The Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease

Senior Thesis

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Abstract

Chronic kidney disease (CKD) has grown over the past four decades as a significant threat to public health. This is due in part to its increasing prevalence with the rise of elderly and obese populations but also because of its eventual progression to end stage renal disease (ESRD), a condition that is covered by Medicare regardless of age or otherwise disability status. Treatment for ESRD, dialysis or transplantation and their respective medications, has proven to be a significant governmental expense. In this light, many have postulated ideas to improve self-management and delay the onset of ESRD. An extensive review of the literature revealed that educational interventions tailored for CKD patients have the potential to yield improved health and quality of life outcomes, delay progression to ESRD and decrease healthcare costs.

This thesis documents a study conducted with CKD Medicare beneficiaries who have received an educational intervention from the Care Management Organization of Montefiore Medical Center, an accountable care organization in Yonkers, NY. It sets out to test the effect of patient education on empowerment and improved health outcomes, especially for those who identify as minorities; a population that is notoriously underserved and is projected to have worse health outcomes than their White counterparts. The study’s conclusions supported the literature review findings that health literacy can yield positive health outcomes and also identified areas for improvement within the educational programming.
Chapter 1: Project Motivation and Contribution to HSSP

Motivation

In the summer of 2012 I was given the tremendous opportunity of serving as a summer intern at Montefiore Hospital’s Care Management Organization (CMO) in Yonkers, NY. At the CMO I was given a number of tasks ranging from conducting literature reviews, compiling meeting notes and analyzing data and insurance claims. It was also at the CMO where I was introduced to the concept of Accountable Care Organizations (ACO’s): groups of healthcare providers working together to provide affordable and high quality healthcare to its Medicare beneficiaries. At the time, the CMO had been awarded a grant by the Centers for Medicare and Medicaid Services (CMS) to be a part of the piloting of a program, known as the Pioneer ACO Model. In receiving this grant, Montefiore’s task was to utilize their preexisting healthcare innovations and to prove cost efficiency and improved clinical outcomes for their patients covered under Medicare.

The CMO consists of physicians, nurses, nutritionists, researchers and dieticians who facilitate a number of different initiatives to meet the requirements of the CMS grant. These initiatives include tele-monitoring and post-discharge phone calls by experienced care managers and registered nurses for a variety of chronic conditions including cardiac and respiratory ailments. Yet, they did not have any care management programs in place for those with End Stage Renal Disease (ESRD), a debilitating condition marking failure of the kidneys. In anticipation of starting a comprehensive, multidisciplinary program of their own, I was instructed to search the literature for existing collaborative care initiatives conducted for ESRD patients by other healthcare institutions. After days of searching countless databases and university libraries
the answer to this question was unfortunately simple: these types of programs are not all that
common, and those that had been executed were by and large, unsuccessful.

The reasons for the lack of success could be attributed to a number of different factors but
most likely due to the complications of the disease and its associated treatment options. ESRD is
associated with many co-morbid conditions that require impressive lists of restrictions, lifestyle
changes, medications and providers in and of itself. Thus, it proved exceedingly difficult to
effectively manage all of patient’s needs in a cost efficient and quality assured manner. The
Health Maintenance Organizations and other kinds of network providers that I researched could
not conjure any significant solutions and ended up losing significant sums while also providing
inadequate healthcare to its sick and vulnerable patients.

My work that summer piqued my interest in the interworking of the kidneys and the
pathogenesis of ESRD. I was invited back to the CMO the following summer and asked
specifically to work with the developing ESRD program under the supervision of Sheila
Felleman and Terrian Smith-Jules, senior staff at the CMO. While my findings from the summer
prior could not directly inform what model Montefiore would use when establishing their
program, Felleman and Smith-Jules were able to identify and avoid the gaps in the other
programs and sought to embellish the few areas that had succeeded. Over the course of that year
they began negotiations with affiliated dialysis centers to implement social work and nutritional
interventions and met with healthcare consulting firms, seeking further advice in planning the
piloting of their program.

I spent the summer of 2013 working closely with Smith-Jules and Felleman on the pilot
program, attending meetings and compiling further literature reviews. While doing so I was
introduced to another Montefiore kidney initiative, the Kidney Care Program, also under the
direction of Felleman and Smith-Jules. This program, to be explained in depth in chapter five, is for patients with various forms of kidney disease. One important part of this programming is the educational workshops that are offered to participants.

The workshops, taking place in a number of Montefiore-affiliated locations throughout Bronx, in the form of PowerPoint presentations is administered by Ms. Smith-Jules and span many aspects of kidney disease: diet, fluid control, exercise, and information on medications to name a few. In some instances specialists are a part of the workshop as well, offering firsthand knowledge about the given topic. For example, for the presentation on transplantation, a transplant surgeon addressed the group, explaining the procedure for being listed, the surgery itself, and proper maintenance of a donor organ.

Upon attending these workshops I was astonished to learn how little these patients seemed to know about having chronic kidney disease and what their future disease prognosis might bring. It also occurred to me, based on the questions patients were asking at the end of the workshop, that many of them did not truly comprehend the information that was being presented to them. Evidently, patients did not understand why lifestyle changes were necessary in improving their overall health and why certain foods and nutritional supplements are contraindicated for their consumption. Smith-Jules, too, expressed her concern and misgivings for the current workshop set-up as attendance was low as was patient adherence to the recommendations made. I was asked to spend time researching health literacy and ways to make this patient education more comprehensive, interactive and attractive to patients, to educate and empower them to take control over their disease which could ultimately lead to better health outcomes.
A significant amount of literature suggests that patients who receive comprehensive education concerning their CKD are able to better care for themselves, which can delay their time to ESRD. ESRD is not only a debilitating and nightmarish way of life but also quite costly in terms of government spending. I was presented with the opportunity of amending this education to help empower patients to change the way they live their lives in hopes of a future free of endless dialysis appointments and costly medications. In thinking about how to improve the program, it was necessary to think about all aspects of educational intervention beginning with what currently exists. I wondered, what kind of information is useful to these patients? What kind of educational resources do they have access to? What are they lacking? How can health literacy be strengthened to be more relatable? Due to Montefiore’s location in the Bronx, most patients identify as part of minority populations, who, due to socioeconomic status, notoriously receive unequal education, information and healthcare and are typically sicker than their White counterparts. In this light, what other types of challenges do they face that prevent them from receiving the education they need to stay well? Do they have trouble paying for medications? Arranging transportation to appointments? How can Montefiore improve their education and available resources while meeting the very specific needs of this especially vulnerable population?

What lies before you is my senior honor’s thesis entitled, “The Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease”— my journey to answer these questions and offer suggestions to Montefiore CMO in hopes of using my talents to improve the healthcare of those around me. This thesis, researched under the supervision of Dr. Darren Zinner, resides in the Health: Science, Society and Policy program at Brandeis University. In many ways, “The Pursuit of Patient Education and Empowerment in the Midst of
Chronic Kidney Disease” is paradigmatic of the multifaceted components of the HSSP major and serves as an appropriate culmination of my tenure as a Brandeis undergraduate student.

**Contributions to HSSP**

*Health* - This thesis focuses on using health literacy and patient education to promote clinical health outcomes and overall well-being of those plagued with CKD. It also provides a discussion surrounding the complex and unique healthcare needs of this very sick and vulnerable population.

*Science* - A crucial components of this thesis uses a scientific lens to discuss the pathogenesis of the disease itself, including its various stages, symptoms, progression, variety of treatment options, deleterious substances and clinical indicators.

*Society* - The issue of society is addressed in the coming pages in multiple capacities. On one hand, it researches how CKD affects the population on an individual level and contains real patient data in the form of responses to interview questions to understand how it is being managed, especially for underserved, publicly-financed, minority and non-English-speaking patients. As such, working to improve the health of those with CKD and ESRD can result in governmental savings, which benefits society at large. With a healthier aging population, less governmental money will go towards providing costly healthcare, are more towards other underfunded services such as the public school system or public works.

*Policy* - The issue of policy is also a recurrent theme in this thesis as it delves into many different policy areas, exploring healthcare policy, specifically those of Medicare on the ESRD population, health insurance policies, and policies pertaining to healthcare institutions. Additionally, this thesis will also discuss the effects of CKD and ESRD on society at large. As will be discussed in a later section, Medicare has enacted programs that take care of patients with
ESRD and spends a significant portion of their yearly budget covering all forms of dialysis, services and medications for ESRD patients.
Chapter 2: Chronic Kidney Disease and its Challenges

The Challenge of CKD

Chronic Kidney Disease (CKD), a growing healthcare concern in the United States, is an umbrella term used to describe the various disorders that affect the structure and function of the kidneys.\(^1\) CKD is indicated by a decrease in the rate of blood filtration through the kidneys, known as glomerular filtration rate (GFR), and abnormalities in urine such as a presence of excess proteins (proteinuria), and red and white blood cells.\(^2\) According to the Centers for Disease Control and Prevention, more than 10% of adults in the United States, about 20 million people, have some degree of kidney disease.\(^3\) As indicated by exhibit one below, kidney disease is increasing at an alarming rate every year: a trend that is projected to continue with the rise of obese and elderly populations.

![Age-Adjusted Prevalence of Chronic Kidney Disease Among US Adults Aged 20 Years and Older, 1999-2010](http://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf)

**Exhibit 1**


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2. C. A. Johnson and others, "Clinical Practice Guidelines for Chronic Kidney Disease in Adults: Part II. Glomerular Filtration Rate, Proteinuria, and Other Markers," *American Family Physician* 70, no. 6 (Sep 15, 2004a): 1091-1097.
Due to its increasing prevalence, high costs and poor treatment outcomes, the medical community has shifted its understanding of the disease from a life-threatening disorder to be left solely in the care of nephrologists, to a public health concern to be attended to by all medical professionals. Conceptualizing CKD as a public health concern provides the opportunity to engage the community in education surrounding prevention, early detection and management, which can yield delay of disease progression, improved clinical outcomes and overall governmental savings.

Causes

Understanding the causes of CKD enables the public health community to think critically about the best way to ameliorate this significant challenge. The causes of CKD are varied and dependent upon biological as well as environmental factors. In developed countries, typical risk factors include age, hypertension, diabetes, increased BMI and smoking, as a lack of control over these conditions puts a strain on the kidneys, leading to their demise (see exhibit two for a breakdown of the prevalence of these conditions). In the developing world more cases of kidney disease are due to bacterial infections, viruses, parasites and environmental and occupational exposures to chemicals such as lead, cadmium and mercury. Despite the differences in causes, the goal of managing CKD in all patients is largely the same: to prevent cardiovascular events and complications in order to delay kidney failure and the need for expensive and debilitating treatments.

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5 Ibid.
7 Ibid.
8 Ibid.
Diagnosis

One of the biggest challenges the healthcare community faces pertaining to CKD is that it is difficult to diagnosis due to the fact that most individuals with early stage kidney disease are asymptomatic. In many instances a presence of kidney abnormality is only detected during an evaluation of a co-morbid condition, such as diabetes or hypertension.\(^9\)

Once practitioners detect an abnormality, they employ a number of different methods to determine the extent of kidney disease. One method uses a urine dipstick test to easily detect proteinuria and other abnormalities in the urine, indicating the inability of the kidneys to filter materials properly.\(^10\) However, a more telling indicator, the estimated level of overall kidney function, eGFR, requires more complex computations.\(^11\) One method, prediction equations, are endorsed by the National Kidney Disease Education Program (NKDEP) as the best overall

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\(^10\) Johnson and others, *Clinical Practice Guidelines for Chronic Kidney Disease in Adults: Part II. Glomerular Filtration Rate, Proteinuria, and Other Markers*, 1091-1097.

\(^11\) C. A. Johnson and others, "Clinical Practice Guidelines for Chronic Kidney Disease in Adults: Part II. Glomerular Filtration Rate, Proteinuria, and Other Markers," *American Family Physician* 70, no. 6 (Sep 15, 2004b): 1091-1097.
measure to obtain an estimated GFR. Two of these equations, found in exhibit three, take serum creatinine levels, (an important blood indicator of kidney health) into account, as well as variables such as age, sex, race, and body size. There are many different types of equations used as they each have their own strengths and limitations. One equation, the modification of diet in renal disease (MDRD) study equation is fairly accurate at eGFRs of 60 mL/min per 1.73 m² while another, the chronic kidney disease epidemiology collaboration (CKD-EPI) equation has less bias at high eGFRs and can be used to report eGFRs greater than 60 mL/min per 1.73 m². 

**MDRD equation:**

\[
GFR = 175 \times (S_{cr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.212 \text{ if African American})^{15}
\]

**CKD-EPI equation:**

\[
GFR = 141 \times \min \left( \frac{S_{cr}}{\kappa}, 1 \right)^{\alpha} \times \max \left( \frac{S_{cr}}{\kappa}, 1 \right)^{-1.209} \times 0.993^{\text{Age}} \times 1.018 \text{ [if female]} \times 1.159 \text{ [if black]}
\]

where: 
- \( S_{cr} \) is serum creatinine in mg/dL,
- \( \kappa \) is 0.7 for females and 0.9 for males,
- \( \alpha \) is -0.329 for females and -0.411 for males,
- min indicates the minimum of \( S_{cr}/\kappa \) or 1, and max indicates the maximum of \( S_{cr}/\kappa \) or 1. 

Exhibit 3


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13 Johnson and others, *Clinical Practice Guidelines for Chronic Kidney Disease in Adults: Part II. Glomerular Filtration Rate, Proteinuria, and Other Markers*, 1091-1097.


16 National Kidney Disease Education Program, *Estimating GFR*
Establishing an accurate eGFR is important as it helps physicians identify the extent to which a patient’s kidneys are functioning and thus, the best way to treat them. CKD is divided into 5 main stages based on eGFR:17

- Stage 1, a patient’s eGFR is greater than 90 mL/min per 1.73 m²
- Stage 2 eGFR is between 60-89 mL/min per 1.73 m²
- Stage 3 eGFR is between 30-59 mL/min per 1.73 m²
- Stage 4 eGFR is between 15-29 mL/min per 1.73 m²
- Stage 5 consists of an eGFR of less than 15 mL/min per 1.73 m²

Stage 5 CKD, also known as end stage renal disease (ESRD), to be discussed in a later section, is the point at which the kidneys have essentially shut down and are no longer able to properly remove wastes from the blood.18

There are many complications that can arise as a result of reduced eGFR.19 One complication, cardiovascular disease, known as the leading cause of mortality in CKD,20 is an all-encompassing term describing a range of conditions affecting heart and blood vessels such as coronary artery disease, heart attack and heart failure.21 These diseases occur as a result of anemia and high blood pressure, conditions that develop as kidney function deteriorates.22

Other complications include acute kidney injury, infection, cognitive and physical impairment23, malnutrition and mineral and bone diseases.24 Further, certain common drugs and procedures such as the use of non-steroidal anti-inflammatory drugs (NSAIDS), phosphorus

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20 Ibid.
22 Ibid.
24 Ibid.
based enemas and iodinated contrasts have the potential to cause further kidney irritation.\textsuperscript{25} Lastly, because the kidneys filter wastes and salts, excess fluids and sodium consumption have the potential to overwork and stress already damaged kidneys.

**Early Stage Treatment**

Timely diagnosis alongside proper treatment for chronic kidney disease is crucial as it prevents further development of the disease, reduces harmful complications and improves patient survival and quality of life.\textsuperscript{26} Initial management of CKD entails identifying reversible disorders such as urinary-tract obstruction, infection and autoimmune diseases: conditions that have the capability to be reversed and respond to specific treatment which leads to improved kidney function.\textsuperscript{27} A physician will review the patient’s history, co-morbid disorders, drug use, family history, lab assessment and kidney ultrasound to reach an assured diagnosis and develop a treatment plan.\textsuperscript{28} While a general practitioner and non-nephrology specialists can treat common problems, referral to a nephrologist is recommended when patients reach stage IV, with early referral for patients with particularly difficult complications or high concentrations of albuminuria (an excess of the albumin protein in urine).\textsuperscript{29}

When assigning a new treatment plan, physicians recommend that the treatment for each stage is cumulative, meaning, that the course of treatment recommended for later stages include those recommended previously.\textsuperscript{30} Nonspecific therapies include angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARBs) to reduce proteinuria, restriction of dietary sodium, diuretics to reduce edema (swelling), statins to reduce hypercholesterolemia

\textsuperscript{25} Ibid.
\textsuperscript{26} Ibid.
\textsuperscript{27} James, Hemmelgarn and Tonelli, *Early Recognition and Prevention of Chronic Kidney Disease*, 1296-1309.
\textsuperscript{28} Levey and Coresh, *Chronic Kidney Disease*, 165-180.
\textsuperscript{29} Ibid.
\textsuperscript{30} Ibid.
(high cholesterol levels) and in some instances, anticoagulants to reduce the risk of deep vein thrombosis (blood clots).\textsuperscript{31} Other medications such as aspirin are recommended for most patients with CKD who are at high risk for cardiovascular disease.\textsuperscript{32} These various treatments work to assist the damaged kidneys in carrying out their ordinary functions and protects the body from future complications.

\textbf{Late-Stage Treatment: Dialysis}

However effective these treatment options might be, kidney function can deteriorate over time. Once an individual has an eGFR of less than 15, they are said to have developed end stage renal disease (ESRD).\textsuperscript{33} At this stage, the kidneys are no longer able to filter wastes on their own and will require a kidney transplant from a live or deceased donor or start one of two main types of dialysis\textsuperscript{34}

During one method called hemodialysis, an external machine called a hemodialyzer acts as an artificial kidney.\textsuperscript{35} During this process, as indicated by exhibit four, the blood flows, a few ounces at a time, through a special filter that removes wastes and excess fluids from the blood, then returns the newly clean blood to the body.\textsuperscript{36} Prior to an official ESRD diagnosis though at a time near dialysis, a surgeon performs minor surgery to the patient’s arm or leg to make an access point into the blood vessels to be connected to the hemodialyzer upon initiation of dialysis.\textsuperscript{37} These access points are created by joining an artery and a vein to make a big blood

\begin{flushright}
\textsuperscript{31}Ibid.
\textsuperscript{32}James, Hemmelgarn and Tonelli, \textit{Early Recognition and Prevention of Chronic Kidney Disease}, 1296-1309.
\textsuperscript{35}Ibid.
\textsuperscript{37}National Kidney Foundation, \textit{A to Z Health Guide: Dialysis}
\end{flushright}
vessel under the skin called a fistula, or a smaller one, known as a graft. On occasion, a catheter is instead inserted into a large vein in the neck as an alternative access.

**Exhibit 4: Hemodialysis**

The process of hemodialysis usually lasts about four hours and is conducted three times per week though frequency and duration can vary based on the overall functioning of the patient’s kidney, the patient’s size, the level of accumulated waste and how much fluid weight has been gained between treatments.

Peritoneal dialysis, the second kind of dialysis, similarly removes wastes but does so without ever leaving the body. During this treatment, the peritoneal cavity (abdominal area) is slowly filled with a dialysis solution, dialysate, through a catheter that was surgically implanted.

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38 Ibid.  
39 Ibid.  
40 Ibid.  
41 Ibid.
previously. The solution contains dextrose, which pulls wastes and excess fluids into the abdominal cavity removing them when the solution is drained.

Exhibit 5: Peritoneal Dialysis

There are multiple kinds of peritoneal dialysis, but the most popular amongst patients are Continuous Ambulatory Peritoneal Dialysis (CAPD), which can be done at home and at work, and Automated Peritoneal Dialysis (APD), which can be conducted while asleep. Although not all ESRD patients are eligible for this type of dialysis, it is seen as highly desirable due to the

42 Ibid.
44 National Kidney Foundation, A to Z Health Guide: Dialysis
fact that is allows for the continuation of an otherwise normal lifestyle that is not interrupted by long and cumbersome trips and shifts to dialysis centers.\textsuperscript{45}

Like the other areas of kidney disease, there are numerous complications that can arise as a result of dialysis. Some patients experience initial discomfort when the grafts and fistulas are put in place and if not cared for properly, they can lead to infections, resulting in hospitalizations. Other consequences of dialysis include decreases in blood pressure, which can cause nausea, vomiting, headaches and cramps.\textsuperscript{46} Further, the process of dialysis which forces the body to rid itself of wastes in a relatively short amount of time puts a significant strain on the body, resulting in fatigue following appointments.

Implications

It is evident that chronic kidney disease and end stage renal disease are serious health conditions, which require amendments to lifestyle, constant monitoring of disease progression and excessive medications. Patients need to always be aware of their diets such as limiting the consumption of foods that are high in potassium, restricting certain amounts of fluid on a daily basis and avoiding foods that have a high sodium content. They might have a decreased quality of life due to feeling pain in their kidneys, lethargic or otherwise unwell. Dialysis patients in particular face further restrictions as many rely on hemodialysis as a lifeline because built up toxins in the body can be lethal. As such, travel and leading an ordinary life away from dialysis centers is often limited for these individuals.

Minority Populations in the Midst of Chronic Kidney Disease

While this burden of disease can be seen as a challenge to the general population, a further complication lies within minority populations. Chronic Kidney Disease and End-Stage

\textsuperscript{45} Ibid.
\textsuperscript{46} Ibid.
Renal Disease are notorious as one of the starkest examples of racial and ethnic disparities in health outcomes in the United States.\(^{47}\) Studies have shown that when using a random sample of the population in the United States, black individuals were found to have a significantly higher risk for all-cause and cardiovascular mortality, with similar trends, observed in the Hispanic population.\(^{48}\) Research in 2008 revealed that the incidence of ESRD is four times more common amongst the African American community as compared to their White counterparts, a difference of incidence of 988 per million and 254 per million, respectively.\(^{49}\) As for the Hispanic population, the incidence rate is 471 per million whereas for non-Hispanic whites the incidence is 325 per million.\(^{50}\)

The reasons behind these blatant healthcare disparities can be attributed to numerous biological and social risk factors for chronic kidney disease. These risk factors include, diabetes, hypertension, and poor diet and lifestyle habits: conditions that tend to effect minority populations at higher rates. For instance, the incidence of type II diabetes mellitus is 1.6, 1.5 and 2.3 times higher in the African American, Hispanic and Native American populations, respectively.\(^{51}\) Interestingly, it has been posited that this higher rate of diabetes can be attributed to a phenomenon known as “thrifty genotype”. The “thrifty genotype” from an evolutionary standpoint allows the body to compensate for various cycles of plenty/famine and rest/physical activity while storing energy in periods of starvation.\(^{52}\) The “thrifty genotype”, is known to be present in higher rates among ethnic/racial groups who once lived in environments with lacking

\(^{48}\) Ibid.
\(^{50}\) Ibid.
\(^{52}\) Ibid.
or inconsistent food sources such as the Black and Hispanic populations. Individuals with this genotype who have unlimited access to food and insufficient physical activity will gain weight, causing the thrifty gene to stimulate increased insulin production. Overproduction of insulin results in impairment and the onset on type II diabetes.

Hypertension, know as both a complication and common risk factor for chronic kidney disease, seems to disproportionately affect minority populations as well, with specific emphasis on the African American population. Data from the National Health and Nutritional Examination Survey (NHANES) revealed that African Americans have higher rates of hypertension than both Whites and Hispanics. This is potentially due to the fact that African Americans have also proven to have a higher rate of low birth weight which makes individuals more susceptible hypertension, in addition to low nephron count. While data from the 1999-2000 NHANES study also revealed that hypertension is not as common in Hispanic populations, it is also evident that those that do in fact have hypertension are typically undertreated which hastens the progression of CKD to ESRD.

From the above discussion of diabetes and hypertension it is evident that biological factors seem to support high rates of CKD specifically within minority populations, shedding light on the reasons behind the disparities. Other biological factors which apply specifically to the African American population include the presence or absence of the sickle cell trait and a

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53 Ibid.
55 Ibid.
56 Norris and Agodoa, *Unraveling the Racial Disparities Associated with Kidney Disease*, 914-924.
57 Ibid.
58 Ibid.
condition called hypovitaminosis D.\textsuperscript{60} The sickle cell trait, found in approximately 8\% of African American individuals, has been known to cause kidney distress and might also be an unrecognized factor for the progression of CKD and its complications.\textsuperscript{61} Hypovitaminosis D, or a deficiency of vitamin D, is also more typical of the African American community, who, due to their darker skin tone, do not absorb this essential vitamin.\textsuperscript{62} Its absence is associated with increased rates of risk factors such as diabetes and hypertension and factors that progress CKD such as inflammation and fibrosis.\textsuperscript{63}

Society would be in remiss to argue that the existing disparities are due in its entirety to biological factors. Glitches in the healthcare system and socioeconomic status for these minority populations play a significant role in the contribution to these disparities as well. The lack of adequate health insurance is common amongst racial and ethnic minorities.\textsuperscript{64} This leads to significant health consequences especially with regard to a progressive disease such as chronic kidney disease. Delayed referral to specialists limits the efficacy of interventions that, when performed earlier, can limit mortality rates, long hospital stays, lifestyle restrictions and expensive medications.\textsuperscript{65} Further, food items high in sugar and fat are more readily available in areas populated with underserved individuals. As such, the consumption of certain diets can lead to obesity, another risk factor. Lastly, inexpensive housing is more readily available in unsafe environments with toxic exposures to chemicals such as lead which can lead to increased risk of hypertension and impaired renal function.\textsuperscript{66}

\textsuperscript{61} Ibid.
\textsuperscript{62} AWC Yuen and NG Jablonski, "Vitamin D: In the Evolution of Human Skin Colour," \textit{Medical Hypotheses} 74, no. 1 (2010): 39-44.
\textsuperscript{63} Norris and Nissenson, \textit{Race, Gender, and Socioeconomic Disparities in CKD in the United States}, 1261-1270.
\textsuperscript{64} Ibid.
\textsuperscript{65} Ibid.
\textsuperscript{66} Norris and Agodoa, \textit{Unraveling the Racial Disparities Associated with Kidney Disease}, 914-924.
As exhibit six below indicates, it is neither biology nor environmental factors alone that are responsible for the stark differences in health outcomes between minority and white populations. Disparities amongst racial minorities for CKD patients seems to consist of a multitude of various complex factors forming a vicious and potentially lethal, cycle.

![Diagram of key socio-cultural determinants of CKD](source)

**Exhibit 6**  
(Source: Norris and Nissenson 2008, 1261-1270)

Methods for closing the gap and improving upon this disparity might be just as challenging as tackling the disease, itself. Yet, one potential solution includes diligence on the part of healthcare providers to recognize and treat the risk factors present in their patients before they become problematic, causing CKD or other chronic diseases. Additionally, healthcare providers should not maintain a standard, one approach for all patients but rather, identify the unique needs of their patients and tailor treatment options that are viable given their condition and resources available to them in their communities.

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67 Ibid.  
68 Ibid.
Chapter 3: Medicare and its Relationship to ESRD

For all patients, regardless of minority status, it is evident that as kidney disease progresses, individuals require more advanced treatments which becomes increasingly expensive. Within the realm of kidney disease, ESRD is at the peak of costliness but fortunately for sick Americans, Medicare, which is government sponsored health insurance typically covering individuals 65 and older and those under 65 with certain disabilities created an entitlement program for those with ESRD. Once a patient has met clinical indicators that their kidneys are failing they become eligible for ESRD coverage, provided that they meet one of the following conditions as well.\textsuperscript{69}

\begin{itemize}
  \item The individual must have worked the required amount of time under social security or as a government employee
  \item The individual must receive or be eligible for Social Security or Railroad Retirement benefits
  \item The individual is the spouse or dependent child of a person who meets any of the aforementioned requirements
\end{itemize}

Medicare is a large program and is broken into “Parts” A-D as indicated by exhibit seven below.

Generally speaking, Medicare Part A covers hospital-related costs, Part B covers medical costs, Part C, known as Medicare Advantage includes Parts A and B and Part D is coverage for prescription drugs. The particulars of which Medicare programs cover which precise treatment and medications is lengthy in detail and beyond the scope of this paper. However, it is worth mentioning that due to the extent of these different programs, Medicare covers many expensive services for the ESRD population, particularly within dialysis and transplantation.

Medicare Coverage: Dialysis

Medicare Part A covers inpatient dialysis services while Part B covers outpatient dialysis treatments and doctor services, self dialysis training, home dialysis equipment and supplies, certain home support services and most drugs required for home dialysis. Transportation via an ambulance service to dialysis sessions is only covered in the event that any other form of

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transportation would be detrimental to the patient’s well being.\textsuperscript{71} Services not included are surgeries or services needed to prepare for dialysis, dialysis aides to provide assistance with home dialysis, a place to stay during treatments, blood, packed red blood cells used in home self-dialysis unless part of doctor’s services.\textsuperscript{72} Further, Medicare does not compensate any lost pay to the patient or the person assisting the patient during the training required for self-administration of peritoneal dialysis.\textsuperscript{73}

Medicare coverage for dialysis patients begins the first day of the fourth month of dialysis treatments.\textsuperscript{74} In the interim, a patient’s employer or union group health plan will cover the lapse of time.\textsuperscript{75} If the individual’s plan does not cover 100\% of the costs, Medicare may pay the remaining balance.\textsuperscript{76} Coverage ends 12 months after the month the individual stopped dialysis treatment but can be extended if the individual needs to start dialysis again or receives a kidney transplant within 12 months following the initiation of dialysis.\textsuperscript{77}

**Medicare Coverage: Kidney Transplantation**

Medicare Parts A and B cover impressive lists of services and supplies in the realm of kidney transplantation as well.\textsuperscript{78} Though not exhaustive, included are inpatient services in a Medicare approved hospital, kidney registry fee, lab tests, costs of finding an appropriate kidney, full cost of the kidney donor’s care, doctors services for the surgery, blood, and immunosuppressive drugs.\textsuperscript{79} Medicare coverage begins the month the patient is admitted to a Medicare-approved hospital for a kidney transplant and ends 36 months after the month the

\textsuperscript{72} Ibid.
\textsuperscript{73} Ibid.
\textsuperscript{74} Ibid.
\textsuperscript{75} Ibid.
\textsuperscript{76} Ibid.
\textsuperscript{77} Ibid.
\textsuperscript{78} Ibid.
\textsuperscript{79} Ibid.
individual has had a kidney transplant. Coverage can be extended if the individual needs to start dialysis again or gets another kidney transplant within 36 months after the month they had their original kidney transplant.

The History of Medicare’s ESRD Coverage

Evidently, coverage for the ESRD patient is fairly comprehensive, allowing individuals of varied socioeconomic backgrounds to receive the life-saving treatment they require. This coverage is the result of four decades of the evolution of a program that would not only enable patients to receive dialysis and other crucial services but one that strives to be cost efficient in relation to governmental spending as well.

The story began in the 1960’s when dialysis and kidney transplantation, relatively new treatment options in the United States, demonstrated clinical effectiveness and were becoming increasingly prevalent. However effective, these treatment options were also prohibitively expensive for the average patient and as such, institutions were rationing and restricting these services. With this realization in 1973, Medicare established a program, which planned to cover these life-saving services with the original mindset that they would not incur significant costs as at the time, only 16,000 people in the United States required dialysis. Thus, the initial establishment of this program was in the standard fee-for-Service model; Medicare reimbursed dialysis facilities on what was known as a “reasonable charge basis”. The reasonable charge basis was a set amount of money predetermined by insurance carriers that process Medicare claims for the government and is based on what is typically charged for that

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80 Ibid.
81 Ibid.
83 Ibid.
84 S. Swaminathan and others, "Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs," *Health Affairs (Project Hope)* 31, no. 9 (Sep, 2012): 2051-2058.
85 Ibid.
service in that particular part of the country. At this time, Medicare was also reimbursing hospital based dialysis centers similarly on a “reasonable cost” basis: this was the cost the hospital incurs in the administration of dialysis minus the costs that are present, though not integral in the delivery of dialysis.

With no cap on the reimbursement rate and an overall lack of program clarity, Medicare expenditures grew dramatically, from $229 million in 1973 to $1.8 billion in 1983 (these costs were also attributed to the rise of ESRD itself as the number of Americans inflicted rose from 16,000 to 64,000). As a result, Medicare felt an urgency to reevaluate their policies and test alternative payment methods. The Omnibus Budget Reconciliation Act of 1981 contained two provisions that were implemented in an attempt to contain program costs. The first was an introduction of a composite rate per dialysis treatment that would cover all of the costs needed to facilitate dialysis, $131 for treatment in a hospital based facility and $127 for treatment in freestanding facilities. The second provision was to keep this composite rate “fixed” throughout the decades.

In 1989 a prominent pharmaceutical company, Amgen, developed a synthetic version of the hormone erythropoietin, used to treat anemia in dialysis patients. While CMS developed a capitated method to pay for this expensive drug, in 2005 overall costs had yet again experienced a dramatic increase with its total annual expenditure nearing $2 billion. Evidence soon surfaced that the administration of erythropoietin has adverse effects in patients with cases of mild anemia and a concern was thus raised that with their own finances in mind, healthcare providers were

86 Ibid.
87 Ibid.
88 Ibid.
89 Ibid.
90 Ibid.
91 Ibid.
92 Ibid.
93 Ibid.
administrating this expensive drug in inappropriate doses. This finding sparked further reform as the Medicare Payment Advisory commission recommended that Medicare integrate financial incentives for quality outcomes into payments for providers. Specifically, when certain pre-established benchmarks were not met, the providers were penalized with respect to their payment. At this time, Medicare also wished to test alternative payment methods, a “bundled” payment method across various providers and models of care.

This new payment system is called the ESRD Prospective Payment System, which went into effect on January 1st 2011. Under this bundled payment arrangement, providers on average receive $230 per patient per dialysis treatment, which covers dialysis costs, injectable medication and a wide range of laboratory tests. This bundled system, in addition to the pay-for-performance model explained above serves as the current method of Medicare funding for ESRD patients, which continuously strives to keep healthcare costs low.

Societal Implications

Despite the various payment methods and models employed, it is evident that keeping healthcare costs low is an issue the government continues to struggle with.

- In 2010 the United States Renal Data System (USRDS) reported that Medicare spent $29 billion in 2009 on ESRD costs, almost 6% of the annual Medicare budget
- In 2013, individuals covered under Medicare due to age or disability per person cost $1700 for stage 2 CKD, $3500 for stage 3, and $12,700 for stage 4

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94 Ibid.
95 Ibid.
96 Ibid.
97 Centers for Medicare and Medicaid Services, Medicare Coverage of Kidney Dialysis and Kidney Transplant Services, 1-55.
98 Swaminathan and others, Medicare's Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs, 2051-2058.
99 Ibid.
2008 Medicare data revealed that hemodialysis was $77,506, $57,639 for peritoneal dialysis and $26,668 for transplantation per person per year.

The public health community has suggested that to combat these costs, it is important to catch CKD in its early stages in order to delay disease progression to ESRD and its resultant Medicare costs. The current recommendation is screening for individuals with diabetes, cardiovascular disease, hypertension, autoimmune diseases, family history of kidney disease and those with renal-tract diseases.\textsuperscript{101} Research has also indicated that early referral to a nephrologist before the onset of kidney failure results in better patient outcomes as it is associated with an increased rate of transplantation, reduced mortality and cost after the onset of dialysis.\textsuperscript{102}

\textsuperscript{101} James, Hemmelgarn and Tonelli, \textit{Early Recognition and Prevention of Chronic Kidney Disease}, 1296-1309.
\textsuperscript{102} Levey and Coresh, \textit{Chronic Kidney Disease}, 165-180.
Chapter 4: Health Literacy as a Solution

Another potential solution to delay disease progression and medical costs can be found in the realm of health literacy. Health literacy, defined by the American Medical Association as, “a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment” is a key component in ensuring desired patient health outcomes. Practically speaking, health literacy is the way in which patients understand their disease, their doctor’s orders, how to take their medications and the type of restrictions that they face. Understanding the health care system and their condition enables individuals to better control their illness. Thus, improving health literacy within the general population, with a specific focus on catering to the unique needs of cultural groups, can cause individuals to come to a better understanding of their disease, yielding positive health outcomes and reducing healthcare disparities.

Although seemingly viable, this solution faces many challenges. Advances in medicine and the ever-evolving health care delivery system establishes a culture that assumes adequate health literacy. Most healthcare materials are written at the 10th grade reading level, whereas most adults read between the eighth and ninth grade reading levels, with 21-23% of adults reading and understanding at approximately the fifth grade level or lower. This problem is particularly apparent amongst minority and immigrant populations with whom for many English is not their first language and may face other comprehension barriers including religious beliefs, gender norms, family ties and a general misunderstanding of Western medicine. Further,

current forms of health literacy are standardized and do not cater to the lifestyle, diet and stresses that effect populations differently.\textsuperscript{107}

These challenges come with significant consequences. Low health literacy serves as a barrier to patients’ activation of their own health care.\textsuperscript{108} It contributes to a lack of compliance and uncontrolled chronic diseases, which ultimately lead to rising healthcare costs.\textsuperscript{109} A lack of health literacy can inhibit a patient’s ability to handle insurance providers, find the appropriate physician, complete important medical forms accurately and understand the nature of their medications.\textsuperscript{110} Patients who do not understand their doctor’s orders may make their own healthcare decisions using alternate treatment options, which might exacerbate their condition. Individuals with lower levels of health literacy are not only more likely to be hospitalized than those with adequate health literacy but also less likely to participate in disease prevention and health promotion programs.\textsuperscript{111} Thus, inadequate health literacy comes with significant consequences as it leads to the need for further resources that have the potential to be costly.\textsuperscript{112}

Improving health literacy can take many forms. One solution might be to simplify the way in which pamphlets, consent documents and prescription slips are written, while another is to provide non-reading options including cartoons, diagrams and videos.\textsuperscript{113} Other solutions rest in the hands of healthcare providers themselves. Clinicians should be cognizant of behaviors that indicate low health literacy skills and find alternate ways to better inform their patients. These behaviors include noncompliance with medication, poor adherence to recommendations,

\begin{thebibliography}{9}
\bibitem{107} Ibid.
\bibitem{108} Linda C. Baumann and Thanh Tran Dang, "Helping Patients with Chronic Conditions Overcome Barriers to Self-Care," \textit{The Nurse Practitioner} 37, no. 3 (Mar 13, 2012): 32-8; quiz 38-9.
\bibitem{109} Safeer and Keenan, \textit{Health Literacy: The Gap between Physicians and Patients}.
\bibitem{110} Ibid.
\bibitem{111} Ibid.
\bibitem{112} Parker, Ratzan and Lurie, \textit{Health Literacy: A Policy Challenge for Advancing High-Quality Health Care}, 147-153.
\bibitem{113} Ibid.
\end{thebibliography}
inability to keep appointments and asking staff for assistance with seemingly straightforward tasks.\textsuperscript{114} Further, they should practice tasks such as reflective listening, reinforcing facts and asking questions to ensure that the point is accurately conveyed.\textsuperscript{115} Lastly, clinicians should become aware of the pressing cultural needs, exhibiting cultural competency, in order to pose treatment recommendations that are not only easily understood, but feasibly met as well.\textsuperscript{116}

Regardless of the precise method for health literacy, the need for improvement is real. An abundance of research has indicated that those who have received some formal education pertaining to their chronic kidney disease yielded better health outcomes. A scrupulous review of existing literature revealed that this claim is supported in three main areas: how patient education can extend time to initiation of dialysis, how patient education can extend a dialysis patient’s life and how generally, patient education has the capability to empower patients about their disease, making their own choices to improve overall well-being.

<table>
<thead>
<tr>
<th>Patient Education Extends Time to Dialysis</th>
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<tbody>
<tr>
<td><strong>“Multidisciplinary Predialysis Education Decreases the Incidence of Dialysis and Reduces Mortality—a Controlled Cohort Study Based on the NKF/DOQI Guidelines” By I-Wen Wu, Shun-Yin Wang et al.\textsuperscript{117}</strong></td>
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\textsuperscript{114} Safeer and Keenan, \textit{Health Literacy: The Gap between Physicians and Patients.}  
\textsuperscript{115} Baumann and Dang, \textit{Helping Patients with Chronic Conditions Overcome Barriers to Self-Care}, 32-8; quiz 38-9.  
\textsuperscript{116} Shaw and others, \textit{The Role of Culture in Health Literacy and Chronic Disease Screening and Management}, 460-467.  
information pertaining to diet control, physical fitness, awareness of nephrotoxins, compliance with medications and adoption of a healthier lifestyle. Study results revealed that fewer people in the MPE group required dialysis; 13.9% verses 43% in the non-MPE group. The average time required for dialysis to reach dialysis was 9.2 months for the non-MPE group and 11.3 months for the MPE group. Thus, the study demonstrated that MPE based on NKF/DOQI Guidelines can effectively reduce the incidence of ESRD and all-cause mortality.

<table>
<thead>
<tr>
<th>“Live and Learn: Patient Education Delays the Need to Initiate Renal Replacement Therapy in End Stage Renal Disease”&lt;sup&gt;118&lt;/sup&gt;</th>
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<tr>
<td><strong>By Yitzchak Binik, Gerald Devins, et. al</strong></td>
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<tr>
<td>A Study conducted by Binik, Devins et al. randomly assigned 204 patients with deteriorating renal function on the brink of the need for dialysis or transplantation to receive either enhanced or general education. Enhanced education consisted of an individually administered slide-lecture presentation on basic kidney function, kidney diseases, dietary management, renal replacement therapies and transplantation, while standard education consisted of whatever educational procedures were already in place by the participating hospital. Findings revealed that individuals in the enhanced education group survived an average of 4.6 months longer without needing dialysis than those in the standard education group.</td>
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<tr>
<th>“Predialysis Psychoeducational Intervention and Coping Styles Influence Time to Dialysis in Chronic Kidney Disease”&lt;sup&gt;119&lt;/sup&gt;</th>
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<tr>
<td><strong>by Gerald Devins, David C. Medelssohn et al.</strong></td>
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<td>A study conducted by Devins, Mendelssohn et al used a prospective randomized controlled trial to evaluate the efficacy of their Pre-dialysis psycho-educational intervention (PPI). Participants included 297 patients with progressive chronic kidney disease expected to need renal replacement therapy (RRT) within 6 to 8 months sampled from 15 Canadian tertiary care nephrology units. The intervention included information on healthy kidney function, kidney</td>
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diseases, common renal replacement therapies (RRTs), dietary and pharmacological regimens, nutrition and lifestyle. In addition, this content was summarized and given to recipients of the PPI in the form of a 60-page booklet and patients received supportive telephone call from the health educator once every 3 weeks. Due to the fact that there were multiple centers participating in this study, usual care varied significantly. In some instances no formal education was present and participants received no PPI, and in other cases, pre-dialysis education patients were identified and provided with comprehensive educational resources. The study revealed that the time to dialysis was significantly longer; an average of 17 months for those in the PPI group compared to those that received the usual care, an average of 14.2 months.

A review conducted by Levin, Lewis et al cited two separate studies to determine whether a multidisciplinary predialysis education program is of benefit to patients. One study, the Vancouver study, was a prospective, nonrandomized cohort study that compared patients who received education from a multidisciplinary clinic-based education and follow-up program, compared to those who received standard care by their physician. The Multidisciplinary education consisted of discussions surrounding renal function, blood pressure, bone disease and diet control. Intervention patients were seen every 2, 3 or 6 months, depending on their level of calculated creatinine. Patients who did not receive this formalized education program were managed by their physician according to local, current practices. Both groups of patients were referred to a formal orientation to dialysis sessions of 2-3 hours long consisting of an educational video, discussion of renal replacement options, demonstrations of hemodialysis and peritoneal dialysis and a discussion of no treatment.

“Multi-Disciplinary Predialysis Programs: Quantification and Limitations of Their Impact on Patient Outcomes in Two Canadian Settings” by Adeera Levin, Mary Lewis et al.

Relevant findings in the Vancouver study revealed that there was a significant difference in the number of patients requiring dialysis emergently between the two groups, 13% in the predialysis clinic verses 35% in the usual care group. Additionally, the average number of hospital days during the first month of dialysis showed significance as well; 6.5 days for the intervention group verses 13.5 for the usual care group.

The second study, the Toronto study, was a retrospective review of patient outcomes to similarly determine the impact of a multidisciplinary program. Patients who were a part of The Toronto Hospital were provided with early contact with a multidisciplinary ESRD team, renal education, and easy entry into ESRD programs. They also received an educational program with their families that covered topics such as options for living with ESRD, nutrition and medications. They attended a predialysis clinic where they met individually with a dialysis physician, renal nurse coordinator and social worker. Results of this study indicated that a predialysis program is useful in identifying patients and ensuring early creation of dialysis accesses, but it is not possible to reduce the number of early dialysis starts or hospital admissions/days if that predialysis program does not have access to adequate dialysis resources. The authors of the study concluded that an approach to predialysis education involving a multidisciplinary team can have a positive effect on qualitative outcomes. In so doing, they identified essential elements for success including early referral to a nephrology center, adequate resources for dedicated program staff and the availability of sufficient resources for those with ESRD.
### Predialysis Patient Education Contributes to Better Patient Outcomes for Those on Dialysis

| “Predialysis Psychoeducational Intervention Extends Survival in CKD: A 20-Year Follow-Up” | Authors of this study collected follow-up data for patients with CKD who participated in a multi-center randomized controlled trial of a predialysis psychoeducational intervention conducted in the mid-1980’s. Participants included 335 patients with CKD, 172 of whom were randomly assigned to receive a predialysis psychoeducational intervention, and 163 patients were assigned to receive usual care. The intervention entailed an individual lecture presentation that provided information about the normal function of the kidneys, kidney disease, dietary management, and different forms of renal replacement therapy. Participants were given the opportunity to ask questions and received a 22 page booklet summarizing the content they reviewed. Patients who received usual care only received relevant information from their physician in the form of either written materials or special referral to a nurse clinician. Results revealed that those who received the predialysis psychoeducational intervention survived a median of 2.25 years longer compared to those receiving usual care. Additionally, those who received the predialysis psychoeducational intervention survived a median of 8 months longer than usual-care patients following the start of dialysis. |
| by Gerald M. Devins, David C. Mendelssohn, et al | |

| “Predialysis Patient Education: Effects on Functioning and Well-Being in Uraemic Patients” | This study sought out to study the effects of a predialysis patient education program on general functioning and well being in patients with kidney failure. The authors identified two clinically comparable groups of patients to serve as the experimental or the conventional groups. The experimental group, consisting of 28 patients received patient education in a series of four sessions in a classroom setting. These sessions included renal disease and dietary management, renal replacement therapies, |
| by Birgitta Klang et al. | |

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physical exercise training, and the possible impacts of kidney failure on the economy, family and social life. This educational program also gave participants an opportunity to establish a connection with other healthcare providers including physicians, a specialist nurse, nutritionist, physiotherapist, and clinical social worker in an effort for them to plan follow-up appointments to provide them with more individual support. Those in the conventional care group only received conventional information that physicians would typically offer their patients. Three to nine months following the commencement of dialysis, both groups of patients were evaluated and revealed that while both groups had similar disease-specific symptoms outcomes, the experimental group showed less functional and mobility disabilities, better moods, less sense of loneliness, and lower levels of anxiety than the comparison group. These differences were mostly notable within the first 6 months of dialysis treatment. Thus, the authors suggest that patient education become ongoing for patients with ESRD, initiated during the predialysis stage and continued for maintenance after the start of dialysis for better patient outcomes.

Patient Education Empowers CKD Patients in Managing Their Condition

“The Impact of Education on Chronic Kidney Disease Patients’ to Initiate Dialysis With Self-Care Dialysis”

by Braden Manns, Ken Taub et al.

Authors conducted a randomized controlled trial in predialysis patients with CKD who were receiving care in a multidisciplinary predialysis clinic to determine the impact of a patient centered educational intervention on their intention to initiate dialysis with self-care dialysis. Participants were randomized to receive a patient centered educational intervention (n=35) or standard care (n=35). The intervention was comprised of two phases: phase 1 included educational booklets and a 15-minute video on self-care dialysis and phase two consisted of a 90-minute small group interactive educational session on self-care dialysis in addition to their regular care. Standard care

consisted of their usual ongoing care and education in the multidisciplinary clinic. Results of the study revealed that 82% of individuals in the intervention group intended to start dialysis with self-care dialysis as compared to 50% in the standard care group. Self-care dialysis is associated with overall improved quality of life in addition to being a significantly cheaper treatment option. Thus, the study revealed that patient education empowers individuals to make better health care decisions.


During 2005-2007, the United States Renal Data System (USRDS) conducted a special study surveying 1123 patients in a national cohort who identified as either black or white, had recently started dialysis and were deemed by their doctor as potentially eligible for a transplant. Patients were asked whether they had ever received information about kidney transplantation before they began dialysis. The survey response was linked with subsequent waiting list and transplants in the USRDS registry. An association was found between those who had received information and made aware of transplantation and subsequent spot on the waiting list. The authors learned that ongoing support and education for patients after the start of dialysis aides in the process of listings, transplantation and thus, the potential for overall improvement in health outcomes.

While each article was different with respect to the authors’ desired outcome and precise methodology used, each similarly concluded that some form of patient education has the capacity to lead to overall improved patient health outcomes. Interestingly, the articles reveal that the face of kidney disease treatment seems to be shifting from a passive role of patients solely following their physician’s instructions in all aspects of their kidney disease, to an active role, empowering them to make better decisions on their own. It can thus be suggested that the transmission of this

knowledge makes patients less reliant upon their doctor’s orders and more responsible for their own healthcare. In so doing, they are more attentive to their bodies, are more proactive, and are better equipped to handle their health needs, which ultimately leads to improvements in their overall condition.
Chapter 5: The Setting and Context of the Kidney Care Program

Setting

Montefiore Hospital, located in the Bronx, NY, is the academic medical center for Albert Einstein College of Medicine, a world-renowned institution for medicine and research. Montefiore’s services span all areas of patient care including cardiovascular services, transplantation, oncology, pediatrics and community health clinics scattered throughout the New York Metropolitan area. Always looking to improve patient care, in 1996, Montefiore developed the Care Management Organization (CMO), which provides care management to individuals with chronic diseases, which strives to achieve better health outcomes in a cost efficient manner. The CMO assumes responsibility for the care management of over 200,000 individuals with different health conditions, while maintaining the distribution of services such as hospital and outpatient care, rehabilitation, home care and mental health counseling.

Exhibit 8
(Source: Montefiore Medical Center: Integrated Care Delivery for Vulnerable Populations (NY, New York: The CommonWealth Fund,[2010])

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125 Montefiore Hospital, "About Montefiore Medical Center," Montefiore Medical Center, [http://www.montefiore.org/about](http://www.montefiore.org/about) (accessed 2/14, 2014).
126 Ibid.
127 Ibid.
As indicated by exhibit eight above, Montefiore CMO provides extensive and innovative care management aimed primarily at high-acuity patients. Managed care is crucial for patients suffering from chronic illnesses due to the many inevitable challenges they face when caring for themselves. This includes having multiple doctors, receiving fragmented care, being prone to having their medical information lost, undergoing repeat procedures and consistently repeating their medical history to different providers.\footnote{Centers for Medicare and Medicaid Services, "Pioneer Accountable Care Organization (ACO) Model Program Frequently Asked Questions," Department of Health and Human Services, \url{http://innovation.cms.gov/Files/x/Pioneer-ACO-Model-Frequently-Asked-Questions-doc.pdf} (accessed 10/14, 2013).} Coordinated care initiatives such as the CMO strive to remedy this problem as it establishes a line of connection between providers, ensuring that patients receive the necessary care, services, tests and medications without undergoing unnecessary procedures, preventing medical errors and thus, reducing overall healthcare costs.\footnote{Ibid.}

**Patient Population**

Perhaps the need for extensive care management can be attributed to the sick and highly vulnerable population that Montefiore Medical Center serves. With the main hospital located in the Bronx, one of the poorest urban counties in this country, it carries a usually high burden of disease associated with those impoverished including obesity, hypertension, cardiovascular disease, asthma and HIV.\footnote{Montefiore Medical Center: Integrated Care Delivery for Vulnerable Populations (NY, New York: The CommonWealth Fund, [2010]).} In addition, Montefiore is tasked with caring for the unique needs of the elderly and of minorities, specifically the African American and Hispanic populations who comprise 35.6% and 48.4% of the Bronx, respectively.\footnote{Ibid.}
To attain financial stability, Montefiore relies heavily on governmental subsidy; Medicare patients account for 39 percent of the patients and Medicaid, 40 percent.\textsuperscript{132} Despite the high proportion of low-income, complex medical conditions and patients insured by the government, Montefiore has been able to achieve financial stability due to the success of innovative, patient-centered care.\textsuperscript{133}

The Pioneer ACO Model

In January 2012 the Centers for Medicare and Medicaid Services (CMS) under the provisions of the Patient Protection and Affordable Care Act launched a care management initiative known as The Pioneer Accountable Care Organization (ACO) model.\textsuperscript{134} An ACO is an example of coordinated care explained by CMS as, “groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to the Medicare patients they serve”.\textsuperscript{135} The purpose of the piloting of the ACO model was to see how healthcare institutions with prior experience managing populations who had provider infrastructure and technology in place could provide Medicare beneficiaries with high quality healthcare while reducing expenses through improved care coordination over the course of three years.\textsuperscript{136} The ACO as a whole is collectively responsible for the health of its attributed population and are given financial incentives to work with each other and save money by

\textsuperscript{132} Ibid.
\textsuperscript{133} Ibid.
\textsuperscript{135} Ibid.
avoiding unnecessary tests and procedure which, importantly, can improve overall patient health outcomes.  

The Medicare Shared Savings Program rewards ACO’s that are able to lower healthcare costs by putting patients at the center of care and are able to meet performance standards. These performance quality measures are within four domains: patient experience of care, care coordination/patient safety, preventative health and at-risk populations (see appendix A for the extent of quality measures). Measures are reported on a yearly basis through “patient experience of care” surveys and web programming that was especially designed for clinical quality measure reporting.  

Measures reported by ACO’s are compared to national performance benchmarks established by CMS using national fee-for-service claims data, national Medicare Advantage quality reporting rates or a flat national percentage for measures in which Medicare Advantage and fee-for-service data was not available. ACO’s whose performance is equal to or greater than the minimum attainment level for a measure, received points on a sliding scale. Additionally, ACO’s whose performance measure at or above the 90th percentile of the performance benchmark earns the maximum points available for that measure. CMS adds the points earned for the individual measure within each domain and divides them by the total points 

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139 Ibid.  
140 Ibid.  
141 Ibid.  
142 Ibid.  
143 Ibid.
available for the domain to determine each of the four domain scores.\textsuperscript{144} To determine the ACO’s overall quality performance score and shared savings rate, the domains are weighted equally and scores are averaged.\textsuperscript{145} To avoid being placed on a corrective action plan and face a penalty, ACO’s need to achieve the minimum level of at least the 70th percent of the measures in each domain.\textsuperscript{146}

ACO’s that saved money while meeting patient health targets get to keep a portion of the savings while those deemed unsuccessful had the potential to be burdened with additional costs of further investments to make needed improvements.\textsuperscript{147}

\textbf{CMO as an ACO}

To participate in this program, CMS conducted a highly competitive application process requiring an extensive application, letter of intent and interview.\textsuperscript{148} Under the direction of Dr. Henry Chung, the chief medical officer of the CMO, Montefiore submitted an application and was among 32 healthcare institutions, and the only one in New York State, selected.\textsuperscript{149}

In participating in this program, the CMO increased patient engagement, care coordination, and patient-centered care in various settings such as the main hospital, doctor’s offices, at home and telephonically.\textsuperscript{150} Further, collaboration with physicians in the community across all areas of the Montefiore healthcare system as well as various nurse-led interventions supported clinical outcomes and positive patient experiences.\textsuperscript{151}

Initial data in July 2013 revealed that over the course of the first year, Montefiore CMO achieved significant savings to the Medicare program; a seven percent reduction in the costs of

\begin{thebibliography}{9}
\bibitem{144} Ibid.
\bibitem{145} Ibid.
\bibitem{146} Ibid.
\bibitem{147} Gold, \textit{FAQ on ACOs: Accountable Care Organizations, Explained}, 1.
\bibitem{148} “Montefiore Pioneer ACO Model Achieves Success in First Year.”
\bibitem{149} Ibid.
\bibitem{150} Ibid.
\bibitem{151} Ibid.
\end{thebibliography}
care against the benchmark established of more than 23,000 patients attributed by CMS to physicians in the Montefiore ACO, thus achieving the highest financial performance among all 32 participants in the program. Based on this success, Montefiore received about $14 million of the savings that it had generated for Medicare, which was reinvested in their healthcare system and shared with participating physicians.

Today, the CMO continues using advanced models of healthcare delivery in partnership with Montefiore physicians and community-based practitioners. Over 60 percent of Montefiore ACO Medicare patients receive their care from physicians in private practice in the community, with the rest receiving their care from Montefiore staff physicians. The ACO provides about 10 percent of patients with complex chronic illnesses with intensive care management services. All ACO patients have access to Montefiore’s care coordination programs as needed, receiving services that will make them well.

The Kidney Care Program

One example of innovative CMO programming and the subject of this research study is the Kidney Care Program. The Kidney Care Program consists of approximately 155 patients with varying stages of kidney disease. The programs’ goals are multi-faceted:

- Improve the education and outcomes of patients with CKD by using evidence based medicine guidelines as well as a multidisciplinary team approach
- Decrease morbidity and mortality
- Decrease emergent dialysis admissions

References

152 Ibid.
153 Ibid.
154 Ibid.
155 Ibid.
156 T. Smith-Jules and others, *Kidney Care Program in an Urban Managed Care Setting Prepares CKD Patients for ESRD* (Bronx, NY: Division of Nephrology, Department of Medicine, Albert Einstein College of Medicine and Montefiore Medical Center, [2014]).
157 Sheila Felleman, *Chronic Kidney Disease Program Description*, 2012)
Increase the use of peritoneal dialysis

Increase coordination to seek transplant as an option

These goals are achieved through comprehensive, multidisciplinary care management initiatives in the realm of geriatric palliative consult, pharmacy review, tracking of ESRD progression, outpatient dialysis services, consult with a renal dietician and one-on-one check-in appointments with Terrian Smith-Jules, the program’s nurse practitioner. These interventions are carried out in the hopes that they will ultimately delay participants’ need for dialysis while also reducing their overall medical costs.\textsuperscript{158} It is clear that there is a need for this programming, as in 2008, the incidence of ESRD in the Bronx was 1.4 times higher than the US average.\textsuperscript{159}

In exchange for receiving care management services, participants are required to attend at least one of the workshops that, as mentioned in chapter one, are offered on a number of different topics pertaining to disease management and treatment options. The next chapter delves into a study of the workshops themselves examining how effective they are, how they can lead patients towards positive health outcomes and identifies the areas for further improvement.

\textsuperscript{158} Smith-Jules and others, \textit{Kidney Care Program in an Urban Managed Care Setting Prepares CKD Patients for ESRD}

\textsuperscript{159} Felleman, \textit{Chronic Kidney Disease Program Description}
Chapter 6: Theory and Methods

Theory

The outcome of the literature review examined in chapter four revealed the importance of the role of educating patients to the point of empowerment, enabling them to be an integral part of their healthcare.\textsuperscript{160} This gave patients the opportunity to make their own health-related decisions, which led to improved health and quality of life outcomes.\textsuperscript{161} The present study under investigation is found in the context of a similar theory.

\begin{center}
\includegraphics[width=0.5\textwidth]{exhibit9.png}
\end{center}

\textbf{Exhibit 9}

As exhibit nine indicates, this theory is cyclical: a patient’s knowledge surrounding their illness empowers them to take charge, ask questions, and try to learn more on their own. This, in turn, leads to a patient’s understanding of how to be compliant: how to take medications, control their diet and amend lifestyle habits accordingly. As a result, patients are able to achieve better health outcomes as well as attain improved quality of life. Further, it can be suggested that this model is cyclical in nature. Once patients have felt as though their health has improved as a

\textsuperscript{160} Wu and others, \textit{Multidisciplinary Predialysis Education Decreases the Incidence of Dialysis and Reduces Mortality--a Controlled Cohort Study Based on the NKF/DOQI Guidelines}, 3426-3433.

\textsuperscript{161} Ibid.
result of the things they have learned and the steps they have taken to change their lives, they want to learn more to further improve their condition starting the process of obtaining knowledge and feeling empowered once again.

**Study Purpose**

This investigation seeks to test the aforementioned theory by asking the following research questions:

1. How successful is health literacy in empowering patients to take control of their condition and achieve improved health and quality of life outcomes?

2. What gaps exist in the current programming that, when amended, patients suspect will help empower them to reach desired outcomes?

To answer these questions, the study focused on obtaining qualitative interviews with participants in an ACO-based disease management program for chronic kidney disease. This method was chosen in order to obtain as many open-ended and honest responses as possible without the restrictions that are common of surveys and questionnaires. Montefiore Hospital’s Kidney Care Program is an excellent setting to test this theory and answer these questions due to their pre-existing programming which strives to improve the health of their patients and achieve financial incentives as a result.

**Recruitment Procedures**

The approach used in collecting data to answer these questions was multi-faceted. The student-researcher was aided by Terrian Smith-Jules, the nurse practitioner for the Kidney Care Program in recruiting patients for this study. Ms. Smith-Jules explained the purpose of the study to her patients at the end of their outpatient check-ups as well at the beginnings of the patient education workshops. In this way, the study aimed to collect information on a variety of program
participants who had (and had not) attended the additional education workshops. On these occasions she distributed the student-researcher’s business card to them, which stated her university email address, cellular phone number and area of research. Ms. Smith-Jules then encouraged her patients to contact the student researcher to set up a time for a telephonic interview. Often, the student researcher was seated in the waiting room during appointments and was formally introduced to interested patients either before or after their appointment.

**Study Implementation**

Once the student researcher was introduced to these patients, some agreed to an interview in a closed, unused exam room while waiting for Ms. Smith-Jules to call them for their appointment or to stay around a few minutes longer following their appointment. Others agreed to a telephonic interview to take place at a later hour. Further, the student researcher was also introduced to patients at the beginning of the workshops that she attended and similarly set up telephonic interviews with these individuals to occur at a later date. Interviews and data collection took place in March 2014. A detailed interview guide (see appendix B) was created and used in conducting interviews. The guide consisted of questions related to the patients’ management of their condition as well as their feelings surrounding the resources and workshops offered to them by Montefiore Medical Center. Subject responses were transcribed from notes and all quotations are nearest estimation to verbatim quotes. All names used are pseudonyms. The Institutional Review Boards at Brandeis University and Montefiore Medical Center approved this study, respectively (see appendix C). In total, approximately 20 patients were approached for interviews and seven accepted.\(^{162}\)

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\(^{162}\) The study was substantially delayed due to a last-minute decision by Montefiore in January to require their IRB to approve the study, even though it had been approved by Brandeis. In the end, the planned 3 month data-collection period was reduced to approximately one week, significantly limiting the number of participants. For this reason, advanced statistics were not conducted
Results

Demographics

Study participants primarily self-identified as minority populations (African American, n=3; Hispanic, n=1; opted not to answer, n=3). They were primarily elderly, ranging 65-80 years of age, which is reflective of national averages for CKD patients. Stage of CKD varied as well (stage 3 n=1; stage 4 n=3, opted not to answer n=3). Half of workshop participants (n=2) have already had a dialysis access implanted, though both disclosed that they have not yet needed to begin dialysis. Participants offered a range for the number of visits with their physician during the 2013 calendar year, which yielded a mode of 4 (minimum=4; maximum=6).

Acquisition of Knowledge

All seven patients interviewed answered that they had very little prior knowledge of CKD, if any at all. Two (~29%) patients stated that at their initial visit with the nephrologist they were not given crucial information about their kidney disease, four (~57%) reported that they received important information alongside their diagnosis, and one reported that he had yet to see his nephrologist altogether. Slightly more than half of patients (~57%, n=4) revealed that they had attended the educational workshops offered by the Kidney Care Program while three (~43%) said that they had not.

Prior to discussing the educational workshops or any of Montefiore’s initiatives, patients expressed significant regret that their disease progressed to this point, and one partially blamed lack of education from the health care system. As one patient, Albert, a 61 year old with stage IV CKD, remarked, “I would have liked to know how to prevent this from happening to begin with. Terrian said that someone should have notified me sooner about my kidney

\(^{163}\) National Chronic Kidney Disease Fact Sheet, 2014, 1-3.
Similarly, another patient, Sam, a 65 year old with stage III CKD, explained, “I wish I knew about all this stuff [how to prevent kidney disease] beforehand. Once it happens you can’t avoid it.” Thus, these participants expressed the need for a formalized diagnosis before their condition worsened.

In terms of receiving knowledge outside of the Montefiore setting, three (~43%) individuals responded that family members assist them in gathering information from various sources, one replied that she consults the pamphlets Terrian had previously given her, one utilizes internet resources and two (~29%) explained that they do not yet have a preferred method of obtaining outside information as their diagnoses are relatively recent. When patients were asked to rank their level of knowledge taking into account all information they obtained from various sources, one reported “novice”, one, “somewhat knowledgeable”, two (~29%) considered themselves “knowledgeable”, three (~43%), “expert”.

Patients were then asked what would help empower them in managing their CKD, and at this point, two key themes emerged. First, patients wanted to obtain more general knowledge about their disease. Specifically, they suggested the need for further information surrounding how to take their medications, what foods to eat and what kind of activities to avoid. These suggestions were made evident by one participant, Anita, with stage IV CKD who remarked, “I feel more in control if I understand how to take my medications properly” and another patient, James, who stated, “I want to learn not only about what foods I should avoid, but also what foods are OK.” These statements indicate the need for further information on topics related to current practices, an integral component to disease management.

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166 Anita, Kidney Care Program Patient Interviews, 3/18/2014, 2014.
167 James, Kidney Care Program Patient Interviews, 3/19/2014, 2014.
Second, patients are acutely interested in looking into learning about future health consequences that might arise. This finding was indicative of Anita, who stated, “I want to know why people go on dialysis, why they would need a transplant and why I might ever need to go on insulin.”168 Similarly, Lynn stated, “I want to learn more but I am not sure exactly what, because this is something I cannot fathom. There are no warnings about disease progression and I don’t know what to expect.”169 Thus, it is clear that patients are not solely interested in managing current conditions but expressed a desire to learn more about preventing future conditions as well.

Modes of Education

The study also examined the effectiveness of the way in which the education, through the workshops, was imparted to patients. Specifically, patients were asked about the configuration of the workshop, the clarity of the information presented and the kind of information given. Of those who attended the workshops, participants expressed the value of gathering in a group setting and being connected with others. As Sam explained:

I enjoy going to the classes and learning new things. I like to hear about other people’s experiences and hear what kind of advice they have for me in terms of what kind of food substitutions to make. It’s important to keep going and stay up to date.170

Along these lines, Sam continued to stress the need for the classes to occur more often. As he said,

It would be nice to have the classes a little more often because [as a result of the interval between the workshops] I strayed a little. Being around other people is a good reminder as to how to take care of myself. Since I don’t normally hang out around people with kidney disease I tend to forget

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168 Anita, *Kidney Care Program Patient Interviews*
170 Sam, *Kidney Care Program Patient Interviews*
[about my limitations] and I appreciate being around others who are experiencing the same thing. It is motivating. ¹⁷¹

Others mentioned appreciated aspects of the workshops such as the discussion topics, which they found interesting, and the pamphlets and fact sheets that they could take home with them. Few also remarked that they enjoyed hearing from different kind of providers, as well as the varied topics that Terrian spoke about. Along these lines, three workshop participants ranked their overall satisfaction on a scale from 1-5 as a 5, “most satisfied” with the workshop (the other workshop participant ended the interview prior to this point). All four workshop participants interviewed answered affirmatively to whether they found the information presented in a clear and easy-to-understand manner.

Another interesting finding stemming from workshop participants, was from one woman, Lynn, who commented on the duration and timing of the workshop. As she said,

I wish that they would not be so long because they run too late into the evenings. It would be nice if it could start earlier in the day and then end earlier in the evenings, especially during the winter when it gets darker, earlier. I don’t go to meetings so often because I do not drive anymore and I have to rely on public transportation. I don’t want to wait around [here] in the dark for a cab or a bus. ¹⁷²

Interestingly, Lynn was the only person to elucidate these issues which is surprising given the location of the workshops and that the participants are elderly and ill, a vulnerable population.

Impact of the workshop on lifestyle

Three out of the four interviewees (75%) who attended the workshop expressed how they have implemented crucial lifestyle changes ever since they began taking part in the workshop. Some of these changes were small as evidenced from James who explained that he made slight

¹⁷¹ Ibid.
¹⁷² Lynn, Kidney Care Program Patient Interviews
diet modifications and incorporated a light exercise routine into his daily happenings173 while others’ changes were larger and thus yielded greater outcomes. One such example is Sam. Sam stated that ever since attending the Kidney Care Program he has become “more knowledgeable in the area of diets and the need for a transplant.”174 Consequently, Sam stated he reached improved health outcomes:

As a result of the class I have already lost five pounds and went from a stage four to a stage three. My overall health improved. I learned to slow down a lot and to think through doing certain things before I do them. I also learned to take better care of my limbs that are damaged from diabetes.175

Similarly, Lynn, another patient, discussed how education, partially through workshop attendance but mostly through information provided by her nurse coordinator, has impacted her life. As she said:

I have had a [dialysis] access in my arm for almost three years now but have not yet needed to use it. I describe myself as happy-go-lucky and not at all depressed about my condition because I feel well informed about so many different aspects: diet, exercising, medications…176

Lynn’s response exuded a sense of self-confidence in her understanding of chronic kidney disease in addition to how her knowledge has helped delay initiation of dialysis over the past three years. She stated that she looks forward to continuing her education by attending the workshops on days that interesting speakers are scheduled to present.177

173 James, Kidney Care Program Patient Interviews
174 Sam, Kidney Care Program Patient Interviews
175 Ibid.
176 Lynn, Kidney Care Program Patient Interviews
177 Ibid.
Chapter 7: Discussion, Limitations, Areas For Future Research and Conclusions

Discussion

Upon analysis, it is evident that these findings have significant implications that speak not only to health literacy, but also to a general standard of care. One finding within the responses was the way in which patients seemed to fit within the proposed theory at the beginning of this section. This was particularly evident from the statements made in chapter six by James, Sam and Lynn. Each of these participants implemented crucial changes to their lives which helped them attain improved health outcomes. Additionally, because they expressed a desire to return back to the workshop and receive more information from Terrian, it is evident that they feel empowered to learn more, continue with their healthy lifestyle and improve their health further.

A second finding surrounded the timing of the educational interventions and how pertinent healthcare information is conveyed to patients. Patients indicated that they were only given crucial information as how to delay disease progression once they already had some indicator of CKD, yet they claimed to have never received information on how to prevent the rise of CKD to begin with. As Albert said, “By the time I was diagnosed, I needed to get on a list for a transplant and would need to start dialysis in the near future.” Similarly Sam also remarked pertaining to his diagnosis that at first he was “very surprised because my sugar and A1c was well controlled and this [news] burst my bubble because I thought that I was doing all that I could.” Thus, it is clear that in some instances, patients were not given fair warning and at the point at which they were diagnosed, the damage to their kidneys could not be undone. This was a surprising finding because it seems to imply that there is a stronger emphasis placed in conveying strategies to help patients through current health challenges as opposed to motivating

178 Albert, Kidney Care Program Patient Interviews
them to prevent long-term deleterious consequences. For example, rather than providing diabetic patients with the information that uncontrolled diabetes could lead to chronic kidney disease, they often instead focus on teaching patients on insulin administration and how to take medications.

It is possible that this situation is due to multiple factors. It may be an issue concerning resources. Physicians simply do not have the time to go through every single complication that might arise with their patients (most of whom are already at high risk for many complications) during an ordinary visit. Institutions such as Montefiore are overwhelmed with their patient volume, and the idea of spending upwards of 30 minutes with each patient to inform them about their dietary needs, restrictions and other diseases on the rise seems implausible. While they may create and implement educational workshops, physicians and nurses cannot actually force anyone to attend any of the workshops, no matter how much they encourage them. At the end of the day, each patient makes their own decision about how they are going to handle their healthcare needs.

Another potential explanation is that healthcare providers are faced with a quandary in terms of the timing of providing pertinent information. On one hand they want to give their patients as much information as they possibly can, provided that time during their appointments enables them to do so. On the other hand, however, if information is given too early, before it is actually relevant, it has the potential to be forgotten or ignored. Patients might readily admit that they wished they could have had more information to prepare them for their current condition but it is not clear whether the distribution of this information in advance would have been implemented or influential. Thus, there is a need to identify the point at which individuals will most benefit from such educational interventions.
Limitations

While it is evident that the findings that have emerged from this study are important in shaping an understanding surrounding patient empowerment, it is not without multiple limitations. Most obviously, the study suffers from having utilized a small sample size of seven patients due to a substantial delay in obtaining approval from the Institutional Review Board at Montefiore Medical Center (see appendix D for timeline). As such, it would be impossible to suggest that the findings of this study are indicative of the feelings and experiences of the majority of the Montefiore Kidney Care Program population. Studying a larger sample and hearing additional stories of patients with chronic kidney disease would have offered more varied results, range of opinions and journeys that might not support the information gathered above.

Another limitation this study faces that may be due in part to its small sample size is its inability to address what additional barriers minority populations face in their receipt of education, their path to empowerment and management of their condition. This was originally one of the foci of the study but when asked, study participants did not believe that it applied to them. It is possible that this particular limited sample never had these experiences and that a wider range of participants might be able to offer significant challenges that do exist. Additionally, it is possible that Montefiore deconstructs these barriers by being keenly aware of their patient population and already offers culturally sensitive information that is relatable, understandable and easy to implement. Further research is needed with a larger sample size and those with more diverse experiences to reach more telling conclusions in this area.

This study also faces the limitation of selection bias. The goal of the study was to measure empowerment, which, the study revealed, is closely linked to knowledge and
compliance. Those who felt empowered in managing their chronic kidney disease were those
who were knowledgeable and thus became compliant in caring for themselves once they were
properly informed. However, this information was gleaned from Kidney Care Program patients
who were recruited when they came to their check-ups as well as from those who attended
educational workshops; individuals who clearly exhibit some form of compliance and
empowerment already. These individuals supply answers that are likely different from those who
do not demonstrate a form of compliance. These are results that might be acquired from “cold
calling” any given patient from the Kidney Care Program but was beyond the scope of this
project. Thus, the results do not address those who may not attend the workshops or their
appointments due to significant barriers they face. Why do patients behave the way they do? Is it
because they can’t understand certain information or have problems pertaining to accessibility?
What would help them feel more empowered, and importantly, how can Montefiore reach out to
them to make their interventions more enticing to all eligible parties? It is precisely these
individuals who could provide crucial perspectives on this issue in an effort to expand the reach
of these patients.

As a third limitation, interviewees were all Medicare beneficiaries, the population that
comprises ACO’s such as the Care Management Organization of Montefiore Medical Center.
This might be an additional explanation as to why respondents denied barriers to their healthcare.
In retrospect this may be due to the fact that otherwise expensive medications and services are
heavily subsidized under Medicare. Thus, the study’s results do not address the needs of those
living with CKD who are either uninsured, underinsured or those who do not yet qualify for
Medicare.
Areas for future research

Establishing the Efficacy of Educational Interventions

The initial findings of this study suggest multiple areas of research deserving further consideration. While this study focused on qualitative responses from program participants, one such area is to measure the health outcomes of those who have received educational interventions versus a control group of patients who did not receive any formalized education. This would determine on a larger scale whether or not the interventions are sufficiently successful to justify the associated costs of production, new staff and materials needed for implementing such programming in other healthcare organizations throughout the country.

If deemed that interventions do have positive results, it would also be ideal to measure their long-term efficacy. Some participants were able to describe how their knowledge helped them achieve successful health outcomes and improved quality of life. However, what remains unknown is how long this lasts and how long patients will remain compliant. What happens during the winter months when educational interventions are temporarily put on hold because patients don’t want to leave their apartments for the workshops or appointments? Are they able to remember what they were taught? Do they adhere to the advice that was once given to them, or stray back to their original habits? This area of further research would focus on what kind of follow-up information or infrastructure is already in place or still needs to be implemented in order to ensure that patients are able to meet their healthcare goals as part of a long-term solution.

Workshop Configuration

Another area for further research surrounds the configuration of the workshop itself. The aforementioned workshop utilizes a peer motivation and support model, closely resembling
traditional support groups available to alcoholics and those battling cancer. At the beginning of the Kidney Care workshops, patients are given the opportunity to introduce themselves and are encouraged throughout to ask questions and offer advice to their peers on topics that they have mastered. As an example, during one workshop, the workshop leader explained how patients with CKD need to avoid the consumption of products containing phosphorus, particularly beverages such as Coca Cola and Dr. Pepper, as it causes further kidney distress. In response to this fact many participants expressed shock that they would need to forgo such a seemingly innocuous beverage from their diet. At that moment another more seasoned workshop participant offered an idea for a substitute beverage (seltzer with a squeeze of lemon) to her peers explaining that this alternative satisfies her craving for a flavored, carbonated beverage without causing further damage to her kidneys. Though not thrilled to hear about yet another restriction, patients seemed to appreciate the advice from someone going through a similar process. They also seemed to take comfort in the fact that they are not enduring this frightening and life changing process on their own; they are surrounded by others in the same situation and understand their struggles.

While this model may be ideal for some, it would also prove useful to study how this peer support group model compares to a different format such as one-on-one health coaching. In this light it is important to note that information offered by participants pertaining to the current configuration varied: some expressed a strong appreciation for the group setting while a different participant stated she would have preferred individual coaching. Thus, it proves difficult to balance giving patients the individualized attention they require within a large educational program.
It is important to consider: what advantages does one-on-one advising offer over the peer motivation group configuration? For instance, it is possible that individuals would actually prefer one-on-one coaching out of concerns of privacy in addition to receiving more personalized attention. Do patients avoid asking certain questions in a group setting that they might otherwise ask in a private session? Are patients hesitant to ask for clarification on certain topics because they feel that their peers might judge them unfavorably? Identifying the answers to these questions allows for a restructuring of a crucial intervention, making it as effective as possible. It is not enough to merely promote health literacy for patients with chronic illnesses but also, the optimal way in which to do so.

*Understanding the Need for Resources*

Montefiore hospital, one of the leading research institutions in the country is privileged to have significant resources allotted to them enabling them to have the workshops and the additional staff needed to strengthen the Kidney Care Program. However, further research might explore how institutions that are not as privileged can similarly provide educational programming without the high costs. One aspect of the study, as indicated by exhibit 10 below, elucidated the fact that those with advanced kidney disease require frequent visits with their doctor.
As such, how can institutions without these resources take advantage of the multiple appointments they spend with their patients, similarly giving them information that otherwise might be provided in a workshop? Further investigation in this situation surrounds researching the kind of information that is thorough, engaging and easy to convey in the short time frame available.

*Patient Education in the Midst of Other Chronic Conditions*

As a final consideration, it is worthy to think about patient education not only in the midst of chronic kidney disease, but also in terms of other chronic conditions as well. Montefiore holds a similar patient education workshop for Diabetics using a “Conversation Map”: a colorful teaching tool developed by Healthy Interactions, the American Diabetes Association and Merck pharmaceuticals. It would be interesting to learn not only how effective this unique patient workshop is, but also, what other, similar programs can be implemented for various other chronic diseases? Further, what important findings can be gleaned from the unique needs of
kidney disease patients and how, if at all, can it be applied to the needs of patients with other illnesses? Alternatively, why might the needs of CKD patients be different than those of others? Lastly, it is crucial to identify what are the issues that clinicians feel are the most pressing or misunderstood amongst their patients and how they can assure clarification and promote compliance.

**Conclusions**

Year One data from Montefiore’s extensive Kidney Care Program revealed an achievement of significant health outcomes for their patients in the CKD program:179

- Improved rates of implantation of graft and fistulas prior to dialysis (55% vs. 18% within national USRDS data)
- 55% began dialysis at an outpatient facility (as opposed to in-hospital) compared to an internal cohort consisting of typical Montefiore patients, in which only 24% began dialysis at an outpatient facility
- This initiation of dialysis at an outpatient facility potentially saved hospitalizations for 20% of ESRD patients
- The Kidney Care Program facilitated important medication reconciliation to ensure that their participants were taking the correct medications at correct dosages

While the Kidney Care Program is multifaceted and its success can stem from any of the interventions, it is reasonable to suspect that the workshops play an integral role in this process. Educating patients and empowering them to make better decisions enabled them to be an active participant in their own well being which helps them reach improved health outcomes. Thus, the results of the Kidney Care Program support the previously mentioned theory and conclusions.

179 All subsequent data in this section from: Smith-Jules and others, *Kidney Care Program in an Urban Managed Care Setting Prepares CKD Patients for ESRD*
reached in the literature review. Despite the apparent limitations and the need for further research, the study revealed important findings, which can help improve the program in the future.
References


Improving Quality of Care for Medicare Patients: Accountable Care Organizations: Department of Health and Human Services: Centers for Medicare & Medicaid Services, 2012.


# Appendix A: CMS Quality Measures for Accountable Care Organizations

## Improving Quality of Care for Medicare Patients: Accountable Care Organizations

## Appendix

### Quality Measures for Accountable Care Organizations

<table>
<thead>
<tr>
<th>Domain</th>
<th>Measure Title</th>
<th>NQF Measure #</th>
<th>Measure Title Steward</th>
<th>Method of Data Submission</th>
<th>Pay for Performance Phase In</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td>AIM: Better Care for Individuals</td>
<td>CAHPS: Getting Timely Care, Appointments, and Information</td>
<td>NQF #5, AHRQ</td>
<td>Survey</td>
<td>R</td>
<td>P</td>
<td>P</td>
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<tr>
<td>1. Patient/ Caregiver Experience</td>
<td>CAHPS: How Well Your Doctors Communicate</td>
<td>NQF #5 AHRQ</td>
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<td>3. Patient/ Caregiver Experience</td>
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<td>NQF #5 AHRQ</td>
<td>Survey</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Patient/ Caregiver Experience</td>
<td>CAHPS: Health Promotion and Education</td>
<td>NQF #5 AHRQ</td>
<td>Survey</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Patient/ Caregiver Experience</td>
<td>CAHPS: Shared Decision Making</td>
<td>NQF #5 AHRQ</td>
<td>Survey</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Patient/ Caregiver Experience</td>
<td>CAHPS: Health Status/ Functional Status</td>
<td>NQF #6 AHRQ</td>
<td>Survey</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Patient/ Caregiver Experience</td>
<td>CAHPS: Risk-Standardized, All Condition Readmission</td>
<td>NQF #TBD CMS</td>
<td>Claims</td>
<td>R</td>
<td>R</td>
<td>P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Care Coordination/ Patient Safety</td>
<td>Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease</td>
<td>NQF #275 AHRQ</td>
<td>Claims</td>
<td>R</td>
<td>P</td>
<td>P</td>
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</table>

1 We note that this measure has been under development and that finalization of this measure is contingent upon the availability of measure specifications before the establishment of the Shared Savings Program on January 1, 2012.
<table>
<thead>
<tr>
<th>Domain</th>
<th>Measure Title</th>
<th>NQF Measure #/Measure Steward</th>
<th>Method of Data Submission</th>
<th>Pay for Performance Phase In</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Care Coordination/ Patient Safety</td>
<td>Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)</td>
<td>NQF #277 AHRQ</td>
<td>Claims</td>
<td>R</td>
</tr>
<tr>
<td>11. Care Coordination/ Patient Safety</td>
<td>Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment</td>
<td>CMS</td>
<td>EHR Incentive Program Reporting</td>
<td>R</td>
</tr>
<tr>
<td>12. Care Coordination/ Patient Safety</td>
<td>Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility</td>
<td>NQF #97 AMA-PCPI/ NCQA</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>13. Care Coordination/ Patient Safety</td>
<td>Falls: Screening for Fall Risk</td>
<td>NQF #101 NCQA</td>
<td>GPRO Web Interface</td>
<td>R</td>
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</table>

**AIM: Better Health for Populations**

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<tr>
<th>Preventive Health</th>
<th>Measure Title</th>
<th>NQF Measure #/Measure Steward</th>
<th>Method of Data Submission</th>
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<tbody>
<tr>
<td>14. Preventive Health</td>
<td>Influenza Immunization</td>
<td>NQF #41 AMA-PCPI</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>15. Preventive Health</td>
<td>Pneumococcal Vaccination</td>
<td>NQF #43 NCQA</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>16. Preventive Health</td>
<td>Adult Weight Screening and Follow-up</td>
<td>NQF #421 NCQA</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>17. Preventive Health</td>
<td>Tobacco Use Assessment and Tobacco Cessation Intervention</td>
<td>NQF #28 AMA-PCPI</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>18. Preventive Health</td>
<td>Depression Screening</td>
<td>NQF #418 CMS</td>
<td>GPRO Web Interface</td>
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<tr>
<td>19. Preventive Health</td>
<td>Colorectal Cancer Screening</td>
<td>NQF #34 NCQA</td>
<td>GPRO Web Interface</td>
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<tr>
<td>20. Preventive Health</td>
<td>Mammography Screening</td>
<td>NQF #31 NCQA</td>
<td>GPRO Web Interface</td>
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## Improving Quality of Care for Medicare Patients: Accountable Care Organizations

<table>
<thead>
<tr>
<th>Domain</th>
<th>Measure Title</th>
<th>NQF Measure ID</th>
<th>Method of Data Submission</th>
<th>Pay for Performance Phase In</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. Preventive Health</td>
<td>Proportion of Adults 18+ who had their Blood Pressure Measured within the preceding 2 years</td>
<td>CMS</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>R</td>
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</tr>
<tr>
<td>22. At Risk Population – Diabetes</td>
<td>Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (&lt;8 percent)</td>
<td>NQF #0729</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
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<tr>
<td>23. At Risk Population – Diabetes</td>
<td>Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (&lt;100)</td>
<td>NQF #0729</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
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<tr>
<td>25. At Risk Population – Diabetes</td>
<td>Diabetes Composite (All or Nothing Scoring): Tobacco Use</td>
<td>NQF #0729</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
<td>P</td>
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<tr>
<td>26. At Risk Population – Diabetes</td>
<td>Diabetes Composite (All or Nothing Scoring): Aspirin Use</td>
<td>NQF #0729</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
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<tr>
<td>27. At Risk Population – Diabetes</td>
<td>Diabetes Mellitus: Hemoglobin A1c Poor Control (&gt;9 percent)</td>
<td>NQF #59</td>
<td>GPRO Web Interface</td>
<td>R</td>
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<tr>
<td>28. At Risk Population – Hypertension</td>
<td>Hypertension (HTN): Blood Pressure Control</td>
<td>NQF #18</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
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<tr>
<td>29. At Risk Population – Ischemic Vascular Disease</td>
<td>Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control &lt;100 mg/dl</td>
<td>NQF #75</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
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<tr>
<td>Domain</td>
<td>Measure Title</td>
<td>NQF Measure #</td>
<td>Measure Steward</td>
<td>Method of Data Submission</td>
<td>Pay for Performance Phase In</td>
<td>Year 1</td>
<td>Year 2</td>
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<tr>
<td>30. At Risk Population – Ischemic Vascular Disease</td>
<td>Ischemic Vascular Disease (IVD); Use of Aspirin or Another Antithrombotic</td>
<td>NQF #68 NCQA</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>P</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>31. At Risk Population – Heart Failure</td>
<td>Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)</td>
<td>NQF #83 AMA-PCPI</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>R</td>
<td>P</td>
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</tr>
<tr>
<td>32. At Risk Population – Coronary Artery Disease</td>
<td>Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL-Cholesterol</td>
<td>NQF #74 CMS (composite) / AMA-PCPI (individual component)</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>R</td>
<td>P</td>
<td></td>
</tr>
<tr>
<td>33. At Risk Population – Coronary Artery Disease</td>
<td>Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)</td>
<td>NQF #66 CMS (composite) / AMA-PCPI (individual component)</td>
<td>GPRO Web Interface</td>
<td>R</td>
<td>R</td>
<td>P</td>
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</tr>
</tbody>
</table>
Appendix B: Interview Guide

CKD patient Interviews question sheet
1. Before the doctor told you that you had kidney disease, did you know anything about kidney disease? (prompt: maybe someone in your family had it, you read about it in the paper, heard about it on TV…)
2. Describe your first meeting with your doctor when you were told that you have CKD. What kind of information were you given? (prompt: what foods to avoid, medications to take or avoid, important lifestyle changes to make…)
3. Where are you getting information for your CKD from?
4. Outside of your doctor’s office, where do you get your information on kidney disease? (prompt: the internet, the library, talking to a friend or family member…)
5. Considering all types of knowledge you have obtained (from your own sources, your doctor, the workshop) how would you rate your overall knowledge of CKD? (prompt: completely clueless, somewhat knowledgeable, knowledgeable, expert)
6. What would help you feel more empowered about managing your CKD?
7. On a scale of 1-5, 5 being the most satisfied, 1 being the least satisfied, how satisfied were you with the kind of information given to you by your doctor?
8. Have you ever been to Terrian’s CKD workshop?
If yes to #8…
a. How many times have you attended?
b. What are some good things about the workshop? (prompt: consider time of day, location, class size)
c. In your opinion, what might make the workshop better?
d. What do you think of the topics that are covered?
e. What do you think of the kind of presentation? (prompt: do you like the powerpoint presentation? Discussions? A leader?)
f. Is the information clear?
g. Do you find that you learn new things about your health and your kidney disease?
h. After the workshop do you feel you know how to manage your kidney disease better?
i. What kind of changes have you made in your daily life after you attended this class and have they improved your health? (Specifically: food, medications)
j. On a scale of 1-5, 5 being the most satisfied, and 1 being the least satisfied, how would you rate your overall experience at this class?
9. If no to #8…
a. Is there a specific reason why you did not attend? (prompt: not a good time, didn’t seem helpful or interesting, didn’t know about it, heard negative reviews, felt like there’s nothing left to learn)
b. What else might help you attend? (better publicity, time of day to accommodate work schedule, location)
10. Are there struggles you encounter in your daily life regarding your CKD that you wish you knew more about? (prompt: maybe you wish you knew how to control fluids better or what exercises to do)

11. In your opinion, are there any factors that stand between you and leading a kidney healthy lifestyle? (prompt: this can be things in your immediate surroundings such as the price of medication, the availability of doctors near you, unavailability of healthy foods)

12. We are working on finding new ways to help patients understand their kidney disease. What kind of topics would you want to learn about? (what foods to eat, medications to take, activities to avoid)

13. What way of learning would help you understand the material better? (prompt: a discussion, listening, talking to others with the disease, a colorful display, hands on activity)

14. What is your ethnicity? (Patient will be told that this is an optional question)

15. What is your age? (Patient will be told that this is an optional question)

16. Do you know your current stage of CKD? (If patient answers “no”, I will then ask for permission to check existing data records for the answer and for consent to use this information in my research)

17. How many times have you seen any healthcare provider related to your kidney disease in the past year? (If patient does not know, I will then ask for permission to check existing data records for the answer and for consent to use this information in my research)

18. Additional comments, concerns
Appendix C: Institutional Review Board Approval Documents

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### Initial Application Form

**Brandeis University**  
Committee for Protection of Human Subjects

Use this form for projects involving data collection or a combination of data collection and existing data analysis.

To save the completed form as a PDF, print the form to "Adobe PDF" from the Print Menu. By simply clicking "Save", the entered data will most likely vanish.

"The Pursuit of Patient Empowerment in the Midst of Chronic Kidney Disease"

**Project Title**

**Principal Investigator**  
Dr. Damon Zinner  
Dept. Heller School  
Phone: 632-711  
E-mail: drzinner@brandeis.edu

**Student Researchers**

Yael Bulin  
Status: Undergraduate  
Phone: 201-506-9498  
E-mail: ybulin@brandeis.edu

---

#### Funding Status

Funding provided by:

800 - or 4-

**Brandeis Award #**

---

#### 1. Study Purpose

- Yes: Class Assignment Only  
- Yes: Thesis/Dissertation Only  
- Yes: Evaluation/Assessment  
- Yes: Presentation  
- No: Publication  
- Other:

#### 2. Study Location

- Yes: This study will be conducted solely at Brandeis University.
- No: This study will be conducted solely by Brandeis University or Olin College.
- Yes: This study involves collaborators from other institutions or organizations.
- No: This study involves a subcontract with an outside institution or vendor.
- Yes: Tentative Smith-Jules will be assisting me in recruiting patients to be interviewed.

#### 3. Collaborations/Outside Researchers

- Yes: This study will be conducted solely by Brandeis University or Olin College.
- No: This study involves collaborators from other institutions or organizations.

#### 4. Existing Data

- Yes: Study involves use of existing data, records, pathological specimens, or diagnostic specimens.
- Yes: Authorization to access the data (if not publicly available) is attached.
- Yes: This study involves the use of Biomedical Information (BHI). If yes, attach BHI Form.

#### 5. Participants to be Recruited

- Yes: Adults (18+)-  
- Yes: Minors (<18)-  
- Yes: Cognitively Impaired  
- Yes: Elderly/Aged  
- Yes: Minorities

#### 6. Number of Participants

140

#### 7. Recruitment Method(s)

Business cards with my contact information

#### 8. Data Recording Method(s)

Handwritten Notes  
Video Recording  
Audio Recording  
Computer  
Photographs  
Other:

---

#### 9. Identifiers to be Collected

- Yes: Name  
- Yes: Date of Birth  
- Yes: Age  
- Yes: Address  
- Yes: Gender  
- Yes: Marital Status  
- Yes: Phone or Fax  
- Yes: Email Address  
- Yes: Name/Type of Employer  
- Yes: Social Security#  
- Yes: Job Title  
- Yes: Income  
- Yes: Medical Record#  
- Yes: Health Plan#  
- Yes: Account#  
- Yes: License/Certificate#  
- Yes: Dates of Service  
- Yes: Vehicle/Serial/Device#  
- Yes: Biometric Identifiers  
- Yes: URL/IP Address  
- Yes: Facial Photographs

#### 10. Collection Tool(s)/Study Instruments

- Yes: Online Survey  
- Yes: Paper Survey  
- Yes: Behavioral Measure(s)

#### 11. Administration Method(s)

- Yes: In person (1-on-1): Online  
- Yes: In person (group): Email  
- Yes: Standard Mail

#### 12. Deception

- Yes: Participants will be involved in deception.

#### 13. Biases

- Yes: This study involves human blood, fluids, tissues, or cell lines:
- Yes: Infectious agents: select agents; or DNA. If yes, IBC Protocol # Approval Date

#### 14. Potential Risk(s)

- Yes: Social  
- Yes: Economic  
- Yes: Psychological/Emotional

#### 15. Compensation

- Yes: Consent will be offered to participants.

#### 16. Informed Consent

- Yes: This protocol will follow standard procedures for obtaining documented informed consent.
- Yes: This protocol seeks an alteration to documented informed consent.
- Yes: This protocol seeks a waiver of informed consent.
- Yes: This protocol involves Parental Consent/Child Assent

---

415 South Street, MS 116 • Bernstein-Marcus, Room 121 • Waltham, MA 02454 • T: 781.736.3133 • F: 781.736.2123 • irb@brandeis.edu
Brandeis University  
Committee for Protection of Human Subjects

Student & Faculty Assurance  
for student-initiated research

Project Title:  
"The Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease"

Principal Investigator: Dr. Daren Dinner  
Dept: Heider School  
Phone: 781-726-711  
E-mail: ddrinner@brandeis.edu

Student Researcher: Yoel Belin  
Status: Undergraduate  
Phone: 201-906-9468  
E-mail: ybelin@brandeis.edu

My signature below indicates I understand my responsibilities as a student researcher as outlined:

- I acknowledge and accept the responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Brandeis University Multiple Project Assurance.
- I will submit a protocol for research involving human subjects to the BCPRS to determine compliance with applicable Federal regulations or provisions of this Assurance.
- I will provide a copy of the BCPRS-approved informed consent document to each subject at the time of consent, unless the BCPRS has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the Office of Research Administration.
- I will request review by the BCPRS for any proposed changes in previously approved human subject research. The proposed changes will not be initiated without BCPRS review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- I will report progress of approved research, as often as and in the manner prescribed by the BCPRS, but not less than once per year.
- I will promptly (within 5 days) report to the BCPRS any injuries or other unanticipated problems involving risks to subjects or others.
- No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credits for, or use data from, patient interventions that constitute the provision of emergency medical care without prior BCPRS approval. A physician may provide emergency medical care to a patient without prior BCPRS review and approval, to the extent permitted by law; however, such activities may not be counted as research nor the data used in support of research.
- I will advise the BCPRS, Office of Research Administration and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, these intimation must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

My signature below indicates I understand and accept my responsibilities as a principal investigator and faculty sponsor for this project as outlined:

- I will ensure that the student researcher is familiar with the ethical practices, regulations, and policies that pertain to human subjects research.
- I will ensure that the student researcher has sufficient training and academic preparation to conduct the research described in the attached protocol.
- I will meet with the student investigator to monitor study progress;
- I will be available to the student researcher to supervise and to address problems, should they arise;
- I will oversee the prompt reporting of any significant or untoward adverse effects within 5 days of occurrence;
- I will arrange for an alternate faculty sponsor to assume these duties if I am unavailable (i.e. vacation, sickness, sabbatical);
- I will monitor the research activity to assure that the protocol approved by BCPRS is followed.

I have reviewed the protocol for the following:

- Research design is sound and appropriate to the discipline.
- Subject selection is equitable and subjects are informed as to how they were selected.
- Recruitment procedures are utilized that help ensure voluntary inclusion
- Informed consent language is appropriate to subjects.
- Confidentiality is protected.
- Potential benefits are described.
- Potential risks (psychological, social, physical, economic, legal) are identified and managed.
- The benefits outweigh the risks.
- Informed consent document is attached (parental permission and assent when applicable).
- Participating agencies/institutions’ letters of approval are attached.

Student: [Signature]  
Date: 9/8/13

PI: [Signature]  
Date: 8/8/13

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Bellin, Y.  
Zinner, D. 

2. The protocol

a. **Title of the Study:** "The Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease"

b. **Purpose of the Study** - Patients with Chronic Kidney Disease (CKD) who are knowledgeable about their condition are better able to manage their medications, diet, and exercise, delaying the progression of their disease towards End Stage Renal Disease (ESRD) and the need for dialysis. Focusing on the educational efforts of the existing, but nascent, Montefiore Hospital's Kidney Care Program, the goal of this study is to explore CKD education—what it is, what it entails, and how it's effective in making changes in people's lives. In this study, we build on previous research and current efforts at Montefiore by exploring these questions in the context of minority populations who may face literacy, social, and financial barriers that impede proper education, effective disease management skills and results in a dying population with significant government spending. An expected benefit of doing this study is attaining an understanding of how to amend CKD education to best improve the health of this vulnerable patient population.

c. **Sponsor of the Study & COI** - N/A — no sponsor; senior thesis research extending HSSP internship work. This research is conducted with the assistance of personnel at the Montefiore Care Management Organization (CMO) as described below. Montefiore considers this research project quality improvement/patient satisfaction, and does not require IRB approval on their end.

d. **Principal Investigator's professional qualifications** - Darren Zinner, Ph.D. - Dr. Zinner is a Scientist and Senior Lecturer at the Heller School for Social Policy and Management, as well as the Associate Chair the Health: Science, Society, and Policy (HSSP) program. He has managed numerous health policy research projects involving surveys, datasets, and qualitative interviews. Prior to coming to Brandeis, he managed several research projects at the Harvard/Massachusetts General Hospital Institute for Health Policy, where he studied the implications of academic-industry relationships on the productivity and innovativeness of life scientists.

e. **Student Researcher's qualifications** - Yael Bellin is a senior HSSP major. Over her tenure at Brandeis, Ms. Bellin has completed a number of courses relevant to her proposed research project. These courses include, *Pathogens and Human Diseases; Health, Community and Society; Dilemmas: Long Term Care and American Healthcare: Law and Policy.* In the summers of 2012 and 2013, Ms. Bellin completed 2 internships for Montefiore Hospital Care Management Organization. The first internship focused on the study and implementation of collaborative care models for Accountable Care Organizations, while the second was associated with Montefiore’s Chronic Kidney Disease Care Program. She has completed CITI training and Montefiore’s prescribed HIPAA training. Holding certification as an Emergency Medical Technician since September 2009, Ms. Bellin has also served as a volunteer EMT in her hometown of Teaneck, NJ, as well as on the Brandeis campus since May 2011.

f. **Other Research Personnel** - Terrian Smith-Jules, nurse practitioner and care manager for Montefiore’s Kidney care program will be assisting me in recruiting patients. She will be distributing a handout describing the study, as well as business cards containing my contact
information to participants in the Montefiore’s Kidney Care Program during their scheduled check up.

g. Results of previous related research- CKD is notoriously costly as it is associated with many co-morbidities and costly treatments. One study from 2010 revealed that the per person annual Medicare expenses that are attributed to CKD were $1700, $3500, $12700 for CKD stages 2, 3, and 4, respectively (Honeycutt, Segal et al). Extensive literature suggests that patients with Chronic Kidney Disease (CKD) who are knowledgeable about their condition and able to self manage, can delay the progression of their disease towards End Stage Renal Disease (ESRD) and the need for dialysis (Devins, Mendelssohn, et al) (Wu, Wang, et al).

h. Subject characteristics & inclusion/exclusion criteria- Participants of my research are those with chronic kidney disease, enrolled in Montefiore Hospital’s Kidney Care Program. The Kidney Care Program focuses on unstable CKD patients affiliated with Montefiore Care Management Organization (CMO), assigning a nurse-educator to educate patients and coordinate and streamline their care. As a part of the program, these patients are required to attend an educational workshop. Thus, they are a good sample to study that will be able to explain what chronic kidney disease education is, how it is or is not effective and how it can be improved upon.

i. Justification for use of special/vulnerable subject populations- N/A

j. Recruitment procedures- There are currently 140 patients in the Montefiore CKD care management program. Terrian Smith-Jules, the Nurse Practitioner/Care Manager in charge of the Kidney Care Program, will give her patients my business card (with my name, phone number, and email address) and a description of the study during their appointments with her, and would encourage them to voluntarily call me. I will leave a voice message on my cell-phone with clear instructions to any patient that tries to call, yet is unable to reach me. For patients that do reach me, I will offer further information to them and answer any questions that they might have. If I am available at that time I will conduct the interview at then, otherwise we will schedule the interview for a later date.

k. Study Design- Patients will be recruited (as described in section j) to volunteer for qualitative 15-30 minute interview via telephone. The discussion will be guided by questions in the attached interview guide, although conversation may skip questions or follow tangents as the discussion flows. Categorical responses will analyzed and open-ended responses be transcribed and coded for themes.

l. Procedures to be performed- In addition to a thorough prior literature search, this study will interview patients from the Montefiore Kidney Care program. These patients should have all received some form of patient education regarding their CKD and will be able to explain what they’ve learned, how their lives have been improved and share interesting perspectives. Importantly, these patients can help identify holes in the current program that can help bolster current patient education efforts. These patient interviews will take place telephonically and behind closed doors to provide utmost privacy to the patient on the line. Patient’s responses to these interviews will be kept in an encrypted excel document.
Bellin, Y.
Zinner, D.

m. Anticipated risks and benefits to subjects- Patients participating in this study will face minimal risks in the area of psychological distress. It sometimes may be difficult and stressful for patients to talk about the hardships they encounter, both medical and social, in their daily lives. Some patients may benefit from being able to express themselves and their needs in a very safe setting. The hope is that the responses of the participants will help shape future programming and improve patient education in the future to further empower and improve the health of this population.

n. Provisions for managing risk-In managing the minimal psychological risk, we will instruct the participants in the study description and at the beginning of the interview that at any point they can choose to not answer any given question or can end the interview altogether, if they feel that it is too emotionally trying. All patient-identifiable responses will be kept in a password protected computer and will not be shared outside the research team. No patients will be identified by name in presentations or reports. Quotes will be identified by a randomly assigned number for each research subject. As an example, Subject 31 stated, "X,Y,Z".

o. Cost and Compensation to subjects- We do not foresee any costs associated or risks to the patients.

p. Plans for obtaining and documenting informed consent- Because data collected in this research will come from telephone interviews, we are seeking a waiver of formal informed consent. Participants will be given a description of the study (see attachment) before the interview is scheduled. This description will give the contact information of the primary student-researcher, as well as the principle investigator and Brandeis IRB if they have further questions. We assume implied consent if patients voluntarily contact the research team and agree to the interview.

We would like to request a waiver of standard documented informed consent procedures as our patient interviews will be conducted telephonically. We understand that we are still required to obtain the patient’s active, verbal consent at the onset of each interview.

q. Plans for data storage-We have created a Microsoft Excel spreadsheet with fields to put the patients randomly assigned identification number, date of interview and responses to the interview questions. This document, along with the others will be kept together in one file on the student-researcher’s computer and will be promptly deleted after the completion of the project, approximately May 2014. All information will be stored in a password-protected computer.

r. Bibliography/citations-


Study Sponsor: Brandeis University

Study Description: I am helping a student, Yael Bellin, recruit patients for a study on Chronic Kidney Disease (CKD). The purpose of this study is to better understand how to improve patient education with regards to CKD. Specifically, we wish to know what types of information can help patients better understand and manage their condition. We would also like to know what kind of factors in patients’ immediate surroundings can impact managing CKD.

You are not required to participate in this study. If you do choose to participate, you will be interviewed over the phone. All answers will not be connected with your name or any identifiable information. You may refuse to answer any question or end the interview at any point.

Key findings will be shared with Montefiore to improve the CKD program.

We hope that the findings of this study will help shape future programming to further empower and maintain the health of the CKD population, both for you and for future patients.

Please call or email Ms. Yael Bellin at 201-906-9498 or ybellin@brandeis.edu to schedule an interview or request further information. Alternatively, you may contact the Principle Investigator, Dr. Darren Zinner, at 781-736-3971 or dzinner@brandeis.edu. If you have questions about your rights as a research subject, you may contact the Brandeis University IRB at irb@brandeis.edu or 781-736-8133.

We look forward to hearing from you.
Yael Bellin

CKD patient interview guide:

1. Before the doctor told you that you had kidney disease, did you know anything about kidney disease? (Prompt: maybe someone in your family had it, you read about it in the paper, heard about it on TV...)

2. Describe your first meeting with your doctor when you were told that you have CKD. What kind of information were you given? (Prompt: what foods to avoid, medications to take or avoid, important lifestyle changes to make...)

3. Where are you getting all of your information for your CKD from?

4. Considering all types of knowledge you have obtained (from your own sources, your doctor, the workshop) how would you rate your overall knowledge of CKD? (Prompt: completely clueless, somewhat knowledgeable, knowledgeable, expert)

5. What would help you feel more empowered about managing your CKD?

6. On a scale of 1-5, 5 being the most satisfied, 1 being the least satisfied, how satisfied were you with the kind of information given to you by your doctor?

7. Outside of your doctor's office, where do you get your information on kidney disease? (Prompt: the internet, the library, talking to a friend or family member...)

8. Have you ever been to Terrisa's CKD workshop?
   If yes to #8...
   a. How many times have you attended?
   b. What are some good things about the workshop? (Prompt: consider time of day, location, class size)
   c. In your opinion, what might make the workshop better?
   d. What do you think of the topic that is covered?
   e. What do you think of the kind of presentation? (Prompt: do you like the powerpoint presentation? Discussions? A leader?)
   f. Is the information clear?
   g. Do you find that you learn new things about your health and your kidney disease?
   h. After the workshop do you feel you know how to manage your kidney disease better?
   i. What kind of changes have you made in your daily life after you attended this class and have they improved your health? (Specifically: food, medications)
   j. On a scale of 1-5, 5 being the most satisfied, and 1 being the least satisfied, how would you rate your overall experience at this class?

9. If no to #8...
   a. Is there a specific reason why you did not attend? (Prompt: not a good time, didn't seem helpful or interesting, didn't know about it, heard negative reviews, felt like there's nothing left to learn)
   b. What else might help you attend? (Better publicity, time of day to accommodate work schedule, location)

10. Are there struggles you encounter in your daily life regarding your CKD that you wish you knew more about? (Prompt: maybe you wish you knew how to control fluids better or what exercises to do)
11. In your opinion, are there any factors that stand between you and leading a kidney healthy lifestyle? (prompt: this can be things in your immediate surroundings such as the price of medication, the availability of doctors near you, unavailability of healthy foods)

12. We are working on finding new ways to help patients understand their kidney disease. What kind of topics would you want to learn about? (what foods to eat, medications to take, activities to avoid)

13. What way of learning would help you understand the material better? (prompt: a discussion, listening, talking to others with the disease, a colorful display, hands on activity)

14. What is your ethnic background? (Patient will be told that this is an optional question)

15. What is your age? (Patient will be told that this is an optional question)

16. Do you know your current stage of CKD? (If patient answers "no", I will then ask for permission to check existing data records for the answer and for consent to use this information in my research)

17. How many times have you seen any healthcare provider related to your kidney disease in the past year? (If patient does not know, I will then ask for permission to check existing data records for the answer and for consent to use this information in my research)
08/05/2013

To Whom It May Concern,

My name is Terrisa Smith-Jules. I am the Nurse Practitioner and Care Manager in charge of Montefiore's Kidney Care Program. This past summer, I supervised Yael Bellin and it has been brought to my attention that she will be incorporating part of her summer assignments into her senior research thesis. Yael plans on interviewing participants of our program to assess the quality of our educational workshop component. She plans to assess what the patients' previous understanding of kidney disease was, how our workshops have improved their education, how it can be improved upon and what impact it has made on their lives. We viewed this project as a quality assurance measure, collecting patient's opinions, and thus, did not deem it necessary for her to obtain approval from Montefiore hospital's Institutional Review Board.

My role in this project is assisting Yael in recruiting subjects. Before Yael returned to Brandeis, she gave me business cards containing her full name, title, phone number and university email address. At the end of my weekly check-ups with my patients, I intend to give each patient one of these cards and encourage them to contact Yael and set up a time for an interview. I have seen the interview questions and guidelines and deem them appropriate and relevant to her research topic. Yael plans to be in touch with me over the coming months to let me know how many patients have contacted her and since I see many of these patients on a regular basis, I can continue to encourage them to connect to her. If we find that very few are actually following through, I have assured Yael that over her winter vacation she can come to my check-ups, meet the patients in person and ask if they would like to participate in her study.

I attest that I fully understand her research project and all it entails on her end as well as my own. I look forward to hearing the results of these interviews as it will allow us to refine our program to better improve the health and quality of life of this very sick and vulnerable population.

Thank You,

Terrisa Smith-Jules, N.P.

[Signature]
Brandeis University
Committee for Protection of Human Subjects

Individual Investigator Agreement

This form is to be completed by the Principal Investigator and signed by the unaffiliated individual investigator. Submit this form along with an Initial Application or Modification Request to the IRB Office for review and execution by the Signatory Official.

Individual Investigator
Terena Smith-Jules

Title
FNP-BC

Institution (if applicable)
Monsore-CMO

Address
200 Corporate Blvd South
City
Yonkers
State
NY
Zip
10701
Phone
914-377-4407

Email
tsmith@monsore.org

Date of Human Subjects Research Training
Nov 1, 2013

Verification Attached
Yes ○ No

Institution Providing IRB Review
Brandeis University

IRB Registration #
FWA #

Expiration

This agreement is limited to the following specific protocol
IRB Protocol # HPE6
Principal Investigator
Dorotea Ziomek

Funding Source

Award #

Title
The pursuit of patient education and empowerment in our multispecialty CHC

1. The above-named individual investigator has reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see section 2.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section 2.1. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

2. The investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

4. The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this agreement. The Investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

7. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

8. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or rational procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

12. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

13. The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Individual Investigator

Signatory Official

Date
10/28/2013

Date

Paul O'Keefe
Assistant Provost for Research Administration

415 South Street, MS 116 • Bernstein-Marcus, Room 121 • Waltham, MA 02454 • T: 781 736 8133 • F: 781 736 2123 • irb@brandeis.edu
IRB Protocol #14016 Zinner (Bellin) - Approval

Mon, Nov 11, 2013 at 3:15 PM

To: Darren Zinner <dzinner@brandeis.edu>, ybellin@brandeis.edu

Monday, November 11, 2013

To: Darren Zinner, Heller
Student Researcher: Yael Bellin

From: Morgen Sarpehkar, IRB Administrator


The Brandeis Committee for Protection of Human Subjects, operating under Federalwide Assurance #FWA00004408, has approved the above-referenced human subjects protocol by expedited review in accordance with 45 CFR §46.110 under category [7].

This approval is valid for one year: November 11, 2013 - November 10, 2014.

If your research, including data analysis, will continue beyond the approval period, you must submit a Continuation Form in time to receive a new approval date before the previous one expires. You must submit this form at least 30 days in advance of your approval expiration.

If you wish to request modifications to your approved protocol, please submit a Modification Request to the Committee for review.

Upon completion of your work, you must submit the Final Report and Termination Form to the IRB office in a timely fashion.

Forms and procedures for Continuing Review Requests, Terminations, and Modification Requests are available at http://www.brandeis.edu/osp/hsintro.html.

Please contact IRB Administration at irb@brandeis.edu or 781 736 8133 should you have any questions or require official notification to an outside agency.
Allyson Walsh  
Senior Compliance Administrator  
Brandeis University  
Office of Research Administration  
Bernstein-Marcus, Room 121, MS 116  
781-736-2114
Notification of Exempt Determination

Date: March 17, 2014

Principal Investigator
Urvashi Patel

Study Title: The Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease

IRB #: 2014-3087

Type of Submission: Submission Response for Initial Review Submission form

Reference #: 002041

Determination Date: 03/17/2014

Exempt Category
Exempt 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

HIPAA Determination
The alteration of HIPAA authorization for oral consent was approved.

Re-review by the IRB will be required if any substantive change is made in the protocol during the course of the study, to determine whether or not the study still qualifies as Exempt Research.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Reviewed Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.
Appendix D: Timeline

December 2012: Initial meeting with Professor Zinner to discuss a potential thesis topic

Spring Semester 2013- Semester abroad in Sydney, Australia

May 2013-August 2013- Internship at Montefiore CMO. Thesis idea pitched to senior staff and permission for the study to take place in their institution was granted. When asked, senior staff explicitly stated that this study is actually a Quality Improvement (QI) initiative rather than a research study and thus, Institutional Review Board approval would not be required from Montefiore Medical Center

September 2013: Check in meeting with Professor Zinner, A plan of action established for the year and an application to the Brandeis IRB was submitted

November 2013: The Brandeis IRB approved the study. Plans for Data collection at Montefiore was set to take place during winter break. In the interim, background sections were written

December 2013-January 2014: CMO staff informed student researcher that they had changed their minds and regardless of the QI nature of the project, IRB approval would be required. Due to the fact that the Brandeis IRB had already approved the study, it would be an “expedited” review and turn around time was projected to be relatively quick

February-March 2014: Waiting on Montefiore IRB approval, finalizing background chapters in the interim

March 2014: Montefiore IRB approved the study. Data collection commenced immediately.

April 2014: Submission of the “Pursuit of Patient Education and Empowerment in the Midst of Chronic Kidney Disease”