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Anemia Management for Patients Receiving Peritoneal Dialysis

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ANEMIA MANAGEMENT FOR PATIENTS RECEIVING PERITONEAL DIALYSIS

by

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Abstract

The purpose of this quality improvement project was to develop an anemia management evidence-based intervention for patients receiving peritoneal dialysis (PD) and to educate staff on implementation of the anemia management protocol in a PD clinic in a southwestern county in Texas. Anemia is a common complication of chronic kidney disease (CKD) resulting from the inability of the kidneys to produce erythropoietin needed for red blood cell production. Erythropoiesis-stimulating agents such as Aranesp or Epogen may be administered to dialysis patients to stimulate erythropoiesis in the presence of kidney disease. Iron storage and iron availability remains imperative in effectively stimulating erythropoiesis for anemia management in the dialysis patient (Kliger et al, 2013). Anemia is one of the most common complications of CKD; over 48 million Americans have CKD attributing to millions with anemia of CKD origin (Centers for Disease Control and Prevention, 2017). A 6-month retrospective and current chart review of CKD patients' undergoing PD was carried out at a PD clinic. An educational toolkit consisting of a pretest, anemia management protocol, and a post-test was developed and administered to staff. A patient educational toolkit consisting of instructional handout and a video was developed and administered to patients. Results indicated an improvement in staff knowledge about anemia management and an increase in patient hemoglobin and iron levels. This implementation was imperative to improving healthcare goals comparable with the Kidney Disease: Improving Global Outcomes (KDIGO) practice guidelines.

Keywords: anemia, peritoneal dialysis, protocols, evidence-based guidelines

Anemia Management for Patients Receiving Peritoneal Dialysis

The kidneys are the major organ for erythropoietin production and are needed to stimulate the bone marrow to produce red blood cells. Erythropoietin is a glycoprotein produced by the kidney which stimulates red blood cell production (National Kidney Foundation [NKF], 2017). When the kidneys start to fail, a condition called CKD may ensue.

Chronic kidney disease is a "condition in which the kidneys are damaged or cannot filter blood as well as healthy kidneys" (Center for Disease Control [CDC], 2017, p. 1) and affects approximately 30 million people or 15% of the general population living in the United States (CDC, 2017). Chronic kidney disease is exhibited by progressive irreversible nephron loss that is clinically manifested when 75% of nephron function is lost and decreases the organ's ability to excrete wastes products, which, if left untreated leads to a high level of toxins in the blood over time (National Kidney Foundation [NKF], 2017).

Chronic kidney disease can be classified into five stages based on the degree of kidney malfunction (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDKD], 2016). The stages of CKD are classified by an estimated glomerular filtration rate (GFR) which is the function of the kidneys based on age, sex, and body size (NKF, 2017).There are 5 stages of CKD: Stage 1 with a GFR of >90ml/min; stage 2 with a GFR of 60-89ml/min; stage 3 with a GFR of 30-59ml/min; stage 4 with a GFR of 15-29ml/min; and the most serious stage, stage 5, also known as end stage renal disease (ESRD) with a GFR < 15ml/min (NIDDKD, 2016).

According to the Centers for Disease Control and Prevention (CDC, 2017), diabetes and high blood pressure remain the leading cause of CKD and the primary cause of ESRD respectively. It further states that a total of 1 in 3 adults with diabetes and 1 in 5 adults with hypertension have CKD (CDC, 2017). Left untreated, CKD is progressive and may be fatal.

African Americans, Hispanics, Pacific Islanders, American Indians, and seniors are at increased risk for CKD (NKF, 2017). It is more common in women than in men. Additionally, approximately 48% of persons with "severely reduced kidney function" (CDC, 2017, p. 1) but not receiving dialysis do not know that they have the disease.

Persons with stage 5 CKD or ESRD require some form of dialysis (hemodialysis [HD] or PD) to manage this chronic disease process, or a kidney transplant for a curative treatment (American Kidney Fund, 2018). Peritoneal dialysis is done in cycles inside the abdominal cavity where dialysis solution is exchanged through filtration and the waste is removed from the peritoneal cavity (NKF, 2017). This modality is often done in the patient's home by the patient. Hemodialysis, on the other hand, is often done at a center where blood is removed from the body using an artificial kidney machine, the blood is cleaned by the artificial kidney and returned through connection tubes to the patient (NKF, 2017). It can also be performed in the patient's home. The decision to utilize hemodialysis as opposed to PD is based on several dynamics and is not unique to one factor.

One of the potential complications of CKD is anemia. Anemia is defined as reduced red blood cell concentration indicated by a low hemoglobin (Hgb) level and is generally diagnosed when the serum Hgb level falls below 12g/dL in women and less than 13g/dL in men (Amgen, 2016; Stauffer & Fan, 2014). Anemia is known to increase mortality, decrease physical functioning, and affect quality of life (Archer, Steinvoort, & Oderda, 2013). According to Stauffer and Fan (2014), in CKD, anemia may be associated with cognitive impairment, sleep disturbances, cardiovascular comorbidities, higher mortality, and CKD progression. Anemia related to CKD can be treated with iron and/or an erythropoietin stimulating agent (ESA) therapy to stimulate erythropoiesis (production of red blood cells) and improve Hgb and hematocrit

levels. Trials that examined the efficacy of ESA use in anemia indicated that two drugs, Epogen and Aranesp, are both effective erythropoietin analogs available to treat anemia in CKD and may prevent the need for blood transfusions (Archer et al., 2013). Aranesp has a longer half-life than Epogen and, therefore it is administered on a weekly basis compared to Epogen which is administered three times per week (McCausland et al., 2017).

The 2012 KDIGO guideline also recommends the use of serum ferritin and transferrin saturation (TSAT) markers to define and evaluate iron stores and iron availability in treating anemia (Kliger et al., 2013; Macdougall, 2017). In addition to an ESA agent, the use of iron therapy such as Venofer is imperative for anemia management to maintain Hgb and should be commenced when TSAT is ≤ 30% and ferritin ≤ 500ng/ml (Kliger et al., 2013; Macdougall, 2017). Intravenous (IV) iron therapy is favorable to achieve and maintain acceptable ferritin and TSAT levels through erythropoiesis response, and this was supported by several studies in both hemodialysis and PD patients (Macdougall, 2017). The guidelines did not specify the type of IV iron to be used however, the cost is a variable in choosing an IV iron (Kliger et al., 2013). In addition to the cost, Venofer is also a component of the Center for Medicare and Medicaid Services (CMS) bundle in this PD clinic.

Clinical Significance

Anemia remains a clinically significant problem among patients receiving HD and PD and is known to impact the mortality and morbidity of CKD patients due to cardiac complications such as left ventricular hypertrophy and cardiovascular disease (Hörl, 2013). Anemia is estimated to affect 22% of patients with CKD stage 3 and 52% of patients with CKD stage 4 and increases the risk of mortality if it progresses to ESRD or stage 5 (McCausland et al., 2017). Anemia related to CKD is caused by the kidney's inability to produce adequate

erythropoietin, which can lead to low hemoglobin levels and possibly result in cardiovascular complications and an increased mortality rate. In dialysis patients, anemia is identified through frequent phlebotomy from laboratory studies including a complete blood count (CBC) and iron studies to include TSAT and ferritin (Rajaram, Himanshu & Pankaj, 2015).

Anemia in CKD impairs a patient's quality of life by exacerbating anemic symptoms such as fatigue, low energy, weakness and shortness of breath (Hörl, 2013). In addition, anemia exacerbates left ventricular hypertrophy and congestive heart failure related to hypoxemia and heart strain, which is common in the dialysis patient (Hörl, 2013). Dialysis patients diagnosed with anemia may need ESA therapy, iron therapy, or a blood transfusion(s) to correct the anemia (Charlesworth, Richardson & Battistella, 2014). Persons who receive HD or PD must be admitted to the hospital to receive a blood transfusion, which is in accordance with CMS regulations (CMS, 2017). The clinic that provides the dialysis services may sustain a financial loss when a patient is hospitalized for a blood transfusion because the clinic cannot bill for the patient's dialysis treatment while the patient is hospitalized. Patients are known to incur the burden of hospitalization for a condition that could be managed on an outpatient basis with appropriate ESA and/or iron treatment instead of blood transfusion(s).

Furthermore, CMS has implemented quality assessment and performance improvement measures (QAPI) to track and analyze patient outcomes continuously to achieve desired outcomes related to anemia. One of the quality indicators that CMS tracks is Hgb level; CMS stipulates that it should be maintained above 10g/dL every month in the dialysis patient. This tracking requires that dialysis centers report hemoglobin levels for every dialysis patient on a monthly basis (CMS, 2017). Successful management of anemia through the implementation of an outpatient anemia protocol based on clinical practice guidelines for ESA and/or iron therapy

significantly improves patient outcomes and can improve quality of life and adherence to dialysis treatment (CMS, 2017; National Kidney Foundation, 2017).

Problem

Anemia is a condition experienced by many patients with CKD who are receiving PD and is brought on by a reduction in the number of red blood cells. It is a contributing factor for structural heart damage and may lead to mortality in the advanced stages of CKD (Correa-Gaviria & McCausland, 2017). In a study of 71,717 Medicare patients with CKD and anemia, there were strong indications that patients with Hgb less than 10g/dL were at higher risk of hospitalization compared to those with a hemoglobin of 11g/dL or 12g/dL (Hörl, 2013). In another study, CKD patients with a decrease in mean Hgb had increased mortality and cardiac complications along with symptoms of fatigue, low energy, weakness and shortness of breath (Hörl, 2013). Treatment of anemia with the prerequisite amount of iron and/or the use of an erythropoietin agent may subsequently improve these symptoms, could negate the need for a blood transfusion(s) which requires hospitalization, and may enhance patient quality of life by improving anemia (Correa-Gaviria & McCausland, 2017).

When comparing costs of iron therapy and ESA therapy, it is noted that iron therapy costs Medicare $255 million while ESA therapy costs $1.8 billion in the ESRD population (Kliger et al., 2013). The cost of anemia management is important because CMS, the major payer for CKD services, has changed the payment of dialysis procedures to include a bundled payment for ESAs and iron. This has significantly affected how anemia is effectively managed in the dialysis patient because one bundled payment is expected to cover all aspects of patient care by the clinic (Kliger et al., 2013).

The specific problem that affects this PD clinic is that up to 48% of the patient population was not meeting the KDIGO guidelines for anemia management on a monthly basis. This information was obtained in a previous needs assessment done by the DNP student in the clinic. Furthermore, this is a new clinic without an anemia management policy or protocol to guide staff on how to improve and maintain patient's Hgb levels.

Review of the Literature

PICOT Question

The PICOT question that guided this inquiry is as follows: In peritoneal dialysis patients (P) how does an anemia management protocol in the dialysis clinic (I) compared to not having an anemia management protocol (C) improve staff ability to manage anemia outcomes?

The search strategy included searching the CINAHL database, accessed through the UIW library. Google scholar was also used to access publications dated January 2013 to April 2018. Key terms and phrases used were anemia in CKD, management of anemia, CKD, PD, anemia goal, goal of Hgb level, patient teaching and effective patient teaching methods. The results yielded multiple publications which were narrowed down and selected based on relevance and evidence-based.

In the CKD patient who is receiving dialysis treatment, the target Hgb is 10-11g/dL. The pathogenesis of anemia in CKD is associated with decrease erythropoietin (EPO) production by the kidneys, iron deficiency, inflammation, and EPO resistance (McCausland et al., 2017). Anemia in CKD worsens and further reduces kidney function if left untreated (McCausland et al., 2017). Additionally, it can contribute to left ventricular dysfunction, increase morbidity, and cause low energy, breathlessness, dizziness, angina, poor appetite, and exercise intolerance (Hahn, Cody, & Hodson, 2014). ESAs and IV iron are the primary treatment for anemia in CKD

to improve anemic symptoms and increase Hgb (Hung, Lin & Tarng, 2013). Common comorbidities of CKD are weak bones, poor nutrition, nerve damage, heart and blood vessel diseases, as well as anemia (NKF, 2017).

Kidney Disease: Improving Global Outcomes (KDIGO) is a global non-profit foundation that aims to improve patient care and outcomes internationally through coordination, collaboration, and initiatives to create and implement practice guidelines for the kidney disease patient. In 2012, the KDIGO clinical practice guidelines for anemia provided guidance on management and treatment for all CKD patients at risk for developing anemia. The guidelines stated that ESA is safe and effective treatment for erythropoietin-deficient anemia and should be administered with a baseline Hgb of less than 10g/dL so that Hgb can be increased and maintained at 11g/dL but not above 11.5g/dL. This guideline is in support of the Normal Hematocrit Study which indicated that dialysis patients with target Hgb of 11-13g/dL had worse outcomes when compared to those with a Hgb of 9-11g/dL (Kliger et al., 2013). Specifically, those with a Hgb of 11-13g/dL experienced increase cardiovascular disease and increase risk of stroke.

ESA therapy is significant in reducing the need for blood transfusion related hospitalizations and reduces erythropoietin-deficient related anemia symptoms (Kliger et al., 2013). ESA therapy eventually decreases the cost and burden associated with blood transfusions and hospitalizations. ESA therapy improves patient quality of life and increases patient safety by improving symptoms (Kliger et al., 2013). Archer et al. (2013) also recommends ESA use in the treatment of erythropoietin-deficient anemia for dialysis patients experiencing CKD and advocates using agents such as Epogen/Erythropoietin (EPO) and Aranesp with an acceptable risk-benefit. Aranesp, which is administered subcutaneously or intravenously, is the more

favorable therapy of the two ESAs used to treat anemia related to chronic kidney disease in PD and HD patients. Aranesp has a 3-fold longer half-life when administered compared to EPO; as a result, it is given weekly while EPO must be administered three times per week (Archer et al., 2013). Additionally, patients can be instructed to self-administer Aranesp, or caregivers can be taught the administration process, thus reducing the need for a clinic visit.

Besides low red blood cell production, CKD dialysis patients may exhibit anemia caused by low iron levels. Iron agents can be used alone or in combination with an ESA to maintain anemia at a desirable level. Iron agents must be used to treat patients when transferrin saturation (TSAT) is ≤ 30% and ferritin level is ≤ 500ng/ml. A TSAT and ferritin level must be obtained when a Hgb level is required to determine if management with an ESA and/or an iron agent is indicated (Kliger et al., 2013).

In a multicenter, open-label study of 101 patients with CKD who were HD dependent, 77 patients received Venofer treatment and 24 patients were followed in the control group (American Regent, 2015). The results indicated that patients in the Venofer treated group showed a greater increase in Hgb and hematocrit than the patients in the control group. The ferritin and TSAT levels also increased in the Venofer group when compared to the control group (American Regent, 2015).

In another study conducted by American Regent (2015), a randomized, open-label multicenter trial compared PD patients receiving EPO and IV iron to those receiving EPO alone. The patients who received Venofer and EPO (59.1%) had an increase in Hgb of ≥ 1 g/dL during the study compared to the patients who received EPO only (33.3%) (American Regent, 2015). Due to the overwhelming literature supporting the use of an ESA and/or an iron agent, it is

imperative to develop and implement measures supportive of the findings to improve anemia among CKD patients in the clinical setting (Macdougall, 2017).

Anemia management protocols (AMPs) should guide ESA and iron dosing for effective management of patients with CKD (Kliger et al., 2013). In four clinical trials conducted by major drug companies, Hgb was maintained using dosing algorithms and a dosing protocol (Charlesworth et al., 2014). The dosing algorithms were designed to achieve and maintain Hgb levels at the desired target. The protocol specified dose adjustments were designed to follow the dosage administration and were successful in maintaining Hgb in the target range of 10-12g/dL (CMS, 2017). A retrospective observational study in 174 patients conducted over 6 months implemented an Aranesp dosing anemia protocol. The results indicated that the use of an anemia management protocol resulted in decreased prescribing of Aranesp and iron while increasing patients target Hgb range to an acceptable level of 10-12g/dL (Charlesworth et al., 2014).

In another study by Pirkle, Paoli, Russell, Petersen and Burkart (2014), 139 PD patients received Aranesp and IV iron for anemia management protocol. The study found that patients on the anemia management protocol maintained stable Hgb levels between 10-12g/dL using Aranesp and IV iron. This treatment intervention is inconsistent with the current KDIGO anemia management guidelines of maintaining Hgb at 10-11.5g/dL. In addition, the anemia protocol might improve Hgb outcomes including identification and treatment of CKD patients with anemia and increase patient responsibility in administering an injectable medication at home (Pirkle et al., 2014).

Patient teaching remains imperative to patient care and is a significant aspect of the home dialysis patient (Schaepe & Bergjan, 2015). Among the patient teaching strategies, patient-centered videos have proven to foster better memory and are more practical for patient learning.

Friedman, Cosby, Boyko, Hatton-Bauer, and Turnbull (2011) examined systematic reviews of the effectiveness of videos on patient education outcomes and 13 of 22 studies indicated increased patient knowledge and greater satisfaction for the patient intervention. In addition, written materials created at a reading level for the general population combined with verbal health information significantly improved knowledge (Friedman et al., 2011). As a result of these findings, the patient education aspect of this quality improvement project will be developed on the foundation of these teaching strategies.

In another study, Marcus (2014) examined verbal education in a 150-bed community hospital. It was concluded that though one on one patient teaching is effective it needs to be individualized taking into consideration, patient culture, literacy level, and effective communication. It also concluded that verbal education should not be the only method of patient teaching. Furthermore, effective patient education practices must be learned and reinforced by staff educators, and an assessment is recommended using a teach-back tool (Marcus, 2014).

Finally, Smith and Zsorhar (2013) suggested other effective patient teaching methods including computer-aid teaching, video education, demonstration, return demonstration, teach back or tell back, and written materials with pictures. These methods have proven to improve patient learning; however, individualization of patient teaching is of utmost importance (Smith & Zsorhar, 2013).

Methodology

The needs assessment conducted by the DNP student indicated that the clinical practice guideline to maintain Hgb at an acceptable goal was nonexistent in this clinic. There was no established anemia protocol and the clinical management skills and expertise are not unique to policy development. Furthermore, staff and stakeholders including the nurse practitioner and

nephrologist expressed the need to implement a successful anemia management protocol in the clinic and gave approval for this project (Appendix A). In addition, there were 27 established patients in the clinic, and of that number only an estimated 50% had reached the Hgb target of 10g/dL in the past 6 months. There was also a gap in patient education in self-administering Aranesp at home. As a result, there was a need for staff and patient education to increase and maintain Hgb level at the target range. This quality improvement project was appropriate for the organizational plan to maintain a high standard and a routine standard of care in accordance with CMS guidelines. In addition, this project encompassed the DNP essentials in using evidence-based data to develop and implement a quality improvement project aligned with the knowledge and expertise of the DNP graduate (American Association of Colleges of Nursing [AACN], 2006).

Design

This project was a quality improvement project that utilized the KDOQI guidelines to develop an evidence-based anemia management protocol administered by staff to the dialysis patients ages 18 to 75 years cared for at the dialysis clinic and included a patient education program related to anemia management.

Setting

The setting was a standalone PD clinic located in the southwestern United States. The clinic was established in 2016 and received CMS approval, and serves clients from a multicounty rural area. The clinic was made up of 5 exam rooms, a patient waiting area, and a patient education room. Patients were seen at the clinic at least on a monthly basis and visit once weekly for lab draws and any other treatment interventions such as Venofer administration. Patients were also seen by the nurse in their homes to provide teaching on PD administration, assessment

of patient condition, environment and potential or actual complications. The medical assistant saw patients in their homes to replenish supplies and obtained lab draws when indicated. Therefore, the patients home and home environment were considered an extension of the setting.

Risk Analysis

The university IRB approved this project prior to implementation. There were no risks involved in this quality improvement project as an evidence-based guideline was implemented. Furthermore, the majority of the participants have diabetes and were receiving insulin injections with a similar administration technique as that used for Aranesp. All patients' allergy records were reviewed for contraindications of Aranesp or Venofer before any medication administration was initiated.

Sample

This project targeted the staff of the clinic including the two registered nurses and the medical assistant (MA) as well as the 24 clinic patients who were receiving PD as of February 2018 and were not already participating in a research study.

Intervention

This project included an intervention for staff related to the anemia protocol implementation and a patient education intervention as described below.

Staff education interventions. Objective 1: By the end of February 2018, 100% of staff would increase their knowledge in managing anemia using evidence-based anemia protocols for the dialysis patient at the clinic. Implementation plan:

1. A pre-test on anemia management was administered to the registered nurses and MA in February 2018. The pre-test was developed by the DNP student according to definitions and guidelines from the KDIGO guidelines (Appendix B).

2. Following the pre-test staff educational materials and instructions regarding the anemia management protocol were developed and provided to staff via an in-service conducted by the DNP student at the dialysis clinic in February 2018. The protocol and educational materials were also placed in a centralized location at the desk readily available to staff for easy access as well as in the electronic medical record (EMR) under policy and procedure. Details of the protocol included the Aranesp dosing guideline which was developed by the DNP student using the guideline designed by Amgen pharmaceutical for the medication and is comparative to the KDIGO guidelines (see Appendix C). The Venofer dosing protocol (see Appendix D) was also designed by the DNP student using the KDIGO guidelines; the anemia clinical practice guidelines were both based on systematic reviews on managing anemia and are used globally (Kliger et al, 2013). The protocols were approved by the nephrologist and the charge nurse.

Outcome. 100% of staff (registered nurses, MA) should increase their knowledge up to at least 90% related to anemia management as measured by a written pre and post-test designed by the DNP student and administered before the in-service and approximately 2 weeks after the initial in-service (see Appendix B).

Evaluation. The pre-test was administered before the initiation of the educational intervention (Appendix B) and given approximately 2 weeks after the in-service to evaluate the effectiveness of staff educational intervention.

Patient education interventions. Objective 2: By the end of April 2018 all patients will have reviewed the Aranesp administration video and teaching materials.

1.The DNP student instructed the registered nurses and the MA to administer the educational pamphlet and video regarding Aranesp administration via the patient iPad or television that was available in the clinic education room.

2. Each patient was to receive an anemia patient educational pamphlet (see Appendix E) at their weekly appointment, sourced from Amgen pharmaceutical patient education. The pamphlet consisted of basic information about anemia, taking medication for anemia and stepwise instructions on administering Aranesp (see Appendix E). These instructions were created by Amgen for patient educational purposes with no stated reliability and validity (Amgen, 2017). The handouts were available in both English and Spanish.

3. Each patient would be asked to watch the 13-minute video (see Appendix F) via the iPad or television during a regular scheduled clinic appointment.

4. At the end of the video, the patients were to be given the Aranesp medication to self-administer if indicated by Hgb level according to the protocol while the staff member observed the administration.

5.The staff were instructed on utilizing the patient teach-back tool to assess patient competency and mastery of the Aranesp injection procedure (see Appendix G). The purpose of this tool was to document that the patient received the educational intervention and demonstrated self-administration of Aranesp.

Outcome. All patients should view the Aranesp medication video and educational information and demonstrate to staff the injection process.

1. The nursing staff should observe all patients to verify that there was a 100% demonstration of the correct administration technique of Aranesp and to provide feedback on administration technique.

Evaluation. The Teach-Back tool was used by staff to evaluate the stepwise process of the patient self-administering Aranesp correctly (Appendix G). No psychometric properties of reliability and validity were available on this tool; however, it was used by the Agency for Healthcare Research and Quality (AHRQ) to improve patient understanding and adherence of a learning activity (AHRQ, 2015).

Objective 3: By the end of April 2018, patients' Hgb level would be maintained at the acceptable clinical goal of 10-11g/dL, with a TSAT of 30% -50%.

Interventions. Staff would utilize the anemia management protocol consisting of an Aranesp protocol (see Appendix C) and the Venofer protocol (see Appendix D) to manage patient anemia immediately after the in-service was provided in February 2018.

Outcome. By the end of April 80% of patients included in the sample ($N = 24$) should have a Hgb level of 10-11g/dL, with a TSAT of 30% -50%.

Evaluation. The DNP student used the demographic chart review tool (see Appendix H) to obtain and assess patient Hgb and TSAT levels after the staff had begun implementing the protocols. These levels were compared with the pre-intervention levels to determine appropriate use of the protocol and assess patient response to the protocol treatments in the form of laboratory findings.

Data Collection

Chart review: The DNP student reviewed patient records pre and post-intervention from December 2017 to April 2018 by the DNP student. The data retrieved included patient age, sex, ethnicity, marital status, Hgb levels and iron levels (TSAT and ferritin level). Additional characteristics such as language spoken were included. The instrument used to collect this data is located in (see Appendix H). No patient identifying information was extracted.

Data Analysis

Descriptive statistics were calculated for adherence to anemia management protocols. Specifically, percentages were calculated for number of patients grouped by Hgb and iron levels, percent that needed protocols, percent that received protocol implementation, and number of patients whose Hgb or iron levels improved after receiving the protocol treatment(s). Percent of patients who received patient education was calculated as well.

Results and Findings

Regarding objective 1: By the end of February 2018, 100% of staff would increase their knowledge in managing anemia using evidence-based anemia protocols for the dialysis patient at the clinic.

By the end of February 2018, 100% of staff increased their knowledge in managing anemia using evidence-based anemia protocols in the dialysis patient at the dialysis clinic after a DNP led in-service on a new anemia protocol and implementation of the protocol. This finding was assessed via the pre and post-test (Appendix B)

Three staff members, two nurses and a MA completed the intervention. One nurse scored 10/10 on both pre-test and post-test, the other nurse and medical assistant scored 9/10 and 7/10 respectively on the pretest and 10/10 and 9/10 respectively on the post-test indicating an increase in knowledge related to managing anemia.

Regarding objective 2: By the end of April 2018 all patients will have reviewed the Aranesp administration video and teaching materials.

The DNP student verified that staff members were implementing the video and teaching materials via chart reviews and observed at least 1 teaching session performed by each staff member. The 3 staff members performed the teaching session 100% correctly. The two

registered nurses were observed by the student in using the Aranesp protocol to dose Aranesp and observed staff in their observation and feedback given to patients in self-administration of the medication in a stepwise manner as shown in the video. The DNP student observed the two registered nurses in dosing patients' Venofer based on their ferritin and iron levels during the comprehensive clinic visit and this was done accurately. The 24 patients received the educational hand out and watched the Aranesp video. Seventeen patients were required to complete return demonstration of Aranesp administration. Among these 17 patients 53% or 9 of the patients demonstrated the administration steps 100% correctly, and 17.6% or 3 demonstrated the administration steps 80% correctly and 5 or 20.8% were not observed because they did not require Aranesp administration.

Regarding objective 3: By the end of April 2018, patients' Hgb level would be maintained at the acceptable clinical goal of 10-11g/dL, with a TSAT of 30% -50%.

After the protocol implementation, 15 dialysis patients or 62.4% had a Hgb at goal and 20 or 83.3% had a TSAT at goal by the end of April.

The demographic characteristics of the 24 dialysis recipients is shown in Table 1. The patients (N = 24) were 50% males (n = 12) and 50% females (n = 12). Their age ranged from 25 to 75 years with a mean age of 58.7 years. Three patients were between the ages of 25 to 44 years, 12 were between the ages 45 to 64 years and 9 were over the age of 65 years. The ethnicity of the dialysis recipients consisted of 71% Hispanics (n = 17), 25% non-Hispanic Whites (n = 6), and one patient's ethnicity was listed as Non-Hispanic. Eleven of the participants were married, two single, one common law marriage, one separated and 9 patients did not have their marital status documented. Fifty-eight percent (n = 14) of the patients had Medicare insurance, 42% were covered by private insurance (n = 10) and 8% (n = 2) had both Medicare

and private insurance. Sixty-six percent or two-thirds of the patient sample (n = 16) had some form of diabetes and were receiving medication for diabetes management. After diabetes, the second most frequent co-morbid diagnosis was hypertension which was noted in one-third or 8 of the 24 participants.

Table 1

Demographic Data

Sex	Participants	Percentage %
Female	12	50
Male	12	50
Age		
25-44 years	3	12.5
45-64 years	12	50
65 years and older	9	37.5
Ethnicity		
Hispanic	17	71
White	6	25
Non-Hispanic	1	4
Marital Status		
Married	11	45.8
Single	2	8.3
Common Law	1	4.1
Separated	1	4.1
Not Stated	9	37.5

Regarding objective 4: By the end of April 2018, patients' hemoglobin level would be maintained at the acceptable clinical goal of 10-11g/dL, with a TSAT of 30% -50% and ferritin level of 100-500ng/ml.

The 24 patient records were reviewed and information concerning hemoglobin level, TSAT, ferritin level, and whether Aranesp and Venofer protocol were indicated and implemented was extracted to determine adherence to the treatment protocols. The results are displayed in Table 2.

Based on data from table 2, the following findings were noted. In December 2017, nine of the 24 patients or 37.5% had a Hgb level below 10g/dl, 29% (n = 7) had Hgb levels of 10g/dL or greater, and 33.3% or eight patients had no Hgb levels documented. Four patients or 16.6% had a TSAT level above 30% (the targeted range), 50% (n = 12) were below 30%, and 33.3% (n = 8) had no TSAT results documented. A total of 8.3% (n = 2) had ferritin levels below 100ng/ml, 50 % (n = 12) had ferritin levels above 100ng/ml and 41.6% (n = 10) had no results documented due to no lab draw from the patient either due to hospitalization or no show for blood work.

In January 2018, 37.5% (nine patients) had a Hgb level below 10g/dL indicating that they were experiencing anemia, 37.5% (nine) were above 10g/dL (the targeted range), and 25% (six patients) had no results. Five patients or 20.8% had a TSAT of 30% and above, 54.1% (thirteen patients) had a TSAT below 30%, 25% or six dialysis recipients had no results and 25% (six patients) who had TSAT levels below target also had low Hgb levels, during the same period. Reasons that no results were documented may include patient hospitalization or no show for lab draw.

Table 2

Patient's Laboratory Values Before and After Protocol Implementation

Pt	Date	Hgb	TSAT %	Ferritin	Venofer mg	Aranesp mcg	Dosage	Protocol used	Note
1	Dec-17	9.4	73	1566	No	No	NA	No	
	Jan-18	8.4 8.2	104 -----	1540 -------	No	No	NA	No	Pt Refuse
	Feb-18	6.8 7.8	57 -----	1332 -------	No	Yes	100mcg	PI: A	
	Mar-18	8.8 9.0	23 -----	1252 -----	No	Yes	100mcg	PI:A	
	Apr-18	10.5	49	1306	No	No	NA	Yes	
2	Dec-17	11.1	21	356	No	No	NA	No	
	Jan-18	11.3	28	369	No	No	NA	No	
	Feb-18	9.7	21	478	Yes	Yes	40mcg 300mg	PI:A PI:V	
	Mar-18	10.0	------	-------	No	No	NA	Yes	
	Apr-18	11.0	28	621	No	No	NA	Yes	
3	Dec-17	----	-----	----	No	No	NA	No	
	Jan-18	----	----	-----	No	No	NA	No	
	Feb-18	10.3	21	484	Yes	Yes	300mg 40mcg	PI:V PI:A	
	Mar-18	10.2	33	414	No	No	NA	Yes	
	Apr-18	10.5	32	337	No	No	NA	Yes	
4	Dec-17	8.6	11	200	Yes	Yes	100mg 100mcg	No	
	Jan-18	10.3	21	238	No	Yes	40mcg	No	
	Feb-18	11.7	25	332	No	No	NA	PI	
	Mar-18	10.6	24	236	No	No	NA	Yes	
	Apr-18	11.4	22	138	No	No	No	Yes	
5	Dec-17	----	----	-----				NA	
	Jan-18	----	-----	------				NA	

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	Feb-18	10.8	18	664	Yes	No	300mg	PI:V	
	Mar-18	12.4	23	575	No	No	NA	Yes	
	Apr-18	11.9	27	241	No	No	NA	Yes	
6	Dec-17	-----	------	------					
	Jan-18	9.6	8	1151	No	No	NA	No	
	Feb-18	12.3	18	871	No	No	NA	PI	
	Mar-18	11.7	25	718	No	No	NA	Yes	
	Apr-18	13.1	22	615	No	No	NA	Yes	
7	Dec-17	11.4	23	791	No	No	NA	NA	
	Jan-18	11	27	859	No	No	NA	NA	
	Feb-18	10.3	23	783	No	Yes	25mcg	PI:A	
	Mar-18	9.5, 9.3	21, 20	758, 765	Yes	Yes	100mg 60mcg	PI:A PI:V	
	Apr-18	10.0	16	771	Yes	Yes	100mg 60mcg	PI:V PI:A	
8	Dec-17	9.6	35	315	No	No	NA	No	
	Jan-18	8.0	21	402	No	No	25mcg	No	
	Feb-18	7.8	19	229	No	Yes	100mcg	PI:A	
	Mar-18	10	24	174	No	Yes	100mcg	PI:A	
	Apr-18	-----	----	----					Hospitalized
9	Dec-17	-----	-----	------					
	Jan-18	8.5	14	199	No	No	NA		
	Feb-18	8.2	8	340	No	No	NA	PI	
	Mar-18	9	7	895	Yes	No	300mg	PI:V	
	Apr-18	9.6	33	419	Yes	Yes	300mg 60mcg	PI:V PI:A	

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10	Dec-17	----	-----	------				
	Jan-18	----	-----	------				
	Feb-18	10.7	11	191	No	No	NA	PI
	Mar-18	10.7	18	180	Yes	Yes	300mg	PI:V
	Apr-18	11.6	20	287	No	No	25mcg NA	PI:A Yes
11	Dec-17	-----	-----	------				
	Jan-18	-----	-----	------				
	Feb-18	9.4	36	244	No	No		PI
	Mar-18	8.6	15	283	Yes	No	300mg	PI:V
	Apr-18	9.7	33	249	No	No	No	No
12	Dec-17	8.7	35	594	No	No	NA	No
	Jan-18	9.0	23	712	No	No	NA	No
	Feb-18	8.3	16	604	No	No	NA	PI
	Mar-18	8.8	25	645	No	Yes	40mcg	PI:A
	Apr-18	9.4	28	748	No	Yes	40mcg	PI:A
13	Dec-17	11	24	37	No	No	NA	No
	Jan-18	10.7	17	192	No	No	NA	No
	Feb-18	10.4	-	-	Yes	No	300mg	PI:V
	Mar-18	11.5	22	99	No	No	NA	Yes
	Apr-18	10.7	24	159	No	No	NA	Yes
14	Dec-17	-	-	-				
	Jan-18	-	-	-				
	Feb-18	17.2	36	219	No	No	NA	PI
	Mar-18	13.2	47	202	No	No	NA	Yes

(continued)

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	Apr-18	12.8	51	173	No	No	NA	yes	
15	Dec-17	12.3	50	281	No	No	NA		
	Jan-18	12.3	37	343	No	No	NA		
	Feb-18	12.1	51	404	No	No	NA	PI	
	Mar-18	10.1	52	597	No	No	NA	Yes	
	Apr-18	9.8	45	471	No	No	NA	No	
16	Dec-17	8.3	26	716	No	No	NA		
	Jan-18	9.8	42	808	No	No	NA		
	Feb-18	9.7	40	707	No	No	NA	PI	
	Mar-18	10	56	793	No	No		Yes	
	Apr-18	9.6	95	1075	No	yes	60mcg	PI:A	
17	Dec-17	-	-	-					
	Jan-18	-	-	-					
	Feb-18	8.7	19	280	No	No	NA	PI	
	Mar-18	10.7	33	309	No	No	NA	Yes	
	Apr-18	-	23	253	No	No	NA		
18	Dec-17	9.7	16	87	No	No	NA		
	Jan-18	9.3	16	87	No	No	NA		
	Feb-18	9	23	124	No	No	NA	PI	
	Mar-18	8.4	15	80	Yes	Yes	100mcg 300mg	PI:A PI:V	
	Apr-18	9.1	14	68	Yes	Yes	100mcg 300mg	PI:A PI:V	? infec
19	Dec-17	8.3	26	716	Yes	No	300mg	PI:V	
	Jan-18	9.8	47	808	No	No	NA	NA	

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	Feb-18	9.7	40	707	No	No	NA	PI
	Mar-18	10.0	56	793	No	No	NA	Yes
	Apr-18	9.6	95	1075	No	No	NA	No
20	Dec-17	9.1	13	246	No	No	NA	
	Jan-18	10.0	11	300	No	No	NA	
	Feb-18	9.8	45	566	No	No	NA	PI
	Mar-18	11.5	17	341	Yes	No	100mg	PI:V
	Apr-18	12.5	36	524	No	No	NA	Yes
21	Dec-17	10.7	21	307	No	No	NA	
	Jan-18	10.4	30	267	No	No	NA	
	Feb-18	10.6	30	529	No	No	NA	PI
	Mar-18	10.2	32	297	No	No	NA	Yes
	Apr-18	9.7	25	296	No	No	NA	No
22	Dec-17	11.0	24	384	No	No	NA	
	Jan-18	9.6	22	303	No	Yes	100mcg	
	Feb-18	11.3	596	427	No	No	NA	PI
	Mar-18	9.8	18	388	Yes	No	300mg	PI:V
	Apr-18	10.3	27	480	No	No	NA	Yes
23	Dec-17	9.9	18	161	No	No	NA	
	Jan-18	12.0	29	123	No	No	NA	
	Feb-18	11.1	41	246	No	No	NA	PI
	Mar-18	9.1	28	439	No	No	NA	No
	Apr-18	-	-	-				No Show

(continued)

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24	Dec-17	11	24	37	No	No	NA	
	Jan-18	10.7	17	19	No	No	NA	
	Feb-18	10.4	-	-	No	No	NA	PI
	Mar-18	11.5	22	99	No	No	NA	Yes
	Apr-18	10.7	24	159	No	No	NA	Yes

Note. PI-Protocol implemented; PI: A-Protocol implemented –Aranesp; PI: V Protocol implemented -Venofer.

During the month of February 2018, when the protocols were first introduced,11 patients (45.8%) had a Hgb level below 10g/dL, and 13 (54%) had a level of 10g/dL and above, which is the targeted range. Forty-two percent or 10 dialysis recipients had a TSAT of 30% and above and 11 patients (45.8%) had a TSAT below 30% and 3 (12.5%) had no results during the same month. Six of the dialysis recipients who had low TSAT levels also had Hgb level below 10g/dL which represents 25% of the patient census.

The Aranesp and Venofer protocols, which are located in Appendix C and Appendix D respectively, were implemented by the nursing staff in February 2018. As of March 2018, eight (33.3 %) dialysis recipients had a Hgb level below 10g/dL, and 16 (66.6 %) had their Hgb levels above 10g/dL. Seven (29.1%) dialysis participants had TSAT 30% and above, sixteen (66.6%) had TSAT level below 30%, and one (4.1%) participant had no laboratory results recorded. Finally, in the month of April, 2018, eight (33.3%) dialysis recipients had Hgb levels below 10g/dL, 13 (54.1 %) had a Hgb level above 10g/dL and three (12.5%) had no laboratory results available. Of the participants, nine (37.5 %) had TSAT above 30%, thirteen (54.1%) had TSAT levels below 30% and two (8.3%) patients had no TSAT results available. TSAT and Hgb values

were not available for patients who missed their complete blood count (CBC) and iron profile blood draws at the clinic or those who were hospitalized.

If the TSAT level is above the target of 30-50% and ferritin which is iron storage is above 100-500ng/ml, the Venofer protocol should not be implemented. However, if the TSAT is below 30% and the Ferritin is below 100ng/ml, the Venofer protocol must be implemented. In March after a full month of having the protocols implemented 10 dialysis participants had their TSAT below 30%; eight (33.3%) of those participants had the Venofer protocol applied resulting in five (20.8%) of them with improved TSAT to target level in April. The two (8.3%) remaining participants who needed Venofer did not receive it, one (4.1%) received Aranesp instead and the other received no treatment; reasons were not documented for this observation. In April, only four (16.6%) dialysis participants had a TSAT below 30%, three (12.5%) of those participants had the Venofer protocol applied and one (4.1%) had the Aranesp protocol applied instead.

If the Hgb level is at 10-11g/dL which is the target range, the Aranesp protocol should not be implemented. However, if Hgb is outside this range then the Aranesp protocol must be implemented. In March, after the implementation of the Aranesp protocol, eight dialysis participants or 33.3% had Hgb levels below 10g/dL but only five (20.8%) of them received the Aranesp per protocol. It is unknown why the other three (12.5%) did not receive Aranesp as needed. Of the five participants who received the Aranesp protocol four had improved Hgb levels to the target. In April, seven of the participants had Hgb levels below 10g/dL and should have the Aranesp protocol implemented however, only four of them had the protocol applied for unknown reasons.

Overall, the protocol implementation was effective; before implementation of the anemia management protocols only 4 of the 12 dialysis participants who needed Aranesp did receive it

which is 33.3% and only 4 of the 11 dialysis participants who needed Venofer received it which is 36.3%. Similarly, after implementation of the anemia management protocols, 9 of the 15 participants who needed Aranesp received it, which is 60% of the dialysis participants indicating a 26.7% increase in Aranesp administration by using the Aranesp protocol. After the implementation of the Venofer protocol, 8 dialysis participants needed Venofer and 6 received it which is 75% of the dialysis participants indicating 38.7 % increase by using the Venofer protocol. Finally, more than 50% of the participants demonstrated accuracy in the return demonstration of Aranesp and 100% verbalized understanding of the written materials available in both Spanish and English after watching the video and receiving an anemia pamphlet. The ultimate goal to improve Hgb levels was obtained and by the end of April 2018, 62.5 % of the dialysis participants had a minimum Hgb level of 10g/dL

Discussion and Conclusions

Findings Related to Evidence

Anemia management protocols (AMPs) guide ESA and iron dosing for effective management of patients with CKD (Kliger et al., 2013). In four clinical trials conducted by major drug companies, Hgb was maintained using dosing algorithms and a dosing protocol (Charlesworth et al., 2014). The dosing algorithms were designed to achieve and maintain Hgb levels at the desired target. A retrospective observational study in 174 patients conducted over 6 months implemented an Aranesp dosing anemia protocol. The results indicated that the use of an anemia management protocol resulted in decreased prescribing of Aranesp and iron while increasing patients target Hgb range to an acceptable level of 10-12g/dL (Charlesworth et al., 2014). These results are comparative to the findings of the quality improvement project that the use of an anemia management protocol is effective in improving Hgb levels.

In a study related to PD conducted by Pirkle et al. (2014) 139 PD patients received Aranesp and intravenous iron for anemia management protocol. The study found that patients maintained stable Hgb levels between 10-12g/dL on the anemia management protocol using Aranesp and IV iron. This treatment intervention is inconsistent with the levels of the current KDIGO anemia management guidelines of maintaining Hgb at 10-11.5g/dL (Kliger et al., 2013). Similarly, in this project, dialysis participants who had the Aranesp protocol and Venofer iron protocol implemented had improvements in their Hgb and TSAT levels. On the other hand, there was an exception of one participant who received the Venofer protocol who showed no improvement in TSAT over a 1-month period and three participants who received the Aranesp protocol did not show improvement in their Hgb levels over the same period. This may be attributed to patient disease process or poor response to iron and Aranesp if an infection is imminent, however patient vital signs and other parameters were not monitored to determine if the patients had a fever or infection. In addition, a longer monitoring period of two to three months would likely yield mature red blood cells and improved Hgb status.

According to these results, Venofer therapy was the most favorable administration and this preference could likely be associated with the less expensive cost of Venofer when compared to Aranesp and its effectiveness in improving Hgb (Kliger et al., 2013). In addition, Kliger et al. (2013) state that for CKD patients, iron therapy has the potential to increase Hgb concentration and decrease ESA dose which could be a possible intent for the favorability results in administering Venofer 100% of the time. It is also important to note that the administration of Aranesp increased each month after the protocol implementation and the administration of Venofer remained consistent at 100% each month.

Protocol implementation involves the patient as a significant component of the intervention. Patient teaching is effective in enhancing patient care and is a significant aspect of the home dialysis patient (Schaepe & Bergjan, 2015). Smith and Zsorhar (2013) also stated that effective patient teaching methods includes computer-aid teaching, video education, demonstration, return demonstration, teach back or tell back, and written materials with pictures. Additionally, written materials created at a reading level for the general population combined with verbal health information significantly improved knowledge (Marcus, 2014). This was evident in the patients' demonstration of the educational materials received through these medium. More than 50% of the participants demonstrated accuracy in the return demonstration of Aranesp and 100% verbalized understanding of the written materials available in both Spanish and English. The other 50% did not demonstrate 100% accuracy of Aranesp administration and received correction in administration.

Implications for Practice

Implementation and consistent utilization of the anemia management protocol was deemed effective in staff and patient learning. This ultimately resulted in improved knowledge and skills among staff and patients resulting in improved patient outcomes. These findings are relevant implications for practice and lessons learned. Anemia is a risk factor of mortality and morbidity in the CKD patient, and as a result, the role of anemia management in CKD is more focused on patient clinical outcomes of mortality, cardiovascular complications, quality of life and progression to ESRD (Horl,2013).

In addition, staff feedback (Appendix I) indicated that the protocols were useful in the clinical practice since no protocol was previously available. One recommendation was that patients with the iPads should record themselves administering their Aranesp at home. The two

registered nurses and medical assistant stated they used the protocols and it did improve their knowledge on anemia management and understanding the goals of Hgb, TSAT and ferritin targets in the CKD patient who is receiving PD. They also observed improvement in patient administration techniques after the patients watched the video and noted improvement in hemoglobin levels after the protocol implementation.

Limitations of Project

Several limitations were noted in this quality improvement project. Most identifiable is that the DNP student could not be present at all the interventions for observation. Secondly, there was a lack of accurate documentation of the patient interventions received. Specifically, patients received educational handouts and self-administered Aranesp with return demonstration, however, it was not documented on all the patients who received these interventions. Additionally, some patients who needed to have one of the protocols implemented did not receive the protocol for undocumented reasons. The charge nurse perceived that the patients who missed the protocols were an oversight by the less experience nurse. Other barriers to note is that this is a rural clinic and the nurses and MA are often out at the patients' homes and not always at the clinic. This is a barrier because the patient may only be available to attend the clinic on the days the nurses and MA are making home visits and as a result not able to get a lab draw that month.

Recommended Sustainability

A television was purchased with a DVD player and the educational DVD was obtained by the DNP student to maintain the sustainability of the patient education portion of this project. The DVD player was placed in the patient educational classroom which is also used as the waiting area. The handouts were ordered with an extra 50 copies available and information to

order these handouts at no additional cost was emailed to the clinic manager and the assistant manager. Finally, the protocols were uploaded to the general policy and procedure in the electronic medical record (EMR) and in each participant's chart.

Relevance to Nursing Practice for APRN With DNP

As an advanced practice nurse with a doctoral degree, there is great opportunity to impact the healthcare system by using advanced knowledge and skills to improve healthcare outcomes (American Association of Colleges of Nursing [AACN], 2006). The changes needed to create an impact in the clinic are unique to the abilities, expertise, and level of education of a doctoral prepared nurse according to the DNP essential of advanced nursing practice (AACN,2006). Despite the strong multidisciplinary team at the clinic, no one is educationally or clinically prepared to develop or implement these changes as an APRN with DNP. Developing and implementing an anemia management protocol using evidence-based clinical guidelines to improve patient outcomes and quality of care is unique to the DNP essential of clinical scholarship and analytical methods for evidence-based practice AACN (2006) and is an exceptional role of the DNP. Engaging members of the healthcare team in the process to make valuable contributions to the quality improvement project is also imperative to the leadership role. These expert measures are consistent with the unique role of the DNP as indicated by the DNP essentials of interprofessional collaboration for improving patient and population health outcomes (AACN, 2006).

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Appendix A: Project Approval Letter

November 15, 2017

To Whom It May Concern: Anemia management quality improvement project

Kenisha Marajah has my permission to conduct a Doctor of Nursing Practice **(DNP)** project for UIW with staff and providers at *Innovative Dialysis Solutions* (IDS) at Home. I am aware that the project involves reviewing medical records pertinent to her project development.

The purpose of the quality improvement project will be to improve patient teaching and improve staff management of anemia using evidence-based guidelines. I support this project entitled, "Anemia management in the adult dialysis patient".

I can be contacted at 2795 *Bulverde* Road (FM 1863) *Bulverde,* TX 78163 or 315 **N** San Saba #102, San Antonio, TX 78207 at 210-277-1418 for further information.

Sincerely,

David Salazar (Clinical Manager IDS)

Appendix B: Staff Anemia Questionnaire (pre-test & post-test)

1. **How do you identify yourself?**
   a. MD or Nurse Practitioner
   b. Clinical Manager or Charge Nurse
   c. Registered Staff Nurse or Medical Assistant
   d. Other

2. **What is anemia?**
   a. More red blood cells than normal
   b. Less red blood cells than normal
   c. I don't know
   d. Other

3. **What is the acceptable clinical value for hemoglobin in the chronic kidney disease (CKD) patient?**
   a. 9-10g/dL
   b. 10-11g/dL
   c. 10-12g/dL
   d. I don't know

4. **How does kidney failure cause anemia?**
   a. It does not
   b. The kidneys fail to produce erythropoietin
   c. The patient loose blood when their kidney fails
   d. I don't know

5. **How is anemia usually treated in the CKD patient?**
   a. Oral iron
   b. IV iron and an erythropeisis agent
   c. It cannot be treated
   d. I don't know

6. **What are the two common Erythropoiesis-stimulating agents (ESAs) used to treat anemia in CKD?**
   a. Vitamin B 12 and Folate
   b. Venofer and Iron
   c. Epogen and Aranesp
   d. I don't know

7. **What are the two common iron therapies used to treat anemia in CKD?**
   a. Aranesp and Iron

b. Epogen and Aranesp
c. Venofer and Ferrlecit
d. I don't know

8. **Do you use an anemia management protocol to treat anemia in the clinic?**
   a. Yes
   b. No
   c. Sometimes
   d. I don't know

9. **Do you have the time to teach patients how to administer their ESA?**
   a. Yes
   b. No
   c. Sometimes

10. **How do you adjust the dose of ESA (Aranesp) and IV iron (Venofer)?**
    a. Clinical judgment
    b. Evidence-based guidelines
    c. Doctors order
    d. Other

Appendix C: Staff Maintenance Therapy Aranesp (Darbepoetin)

Hemoglobin (hgb) level should be maintained at 10-11g/dL
For darbepoetin alfa (DPA): "titrate as necessary to maintain a target hgb of 10-11 g/dl not to exceed 11.5 g/dL".
If the hemoglobin exceeds 11.5 g/dL, dose should be temporarily withheld until the hemoglobin begins to decrease, at which point therapy should be reinitiated at a dose of 25% below the previous dose.
If the hemoglobin increases by more than 1 g/dL in a 2-week period, the dose should be decreased by 25%.
If the increase in the hemoglobin is less than 1 g/dL over 4 weeks and iron stores are adequate, the dose of Aranesp may be increased by approximately 25% of the previous dose.
If hemoglobin is 10.1g/dL -11.0 g/dl, no change in Aranesp dosage
If hemoglobin is > 11g/dL, decrease Aranesp by 25%
If hemoglobin is > 11.5 g/dL **HOLD** Aranesp
If patient is at Aranesp lowest dose and need to be further decreased then administer the lowest dosage every 2 weeks.

Appendix D: Staff Venofer Dosing Protocol

Patients with CKD on peritoneal dialysis (PD), to a target of serum ferritin > 100 ng/ml (up to 500 ng/ml) and TSAT > 30% (up to 50%).
KDIGO Clinical practice guidelines suggest treating patients with iron supplementation when TSAT ≤ 30% and ferritin ≤ 500 ng/ml if an increase in Hgb or reduction in ESA dose is desired.

Test iron status frequently (TSAT and Ferritin) when monitoring response after a course of iron.

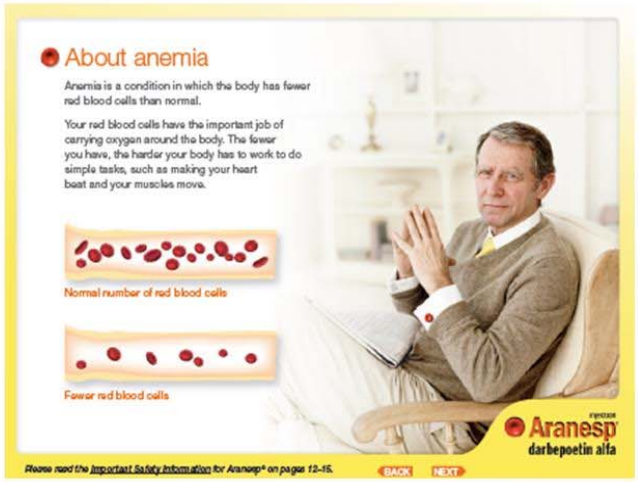
Avoid administering IV iron to patients with active systemic infections.

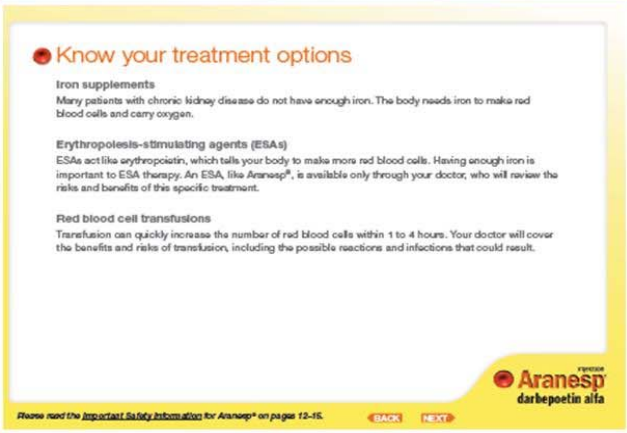
Venofer 300 mg (in 250 ml; over 1.5 hours) then **Venofer** 400 mg (in 250 ml; over 2.5 hours)	2 doses of the 300mg 14 days apart; then [400 mg dose] after another 14 days

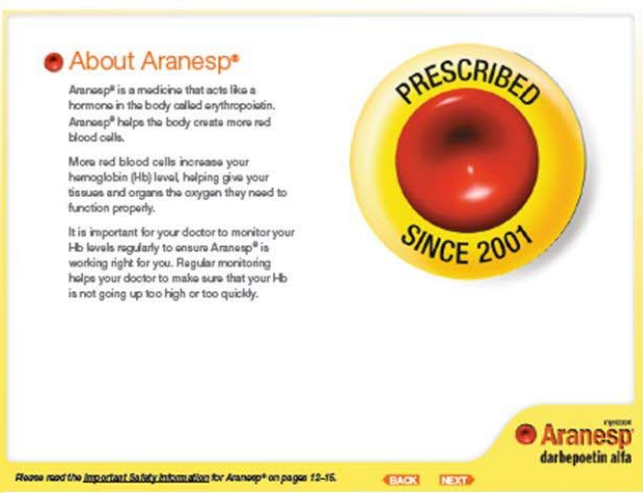
That is Day 1 =300mg, Day 15 = 300mg then Day 29th = 400mg
NOTES
Peritoneal Dialysis Dependent - Chronic Kidney Disease (PDD-CKD) 300 mg for 2 doses 14 days apart, as infusion diluted in a maximum of 250mL of 0.9% NaCl. over 1.5 hours, followed by 400 mg infusion over 2.5 hours 14 days later.

That is Day 1 = 300mg, Day 15 = 300mg and Day 29th = 400mg

Appendix E: Patient Educational Handout








Aranesp® has been prescribed since 2001 to patients with chronic kidney disease on dialysis and patients not on dialysis.
Aranesp darbepoetin alfa
Please read the Important Safety Information for Aranesp® on pages 12–15.
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Is Aranesp® right for you?
Aranesp® is not right for everyone. Tell your nurse and doctor about any conditions you have, especially if you:
• Have high blood pressure
• Have heart disease
• Have had a seizure (convulsion) or stroke
• Are pregnant or planning to become pregnant
• Are breast-feeding or planning to breast-feed
• Have any allergies, including to latex
• Have cancer
• Have any other medical conditions
These conditions can have a serious impact on the way your body responds to Aranesp®. Your doctor needs to be aware of these conditions in order to decide if Aranesp® is right for you.
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Please read the Important Safety Information for Aranesp® on pages 12–15.
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Tell your doctor about all of the medications you take, including vitamins, prescription and nonprescription medications, and herbal supplements. They can affect your anemia or interact with Aranesp®, so it's very important information for your doctor to know. Your doctor may have you start to take or change to a different blood pressure medication. It is very important to have well-controlled blood pressure levels while you are being treated with Aranesp®.
If you know you are allergic to latex, talk to your healthcare provider before using Aranesp® because the needle cover on the prefilled syringe contains latex.
Aranesp darbepoetin alfa
Please read the Important Safety Information for Aranesp® on pages 12–15.
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How to take Aranesp®
If you are on dialysis:
• Your doctor will decide if you will take Aranesp® in your dialysis facility or if you and/or your caregiver will be trained to self-inject Aranesp® at home.
• You can be treated once a week or once every 2 weeks.
• If you are on hemodialysis, you should receive Aranesp® during dialysis treatment.
If you are not on dialysis:
• You are usually treated once every 4 weeks.
Aranesp® should not be used in place of red blood cell transfusion for the immediate correction of anemia.
Aranesp darbepoetin alfa
Please read the Important Safety Information for Aranesp® on pages 12–15.
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Your doctor will determine the right hemoglobin level for you and treat you with the smallest dose of Aranesp® needed to reduce your need for blood transfusion.
Aranesp darbepoetin alfa
Please read the Important Safety Information for Aranesp® on pages 12–15.
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Indications
Aranesp® is a prescription medicine used to treat a lower than normal number of red blood cells (anemia) caused by chronic kidney disease in patients on dialysis and not on dialysis.
Aranesp® is a prescription medicine used to treat a lower than normal number of red blood cells (anemia) caused by chemotherapy that will be used for at least two months after starting Aranesp®.
Aranesp® should not be used for the treatment of anemia:
• If you have cancer and you will not be receiving chemotherapy that may cause anemia for at least 2 more months
• If you have a cancer that has a high chance of being cured
• In place of emergency treatment for anemia (red blood cell transfusions)
Aranesp® has not been proven to improve quality of life, fatigue, or well-being.
Important Safety Information
Aranesp® may cause serious side effects that can lead to death, including:
For people with cancer:
• In patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers: Your tumor may grow faster and you may die sooner if you choose to take Aranesp®.
• Your healthcare provider has received special training in order to prescribe Aranesp® and will talk with you in detail about these risks.
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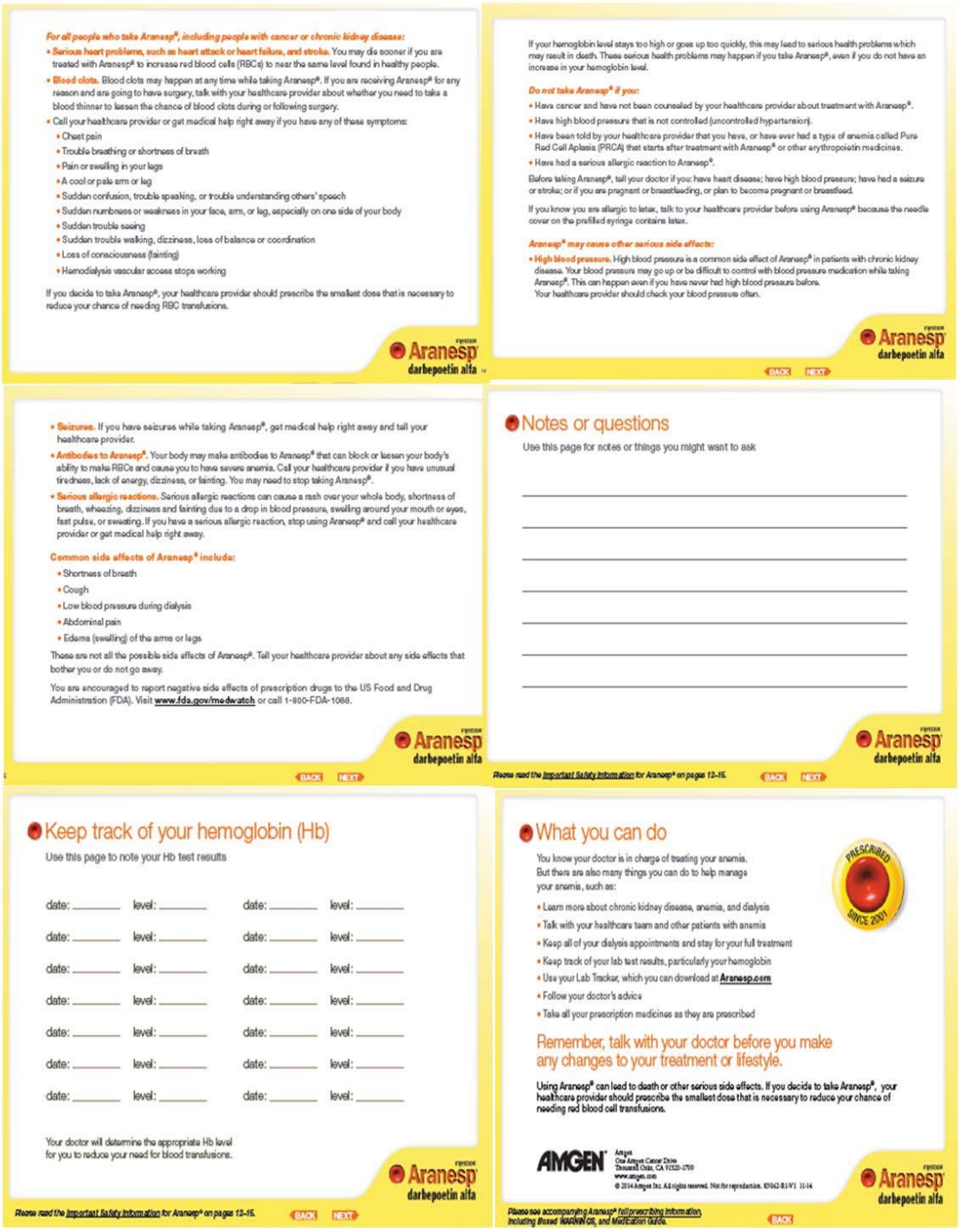

For all people who take Aranesp®, including people with cancer or chronic kidney disease:

- **Serious heart problems, such as heart attack or heart failure, and stroke.** You may die sooner if you are treated with Aranesp® to increase red blood cells (RBCs) to near the same level found in healthy people.
- **Blood clots.** Blood clots may happen at any time while taking Aranesp®. If you are receiving Aranesp® for any reason and are going to have surgery, talk with your healthcare provider about whether you need to take a blood thinner to lessen the chance of blood clots during or following surgery.
- Call your healthcare provider or get medical help right away if you have any of these symptoms:
  - Chest pain
  - Trouble breathing or shortness of breath
  - Pain or swelling in your legs
  - A cool or pale arm or leg
  - Sudden confusion, trouble speaking, or trouble understanding others' speech
  - Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
  - Sudden trouble seeing
  - Sudden trouble walking, dizziness, loss of balance or coordination
  - Loss of consciousness (fainting)
  - Hemodialysis vascular access stops working

If you decide to take Aranesp®, your healthcare provider should prescribe the smallest dose that is necessary to reduce your chance of needing RBC transfusions.

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If your hemoglobin level stays too high or goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen if you take Aranesp®, even if you do not have an increase in your hemoglobin level.

Do not take Aranesp® if you:

- Have cancer and have not been counseled by your healthcare provider about treatment with Aranesp®.
- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have been told by your healthcare provider that you have, or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with Aranesp® or other erythropoietin medicines.
- Have had a serious allergic reaction to Aranesp®.

Before taking Aranesp®, tell your doctor if you: have heart disease; have high blood pressure; have had a seizure or stroke; or if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed.

If you know you are allergic to latex, talk to your healthcare provider before using Aranesp® because the needle cover on the prefilled syringe contains latex.

Aranesp® may cause other serious side effects:

- **High blood pressure.** High blood pressure is a common side effect of Aranesp® in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medication while taking Aranesp®. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often.

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- **Seizures.** If you have seizures while taking Aranesp®, get medical help right away and tell your healthcare provider.
- **Antibodies to Aranesp®.** Your body may make antibodies to Aranesp® that can block or lessen your body's ability to make RBCs and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking Aranesp®.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness and fainting due to a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using Aranesp® and call your healthcare provider or get medical help right away.

Common side effects of Aranesp® include:

- Shortness of breath
- Cough
- Low blood pressure during dialysis
- Abdominal pain
- Edema (swelling) of the arms or legs

These are not all the possible side effects of Aranesp®. Tell your healthcare provider about any side effects that bother you or do not go away.

You are encouraged to report negative side effects of prescription drugs to the US Food and Drug Administration (FDA). Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Notes or questions

Use this page for notes or things you might want to ask

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Please read the Important Safety Information for Aranesp® on pages 12–15. BACK NEXT

Keep track of your hemoglobin (Hb)

Use this page to note your Hb test results

date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____
date: _____	level: _____	date: _____	level: _____

Your doctor will determine the appropriate Hb level for you to reduce your need for blood transfusions.

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Please read the Important Safety Information for Aranesp® on pages 12–15. BACK NEXT

What you can do

You know your doctor is in charge of treating your anemia. But there are also many things you can do to help manage your anemia, such as:

- Learn more about chronic kidney disease, anemia, and dialysis
- Talk with your healthcare team and other patients with anemia
- Keep all of your dialysis appointments and stay for your full treatment
- Keep track of your lab test results, particularly your hemoglobin
- Use your Lab Tracker, which you can download at **Aranesp.com**
- Follow your doctor's advice
- Take all your prescription medicines as they are prescribed

PRESCRIBED SINCE 2001

Remember, talk with your doctor before you make any changes to your treatment or lifestyle.

Using Aranesp® can lead to death or other serious side effects. If you decide to take Aranesp®, your healthcare provider should prescribe the smallest dose that is necessary to reduce your chance of needing red blood cell transfusions.

AMGEN

Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
www.amgen.com

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Please see accompanying Aranesp® full prescribing information, including Boxed WARNING, and Medication Guide. BACK

Appendix F: Patient Education Video

..\..\EBP 1\ARANESP\Aranesp patient video.mp4

Appendix G: Teach-Back Self-Evaluation- Post patient educational intervention

Patient #:_____ Date: _____/_____

Patient #	# Items to do or remember	Did patient perform correctly	
		Yes	*No*
	Use stepwise process to: Wash hands thoroughly Clean injection site with alcohol wipe Push syringe barrel to match prescribed dose Pinch injection site and inject medication subcutaneously	_____ _____ _____ _____	_____ _____ _____ _____

Appendix H: Demographics & Hemoglobin Levels

Chart Review Form

Chart #: _____ **Patient's Gender**: (1) Male (2) Female

Patient's Age (years): (1)_____ (2) Not Documented

Marital Status: Single_____ Married____ Divorced _____Widowed_____

Ethnicity: White ____ Hispanic_____Asian_____African American ____ Other

Hemoglobin levels (December 2017) pre-in: Greater than 10_____ Less than 10_____

Hemoglobin levels (April 2018) post-in: Greater than 10_____ Less than 10_____

TSAT levels (December 2017) pre-intervention: _____

TSAT levels (April 2018) post intervention: _____

Ferritin levels (December 2017) pre-intervention: _____

Ferritin levels (April 2018) post-intervention: _____

Appendix I: Project Feedback

1.Were the protocols useful in your clinical practice? How so

_____

2.What would you change about the anemia management protocols or patient education?

_____

3. Do you use the protocols? If no, why not

_____

4. Did the protocols improve your knowledge on anemia management?

_____

5. Have you observed any improvement in patient hemoglobin level after administering the patient educational materials (pamphlet and Video)? If so what improvement did you observe

_____

6. Have you observed any improvement in patient administration technique after watching the video? If so what improvement did you observe

_____