Renal Team Data Science Overview

The Executive Order on Advancing American Kidney Health will have a large effect on the Renal Care industry.. There will be a rapid shift towards home dialysis in the form of Peritoneal Dialysis (PD) that will take place over the course of the next 10 to 15 years. The PD population is likely to increase 10-fold, corresponding to a proportional increase in the incidence of Peritonitis. The goal of this application of data science is to project the possible numbers of PD patients, propose a validation of the model based upon the UVA Population, and envision how our PD infection-mitigating device may affect those numbers.

This inquiry is also a chance to probe the model for unaccounted-for parameters and suggest new methods of projection that can be undertaken in the future.

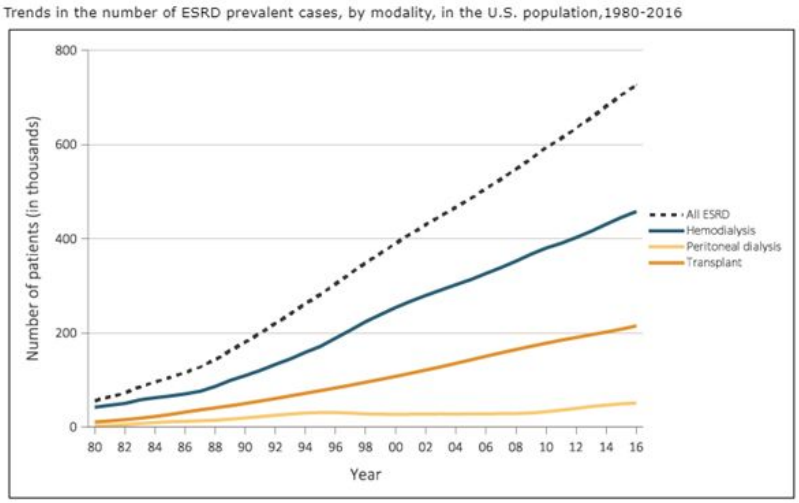
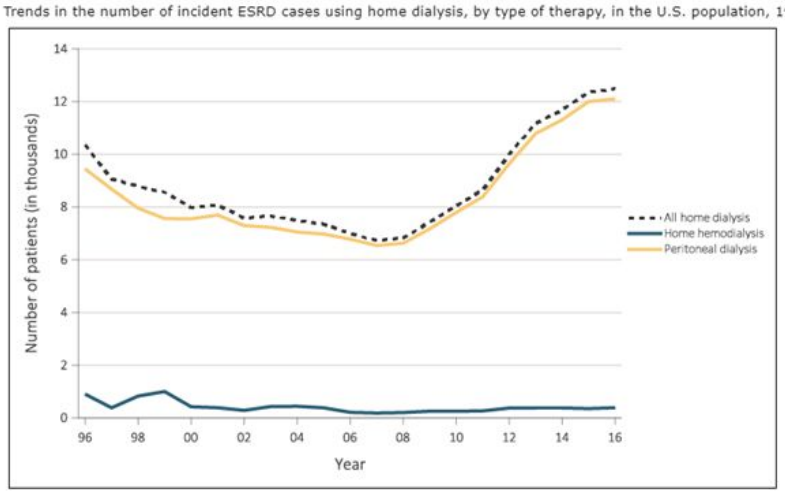
Contents

Phase 1: Data Background and Projection of PD patients and peritonitis

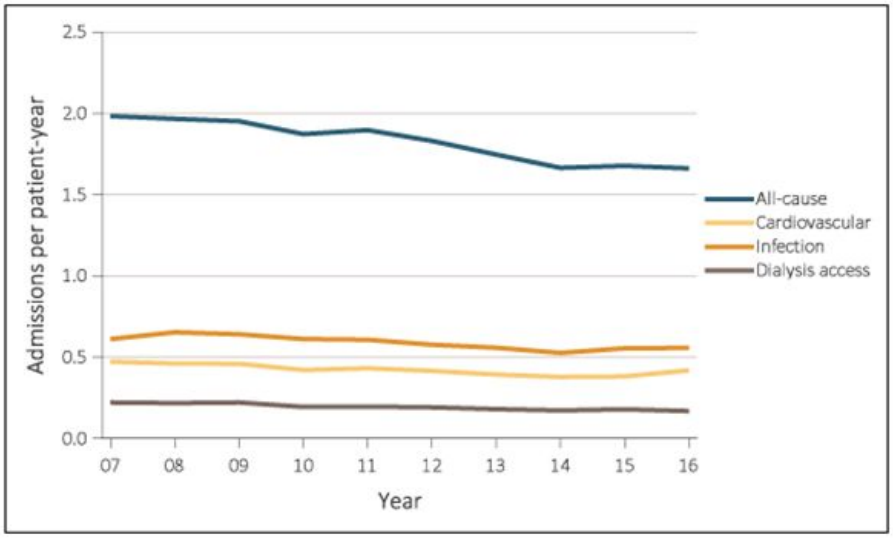
Data Foundation

Nearly all of the data that was used in Phase 1 of this Data Science overview was sourced from the United States Renal Data System Annual Report from 2018. The 2019 report was released in an abbreviated version (due to unforeseen administrative issues) that does not come close to the completeness of the 2018 report. This report is completed by the University of Michigan, funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) under the National Institutes of Health (NIH). This data is in the public domain.

First we will review some of the historical graphs related to this project (all from USRDS 2018)

	End Stage Renal Disease (ESRD) cases have been increasing in the US – prevalent cases are at approximately 750,000 in America, with the value increasing by about 25K every year due to increased levels of diagnosis and lifespan.
	Most people that choose home dialysis every year opt for PD: 12,000 patients a year. PD is a considerably simpler dialysis modality, does not require the creation of dialysate from home water, and allows patients to be mobile while dialyzing, making it the gold standard for home dialysis.

(c) Peritoneal dialysis



The top cause that PD patients are admitted to the hospital is infection. Hospital admissions have decreased over time, but infection admissions have not.

vol 2 Table 1.7 Number and percentage of prevalent ESRD patients receiving hemodialysis, peritoneal dialysis, and a transplant, by age, sex, race, ethnicity, and the primary cause of ESRD, in the United States, 2016

	Total	HD		PD		Transplant	
		n	%	n	%	n	%
Age							
0-21	9,705	1,697	17.5	1,027	10.6	6,981	71.9
22-44	103,213	51,001	49.4	9,110	8.8	43,102	41.8
45-64	316,051	188,339	59.6	22,369	7.1	105,343	33.3
65-74	176,579	119,105	67.5	11,698	6.6	45,776	25.9
75+	118,527	97,815	82.5	6,853	5.8	13,859	11.7
Sex							
Male	419,275	262,716	62.7	28,469	6.8	128,090	30.6
Female	304,745	195,214	64.1	22,587	7.4	86,944	28.5
Race							
White	444,789	259,731	58.4	33,928	7.6	151,130	34
Black/African American	220,616	164,223	74.4	12,391	5.6	44,002	19.9
American Indian or Alaska Native	7,693	5,375	69.9	464	6.0	1,854	24.1
Asian	35,082	20,037	57.1	3,386	9.7	11,659	33.2
Native Hawaiian or Pacific Islander	9,067	6,706	74.0	670	7.4	1,691	18.7
Other or Multiracial	3,508	1,332	38.0	173	4.9	2,003	57.1
Unknown	3,320	553	16.7	45	1.4	2,722	82
Ethnicity							
Hispanic	127,337	85,415	67.1	8,058	6.3	33,864	26.6
Non-Hispanic	579,637	370,249	63.9	42,751	7.4	166,637	28.7
Unknown	17,101	2,293	13.4	248	1.5	14,560	85.1
Primary Cause of ESRD							
Diabetes	278,409	211,695	76.0	19,205	6.9	47,509	17.1
Hypertension	186,213	135,279	72.6	14,174	7.6	36,760	19.7
Glomerulonephritis	114,155	45,363	39.7	8,911	7.8	59,881	52.5
Cystic Kidney	34,987	10,907	31.2	2,600	7.4	21,480	61.4
Other/Unknown	110,311	54,713	49.6	6,167	5.6	49,431	44.8
Total	724,075	457,957	63.2	51,057	7.1	215,061	29.7

Demographics Major Takeaways:

Patients that are younger are more likely to use PD than those that are older. This may point to the fact that PD is more hands-on than in-clinic dialysis

Patients that are White or Asian are most likely to use PD than those that are Black or Hispanic

Datapoints and Projections

All of the following projections were based upon data from year 2000 until year 2016, which is the latest year that the 2018 USRDS Annual report had data on.

First the some of the population characteristics were determined

Datapoint	Explanation	How it was projected forward from 2016
Continued ESRD Cases	Total number of patients in the ESRD Population	Last year's Continued ESRD Cases plus the Patient Growth
New ESRD Cases	Patients that are diagnosed with ESRD, requiring some form of Renal Replacement Therapy	Linear Regression using the slope of the New ESRD Cases from years 2000-2016
Patient Mortality	All Patient Mortality of those undertaking dialysis. Also separated by mortality in each of the hemodialysis, peritoneal dialysis, and transplant populations	Linear Regression using the slope of Patient Mortality from the years 2006-2016 Additionally, this value is multiplied by an exponentially decreasing function to model improvement in patient care
Patient Growth	The net change in number of patients every year	The difference of the New ESRD cases and Patient Mortality

Next, the first choice in dialysis modality was considered:

Datapoint	Explanation	How it was projected forward from 2016
Number of Patients that choose Hemodialysis	The vast majority of patients choose this first	Subtract the numbers of patients that choose a different modality from the number of New ESRD Cases
Percent of Patients that choose Hemodialysis	The vast percentage of patients choose this first	Subtract the percentage of patients that choose a different modality from 100%
Number of Patients that choose Peritoneal Dialysis	Patients that choose PD first, this changes due to the Executive Order	Great increase in the number of patients that choose PD between the years of 2020 and 2025 modeled by: - Rapid constant incline to 75% of new patients until 2025 (the

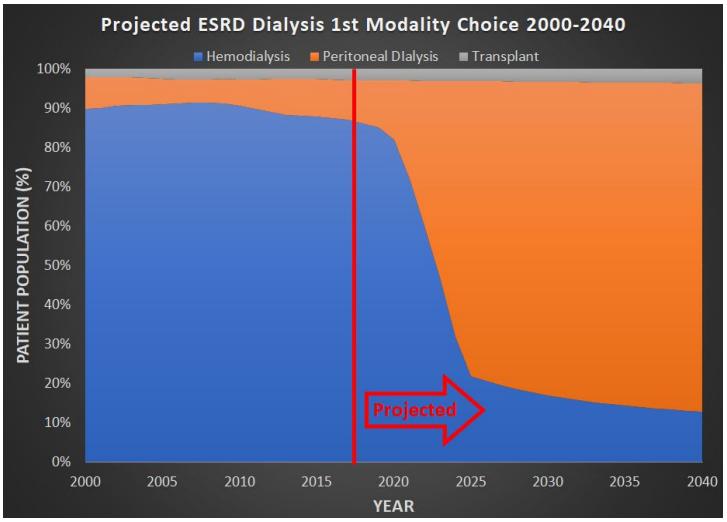
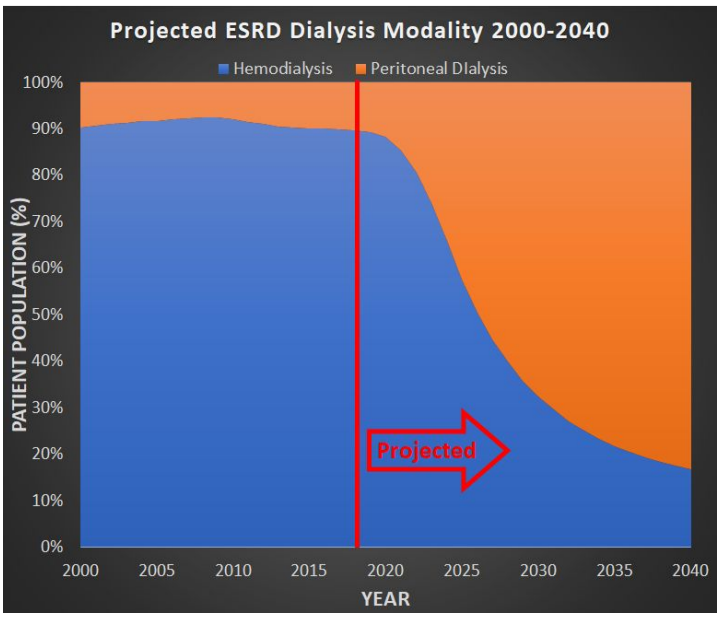
		Executive Order guidelines are ambitious) - Slower increase in patients afterwards asymptotically to 85% of new patients
Percent of Patients that choose Peritoneal Dialysis	Percent of patients that choose PD first, this changes due to the Executive Order	
Number of Patients that choose Transplant	The (very few) number of patients for which transplant is suitable and able to be acquired	Linear regression - a slow increase in the number of patients that have transplant as their first therapy
Percent of Patients that choose Transplant	The (very few) percent of patients for which transplant is suitable and able to be acquired	Same as above, but percent

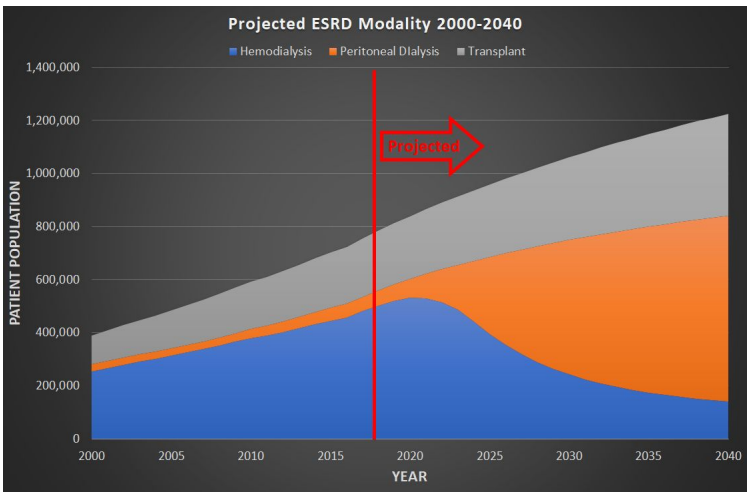
Then we probed the effect upon the entire ESRD Population, which the new patients would be added to:

Datapoint	Explanation	How it was projected forward from 2016
Patients on Hemodialysis	Current patients on hemodialysis plus new patients that choose hemodialysis minus those that die and those that receive a transplant	All inputs were taken other variables that had already been projected forward in other means: Number of New Patients that choose Hemodialysis, Peritoneal Dialysis, or Transplant Mortality of Patients from the Hemodialysis, Peritoneal Dialysis, and Transplant populations Transfer rate from Hemodialysis and Peritoneal Dialysis to Transplant was taken as a percent of the current number of patients in their respective populations
Percent of Patients on Hemodialysis	Convert the number of patients to percent	
Patients on Peritoneal Dialysis	Current patients on peritoneal dialysis plus new patients that choose peritoneal dialysis minus those that die and those that receive a transplant	
Percent of Patients on Peritoneal Dialysis	Convert the number of patients to percent	
Patients with Transplant	Current patients living with a transplant plus new patients that choose transplant and those from other modalities that receive a transplant minus those that die and those whose transplants fail	

Percent of Patients with Transplant	Convert the number of patients to percent	

Outputs

	The graph shows the immediate effect that the Executive order will have on patients that dialyze. The ratio of patients undergoing HD vs PD is turned on its head.
	This graph shows the more gradual effect of the “assimilation” to home dialysis in the current ESRD population. As time goes on, more of the current population are replaced by new ESRD patients that are dialyzing using PD.



This shows the total number of patients that must undergo some form of renal replacement therapy as a result of ESRD. As one can see, the transplant and PD populations increase while the HD population decreases. Overall, there is still an increase in the number of prevalent cases.

Further Analysis and Improving the Model

Further analysis may be completed by integrating other parameters in the models such as:

Effects of the Executive Order on the number of new patients needed dialysis:
The Executive Order may lower the incoming ESRD population because there is a focus on referral to Nephrologists at earlier stages in CKD to conserve kidney function before ESRD. If there is an even larger policy change, such as Medicare For All, there will be major effects upon the industry.

New populations of Americans growing older:
Different populations getting older mean different problems and different volumes. After the Baby Boomer population, there is a decrease in the number of people getting older that will need treatment because that is the generational cycle. Perhaps as Millenials reach the age at which their kidneys start failing, there will be another bump in new ESRD cases.

Distribution of comorbidities in the population
Again, with different populations, there exist different problems. It is known that more comorbidities such as Diabetes, Hypertension, and Obesity can stress the kidneys and cause failure at earlier ages. These comorbidities differ by location and demographic. The model could account for these variables as an input.

The availability of new products due to innovation in the industry
Groundbreaking new products such as the artificial kidney could completely change therapy in the ESRD population. Instead of being gated by the number of available transplants, ESRD modality change would be based upon the manufacturing capacity of this revolutionary product. The Executive Order has a hand in this as well, since it is promoting public-private partnership for the reason of improving renal care.

Most up-to-date data
An unforeseen shift in the data could change how it should be interpreted. Thus the model should be updated to account for or explain the shift in the data and be able to project based upon that new information

Use of other Methods
Methods such as Machine Learning have a low bar in terms of availability of use. It may be worthwhile to probe these methods for use in projections.

Evaluation of rigor in the current model
Projects like these where there is lots of data involved can have many pitfalls that make certain data evaluation methods that were utilized invalid.

Phase 2: Validation of Phase 1 projections based on the UVA Population

Requested Data

Phase 2 of this data science project is forthcoming. As an outline, these are the current thoughts on data to be requested from UVA Data Systems:

ESRD Patients	Which modality are they choosing first? How much education do they have of the different modalities before they decide (sessions attended, consultations, appointments)? Comorbidities? Demographics? Location or proximity to clinic At what stage was CKD detected? ESRD cause Mortality Rate by modality
PD Patients	How long have they been on PD? Automatic (cycler, overnight) or Continuous Ambulatory PD (CAPD) Compliance – sessions performed vs missed, checkups Remote or in-person checkups (this is only a recent option with TYTO) How expensive is PD as a service per patient?
Peritonitis (per PD patient)	Number of Previous Events Length of time on PD What type of bacteria (gram positive or gram negative) or pathogen? Patient Location Readmissions within 1 month Did patient have to switch to Hemodialysis after this event? Demographics of patient
Hospital Admissions (per PD Patient)	Cause for admission Alternative pathogenesis of Peritonitis? Length of admission Total cost of admission

Output Metrics

In a more holistic sense, these are the metrics we wish to synthesize from this data. Note that for each of these metrics we shall compare results if peritonitis rates were lowered or if peritonitis cases were caught earlier. Then we will extrapolate this data as if the PD population were to increase as projected in Phase 1.

Metric	Input	Output
Outcomes for PD	Number of years on PD Differential time of dialysis: PD vs HD Rate of mortality Rate of Peritonitis events Rates of switching to HD Number of hospital admissions Amount of education receive	Mortality
Cost to the Health System	Cost of PD vs HD Hospital admission cost Hospital admission length Readmissions Cost of Peritonitis treatment	Dollar cost Amount of clinician time use Positive margin generated?
Quality of Life for PD patients	Rate of Peritonitis events Length of time on PD Distance from clinic (time saved) Number of Hospital admissions Number of days spent in hospital	Length of time on PD Success of patient reaching transplant

Phase 3: Evaluation of how our device would mitigate Peritonitis

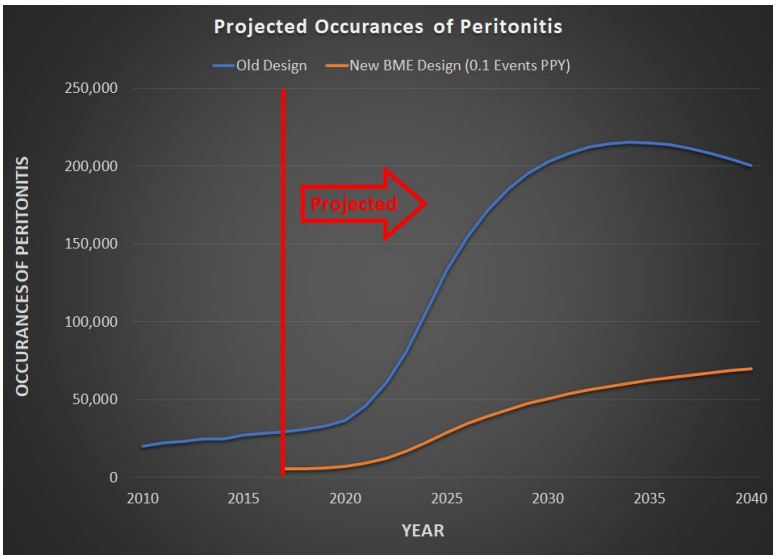
Projection Explanation

Phase 3 is a continuation of Phase 1, given that the model has been validated in Phase 2. However, with a currently unvalidated model, the rates of Peritonitis given the large increase in the PD population can still be investigated. Data regarding Peritonitis from USRDS only goes as far back as 2010, so projected rates of Peritonitis were projected from there. We assume that the rate of Peritonitis with our device could decrease six-fold, from approximately 0.67 events per patient year to 0.1 events per patient year. This is in-line with the gold standard, Singapore, which has a collective rate of 0.05 events per patient year.

Datapoints and Projections

Datapoint	Explanation	How it was projected forward from 2016
Peritonitis Rate (old)	How many events of peritonitis per patient year	Values from 2010 to 2016 showed a linear decrease in peritonitis rate, so this slope was carried forward in the projection. By 2040, the rate was forecasted at 0.29
Occurrences (old)	How many patients were affected by peritonitis	Number of projected PD patients multiplied by the Peritonitis Rate (old)
Peritonitis rate (new)	New events of peritonitis per patient year with use of our device	Constant at 0.1
Occurrences (new)	How many patients were affected by peritonitis given they were using our device	Number of projected PD patients multiplied by the Peritonitis Rate (new)

Outputs



This shows the cases of Peritonitis are kept in the 10s of thousands with the new device as opposed to in the 100s of thousands with the current method. Without proper action before the steep rise in PD, hospital admissions due to peritonitis could soar.

Sources

"United States Renal Data System. 2018 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States." 2018. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. https://www.usrds.org/2018/view/Default.aspx.