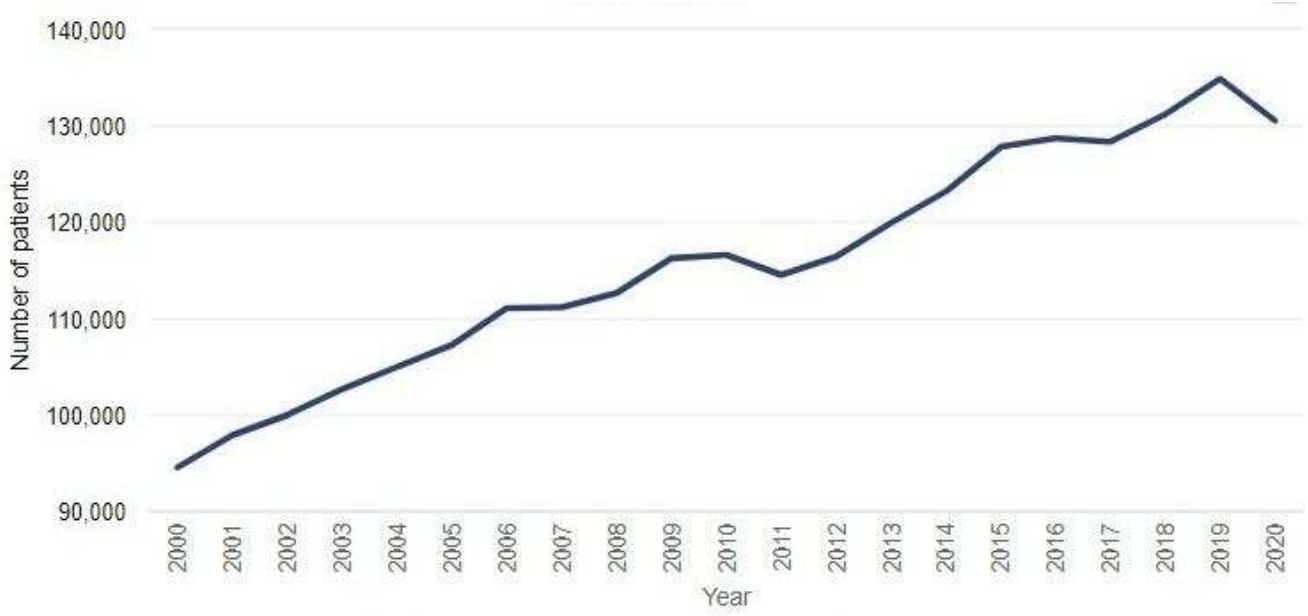
- Relentless growth of the ESKD and dialysis population in the US and the USVI:

Total ESKD patient population (per USRDS 2000 to 2020)



Data Source: USRDS ESRD Database. All U.S. ESRD prevalent patients were included for Prevalent Count; unknown sex and other or unknown race/ethnicity were excluded for Prevalence Rate (adjusted and unadjusted). Adjusted rates are standardized to the age, sex, and race/ethnicity distribution of the 2015 US population.

New ESKD patients entering every year (USRDS 2000 to 2020)

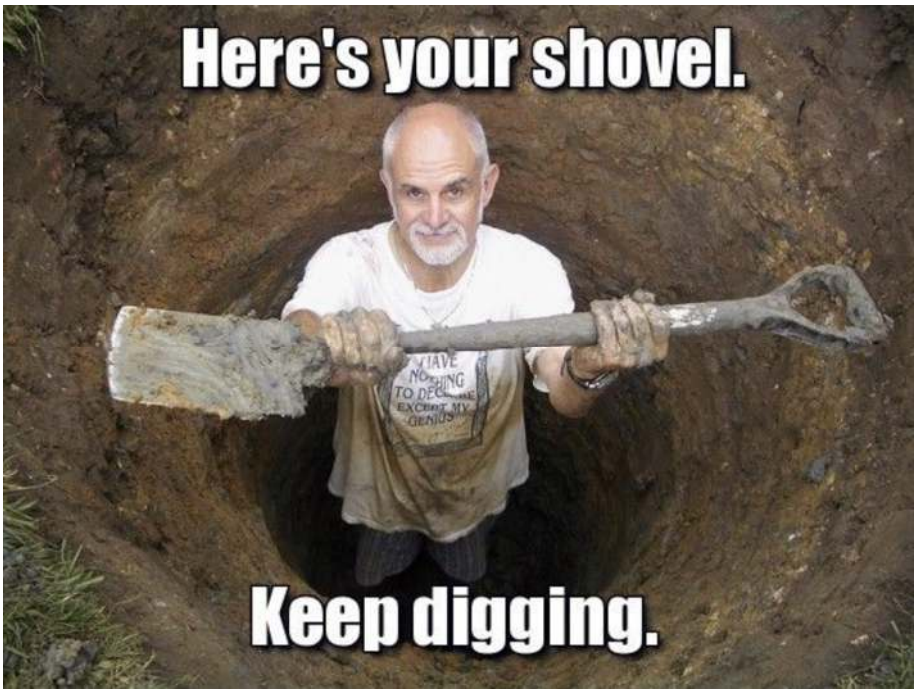


Data Source: USRDS ESRD Database. All U.S. ESRD incident patients were included for Incident Count; unknown sex and other or unknown race/ethnicity were excluded for Incidence Rate (adjusted and unadjusted). Adjusted rates are standardized to the age, sex, and race/ethnicity distribution of the 2015 US population.

The total End stage kidney disease population in the US has steadily grown from 400,000 in the year 2000 to 808,000 in 2020 and continues to grow relentlessly. More than 80% of the costs for this care is covered by Medicare. While the patient total accounts for 0.24% of the US population, costs for these services have now reached a disproportionately large Medicare pie, currently about 7%. This triggered a number of cost cutting interventions by Medicare that lead to shrinking profit margins, resulting in concentration of dialysis services in the hands of fewer and fewer operators. 2 very large for profit dialysis chains, DaVita and Fresenius Medical Care, now provide dialysis care for over 75% of the Dialysis patients (Chertow, CJASN 2017).

In the USVI, this economic pressure has left patients with ESKD with few and financially unstable options. In the 1980s under Dr Schneider, treatment options in the USVI included home dialysis and even kidney transplantation. Now we have only in-center hemodialysis as sole treatment option left on the USVI. And even this treatment option is becoming less and less self-sustainable. On St Thomas, the privately run Crown Bay dialysis center opened 2014 and then closed suddenly in 2017 due to inabilities to meet costs. The Senate recently took the difficult decision to bail out the remaining for-profit dialysis provider with an inflow of $72,000 every 2 weeks going forward, with an initial grant of $700,000 allocated in June 2023. At the government run hospitals, dialysis continues to generate negative balances and draws on staffing. This has required more and more diversion of resources to dialysis that are needed elsewhere (example: cancer care and mental health in the USVI). This was recently further complicated by a yet unresolved issue: Medicaid Unwinding. During the COVID19 emergency, VI Medicaid insurance was automatically renewed without review of entitlement criteria. Since the emergency was lifted earlier this year, a number of patients currently on dialysis in the USVI have unexpectedly lost their Medicaid insurance and may become burden of emergency dialysis services at the local hospital emergency rooms unless covered in some form

What are the options out of the economic crisis and the insufficient treatment options available in the USVI for patients with kidney disease ?



As outlined, we are sitting in a hole that has kept growing for some time. Just to continue with what we are doing and hoping that the situation will somehow improve on its own is like trying to getting out of a hole by digging deeper. If nothing changes, demand for dialysis chairs will continue to grow because of the ever increasing number of people with End Stage Kidney disease in the USVI. And deficits caused by insufficient reimbursement rates and diminishing insurance coverage will require larger and more frequent bail outs of private and government owned facilities while still not meeting the needs of the patient population with ESKD.

Which way out of the situation?

I will talk about options that will address the following currently unmet needs for CKD patients in the USVI as well as improvements of their financial viability:

1) Option to bring in new treatment choices (CKD mitigation program, Home dialysis)
2) Option to decrease the number of patients that will ever require dialysis services (Outreach program that mitigates chronic kidney disease and delays or entirely prevents dialysis needs)
3) Options to improve survival of patients with ESKD (transplantation, home dialysis)
4) Options to improve the quality of life for patients (transplantation, home dialysis)
5) Option to improve the quality and stability of services (To achieve increased staff retention, backup staff availability, ongoing ESKD staff training, financial stability of services, pre-established emergency evacuation routes for ESKD patients for the next big hurricane)
6) Option to achieve financially self-sustainable kidney care services that does not require on-going USVI government intervention and subsidies.

1) How much could be gained by increasing treatment choices (estimates):

Current USVI situation	Average USA (USRDS 2022)	With Mitigation Program*)
250 – dialysis on island 20-40 patients off island	213 – in-center dialysis	109 – in-center dialysis
0 home dialysis	27 – peritoneal dialysis	105 – peritoneal dialysis
0 transplant before dialysis	8 – transplant before dialysis	16 – transplant before dialysis

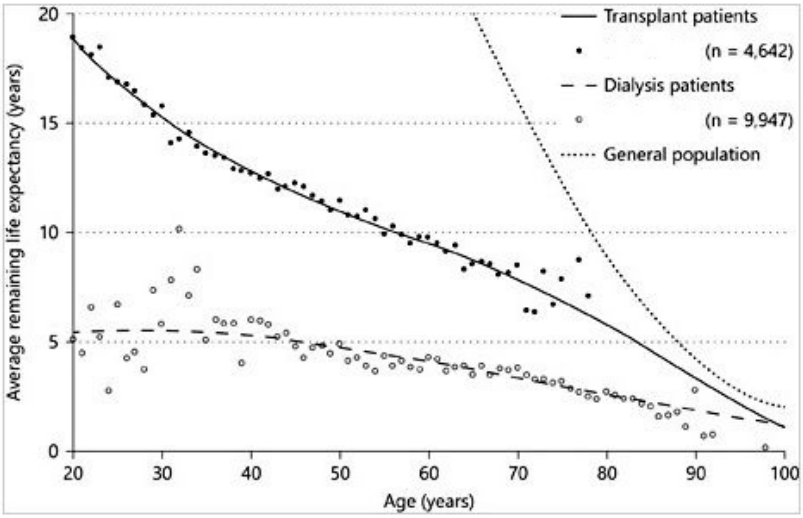
*) Aspirational. Assuming Average USA numbers as base, using REACH real world mitigation results, also assuming that all current patients would have gone through the REACH program and that an overall reduction of need for kidney replacement therapy of 8% can be achieved

2) Outreach program to mitigate kidney disease in order to delay or entirely avoid need for dialysis. Given growing new insights into contributors of kidney disease and appearance of powerful new medications have made delay of need for dialysis possible for most patients with chronic kidney disease and avoidance of dialysis for many that participate in such programs. They also allow for higher life expectancy since they will also mitigate cardiovascular disease. Such programs have been found to be cost effective in financial models and hold the promise to achieve a fall of people requiring kidney replacement treatments rather than a continued rise.
   Such programs typically focus on control of diabetes and hypertension, lifestyle modifications such as weight control and smoking cessation, dietary protein replacement or reduction, avoidance of toxic substances such as non-steroidal-anti inflammatory drugs, certain herbs and plants (Especially relevant for the Caribbean region: Aloe vera and carambola).
   In addition, multiple pharmaceutical strategies have shown promising in further improving these goals.
   Example: REACH kidneycare program:
   Reported benefits of REACH Kidney Care (www.reachkidneycare.org) over national average:

Patients start with home dialysis rather in-center dialysis	46%	vs	11%
Patient obtain a kidney transplant before need of dialysis arises:	7%	vs	3%
Patient start dialysis with a safe permanent access	71%	vs	19%
Patients avoid hospitalization before start of dialysis	81%	vs	54%

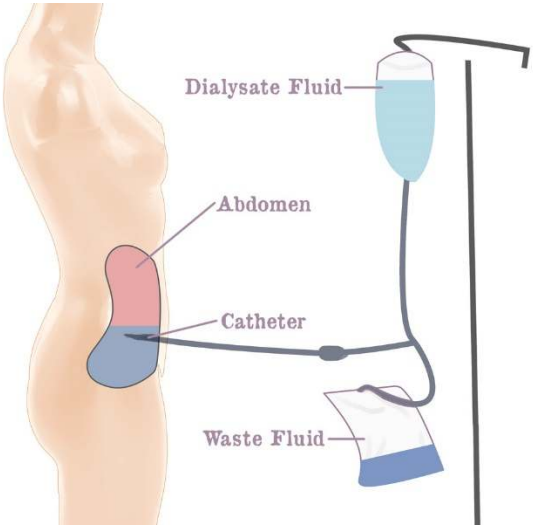
3) Transplantation. Kidney transplantation offers the best potential outcome in terms of years of life and quality of life gained and its benefits are most notable for younger people in pursuit of an active life. People transplanted at any age will more than double their remaining life expectancy

   Age dependent remaining life expectancy dialysis vs transplant Netherlands - 2016 Nephron



Transplantation is mostly limited by patient suitability and availability of organs. It can only be done off island. Costs, efforts and risks of transplantation are frontloaded in comparison to hemodialysis and benefits over starting dialysis start to accrue after about 18 months following the kidney transplantation procedure. Proper evaluation and preparation requires time and effort and patients need to be able to stay from 3 to 6 months in the area of the transplant center to attend to potential problems in the early post transplantation period.

4) Home dialysis. Most commonly used: peritoneal dialysis. This is a form of dialysis that is less resource dependent since it is done by the patient at his home after a training of about 2



weeks with the home dialysis nurse (36 minute patient training video: https://www.youtube.com/watch?v=7HsE90bT8wI).

To allow dialysis, a soft catheter is permanently inserted into the abdominal space surrounding the abdominal organs. The lining of the abdominal organs can then act as a filter to allow dialysis.

Manual fluid bag exchanges – no machine, no electricity needed

Automated fluid bag exchanges while you sleep – small machine, electricity needed

In principle, a prescribed amount of clean sterile fluid is inserted into the abdominal space through the catheter and is left there for a number of hours. Accumulated body waste products and excess body water will then be attracted from the blood stream into the inserted fluid. The soft catheter is then connected to allow drainage of the accumulated fluid and then also used to insert the next batch of clean fluid in the same procedure. It can be performed manually without need for electricity or running water, taking approximately 30 minutes each time. Typically, 4 exchanges of fluid are done during the day when performed manually. Alternatively, for convenience of the

patient and to free the day from need for procedures, a machine can be used that does all or most of the fluid exchanges safely and unattended during sleep time.

“Home dialysis is generally less expensive than in-center dialysis. Compared with in-center dialysis, home dialysis provides significant economic, quality-of-life, and clinical advantages. Clinically, peritoneal dialysis has been associated with better preservation of residual kidney function, fewer hospitalizations, and better quality of life, and some data suggest improved short-term survival compared with in-center HD” (from Mallika L Mendu: Expanding Utilization of Home Dialysis An Action Agenda from the first International Home Dialysis Round Table meeting 2020)

Patients meet with the nurse and the doctor in person only once per month to review and adjust treatments. Need for commuting thus only occurs once per month and therefore also only one home dialysis base is needed in the USVI. Home dialysis would be particularly attractive for younger people pursuing active lives and people living on St John and Water island since these islands are too small to make in-center dialysis a viable option there. Dialysis patients on St Thomas were asked how they would feel about switching to home dialysis – about 20% voiced interest to switch when it becomes available.

Home dialysis depends on 2-3 nurses experienced with home dialysis at its core of operations. It needs logistics to bring and store large amounts of exchange fluids to the islands. As past failures have taught, these requirements can only be fulfilled by partnering with a large corporate partner that can offer the necessary longevity, financial and logistical stability of operations.

5) Improved quality and stability of services (Increased staff retention, backup staff availability, ongoing ESKD staff training, financial stability of services, receiving mainland dialysis centers, pre-established evacuation routes after the next big hurricane)
   This has been aimed for by multiple singular private and governmental entities in the USVI – the hospitals and the private dialysis providers. Previous home dialysis and transplantation option through Schneider Hospital fizzled out even during the lifetime of Dr Schneider, leaving only in-center dialysis as available option in the USVI. Crown Bay dialysis planned to open home dialysis services but closed its doors in 2017 before the home program ever came around. Caribbean Kidney Center now requires constant financial support to keep its operations running. JFL Hospital Dialysis is operating out of only one of two long dilapidated dialysis trailers and both hospitals have chronic difficulties in maintaining appropriate staffing and stable financing.
   Recurring delays in payments for services and materials have left the hospitals with a reduced number of vendors willing to do business and the remaining vendors will charge premium prices rather than offer customary discounts offered for customers paying on time. In addition, the amount of material being shipped to a singular institution remains too low to allow for significant bulk savings. Medicare payments for dialysis have relatively decreased and are not adjusted for the higher operation costs in the USVI.
   I believe that the only way out of this situation is an alignment with a large dialysis organization that is capable to reduce material costs through bulk purchasing, cut overhead costs through nimble in house IT services, billing, ongoing staff training, shipping logistics, laboratory and pharmacy services and can draw from a larger workforce pool when local staff shortages arise.

6) Financially self-sustainable kidney care that does not require on-going USVI government intervention and subsidies.
   As just pointed out, this will be best achieved by aligning local dialysis providers with a large national dialysis organization. DaVita, a for profit corporation and the second largest dialysis chain had won a RFP to enter joint dialysis services with Schneider Hospital in 2014 but pulled out after being sued by a for profit USVI dialysis provider. Fresenius, also a for profit corporation and the largest dialysis chain worldwide has at times considered extending its services from PR also to the USVI and spoken to both hospitals and several nephrologists but this has not lead to any engagements.
   DCI, the largest national not for profit provider of kidney services has now been engaged in operating the new dialysis center on St Croix once it has been opened by the dialysis patient inspired charity, the Virgin Island Health Care Foundation.
   In my view, this is the truly golden opportunity for the USVI to put the islands on a path to improving the lot for people with kidney disease and also solving many of the fore mentioned issues
   .
7) New dialysis center at Sunny Isles, USVI, to be opened and built out by VIHCF and to be managed by DCI once opened.
   As the VIHCF.org website states, “The Virgin Islands Healthcare Foundation (VIHCF) is a 501(c)3 non-profit established in 2018 in response to healthcare needs identified in the aftermath of 2017 Hurricanes Irma & Maria.”.” The Foundation aims to open an outpatient dialysis center and clinic that will provide services such as outpatient dialysis, renal dietetic services, and COVID-19 testing for the dialysis patients” The creation of the VIHCF was inspired by dialysis patients on St Croix who were particularly exposed to the uncertainties of care in the wake of the two hurricanes Irma and Maria. They experienced a chaotic forced exodus to Puerto Rico and further on to lonely places on the mainland, from where many never returned. Returnees to St Croix found their former hospital dialysis facility condemned and replaced with temporary dialysis trailers. When the federal license for the trailers came to its expected end, the St Croix hospital had failed to rebuild a permanent dialysis unit and told the patients to sign up with the only other option, the for profit dialysis facility on St Croix. All 49 affected patients held a public meeting in September 2021, and all 49 refused to go to the for profit dialysis center. They then successfully petitioned the federal agency (CMS) to allow continued use of the trailers on an exceptional monthly relicensing basis. The trailers deteriorated further and only one remains functional at this time. In the meantime, the dialysis patients themselves inspired the creation of the Virgin Island Health Care Foundation, which aligned with DCI to operate the facility. The facility has received $1,000,000 in federal ARPA funds allocated by Governor Bryan as well as significant donations from the community but a reported hold up of allocated funds at the Office of OMB for unclear reasons as well as a remaining shortfall of $940,000 (June 7 2023 Committee on Health and Hospital meeting) still prevents opening of the 95% built center to begin its operations.
   I believe that the Senate should consider to assist the VIHCF by working with the OMB to resolve the remaining hurdles to obtain the funds currently still held up at OMB as well as considering to fund VIHCF in equal measure to the support given to shore up the private dialysis operator. In my assessment, the overall return on the investment will be substantially greater since the operation of the VIHCF built center will then allow DCI to operate the dialysis

center in a financially self-sustaining manner that does not require further or ongoing bail outs through the USVI government. This will then also allow for the transformational changes necessary to meet the needs of the people with kidney diseases in the USVI.

8) DCI. DCI was founded in 1971 as a not for profit operation and has since then focused on excellence in patient's care. DCI provides the best patient outcome among the national large chain kidney care providers, invests a substantial portion of its resources to spearhead improvements of kidney care through research in its alignment with University based centers, more than 300 outpatient clinics, and over 120 hospital dialysis programs across 30 states. DCI is the nation's largest non-profit dialysis provider. Headquartered in Nashville, Tennessee, DCI employs over 5,000 people serving more than 14,000 people with kidney disease. DCI operates under the mission "We are a non-profit service organization. The care of the patient is our reason for existence".
Once DCI comes to the USVI, many of its services - routinely available to its patients on the mainland - will over time likely also become available to the USVI:

   These include:

   -REACH, the outreach program aligned with DCI in delaying or even preventing need for dialysis services through slowing progression of chronic kidney disease as well as facilitating better and safer patient choices such as home dialysis and kidney transplantation instead of in-center dialysis

   -Easier access to get a kidney transplant since DCI has its own kidney transplant donor procurement program, which provides an additional source of organs to transplantation centers of the patient's choice.

   - Home dialysis such as peritoneal dialysis, which could be operated for all islands of the USVI from a single base on St Croix.

   -financial self-sustainability through lower costs achieved by bulk purchasing, in house billing, IT services, logistics, staff training, laboratory services and access to a large staffing pool to fill shortages.

   -Emergency access/transfer to more than 300 mainland DCI dialysis centers when the next hurricane hits

About myself:

I was born in Bavaria, Germany, studied Medicine and Kidney diseases in Berlin, Germany; London, Great Britain, and later Tulane University, New Orleans, USA. Subsequently, I worked in multiple states of the US in hospital and kidney medicine, including as a kidney specialist at a kidney transplantation program in Albuquerque, NM. Following a work experience at the JFL hospital on St Croix during winter Carnival 2012, I became enchanted with the USVI. I was hired as then director of dialysis at Schneider Regional Medical Center in 2014 and later volunteered as medical director at the St Thomas Dialysis center at Crown Bay. When hired at SRMC, I was asked by then CMO Dr. Thelma Watson to help establish home dialysis options for people on St Thomas. I changed my emphasis of

care to Prevention of End Stage Kidney disease and work now in private practice. I continue to advocate for kidney disease care improvements in the USVI.

About my motivation for this talk and my involvement?

One of my motivations for coming to live and work in the USVI was the given challenge to improve treatment options, in particular bring about home dialysis. I participated in no less than 4 efforts to bring this about, which included DaVita, Fresenius, DCI, SRMC hospital and Crown Bay dialysis in 2014, 2016, 2017 and 2018. Unfortunately, despite my best efforts this did not come to fruition. During the same time, I have witnessed the death of many young people in their 20's and 30's while on hemodialysis on St Thomas. Many of these likely would still be living and would have longer and better lives had they had other options than In-center dialysis. My immediate predecessor at SRMC had also attempted to get home dialysis off the ground and failed. I have come to the conclusion that the complexity of aspects required to achieve both financial viability and extension of services to meet the needs of the patients cannot be achieved by a single person or institution alone but requires the partnership with the best possible corporate partner that can provide these operations. Compared to the previous efforts I was involved with, the alignment of dialysis patients on St Croix, VIHCF and DCI appears to be by far the best match with the most promising chance to achieve this difficult goal.

Other than being an advocate for and financial donor to the dialysis center on St Croix, I have no financial or organisatorial ties or arrangements with VIHCF, the new dialysis center, DCI or any of its operators.

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