IMPROVING ANEMIA OUTCOMES FOR ERYTHROPOEITIN STIMULATING AGENT HYPORESPONSIVE HEMODIALYSIS PATIENTS

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OPTIMIZING ANEMIA CARE IN HEMODIALYSIS: INTEGRATION OF A HYPORESPONSE TO ESA CHECKLIST

By
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This DNP Dissertation Project by **Charla L.R. Naone has been approved by the committee members** below, who recommend it be accepted by the faculty of Hawaii Pacific University in partial fulfillment of requirements for the degree of Doctor of Nursing Practice.

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Abstract

Purpose: To evaluate the effectiveness of the Supplemental Hyporesponse to ESA Checklist in managing anemia among hemodialysis patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs). The checklist aims to improve hemoglobin levels and optimize anemia management by identifying and addressing underlying causes of ESA hyporesponsiveness.

Background and Significance: Anemia is a common and serious complication in patients with end-stage renal disease (ESRD), contributing to reduced quality of life, cardiovascular disease, and increased mortality (Bae et al., 2019). While ESA therapy is standard, many patients exhibit suboptimal responses, often requiring high doses that raise cardiovascular risk (Shah et al., 2020)

Intervention and Implementation Plan: The intervention was implemented using a multidisciplinary team including nurses and nurse practitioners. Prior to implementation staff undertook a comprehensive training session. The checklist was used to monitor and adjust treatment for hyporesponsive patients. Data collected included hemoglobin levels, ESA dosages, referrals, and post-intervention survey responses evaluating the checklist's utility.

Results and Implications: Use of the checklist was associated with increased hemoglobin levels and reduced ESA doses in most patients. This targeted, individualized approach to anemia management enhanced clinical decision-making and may reduce cardiovascular risks. The positive results support the broader adoption of the checklist to improve anemia outcomes across the ESRD population in other dialysis settings.

Acknowledgment

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Chapter 1

Introduction to the Project

Problem

End-stage renal disease (ESRD) affects over 800,000 individuals in the United States, with approximately 71% undergoing renal replacement therapy, commonly referred to as dialysis (U.S. Renal Data System [USRDS], 2020). Dialysis serves as a life-sustaining therapy by regulating fluid balance, removing waste, and correcting electrolyte and hormonal imbalances (Himmelfarb et al., 2020). Treatment modalities include in-center hemodialysis, home hemodialysis, and peritoneal dialysis. Among these, in-center hemodialysis is the most commonly utilized, requiring patients to receive treatments three to four times per week for sessions lasting three to five hours (Fotheringham et al., 2020).

Despite its therapeutic benefits, hemodialysis is associated with a multitude of complications. Patients frequently experience side effects such as muscle cramps, headaches, hypotensive episodes, nausea, and vomiting (Ikizler & Cuppari, 2021). One of the most debilitating complications is anemia, which contributes to chronic fatigue, decreased physical functioning, and reduced quality of life (Bae et al., 2019; Bossola et al., 2020).

Significance

Anemia in ESRD primarily results from reduced production of erythropoietin, a hormone synthesized by the kidneys. This condition is associated with increased cardiovascular morbidity, decreased quality of life, and elevated mortality risk (Weir, 2021; Bae et al., 2019). Erythropoiesis-stimulating agents (ESAs) are commonly prescribed to stimulate red blood cell production and is standard practice in anemia management for hemodialysis patients (Ross et al., 2020). Anemia management includes regular monitoring of hemoglobin (Hgb) and iron indices

(e.g., transferrin saturation and ferritin) and the administration of appropriate ESA and iron dosages.

While most patients respond well to ESA therapy, Shah et al. (2020) noted that hemodialysis patients generally achieve adequate Hgb levels unless complicated by underlying inflammation, iron deficiency, or other clinical factors. However, a subset of patients remains hyporesponsive to treatment, continuing to experience symptoms of anemia despite escalating ESA doses. Hemodialysis clinics typically utilize standardized anemia management protocols led by anemia managers, including nephrologists, nurse practitioners, and dialysis nurses. Despite these protocols, individualized patient factors contributing to ESA resistance are often unaddressed (Hamad et al., 2021). As a result, hyporesponsive patients may receive unnecessarily high ESA doses, increasing their risk of serious adverse outcomes, including myocardial infarction, thrombosis, and mortality (Karimi et al., 2023).

In addition to the clinical risks, the financial burden of excessive ESA use is significant. In 2019, the U.S. incurred an estimated $2.5 billion in excess costs related to ESA administration among 462,005 non-dialysis-dependent chronic kidney disease (CKD) patients with anemia (Gauthier-Loiselle et al., 2021). The vast majority (94.4%) of these costs were linked to in-clinic ESA use, primarily covered by Medicare. Overuse of ESAs may also negatively impact facility reimbursement, as Medicare payments are partially based on performance indicators through programs such as the ESRD Quality Incentive Program (ESRD QIP).

Purpose and Aim

The purpose of this Doctor of Nursing Practice (DNP) project was to implement a method for managing anemia in hemodialysis patients who are hyporesponsive to ESAs. While standardized anemia management protocols exist, they often fall short in guiding care for

patients who continue to have low Hgb levels despite high ESA doses. In these cases, providers may resort to simply increasing ESA dosages, which can elevate the risk of adverse events such as cardiovascular complications, thromboembolic events, and mortality. This project introduced the Supplemental Hyporesponse to ESA Checklist (Appendix A) as a structured decision-support tool aimed at helping anemia managers—including nurse practitioners and dialysis nurses—systematically identify and address the underlying causes of ESA hyporesponsiveness. Rather than relying solely on dose escalation, the checklist guides providers to consider contributing factors such as iron deficiency, inflammation, malnutrition, or missed treatments and to initiate appropriate referrals or adjustments in care.

The overall aim was to support more consistent, evidence-based anemia management by integrating a tool that promotes individualized interventions, optimizes ESA use, enhances referral practices, and reduces the risks associated with high-dose ESA therapy—ultimately improving patient outcomes and aligning with quality care standards.

Operational Definitions

The following terms were used throughout the project and operationally defined as follows:

Anemia Manager: A dialysis nurse or nurse practitioner responsible for managing anemia by monitoring laboratory trends and ordering appropriate ESA and iron doses in alignment with clinical guidelines.

ESA Hyporesponse: An inadequate rise in hemoglobin despite high ESA doses, typically defined as >30,000 units per week or hemoglobin levels <9.5 g/dL for three or more consecutive months.

Standard Protocol: A nephrologist-approved dosing algorithm used by anemia managers to guide ESA therapy based on anemia-related lab values, ensuring consistency in treatment decisions.

Background

Quality Initiatives

The ESRD QIP, administered by the Centers for Medicare & Medicaid Services (CMS), aims to improve care quality by linking reimbursement to anemia-related metrics and other quality benchmarks (CMS, 2020). Failure to meet these benchmarks can result in financial penalties. With nearly 480,500 patients receiving in-center hemodialysis and close to half enrolled in Medicare (Wills & Carrioc, 2022), dialysis clinics face considerable pressure to ensure compliance with quality standards. To support quality improvement, CMS mandates that dialysis centers hold monthly Quality Assurance and Performance Improvement (QAPI) meetings and adhere to the ESRD Conditions for Coverage. These regulations emphasize performance measurement, patient-centered care, and the integration of evidence-based standards (CMS, 2020). QAPI functions as a framework for continuous quality improvement through structured data analysis and performance enhancement (Givens, 2018). The first phase involves root cause analysis to identify systemic inefficiencies or gaps in care. The second phase focuses on implementing strategies to address identified issues and improve clinical outcomes. A tool or intervention that systematically identifies the causes of ESA hyporesponsiveness may assist anemia managers in tailoring treatment plans, promoting optimal ESA use, and ultimately improving patient outcomes.

Challenges with Anemia Management

At the site level, the absence of a standardized, systematic approach to managing ESA hyporesponsiveness often results in fragmented care and provider variability, leading to under- or over-prescription of ESA therapy. This approach can negatively affect patient outcomes by contributing to persistent anemia, increased cardiovascular risk, and hospitalizations (Karimi et al., 2023). Patients may experience a decrease in quality of life when anemia-related symptoms persist and may result in unplanned acute care utilization (Gauthier-Loiselle et al., 2021). Implementing a structured tool, such as the Supplemental Hyporesponse to ESA Checklist offers a promising strategy to standardize care across providers, support appropriate referrals, reduce therapeutic inertia, and guide clinical decisions based on individualized patient factors.

Structure in Anemia Management

Literature consistently highlights the need to address ESA hyporesponsiveness by identifying its multifactorial causes—including inflammation, acute bleeding, and nutritional status—while promoting safer, more cost-effective care (Weir, 2021; Hamad et al., 2021; Ross et al., 2020; Shah et al., 2020). The themes that emerge across the literature—such as ESA risk factors, clinical and financial consequences of dosing practices, and the lack of individualized protocols—underscore the urgent need for structured interventions in dialysis anemia management.

Clinical Question

In patients on hemodialysis what is the impact of implementing the Supplemental Hyporesponse to ESA Checklist for anemia managers compared to using the standard anemia management protocol on anemia in 8–10 weeks?

Summary

The use of ESAs has been instrumental in managing anemia in patients with ESRD. While standardized anemia protocols have streamlined anemia management in dialysis centers, they do not always accommodate the needs of hyporesponsive patients. These patients face increased risks of complications due to high ESA doses and continued anemia symptoms. The Supplemental Hyporesponse to ESA Checklist offers an evidence-based, structured approach for identifying factors contributing to ESA hyporesponsiveness. Its implementation may support more individualized treatment strategies, improve patient outcomes, and help clinics meet quality benchmarks, thereby aligning with both clinical and economic priorities in dialysis care.

Chapter 2

Literature Review

Introduction

Exploring existing literature in relation to the impact of using a standardized approach or checklist for anemia management or anemia outcomes for hemodialysis patients who are unresponsive to ESA medications produced surprisingly little information. Use of the standard anemia management protocol improves efficiency when managing anemia therapy for hundreds of patients but does not adequately address the needs of the small population of patients that do not respond appropriately to ESA and remain negatively affected by anemia. Patients that are hyporesponsive to ESA are often given high doses of ESA which can increase their risk of cardiac mortality. Knowledge gaps among healthcare providers resulting from the routine use of protocol is evident.

The topic of ESA hyporesponse is widely researched and published. Renal experts acknowledge that ESA hyporesponsiveness is a multifactorial clinical issue associated with inflammation, malnutrition, iron deficiency, and chronic disease burden (Weir, 2021; Karaboyas et al., 2020). The consensus in the nephrology community is that while standardized protocols serve as a necessary foundation for care, they fall short in guiding individualized assessment and interventions for patients with persistent anemia (Hamad et al., 2021). Professional guidelines from the Kidney Disease: Improving Global Outcomes (KDIGO) initiative and the Centers for Medicare & Medicaid Services (CMS) also emphasize the importance of evidence-based, patient-centered care in anemia management. These perspectives highlight a growing need for supportive tools that enable clinicians to systematically identify and address contributing factors to ESA resistance. As such, decision-support mechanisms like checklists may offer a promising

approach to enhancing individualized care, improving patient outcomes, and aligning practice with quality benchmarks (CMS, 2020; Bae et al., 2019).

Methodology

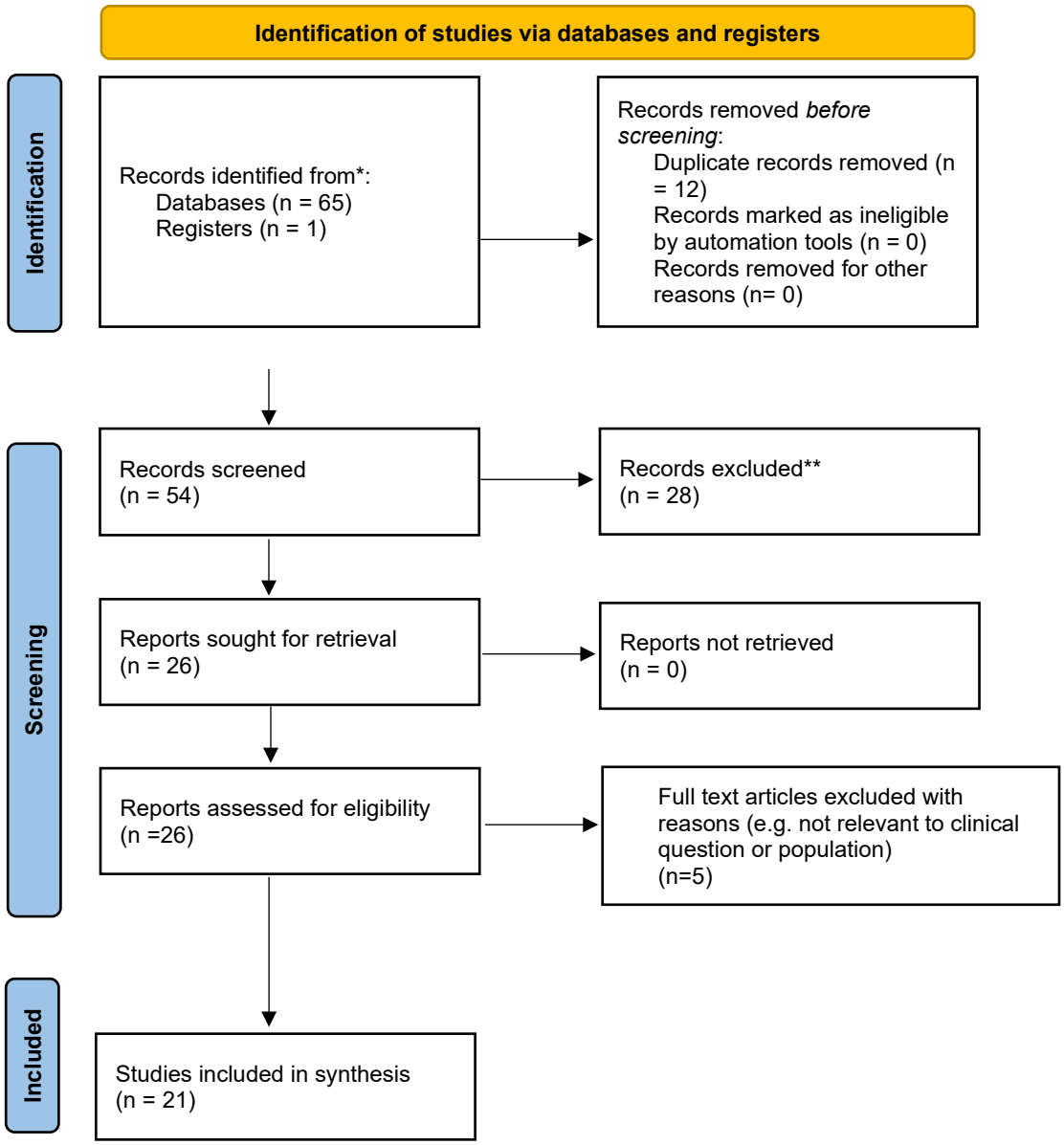
A comprehensive literature search was performed using the CINAHL, PubMed of the National Library of Medicine, EBSCOhost, and Cochrane Library databases. The search terms used to find relevant literature were "hemodialysis," "anemia," "erythropoietin stimulating agents," and "hyporesponse." Expanded search terms included "hemodialysis anemia management," "anemia protocol," "anemia outcomes," "ESA hyporesponse," and "anemia quality."

Inclusion criteria consisted of full-text availability within the past five years (2019 to the present), peer-reviewed journals, English language, and an adult hemodialysis population. Exclusion criteria included studies that contained the terms "pediatric," "child," or "adolescent." The initial database search returned 210 articles. After applying filters for peer-reviewed publications, English language, and adult populations, 66 articles remained. Following the removal of 12 duplicate records, 54 unique articles were screened by title and abstract. Of these, 28 articles were excluded for not meeting inclusion criteria. A total of 26 full-text articles were reviewed for eligibility. After full-text review, 5 articles were excluded due to lack of relevance to the clinical question or target population, resulting in the inclusion of 21 articles for critical appraisal and thematic synthesis.

These 21 peer-reviewed articles (Appendix B) were selected based on their relevance to anemia management in hemodialysis patients, particularly those who are hyporesponsive to erythropoiesis-stimulating agents (ESAs). The search and selection process is summarized in the PRISMA flow diagram (Figure 1).

Figure 1

PRISMA Flow Diagram



Note: *This diagram outlines the study selection process for identifying evidence supporting the use of the Supplemental Hyporesponse to ESA Checklist in ESRD management*

Findings

The following themes emerged: (1) prevalence and risk factors associated with ESA hyporesponsiveness, (2) morbidity, mortality, and cost implications of high ESA dosing, (3) limitations of standardized anemia management protocols, and (4) evidence-based recommendations for improving patient outcomes.

Erythropoietin Stimulating Agent Hyporesponsiveness in Hemodialysis Patients

Hyporesponsiveness to erythropoiesis-stimulating agents (ESAs) in hemodialysis patients is a clinically significant issue characterized by a multifactorial etiology. According to the U.S. Renal Data System (2023), anemia remains a highly prevalent and persistent complication among hemodialysis patients, with suboptimal Hgb control contributing to increased morbidity and mortality. Karaboyas et al. (2020) identified systemic inflammation—particularly elevated C-reactive protein (CRP) levels—as a persistent marker of ESA resistance across global dialysis populations. This finding was reinforced by Weir (2021), who explained that inflammation induces hepcidin production, which traps iron in storage sites and impairs its availability for erythropoiesis. Shah et al. (2020) emphasized that persistent inflammation is a key driver of ESA hyporesponsiveness in hemodialysis patients, often leading to inadequate Hgb response despite escalating ESA doses. This mechanism often goes unaccounted for in standard anemia protocols.

While most patients respond well to ESA therapy, Shah et al. (2020) noted that hemodialysis patients generally achieve adequate Hgb levels unless complicated by underlying inflammation, iron deficiency, or other clinical factors. However, a subset of patients remains hyporesponsive to treatment, continuing to experience symptoms of anemia despite escalating ESA doses. Hemodialysis clinics typically rely on standardized anemia management protocols led by anemia managers, including nephrologists, nurse practitioners, and hemodialysis nurses.

Despite these protocols, individualized patient factors contributing to ESA resistance may be overlooked (Hamad et al., 2021). As a result, hyporesponsive patients may receive unnecessarily high ESA doses, increasing the risk of adverse outcomes such as myocardial infarction, thrombosis, and mortality (Karimi et al., 2023).

Although the literature supports a multifactorial approach to ESA resistance, isolating specific causative factors remains complex. For instance, Hamad et al. (2021) demonstrated improvements in Hgb levels through nurse-led anemia protocols but acknowledged that inflammation and hormonal abnormalities were not consistently assessed, making it difficult to attribute outcomes solely to protocol implementation. Shah et al. (2021) highlighted that ESA hyporesponsiveness in dialysis patients remains a significant clinical challenge, often driven by complex, multifactorial causes that necessitate individualized management strategies.

Morbidity, Mortality, and Economic Impact of ESA Overuse

High-dose ESA therapy in hyporesponsive patients is associated with increased morbidity and mortality. In a meta-analysis of over 370,000 hemodialysis patients, Karimi et al. (2023) reported heightened risks of thrombotic events and cardiovascular mortality linked to supratherapeutic ESA dosing, particularly among elderly and cardiovascular-compromised individuals. These concerns are echoed by Ross et al. (2020), who found that patients with high ESA Resistance Index (ERI) values experienced poorer hemoglobin stability and more frequent dose escalations, indicating limited efficacy of aggressive dosing. Bae et al. (2019) contributed further by showing that frequent Hgb cycling—often a consequence of reactive ESA adjustments—was associated with increased hospitalization and clinical instability. This pattern of Hgb variability highlights the risks of dose-centric management strategies that overlook underlying causes. However, not all evidence fully discredits ESA-based protocols. George and

McCann (2020) found no significant change in hemoglobin or ESA dosing following implementation of a nurse-led anemia management protocol. Nonetheless, they observed improvements in iron indices, suggesting that some structured protocols may enhance biochemical parameters without fully resolving hyporesponsiveness. These findings collectively underscore the clinical dangers of over-reliance on ESA therapy without individualized evaluation**.** Gauthier-Loiselle et al. (2021) emphasized the economic burden associated with ESA hyporesponsiveness, noting that higher ESA doses and poor anemia control are linked to increased healthcare costs and hospitalization rates.

Regarding the economic burden of high ESA use, Gauthier-Loiselle et al. (2021) emphasized the economic burden associated with ESA hyporesponsiveness, noting that higher ESA doses and poor anemia control are linked to increased healthcare costs and hospitalization rates. Cizman et al. (2020) similarly reported that patients with ESA hyporesponsiveness experienced significantly higher healthcare costs, increased cardiovascular hospitalization rates, and greater mortality compared to patients who responded normally to ESA therapy.

Limitations in Standard Anemia Management Protocols

While standardized anemia protocols support operational consistency and regulatory compliance, they may fall short in addressing the complex nature of ESA hyporesponsiveness. Hamad et al. (2021) observed improved Hgb outcomes under a nurse-led anemia management model but noted that critical contributors such as inflammation, bleeding, and secondary hyperparathyroidism were not uniformly assessed. This limitation suggests that algorithm-driven care may improve metrics without addressing root causes.

Locatelli and Del Vecchio (2019) also criticized the limited diagnostic exploration often observed in ESA-focused protocols. Their commentary highlighted the frequent oversight of

factors such as occult bleeding, functional iron deficiency, and inflammation, which require more than protocolized dose adjustments. Weir (2021) similarly called for the integration of diagnostic frameworks, emphasizing individualized anemia management strategies that account for patient-specific factors.

Conversely, Ross et al. (2020) demonstrated that protocol enhancements—such as incorporating the ESA Resistance Index—can improve anemia outcomes when used to stratify patients and guide referral for diagnostic evaluation. Likewise, George and McCann (2020) reported improvements in iron indices under a structured, nurse-led model, even in the absence of Hgb gains. These studies suggest that standardized protocols, when augmented by individualized tools, can still play a role in effective anemia management.

Together, these findings point to a critical gap in standard anemia care: the need for tools that support personalized assessment. The Supplemental Hyporesponse to ESA Checklist addresses this need by guiding anemia managers to evaluate common contributors to ESA resistance, including inflammation, iron status, and bleeding, before modifying therapy. The Prosci ADKAR Model (Prosci, 2024) provides a structured, evidence-based framework for managing individual and organizational change, supporting successful implementation of clinical practice interventions such as anemia management checklists. This approach supports the integration of standardization and clinical reasoning in complex cases.

Evidence-Based Recommendations and Interventions

Several evidence-based interventions have been identified to improve outcomes in ESA-hyporesponsive patients. Bae et al. (2019) recommended mid-week Hgb testing to reduce variability and prevent reactive ESA titration. Their findings support a simple, low-cost strategy for improving Hgb stability. In a broader systems approach, Hamad et al. (2021) reported that

nurse-led anemia protocols enhanced adherence, facilitated earlier identification of nonresponse, and improved patient satisfaction. Similarly, Ross et al. (2020) emphasized that using structured anemia review templates increased diagnostic consistency and prompted referrals for iron repletion and inflammatory workups. Wills and Carrioc (2022) also found that nurse-initiated protocols embedded with checklists led to a 20% reduction in Hgb cycling, demonstrating the utility of structured tools in clinical decision-making.

Additional research reinforces the value of individualized care pathways. Ogawa and Nitta (2024) identified wide variation in how ESA hyporesponsiveness is defined and managed globally, underscoring the need for context-specific strategies. Cizman et al. (2020) added that ESA hyporesponsiveness is associated with higher mortality and cardiovascular risk, further justifying the use of early intervention tools. Bossola et al. (2020) contributed a patient-centered perspective, noting that anemia-related fatigue significantly impacts post-dialysis recovery, reinforcing the clinical importance of timely and effective anemia management.

Finally, Himmelfarb et al. (2020) called for innovation in dialysis care models, including individualized anemia protocols and structured decision-support tools. These priorities are echoed by current clinical guidelines, including those from KDIGO (2024), which advocate for comprehensive assessment of iron status, inflammation, and bone-mineral disorders. Ikizler and Cuppari (2021) further supported these recommendations by identifying nutritional factors that contribute to anemia and emphasizing their role in anemia care pathways.

Collectively, these studies validate the development and application of structured, evidence-based tools such as the Supplemental Hyporesponse to ESA Checklist. By supporting the identification of modifiable contributors to ESA resistance, the checklist enhances clinical reasoning, promotes individualized care, and improves outcomes in the hemodialysis population.

Identified Gaps and Opportunities

While there is a strong body of evidence outlining the multifactorial nature of ESA hyporesponsiveness, the literature reveals a clear but not unanimous consensus on the challenges involved. Most studies agreed that ESA hyporesponsiveness is influenced by a complex interplay of factors—including chronic inflammation, malnutrition, comorbid conditions, and inconsistencies in protocol adherence (Karaboyas et al., 2020; Weir, 2021; Himmelfarb et al., 2020; Ikizler & Cuppari, 2021). This shared understanding affirms that anemia management requires a broader, more individualized approach beyond Hgb-based ESA titration.

However, while the majority of authors advocated holistic assessment and individualized interventions, some differed in the emphasis placed on specific contributors. For example, Karimi et al. (2023) focused primarily on the cardiovascular risks of ESA overuse, while Imaizumi et al. (2025) stressed long-term renal function preservation in peritoneal dialysis patients, suggesting that the implications of ESA hyporesponsiveness may vary across dialysis modalities. Such differences underscore the importance of flexible, adaptable frameworks that accommodate patient-specific variables.

Despite the recognition of these challenges, few studies offered actionable, frontline tools for providers to systematically identify the root causes of hyporesponsiveness or guide clinical decision-making. Existing guidelines often remain theoretical or broad in scope, leaving a practical gap in day-to-day management strategies. This absence of structured, user-friendly tools within the clinical workflow presents a critical opportunity for innovation.

The proposed Supplemental Hyporesponse to ESA Checklist directly addresses this need by translating evidence-based recommendations into a pragmatic decision-support tool. It enables anemia managers to conduct targeted assessments, facilitates appropriate referrals (e.g.,

to dietitians or primary care providers), and promotes early, individualized interventions. By integrating seamlessly into existing anemia management protocols, this checklist builds upon the collective findings of the literature and offers a tangible solution to a well-documented clinical gap.

Theoretical Framework

The alignment of this project with the mission, vision, and values of the project site further reinforces its relevance and potential impact. Their mission is to change the lives of people living with kidney disease. Their vision is to shape the future of kidney care in partnership with physicians, patients, and communities. The organization's core values—Excellence, Partnership, Inclusion, and Compassion—emphasize high-quality care, collaborative success, belonging, and empathetic service).

The project was guided by the Prosci ADKAR model, a change management framework designed to support successful implementation of new practices by addressing individual readiness and organizational change. ADKAR is an acronym representing the five key stages of change: Awareness, Desire, Knowledge, Ability, and Reinforcement (Prosci, 2024). These stages provided a structured approach to promoting sustained behavior change and practice improvement in clinical settings.

1. Awareness: Anemia managers were educated about the limitations of the standard ESA protocol to build awareness of the need for change.
2. Desire: Educational efforts aimed to cultivate a genuine desire among anemia managers to improve outcomes for patients.

3. Knowledge: Structured educational sessions provided anemia managers with the necessary knowledge to effectively utilize the Supplemental Hyporesponse to ESA Checklist.
4. Ability: Hands-on guidance during implementation helped anemia managers develop the ability to apply the checklist consistently within their clinical workflows.
5. Reinforcement: Ongoing engagement and follow-up meetings were implemented to reinforce the use of the checklist, ensuring long-term sustainability and integration into standard anemia management practices.

By fostering clinician engagement and supporting individualized patient assessment, the use of the ADKAR model helped operationalize the goals of the project. It provided a replicable framework for implementing clinical change, enhancing both the process and outcomes of anemia management in hemodialysis patients with ESA hyporesponsiveness.

Summary

The use of a standardized checklist highlighted the clinical significance of properly addressing ESA hyporesponsiveness. The literature revealed the risks associated with high ESA dosing, the limitations of standardized anemia protocols, and the need for a more tailored approach to care. Evidence supported the use of structured tools to assist providers in identifying contributing factors to ESA resistance and implementing appropriate interventions.

The overall aim of the implementation strategy was to enhance clinical decision-making through the use of the Supplemental Hyporesponse to ESA Checklist. This intervention was designed to promote more effective anemia management, reduce unnecessary ESA use, improve Hgb outcomes, and support compliance with CMS quality measures. The information presented

provided the foundation and justification for implementing this targeted quality improvement initiative in the dialysis setting.

Chapter 3

Methods

Introduction

Anemia is a prevalent characteristic of end-stage renal disease (ESRD) and is associated with adverse outcomes, including diminished quality of life, heart disease, and increased mortality. End-stage renal disease patients on hemodialysis with anemia are prescribed ESA's to increase the production of red blood cells. Nephrology providers including nephrologists, nurse practitioners and trained hemodialysis nurses often use a standardized anemia management protocol when calculating the dose of ESA to administer for the appropriate Hgb value. Patients who do not respond to ESA, referred to in this study as hyporesponsive patients, can create a new challenge for providers and hemodialysis anemia managers. Hyporesponsive patients are often given high doses of ESA which can increase their risk of cardiovascular mortality. Although a useful tool, the standardized anemia management algorithm does not individualize care for hyporesponsive patients. The Supplemental Hyporesponse to ESA Checklist will streamline the process for providers and hemodialysis anemia managers in addressing other factors that affect anemia in hemodialysis patients.

Project Design

This quality improvement project focused on improving Hgb values in hemodialysis patients who are hyporesponsive to ESA medications through the implementation of the Supplemental Hyporesponse to ESA Checklist. Lab draws, including Hgb levels were obtained at two points, week one and week five, as is standard practice. The checklist was integrated into the workflow to standardize and streamline anemia management and minimize workflow disruption. Education on the use of the Supplemental Hyporesponse to ESA checklist was

provided to an interprofessional group of staff including nephrologist, advanced practice registered nurses (APRNs), registered nurses (RNs), and designated anemia care coordinators. Ultimately six staff members (three RNs and three APRNs) –termed anemia managers for this project, utilized the checklist.

Sample and Setting

The project was implemented between three hemodialysis clinics in Hawaii. Each dialysis clinic has a patient census of 60-85 patients, all of whom attend treatment two to four times weekly for three to five hours a treatment. A sample of 18 patients was expected but a sample of 34 patients was ultimately included in the project after applying inclusion and exclusion criteria.

Inclusion criteria for patient participants consisted of adults aged 18 years or older undergoing maintenance hemodialysis three times weekly, who demonstrated hyporesponsiveness to ESA's. Hyporesponsiveness was defined as having a Hgb level less than 9.5 g/dL for three consecutive months or a Hgb level between 9.5 and 9.9 g/dL while receiving more than 30,000 units of ESA per week.

Exclusion criteria included patients with a Hgb level greater than 10 g/dL, active infection requiring antibiotics, ongoing gastrointestinal or vascular bleeding, active autoimmune disease, or a pattern of chronic missed dialysis treatments. Patients who met any of the exclusion criteria were removed from eligibility to ensure the intervention focused specifically on modifiable contributors to ESA hyporesponsiveness.

Protection of Human Subjects

Anemia managers were informed prior to the start of the project and notified on the day of the educational session that the implementation had begun. The project received prior

approval from the project site and was submitted for expedited review and approved by the Institutional Review Board (IRB) of Hawaii Pacific University (Appendix C).

Individual patient consent was not required for this project, as access to laboratory values and medication regimens was part of routine anemia management within the standard of care. Patient data were reviewed solely for quality improvement purposes. All participant information was handled with strict confidentiality protocols: data were reviewed on secure systems, and all files were password protected. Additionally, information was stored on a password-protected computer and an encrypted zip drive, both of which were kept in a locked safe accessible only to the primary project manager.

Data Collection Instruments

Data for this project were extracted from multiple clinical information systems within the practicum site, including the electronic medical record (EMR), the laboratory reporting system, and the medication reporting system. Relevant patient information, such as Hgb levels, ESA dosing, iron indices, inflammatory markers, and clinical referrals, was obtained and compiled into secure, password-protected Excel spreadsheets for analysis.

Demographic Survey

Demographic and clinical characteristics of the patient sample were collected through chart review using the EMR and laboratory data. Data points included patient age, sex, dialysis vintage (length of time on dialysis), baseline Hgb levels, ESA dosing history, and presence of comorbidities relevant to anemia management.

Supplemental Hyporesponse to ESA Checklist

The Supplemental Hyporesponse to ESA Checklist (Appendix A) served as a primary data collection tool throughout the intervention. Anemia managers completed the checklist for

each eligible patient, systematically documenting evaluations of hyporesponsiveness factors, clinical findings, and any resulting referral actions. Checklist data provided structured insights into the management decisions and identification of underlying causes of ESA hyporesponsiveness.

Data Collection Procedures

Implementation of the Supplemental Hyporesponse to ESA Checklist began with education for the anemia managers and included introduction to the checklist, review of its purpose, and how to integrate its use into daily clinical workflows. Following education, the intervention was launched with active use of the checklist.

Data for this project were collected through a retrospective review of patient information from the clinical data resources available at the participating dialysis clinics. Pre-intervention data included Hgb values and ESA dosages and were collected for the two months prior to implementation, as well as during the month of implementation. These data were extracted from the EMR laboratory reporting systems, and medication administration records used at the clinical sites.

Monthly Hgb values and weekly ESA dosages were extracted after each routine monthly lab draw, in alignment with standard dialysis clinic practices.

Additionally, referral data were collected starting in January and continued throughout the project period. Referrals captured included those to primary care providers, nephrologists, renal dietitians, or specialists, based on findings identified through the checklist review process. Referral data were documented contemporaneously as referrals were initiated.

Data Analysis

Data analysis for this quality improvement project focused on evaluating changes in anemia management outcomes following the implementation of the Supplemental Hyporesponse to ESA Checklist. Quantitative data included Hgb levels, ESA dosages, and the number and types of referrals made during the intervention period.

Descriptive statistics were used to summarize baseline demographic and clinical characteristics of the patient population, including age, sex, dialysis vintage, baseline Hgb levels, and baseline ESA dosages. Monthly mean Hgb levels and weekly ESA dosages were calculated for the three-month pre-intervention period and during the two-month intervention period.

To evaluate the effectiveness of the checklist intervention, pre- and post-intervention comparisons of Hgb levels and ESA dosages were conducted using paired t-tests, appropriate for analyzing differences in continuous variables within the same group over time. A significance level of $p < 0.05$ was set a priori for all statistical tests.

Referral data were analyzed descriptively. The number of referrals initiated, the reason for referral (e.g., inflammation, nutritional deficits, elevated parathyroid hormone levels), and the referral destination (e.g., renal dietitian, primary care provider, nephrologist) were tallied. These outcomes provided insight into changes in anemia management practices prompted by the checklist.

Graphical representations, including line graphs and bar charts, were developed to visualize trends in Hgb values, ESA dosage adjustments, and referral activity over the course of the intervention. All analyses and figures were generated using Microsoft Excel and cross-checked manually to ensure data integrity.

This multi-level analysis strategy allowed for evaluation of both clinical outcomes (Hgb improvement, ESA dosage efficiency) and process outcomes (increased systematic referrals), providing a comprehensive assessment of the impact of the Supplemental Hyporesponse to ESA Checklist on anemia management practices.

Resources and Budget Considerations

This project was conducted with minimal resource requirements and no formal project budget. Implementation and data collection utilized existing clinical infrastructure, including the EMR system, laboratory reporting systems, and medication administration records, all of which were routinely accessible to anemia management staff as part of standard clinical operations. No additional staffing, equipment, or software beyond what was already available at the sites was required to support the intervention or data analysis. The only notable cost associated with the project was the investigator's personal expense related to travel between participating dialysis clinics located in the state. Fuel costs were incurred to facilitate face-to-face meetings with anemia managers, deliver checklist education sessions, and conduct periodic site visits for project oversight. These costs were not reimbursed and were considered minimal.

Overall, the project was cost-efficient, utilizing existing systems, staff, and workflows to achieve its objectives without requiring additional financial investment from the clinical sites or external funding sources.

Project Timeline

The project followed a structured, phased timeline spanning proposal development, implementation, and dissemination. A detailed overview can be found in Table 1.

Table 1

Project Timeline

Component	Projected Completion Date
Project Proposal Presentation	November 2024
Institutional Review Board Approval	December 2024
Recruitment	January 2025
Delivery of Educational Sessions	January 2025
Data Analysis	February 2025
Write-up of results and discussions	March - April 2025
Final Project Presentation	May 2025

Summary

This chapter outlined the methodology used to implement and evaluate the Supplemental Hyporesponse to ESA Checklist intervention for anemia management in hemodialysis patients. The project was conducted across three dialysis clinics in Hawaii, utilizing a pre- and post-intervention design. Patient demographic and clinical data were collected through retrospective and prospective review of clinical information systems, supplemented by data gathered from the checklist tool and pre- and post-intervention surveys administered to anemia managers. Education of the anemia management team preceded the intervention, ensuring familiarity with the checklist and supporting its integration into clinical practice. Monthly data collection aligned with routine laboratory draws, allowing systematic tracking of Hgb levels, ESA dosing patterns, and referral actions throughout the project period. The structured approach to data collection and

the targeted use of the ADKAR change management model provided a framework for promoting sustainable practice change and evaluating the impact of the intervention.

Chapter 4

Results

Introduction

The project was implemented over 10 weeks with the intervention implementation over 8 weeks. The checklist was designed to enhance anemia management by guiding the anemia manager team through a more individualized approach that addressed underlying factors contributing to ESA hyporesponsiveness. The findings are organized in alignment with the project's question: In patients on hemodialysis, what is the impact of implementing the Supplemental Hyporesponse to ESA Checklist for anemia managers compared to using the standard anemia management protocol on anemia in 8–10 weeks?

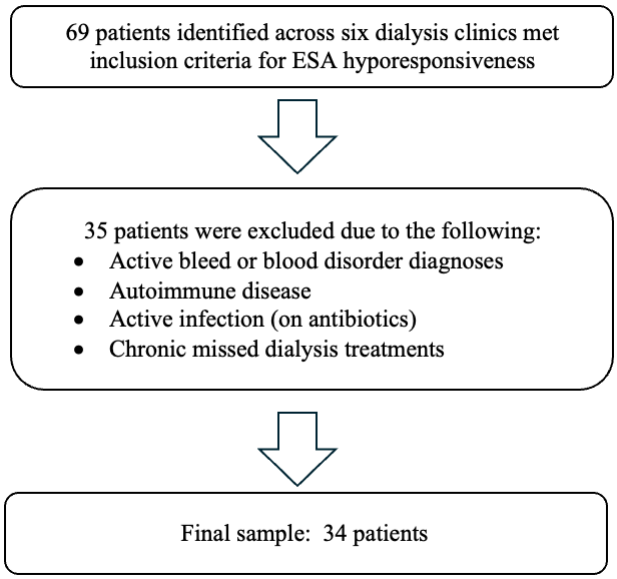
Primary outcomes of the checklist implementation included changes in Hgb levels and ESA dosage. Secondary outcomes of implementation included the number of referrals made to other specialists (e.g., dietitians, social workers, physicians) and anemia manager perceptions of the checklist's usability.

Demographics

A total of 69 patients across six dialysis clinics were initially identified as meeting the inclusion criteria of ESA hyporesponsiveness, defined as having a Hgb level less than 9.5 g/dL for three or more consecutive months or a hemoglobin level of 9.5–9.9 g/dL while receiving more than 30,000 units of ESA weekly. After applying exclusion criteria—known history of bleeding or blood disorders, autoimmune diagnoses, active infection with antibiotic use, and chronic missed dialysis treatments—35 patients were excluded. The final sample included 34 patients. (Figure 2)

Figure 2

Participant Flow Diagram



Demographically, the sample consisted of adult patients receiving hemodialysis three times weekly. The average age of participants was 64 years, with 63% identifying as male and 37% as female. Common comorbidities included hypertension, diabetes, and cardiovascular disease (as documented in medical records).

The anemia manager team consisted of three nurse practitioners and three hemodialysis nurses, all of whom received training on the use of the Supplemental Hyporesponse to ESA Checklist during week one of implementation. A pre and post-intervention survey was administered to assess baseline knowledge and current practices related to ESA hyporesponsiveness. The subsequent sections of this chapter will provide details on the participant sample, data analysis procedures, and the results observed. Findings including unexpected outcomes will be presented.

Findings

Data Analysis Procedures

The implementation plan was largely followed as written; however, a minor modification was necessary. Additional education on the clinic's reporting system and data filtering process was incorporated to ensure the anemia manager team were equipped to extract and apply relevant patient data effectively throughout the project.

Quantitative data were collected from patients' electronic medical records before and after the implementation of the Supplemental Hyporesponse to ESA Checklist. The primary outcomes analyzed were Hgb levels and ESA dosing. Descriptive statistics were first used to summarize the pre- and post-intervention data, including mean Hgb levels. To evaluate whether the changes in Hgb levels were statistically significant, a paired t-test was performed comparing the pre- and post-intervention means.

Findings: Changes in Hemoglobin Levels

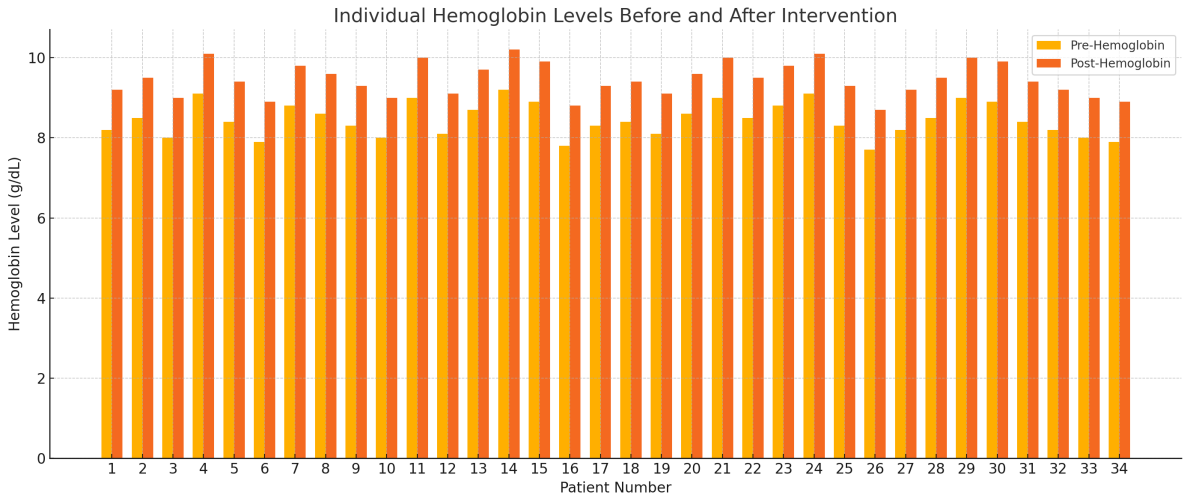
The implementation of the Supplemental Hyporesponse to ESA Checklist was associated with a notable improvement in anemia management. Patients' Hgb levels were assessed at two time points: pre-intervention and post-intervention. In select cases, Hgb was also evaluated a third time to ensure accuracy, but the primary analysis was based on two standardized data points for all 34 patients.

The mean Hgb increased from 8.5 g/dL to 9.9 g/dL post-intervention. This shift represents a mean increase of 1.38 g/dL, with a 95% confidence interval [1.09, 1.66], and a p-value $< .001$, indicating statistical significance.

The change in individual participant hemoglobin levels can be seen in Figure 3.

Figure 3

Individual Hemoglobin Levels Before and After Intervention for 34 Patients

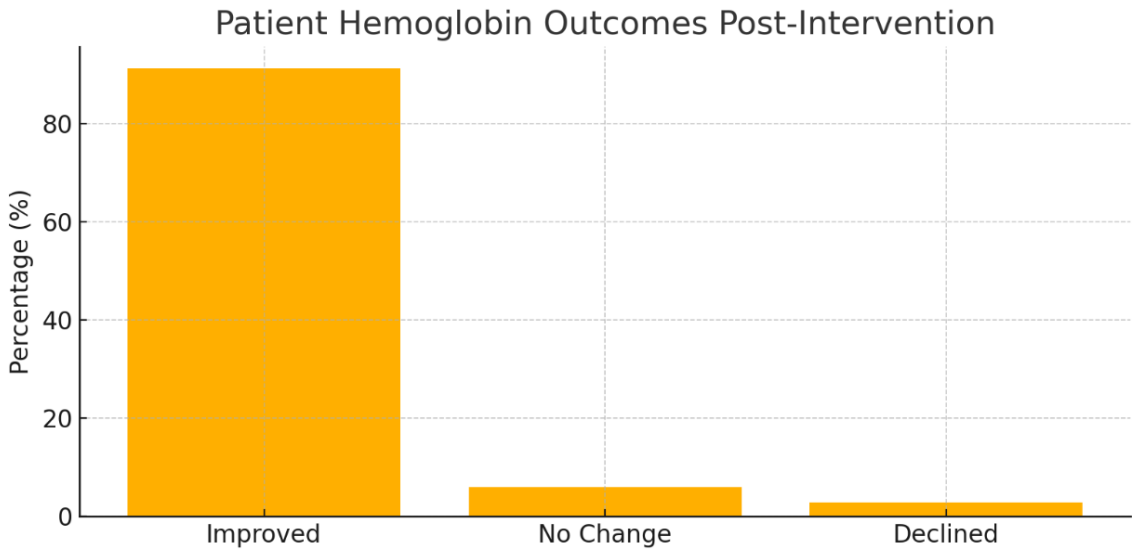


Note: *Individual hemoglobin levels before and after implementation of the Supplemental Hyporesponse to ESA Checklist.*

Individual Patient Outcomes:

Figure 4

Hemoglobin Outcomes Following Intervention



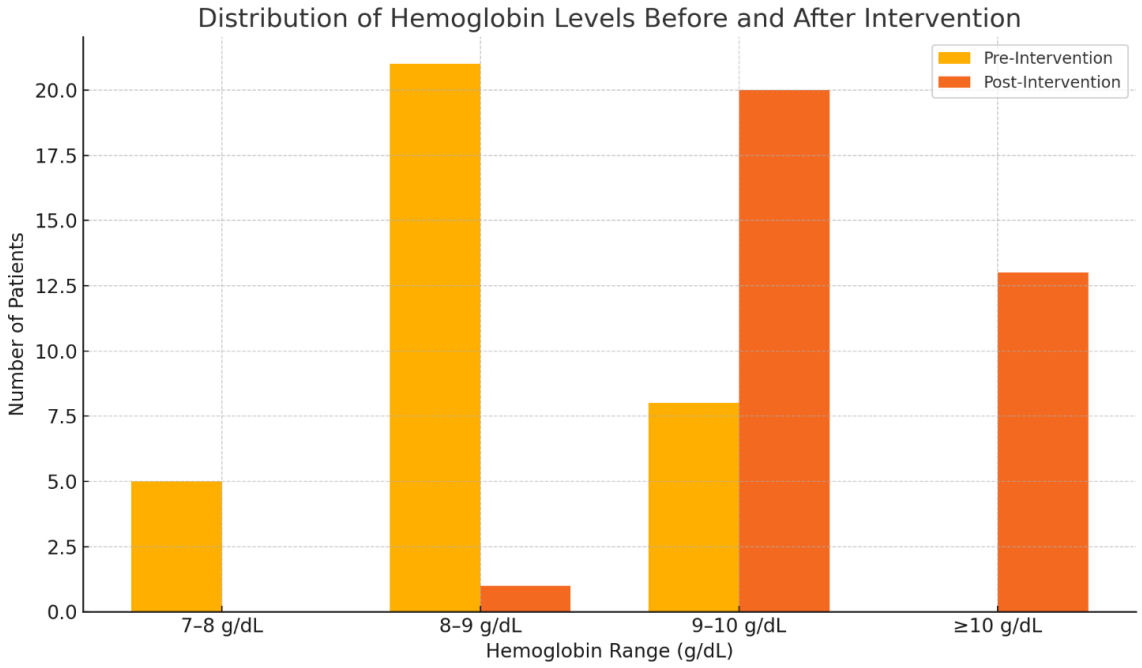
Note: *Patient hemoglobin outcomes after implementation of the Supplemental Hyporesponse to ESA Checklist.*

These results demonstrate that the majority of patients (over 90%) individually benefited from the intervention, which strongly supports the use of the checklist as a standardized practice rather than relying solely on the standard anemia management algorithm. (Figure 4). The widespread improvement makes the case for systemic adoption across clinics, particularly when viewed through the lens of quality improvement and cost containment.

Prior to the intervention, the majority of patients (26 out of 34) had Hgb values below 9 g/dL, with 5 patients falling into the 7–8 g/dL category. Post-intervention, the distribution shifted dramatically. (Figure 5).

Figure 5

Distribution of Hemoglobin Levels Before and After Intervention



Note: *Distribution of hemoglobin levels before and after implementation of the Supplemental Hyporesponse to ESA Checklist.*

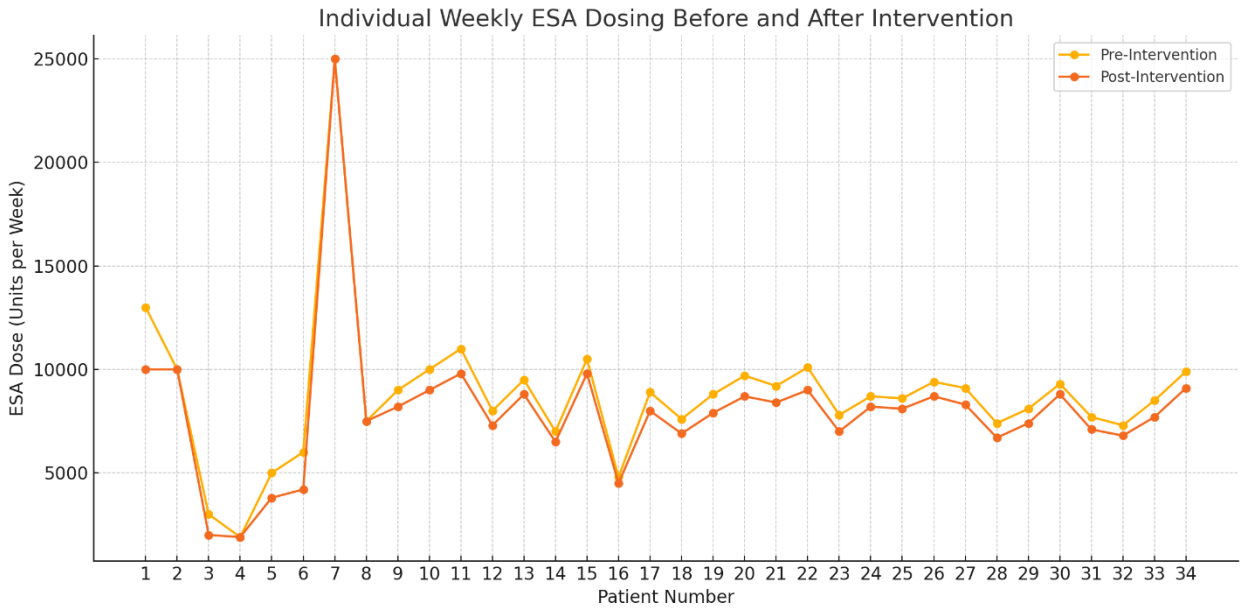
This shift reflects both a clinical and statistical improvement in anemia status and supports the checklist's effectiveness in targeting ESA hyporesponsiveness.

Finding: Changes in Erythropoietin Stimulating Agent Dosing

In addition to improvements in Hgb levels, the Supplemental Hyporesponse to ESA Checklist was associated with more efficient and targeted use of ESAs. ESA dosing was assessed at baseline (pre-intervention) and at the conclusion of the 8–10-week implementation period (post-intervention). (Figure 6). Doses were recorded in units administered three times per week, consistent with standard hemodialysis treatment schedules. The mean weekly ESA dose decreased from 7,500 units to 6,300 units, reflecting a mean reduction of 1,132 units. A paired t-test revealed a statistically significant decrease in ESA usage, with a t-statistic of 3.07 and a p-value = 0.0042. The 95% confidence interval for the mean difference was [-1882.16, -382.55], indicating that the reduction in dosing was not due to chance.

Figure 6

Individual Weekly ESA Dosing Before and After Intervention



***Note**: Individual participant ESA dosing pre and post implementation of the Supplemental Hyporesponse to ESA Checklist.*

Individual Patient Outcomes:

- 52.9% (n = 18) of patients had a decrease in ESA dosage
- 44.1% (n = 15) had no change
- 2.9% (n = 1) had an increase

This distribution highlights that the intervention led to more judicious ESA use in over half the patients, without a need for dosage escalation in nearly all cases.

Finding: Checklist-Driven Referrals and Clinical Findings

A pre-intervention survey was completed by six anemia managers, comprising three APRNs and three RNs, to evaluate referral practices over the past year for common contributors to ESA hyporesponsiveness. The data revealed that all respondents, regardless of role, reported making referrals related to elevated parathyroid hormone levels (PTH > 600 pg/mL), and active bleeding. However, although all APRNs reported making referrals for elevated PTH, only two included specific instructions linking PTH to anemia and the need for mineral bone disease management. None of the participants—APRNs or RNs—reported ordering or referring for C-reactive protein (CRP) testing related to anemia management, despite its known association with inflammation and ESA hyporesponsiveness. Additionally, only APRNs indicated referring patients with menorrhagia to OB/GYN providers, while RNs did not report making such referrals. These findings highlighted inconsistency in clinical evaluation strategies and supported the need for a supplemental checklist to support the current standard process and to promote consistent, comprehensive anemia management.

The use of the Hyporesponse to ESA Checklist prompted additional assessments and the following referrals (Table 1) that may have contributed to improved anemia management.

Table 1

Clinical Issues Identified and Corresponding Actions Taken (N = 34)

Clinical Issue	Action Taken	Number of Patient Referrals
iPTH > 600	Referral to renal dietitian for education on anemia and mineral metabolism	11
Inflammation: Elevated CRP (>10)	Referral to primary care provider	11
Acute Bleeding	New bleed reported (3 vascular access, 2 gastrointestinal)	5
Menorrhagia	OB/GYN referral for heavy menstruation	3

Note. *iPTH = intact parathyroid hormone; CRP = C-reactive protein; GI = gastrointestinal. Referrals were made based on checklist criteria during the intervention period.*

These referrals led to the identification of contributing factors such as inflammation, mineral metabolism issues, and bleeding that may have previously gone unaddressed in standard ESA management.

Findings Anemia Manager Team Feedback (Qualitative Results)

All six anemia managers completed a post-intervention survey to provide feedback on the usability, feasibility, and overall perception of the Supplemental Hyporesponse to ESA Checklist. Qualitative responses were analyzed using open coding, and three major themes emerged: practical utility, workflow integration challenges, and preference for individualized tools.

Theme 1: Practical Utility

Four anemia managers expressed a willingness to continue using the checklist in its current form, noting that it supported a more comprehensive and organized approach to assessing ESA hyporesponsiveness. One RN commented, *"I found the checklist helpful to guide our focus on specific causes of hyporesponsiveness."* Managers shared that the tool encouraged them to

review patient factors beyond laboratory results, including underlying issues such as heavy menstrual bleeding and mineral metabolism disturbances. Several noted that the checklist served as a reminder to consider multifactorial causes and prompted timely referrals when additional evaluation was warranted.

Theme 2: Workflow Integration Challenges

Despite recognizing its usefulness, all six participants reported challenges incorporating the paper checklist into their workflow. One anemia manager stated, *"We need this in electronic format; it's too hard to track manually."* The feedback emphasized that current workloads are demanding, and unless a tool is seamlessly integrated into the existing electronic systems, it is unlikely to be used consistently. Many participants expressed that they would be more inclined to use the checklist if it were embedded within the electronic health record (EHR) or an existing documentation platform. The suggestion to automate portions of the tool or have it link to lab results was also mentioned as a potential solution to reduce redundancy and improve usability.

Theme 3: Preference for Individualized Tools

Two anemia managers indicated they would not continue using the checklist as written, explaining that they already had personalized systems in place for managing anemia during clinical rounds. One APRN shared, *"I already have my own system during rounding,"* while another recommended shortening the checklist to make it easier to reference. These comments reflect a desire for tools that are adaptable to individual practice styles and workflows, particularly for experienced clinicians who have already developed effective processes.

In summary, the qualitative feedback from anemia managers demonstrated that while the checklist was generally well received and considered clinically relevant, its format and integration posed barriers to consistent use. Most managers agreed that digital access and

customization would enhance adoption and long-term sustainability, particularly in busy dialysis environments.

Summary

The results of this project demonstrated the positive impact of implementing the Supplemental Hyporesponse to ESA Checklist across three dialysis clinics. The intervention led to an increase in mean Hgb levels from 8.5 g/dL to 9.9 g/dL and a reduction in mean ESA doses from 7,500 to 6,300 units. The implementation of the checklist enhanced clinical decision-making by prompting timely and targeted referrals, supporting a more comprehensive evaluation of contributing factors to ESA hyporesponsiveness. Survey feedback from six anemia managers showed general support for the tool, especially in an electronic format, with four willing to continue using the current version. These findings demonstrate that the checklist improved clinical evaluation and guided appropriate interventions for ESA hyporesponsiveness.

Chapter 5

Discussion

Introduction

The purpose of this quality improvement project was to implement and evaluate the effectiveness of the Supplemental Hyporesponse to ESA Checklist in identifying and addressing the underlying causes of ESA hyporesponsiveness in adult hemodialysis patients across several outpatient clinics in Hawaii. The primary goal was to improve anemia outcomes through increased Hgb levels, appropriate ESA dose adjustments, and enhanced referrals for additional medical evaluation.

The findings generally supported the intended outcomes. Post-implementation data revealed modest but clinically relevant improvements in Hgb levels for most patients, appropriate reductions in ESA dosages, and increased documentation of referrals related to mineral bone management, inflammation, addressing vascular access and/or acute bleeds including menorrhagia in menstruating women. Although variations existed among clinics in checklist adoption and patient outcomes, the overall results indicated that the checklist served as a beneficial tool for structured anemia management.

Implications of Findings

The findings of this project aligned with the PICOT question, which posited that in hemodialysis patients the implementation of the Supplemental Hyporesponse to ESA Checklist by the anemia manager team would lead to improvements in anemia management.

The implementation of this project was guided by the Prosci ADKAR Change Management Model, which provided a structured, outcome-oriented framework for facilitating individual and organizational change. Each component of the ADKAR model was intentionally

integrated into the project to facilitate successful change. Awareness was created by presenting local data that highlighted the prevalence and clinical consequences of ESA hyporesponsiveness in the participating clinics. Desire was fostered through discussions emphasizing the potential for improved patient care, reduced ESA costs, and enhanced clinical decision-making. Knowledge was imparted via structured educational sessions that explained the checklist's purpose, interpretation, and actionable steps. Ability was demonstrated as staff members independently used the checklist during monthly anemia reviews, with support provided as needed. Finally, reinforcement was achieved through verbal encouragement, leadership support, and ongoing follow-up communications that acknowledged and reinforced the impact of using the checklist.

The intervention improved clinical decision-making regarding ESA adjustments and contributed to more comprehensive anemia evaluations. These improvements were particularly evident in patients with previously undocumented or unmanaged factors contributing to hyporesponsiveness.

The findings of this project are consistent with existing literature that emphasizes a multifactorial and structured approach to ESA hyporesponsiveness. KDIGO (2021) guidelines, for example, advocate for systematic evaluation of contributing factors such as inflammation, malnutrition, and secondary hyperparathyroidism, all of which were included in the checklist tool. By prompting clinicians to consider these factors routinely, the checklist helped operationalize guideline-recommended practices.

Similarly, structured anemia management tools have been shown to enhance Hgb stability and promote more judicious ESA use, as evidenced by findings from Ross et al. (2020) and George and McCann (2020).

Although the current project did not use advanced electronic decision support systems, the low-tech checklist achieved comparable provider engagement and care improvements, suggesting that meaningful change is possible even in resource-limited settings. Furthermore, findings align with research by Gauthier-Loiselle et al. (2021), which highlighted the economic burden of ESA administration. By facilitating more targeted ESA use, the checklist has the potential to reduce costs, aligning with broader health policy goals promoted by the CMS ESRD Quality Incentive Program (2022).

However, the project did not directly assess cardiovascular outcomes associated with ESA use—a limitation in contrast to studies like Karimi et al. (2023), which emphasize cardiovascular risk as a key consideration. Additionally, unlike Bossola et al. (2020), who explored patient-reported fatigue, this project focused solely on clinical process improvements without integrating patient-centered outcomes, representing a gap in evaluation.

Limitations

Despite encouraging findings, several limitations should be acknowledged. The short implementation period of 10 weeks limited the ability to assess longer-term outcomes and the sustainability of the intervention. The small sample size and limited geographic scope—restricted to three clinics in Oahu—reduce the generalizability of the findings. Inconsistent checklist usage across sites may have affected the uniformity of the intervention, and variability in documentation could have impacted the accuracy of recorded referrals and ESA dosage adjustments. Additionally, iron management practices were not included, limiting the intervention's full effectiveness. Nevertheless, the project demonstrated the feasibility and practical utility of incorporating an evidence-based tool within a real-world, resource-limited clinical setting.

Recommendations for Implementation

The successful implementation of the Supplemental Hyporesponse to ESA Checklist in this project highlights the importance of structured, sustainable strategies to support its continued use across dialysis clinics. Guided by the Johns Hopkins Evidence-Based Practice (JHEBP) model, the following recommendations consider financial implications, barriers to implementation, and supportive facilitators that can enhance adoption. This framework ensures that the checklist is not only introduced effectively but also maintained as a standard practice for improving anemia management in ESA-hyporesponsive hemodialysis patients.

Cost-Benefit Analysis

The checklist is a cost-effective tool that requires minimal training and physical resources, making it a feasible intervention even in clinics with limited budgets. By supporting more individualized and accurate anemia management, the checklist has the potential to reduce high ESA dosing, lower the frequency of blood transfusions, and minimize hospital admissions caused by unmanaged anemia complications. These clinical improvements contribute to long-term financial savings for both dialysis providers and healthcare systems. Additionally, earlier identification of reversible causes of ESA hyporesponsiveness may prevent prolonged treatment with ineffective dosing strategies, thereby improving efficiency. Implementation of the checklist also supports performance metrics linked to reimbursement under the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), making it valuable not only for clinical outcomes but also for regulatory and financial alignment.

Potential Barriers

Despite its advantages, several barriers may hinder the consistent and widespread use of the checklist. Time constraints are a significant concern, particularly for staff already managing high patient loads and complex care routines. Competing clinical priorities may result in inconsistent use or incomplete checklist application. Additionally, the perception that the checklist adds to documentation burden—especially in the absence of direct incentives—may reduce motivation among providers. Another concern is the variability in provider engagement, which may lead to inconsistent follow-through after the checklist is completed. Without strong accountability measures, the intended benefits of the checklist may not be fully realized. These challenges highlight the need for leadership-driven solutions that prioritize integration into workflow and address staff concerns through education and reinforcement.

Key Facilitators

Several factors were identified that facilitated the effective use of the checklist during implementation. Leadership support, particularly from nephrologists, nurse practitioners, and clinic administrators, played a key role in promoting adoption. Their endorsement helped align the checklist with broader clinical goals and encouraged staff participation. Regular staff education, along with opportunities for feedback and discussion, helped clarify the purpose and benefits of the tool. Embedding the checklist into existing workflows, such as monthly anemia management meetings, ensured minimal disruption and promoted routine use. To further enhance sustainability, the checklist should be integrated into the EHR system to streamline access and documentation. Assigning “checklist champions” at each clinic site is also recommended; these individuals can serve as peer leaders who support colleagues, reinforce checklist usage, and advocate for its continued use as a quality improvement measure. Together,

these facilitators form the foundation for a scalable and enduring intervention that aligns with evidence-based, patient-centered care.

Recommendations for Future Practice, Education, Policy, and Research Practice

Based on the outcomes of this quality improvement initiative, several recommendations can be made to guide future efforts in practice, education, policy, and research.

Practice

From a clinical practice perspective, it is recommended that the Supplemental Hyporesponse to ESA Checklist be standardized for all patients identified as hyporesponsive to ESAs. Routine use of the checklist can ensure that all potential contributing factors to ESA hyporesponsiveness are systematically assessed and addressed in a timely and consistent manner. To further support this effort, clinics should consider implementing regular interdisciplinary team huddles dedicated to reviewing checklist findings and collaboratively determining the most appropriate next steps in patient care. Additionally, integrating checklist data into multidisciplinary rounds or formal care planning meetings can enhance communication across providers, promote coordinated interventions, and improve the continuity and quality of care.

Education

There is a strong need for the development of comprehensive training modules focused on anemia management, with a particular emphasis on incorporating the checklist into clinical decision-making. These modules should include case-based learning scenarios to enhance critical thinking and real-world application and should be embedded into both annual competency reviews and new hire orientation programs for nurses, nurse practitioners, and physicians. Such ongoing education can help to reinforce evidence-based practices, improve consistency in

anemia management, enhance documentation accuracy, and increase provider confidence in addressing complex anemia cases

Policy

There is an opportunity to advocate for the adoption of formal regional or institutional policies that support the use of structured, evidence-based tools such as this checklist. Embedding the checklist within institutional quality assurance initiatives and patient safety protocols can reduce clinical variability, improve standardization of care, and support consistent practices across dialysis centers. Making the checklist utilization a component of official policy can also improve accountability among staff and serve as a measurable performance metric for quality improvement initiatives.

Research

Further investigation is warranted to evaluate the broader impact and scalability of this intervention. Expanding the project to include iron studies, a more diverse patient population, as well as dialysis clinics across varying geographic and organizational contexts, would help determine the generalizability of the findings. Longitudinal studies should be designed to examine key outcomes such as hospitalization rates, Hgb stability, ESA dose reduction, cost savings, and patient-reported quality of life, providing a more comprehensive understanding of the checklist's long-term value. Furthermore, exploring the transition of the checklist from a paper-based tool to an electronic format—potentially integrated into an existing clinical decision support system—would offer insights into its impact on workflow efficiency, provider adoption, and overall clinical effectiveness in a technology-driven healthcare environment.

Summary

This QI project successfully demonstrated that implementation of the Supplemental Hyporesponse to ESA Checklist improved the evaluation and management of ESA hyporesponsiveness among hemodialysis patients. It underscored the power of simple, structured tools to drive quality improvement in complex care settings. By promoting a culture of inquiry and accountability, the checklist served as a catalyst for sustained change and better patient outcomes in anemia management.

Through the lens of the Prosci ADKAR Model, the project fostered behavior change at the individual and organizational level, creating awareness, building desire and knowledge, enabling ability, and reinforcing change through education and leadership support.

Although the project had limitations in duration and scale, the intervention proved to be a low-cost, high-impact tool that enhanced clinical decision-making and improved key anemia management metrics.

Dissemination will occur through small-scale strategies to ensure that the results reach the appropriate stakeholders and contribute to practice improvement. The plan is to conduct presentations for key stakeholders, including anemia managers, nephrologists, nurses, and clinic staff. These sessions will be delivered in both small group formats and webinars to facilitate open dialogue on the project's outcomes and clinical implications. To support knowledge retention and accessibility, a concise one-page summary report will be developed, highlighting the intervention's key findings, recommendations, and impact. This report will be distributed to clinic personnel and administrators. Additionally, a section in the clinic's internal newsletter will reinforce the findings and maintain communication with staff. In-service training workshops may also be organized to provide opportunities for staff to explore the results in greater depth and discuss practical applications to enhance patient outcomes.

Beyond the clinic, the aim is to extend the project's reach by sharing results at local healthcare conferences and submitting findings to peer-reviewed journals focused on nephrology and nursing. A project poster detailing the objectives, methods, results, and implications has been prepared for display in clinical settings and professional events. To further promote collaborative reflection and strategic planning, feedback meetings will take place with clinic administrators and stakeholders to review outcomes and consider steps for sustaining or expanding the intervention. These dissemination strategies are intended to ensure broad awareness of the project, encourage adoption of best practices, and ultimately improve anemia management for hemodialysis patients experiencing ESA hyporesponsiveness.

This project aligns with the American Association of Colleges of Nursing (AACN) Doctor of Nursing Practice (DNP) Essentials by demonstrating the integration of scientific knowledge, systems leadership, and evidence-based practice to improve clinical outcomes in a vulnerable population. Through the implementation of the Supplemental Hyporesponse to ESA Checklist, the project exemplifies advanced nursing competencies in quality improvement, interprofessional collaboration, and population health. The alignment with each of the DNP Essentials is detailed in Appendix D

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Ross, E. A., Paugh, M. J. L., Wen, X., & Nappo, R. W. (2020). Use of the ESA resistance index to guide dosing for anaemia management. *Journal of Renal Care, 46*(4), 216–221. https://doi.org/10.1111/jorc.12324

Shah, H. H., Uppal, N. N., & Fishbane, S. (2020). Inflammation and erythropoiesis-stimulating agent hyporesponsiveness: A critical connection. *Kidney Medicine, 2*(3), 245–247. https://doi.org/10.1016/j.xkme.2020.05.001

U.S. Renal Data System [USRDS]. (2020). *2020 USRDS annual data report: Epidemiology of kidney disease in the United States.* https://adr.usrds.org/2020

Weir, M. R. (2021). Managing anemia across the stages of kidney disease in those hyporesponsive to erythropoiesis-stimulating agents. *American Journal of Nephrology, 52*(6), 450–466. https://doi.org/10.1159/000516901

Wills, C. A., & Carrioc, C. (2022). Use of an RN-initiated protocol for recognition, management, and documentation of intradialytic hypotension in patients with end-stage kidney disease on in-center hemodialysis: A quality improvement project. *Nephrology Nursing Journal, 49*(6), 495. https://doi.org/10.37526/1526-744x.2022.49.6.495

Yasin, A., & Omran, N. (2023). Hyporesponsiveness to erythropoietin-stimulating agents: Possible solutions. https://doi.org/10.5772/intechopen.109988

Appendix A

Supplemental Hyporespone to ESA Checklist

DNP Project – Charla Naone, RN, BSN, DNP Student

Inclusion Criteria

- Hemoglobin < 9.5g/dL for 3 months or more
- Hemoglobin 9.5-9.9 g/dL on ESA > 30,000 units per week

Exclusion Criteria

- Hemoglobin > 9.5 g/dL on ESA < 10,000 units IV with HD 3 times per week
- Known acute bleed, post-surgery
- Known chronic inflammation disorder including auto immune disease
- Active infection and on antibiotics
- Chronic non-compliance to hemodialysis

Iron Deficiency - Iron management should be addressed separately with standard protocol.

Supplemental Hyporesponse to ESA Checklist

Once you have a list of the patients who meet the above criteria, you may utilize the checklist to address causative factors, then determine the plan of action and/or initiate internal or external referrals.

1. Hyperparathyroidism
    - If iPTH is > 600
        - ☐ Refer to Renal Dietician for management
        - ☐ If long-standing (> 1000 for more than 6 months), confirm documentation on education and request from MD/NP to refer for parathyroidectomy
2. Chronic Inflammation or Infection
    - C-Reactive Protein level
        - ☐ If > 10 refer to PCP
3. Acute Bleed Assessment
    - Review vascular access history
    - Assess patient for vascular access bleeding
        - If patient reports post dialysis access bleeding
            - ☐ Refer to vascular surgeon
    - Assess patient for blood in stool (FOBT)
        - ☐ If positive, refer to PCP
    - Female patients – Assess for menorrhagia
        - ☐ Request MD/NP to refer to women's health provider (OB/GYN)

Referrals Made:

- ☐ RD
- ☐ PCP for elevated CRP
- ☐ PCP for positive FOBT
- ☐ Vascular Surgeon - AVF/AVG bleed
- ☐ OB/GYN - menorrhagia

Appendix B

Evidence Table Synthesis of the Literature

Article Number	Author, Date, and Title	Population, size, and setting	Intervention	Findings that help answer the EBP question	Measures used	Limitations	Evidence level & quality
1	Bae, S. Y., Jeon, J. W., Kim, S. H., Baek, C. H., Jang, J. W., Yang, W. S., Kim, S. B., Park, S.-K., Lee, S. K., & Kim, H.. (2019). Usefulness of mid-week hemoglobin measurement for anemia management in patients undergoing hemodialysis: a retrospective cohort study. *BMC Nephrology*, *20*(1). https://doi.org/10.1186/s12882-019-1492-x	234 adult hemodialysis patients; hospital-based HD center in South Korea	Compared hemoglobin values obtained mid-week vs. early-week to determine optimal timing for anemia management	Mid-week hemoglobin measurements provided more stable and reliable values, aiding in better ESA titration and anemia control	Hemoglobin levels, ESA dose	Regional population; observational design; potential measurement variability	Level III, Quality B Retrospective cohort study
2	Bossola, M., Di Stasio, E., Monteburini, T., Antocicco, M., & Tazza, L. (2020). Intensity, duration, and frequency of post-dialysis fatigue in patients on chronic haemodialysis. *Journal of Renal Care, 46*(2), 115–123. https://doi.org/10.1111/jorc.12314	100 chronic HD patients; single dialysis unit in Italy	No intervention; study aimed to describe fatigue after dialysis and its characteristic	Post-dialysis fatigue was prevalent, impacting recovery time and quality of life; anemia is a potential contributing factor to post-dialysis fatigue	Self-reported questionnaires (fatigue intensity, frequency, duration); hemoglobin levels were considered	Single-center design; subjective reporting; no control group	Level III, Quality B Quantitative cross-sectional observational study
3	Cizman, B., et al. (2020). Clinical and economic outcomes of erythropoiesis-stimulating agent hyporesponsiveness in the post-bundling era. *Kidney Medicine, 2*(5), 589–599.e1. https://doi.org/10.1016/j.xkme.2020.06.008	Hemodialysis patients in the United States	Analysis of outcomes associated with ESA hyporesponsiveness	ESA hyporesponsiveness associated with higher mortality, cardiovascular events, and healthcare costs	Mortality rates, hospitalization rates, healthcare costs	Observational design; potential confounding factors	Level III, Quality B Retrospective cohort study
4	Gauthier-Loiselle, M., Michalopoulos, S. N., Cloutier, M., Serra, E., Bungay, R., Szabo, E., & Guérin, A. (2021). Costs associated with the administration of erythropoiesis-stimulating agents for the treatment of anemia in patients with non-dialysis-dependent chronic kidney disease: a US societal perspective. *Journal of*	Non-dialysis CKD patients in the U.S. health system; modeling based on claims and registry data	Analysis of cost associated with different ESA formulations and administration settings	ESA administration (especially via IV in clinical settings) significantly increased healthcare costs; findings support need for	Cost per administration, ESA type, total treatment cost	Non-clinical data; extrapolated outcomes; may not directly apply to HD patients	Level IV, Quality B Economic evaluation / cost analysis

	Managed Care & Specialty Pharmacy, 27(12), 1703–1713. https://doi.org/10.18553/jmcp.2021.27.12.1703			more efficient and targeted ESA use			
	George, C., & McCann, M. (2020). Evaluation of a nurse prescriber-led anemia management protocol in hemodialysis patients. British Journal of Nursing, 29(17), S10–S17. https://doi.org/10.12968/bjon.2020.29.17.S10	Adult hemodialysis patients in a single outpatient dialysis clinic in the UK; approximately 80 patients evaluated pre- and post-protocol	Implementation of a nurse prescriber-led anemia management protocol, including ESA and iron therapy oversight	No statistically significant changes in hemoglobin or ESA dosing post-implementation; however, improvements in ferritin and transferrin saturation levels were observed, indicating enhanced iron management.	Hemoglobin (g/dL), ESA dosage (units/week), serum ferritin (ng/mL), transferrin saturation (TSAT, %)	Small sample size; single-site design; no control group; short follow-up period	Level III, Quality B Quantitative comparative study (pre/post design)
	Hamad, A., Ezzat, H., Latif Ghonimi, T. A., Ibrahim, R., Ramadan, F., Noor, N., Yasin, F., Ismail, S., & Al-Ali, F. (2021). Effects of novel anemia nurse manager program on hemodialysis: a retrospective study from Qatar. *Qatar medical journal*, *2021*(3), 46. https://doi.org/10.5339/qmj.2021.46	Sample Size = 645 Setting = Ambulatory dialysis centers in Qatar	The study was conducted to describe the effects of the anemia nurse manager (ANM) model on the hemoglobin level of patients on hemodialysis living in the State of Qatar	A comparison of the entire HD population revealed a remarkable increase in the percentage of patients within the target Hb level (10–12 g/dL) from June 2015 (56%) to July 2018 (71%) ($p < 0.001$).	The researchers measured hemoglobin in patients on hemodialysis.	This retrospective cohort study used limited data and analysis (although most of the data were available in the electronic medical record; nationwide for the study duration). In addition, the comparison of anemia outcomes with baseline values has included some but not all the confounding factors that affect these values.	Level III, Quality B Retrospective longitudinal epidemiologic study
	Himmelfarb, J., Vanholder, R., Mehrotra, R., & Tonelli, M. (2020). The current and future landscape of dialysis. *Nature Reviews Nephrology, 16*(10), 573–585. https://doi.org/10.1038/s41581-020-0315-4	Global overview of dialysis practice; not population-specific	Broad review of trends and innovations in dialysis, including anemia management	Identifies ESA overuse and anemia under-treatment as global quality concerns; encourages innovations like individualized protocols and nurse-led care models	None specified – review-based	No primary data; generalized trends; limited direct application to specific interventions	Level V, Quality B Narrative review / expert opinion

	Ikizler, T. A., & Cuppari, L. (2021). The 2020 Updated KDOQI Clinical Practice Guidelines for Nutrition in Chronic Kidney Disease. *Blood Purification, 50*(4–5), 667–671. https://doi.org/10.1159/000513698	CKD patients across all stages; guidelines based on global expert consensus and systematic reviews	Provides nutritional management guidelines including anemia-related nutritional parameters (iron, B12, folate, protein-energy intake)	Supports the importance of correcting nutritional deficiencies as part of anemia management and ESA responsiveness	Ferritin, TSAT, albumin, dietary intake measures	Not a primary research study; general guidelines requiring clinical interpretation	Level IV, Quality A Clinical practice guideline
	Imaizumi, T., et al. (2025). Renal anemia and hyporesponsiveness to ESA for preservation of residual kidney function in patients undergoing peritoneal dialysis. *Scientific Reports, 15*(1), 2689. https://doi.org/10.1038/s41598-025-87456-z	1,640 peritoneal dialysis patients from the Japanese Society for Dialysis Therapy registry	Analysis of ESA resistance index (ERI) and hemoglobin levels in relation to residual urine output	Lower hemoglobin levels and higher ERI were associated with faster decline in residual kidney function; anemia management may help preserve residual kidney function	Hemoglobin, ERI, residual urine volume	Observational design; specific to peritoneal dialysis patients in Japan	Level III, Quality B Retrospective cohort study
	Karaboyas, A., Morgenstern, H., Fleischer, N. L., Vanholder, R. C., Dhalwani, N. N., Schaeffner, E., Schaubel, D. E., Akizawa, T., James, G., Sinsakul, M. V., Pisoni, R. L., & Robinson, B. M. (2020). Inflammation and Erythropoiesis-Stimulating Agent Response in Hemodialysis Patients: A Self-matched Longitudinal Study of Anemia Management in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Medicine, 2*(3), 286–296. https://doi.org/10.1016/j.xkme.2020.01.007	Over 2,000 adult HD patients from multiple countries participating in the DOPPS study	Analysis of inflammatory markers (CRP) and ESA response over time in hemodialysis patients	Elevated inflammation was consistently associated with ESA hyporesponsiveness; CRP was a strong predictor of ESA dose requirements and hemoglobin variability	C-reactive protein (CRP), ESA dose, hemoglobin level	Observational nature limits causal conclusions; variability in inflammation markers over time	Level II, Quality A Longitudinal observational study (self-matched cohort)
	Karimi, Z., Shahraki, H. R., & Mohammadian-Hafshejani, A. (2023). Erythropoiesis-stimulating agents and cardiovascular mortality: A systematic review and meta-analysis of 17 studies and 372,156 hemodialysis patients. *International Journal of Cardiology Cardiovascular Risk and Prevention*, *19*, 200220. https://doi.org/10.1016/j.ijcrp.2023.200220	372,156 adult HD patients across 17 international studies	Intervention: Use of ESAs and their relationship to cardiovascular mortality	High ESA dosing was associated with increased cardiovascular mortality; emphasizes the need for judicious dosing and individualized anemia management	Mortality rates, ESA dose, hemoglobin levels	Heterogeneity across studies; limited control over confounding variables in original research	Level I, Quality A Systematic review and meta-analysis
	KDIGO (2024). KDIGO 2025 Clinical Practice Guideline for Anemia in Chronic Kidney Disease. https://kdigo.org/wp-content/uploads/2024/11/KDIGO-2025-Anemia-in-CKD-Guideline_Public-Review-Draft_Nov42024.pdf	Global CKD population	Updated guidelines for anemia management, including recommendations for ESA	Provides updated recommendations for managing ESA hyporesponsiveness, including consideration of HIF-	Hemoglobin targets, ESA dosing strategies	Guidelines based on current evidence; may evolve with new research	Level I, Quality A Clinical practice guideline

			hyporesponsiveness and use of hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs)	PHIs after addressing underlying causes			
	Locatelli, F., & Del Vecchio, L. (2019). Are we approaching a new era in the treatment of anemia of chronic kidney disease patients? Annals of Translational Medicine, 7(Suppl 8), S333. https://doi.org/10.21037/atm.2019.09.119	Not a primary study; discussion centers on patients with anemia in chronic kidney disease (CKD), particularly those on dialysis, in the context of emerging therapies	Overview of traditional and emerging treatments for renal anemia, focusing on the potential role of hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHIs)	Highlights the limitations of current ESA-based treatment strategies in CKD patients, especially those who are hyporesponsive. Advocates for innovative, individualized treatment strategies, including the integration of HIF-PHI agents, to address ESA resistance more physiologically	Narrative synthesis of clinical trial data and expert insights; no empirical measures presented	Editorial review format; lacks original data, control groups, or statistical analysis; recommendations are based on expert interpretation rather than direct patient outcomes	Level V, Quality C Expert opinion/editorial commentary
	Ogawa, T., & Nitta, K. (2024). Hyporesponsiveness to erythropoiesis-stimulating agents in patients with anemia of chronic kidney disease: A real-world study. *Advances in Therapy, 41*(1), 123–135. https://doi.org/10.1007/s12325-024-03015-4	85,259 CKD patients across 24 countries	Assessment of ESA hyporesponsiveness incidence using various definitions	Incidence of ESA hyporesponsiveness varied widely (5.2% to 47.9%) depending on the definition used; highlights the need for individualized assessment	ESA dosing, hemoglobin levels, definitions of hyporesponsiveness	Retrospective design; variability in definitions	Level III, Quality B Retrospective observational study
	Prosci, Inc. (2024). A goal-oriented change management model to guide individual and organizational change. https://www.prosci.com/	Not population-based; organizational and behavioral change framework	ADKAR model—Awareness, Desire, Knowledge, Ability, and Reinforcement—used to implement change among anemia managers in the DNP project	Facilitates structured staff engagement and adoption of new clinical tools like the ESA Checklist	None empirically; conceptual application in QI projects	Not specific to healthcare or anemia management; theoretical application	Level V, Quality A Theoretical framework / model description
	Ross, E. A., Paugh, M. J. L., Wen, X., & Nappo, R. W. (2020). Use of the esa resistance index to guide dosing for anaemia management. *Journal of Renal Care*, *46*(4),	50 adult hemodialysis patients; single center in the U.S. Intervention: Use of ESA resistance index	Use of ESA resistance index (ERI) to tailor anemia management	ERI-guided dosing allowed more precise ESA use and improved anemia control; patients with	ESA dose, hemoglobin level, ERI	Small sample size; single-center study; limited generalizability	Level III, Quality B Quantitative retrospective cohort study

	216–221. https://doi-org.hpu.idm.oclc.org/10.1111/jorc.12324	(ERI) to tailor anemia management and guide ESA dosing decisions	and guide ESA dosing decisions	higher ERI had poorer hemoglobin outcomes			
	Shah, H. H., Uppal, N. N., & Fishbane, S. (2020). Inflammation and Erythropoiesis-Stimulating Agent Hyporesponsiveness: A Critical Connection. *Kidney Medicine*, *2*(3), 245–247. https://doi.org/10.1016/j.xkme.2020.05.001	Not a primary research study; summary of data and clinical observations related to inflammation and ESA hyporesponsiveness in chronic kidney disease and hemodialysis patients	N/A – Discusses the pathophysiological link between chronic inflammation and ESA resistance	Highlights that inflammation is a key contributor to ESA hyporesponsiveness, suggesting the need for identifying and treating inflammatory conditions in anemic HD patients	C-reactive protein (CRP), interleukin-6, and other inflammatory biomarkers discussed in context	Not a primary research study; lacks empirical data or outcome measures from a trial or observational study	Level V, Quality C Expert opinion/editorial review
	U.S. Renal Data System [USRDS]. (2020). 2020 USRDS annual data report: Epidemiology of kidney disease in the United States. https://adr.usrds.org/2020	All U.S. patients with ESRD; national data registry	Reports trends in dialysis care including ESA use, anemia outcomes, and mortality	High rates of ESA use; persistent challenges in anemia control; rising interest in anemia management protocols	Hemoglobin levels, ESA dose, mortality, hospitalization rates	Retrospective registry data; does not assess specific interventions	Level II, Quality A National registry / epidemiological report
	Weir, M. R. (2021). Managing Anemia across the Stages of Kidney Disease in Those Hyporesponsive to Erythropoiesis-Stimulating Agents. *American Journal of Nephrology, 52*(6), 450–466. https://doi.org/10.1159/000516901	Adults with CKD and HD patients; multidisciplinary review of multiple studies	Review of anemia management strategies for ESA hyporesponsive patients across CKD stages	Emphasizes multifactorial causes of hyporesponsiveness (inflammation, iron deficiency, infection, etc.) and supports individualized protocols and diagnostic checklists	Hemoglobin, ferritin, TSAT, ESA dosage (discussed across studies)	Secondary data from various sources; not a primary study	Level V, Quality B Narrative review / clinical practice guidance
	Wills, C. A., & Carrioc, C. (2022). Use of an RN-Initiated Protocol for Recognition, Management, and Documentation of Intradialytic Hypotension in Patients with End-Stage Kidney Disease on In-Center Hemodialysis: A Quality Improvement Project. *Nephrology Nursing Journal, 49*(6), 495. https://doi.org/10.37526/1526-744x.2022.49.6.495	Adult in-center HD patients; single dialysis clinic	Implementation of an RN-initiated intradialytic hypotension (IDH) protocol	Demonstrated improved documentation and timely interventions by nurses; relevance to nurse-led protocols like ESA Checklist	Episodes of IDH, RN response time, patient stability metrics	Single-site project; outcomes may not generalize; not focused on anemia directly	Level IV, Quality B Quality improvement project

	Yasin, A., & Omran, N.. (2023). *Hyporesponsiveness to Erythropoietin-Stimulating Agents: Possible Solutions*. https://doi.org/10.5772/intechopen.109988	Not a primary research study; review of literature addressing global adult HD populations with ESA hyporesponsiveness	Synthesizes various management strategies including iron optimization, inflammation control, and addressing secondary hyperparathyroidism	Recommends a structured, individualized approach to anemia management; identifies common contributors to ESA hyporesponsiveness; advocates for nurse engagement in ESA decision-making	Not applicable – discusses hemoglobin levels, ESA dosing, TSAT, ferritin, and CRP in theoretical terms	Narrative review with no original data; evidence from secondary sources	Level V, Quality B Book chapter narrative review

Adapted from 'Johns Hopkins Nursing Evidence-Based Practice – Individual Evidence Summary Tool Appendix G by D. Dang & S.L. Dearholt. p.298

Appendix C

Appendix A

Hawai'i Pacific University
Institutional Review Board
Project Application

Please complete and submit the form to the IRB chair via email: to irbchair@hpu.edu

Study title: IMPROVING ANEMIA OUTCOMES FOR ERYTHROPOEITIN STIMULATING AGENT HYPORESPONSIVE HEMODIALYSIS PATIENTS

Investigator:

Name: Charla L.R. Naone
(Please check one)
· Faculty · X Student · Outside Investigator

Phone: 808-256-3044

Email: cnaone4@my.hpu.edu

Sponsoring HPU Faculty Member: Dr. Jacqueline Thomas, DNP, RN, CFRN

(if Investigator is not an HPU faculty member)

Please attach a brief summary of the project. This should include an explicit statement of methods, data collection, and how confidentially of subjects/data will be protected including consent form.

Category for Review:

Check one level of review (Exempt, Expedited, Full) for which you believe the project qualifies, and each criterion that your project meets.

____ **Exempt from review (nil or minimal risk study, or already reviewed by an IRB)**

____ Research involves ONLY investigation into or comparison of normal instructional strategies.

____ Tests, interviews, and surveys are unlikely to elicit emotion or place subjects at risk of civil/criminal liability or damage to their reputation, financial standing, employability, etc. AND information will not be recorded in such a way that subjects can be identified.

____ Research involves only the study or analysis of existing data, documents, records, or specimens that are publicly available or recorded in such a way that subjects cannot be identified.

____ If study involves ingestion of food: only wholesome food without additives in excess of USDA recommended levels is consumed.

____ Brief informed consent will be done (except in the case of existing data, etc.).

____ No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, etc.).

____ Has already been approved by IRB at _____.

Appendix A

(Include copy of signed IRB approval form.)

__X__ **Expedited review (minor risk study)**

__X__ Research and data collection methods are unlikely to elicit strong emotion and deception is not involved.

____ Research involves only noninvasive, painless, and non-disfiguring collection of physical samples, such as hair, sweat, excreta.

____ No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, disabled, etc.).

____ Data are recorded using noninvasive, painless, and non-disfiguring sensors or equipment, such as EKG, weighing scales, voice/video recording.

____ Research involves only moderate levels of exercise in healthy volunteers.

____ Research does not involve ingestion of drugs or use of hazardous devices.

__X__ If existing data, documents, records, or specimens with identifiers are used, procedures are in place to ensure confidentiality.

_X___ Informed consent process will be done (attach copy of informed consent form).

__X__ Data will be kept confidential and not reported in identifiable fashion.

____ **Full review required (more than minor risk)**
Attach a statement that describes the use of vulnerable subjects or the study procedures and conditions that place subjects at risk. Describe the precautions that will be taken to minimize these risks. Attach a copy of the informed consent form that will be used.

Certification by Principal Investigator: The above represents a fair estimate of risks to human subjects.

Charla L.R. Naone November 19, 2024
Name/ Title/ Date

FOR IRB USE ONLY

Certification by IRB Chair: I have read this application and believe this research qualifies as:
____ Exempt from IRB review
__/__ Appropriate for expedited review, and
__/__ approved
____ disapproved
____ Appropriate for review by the full IRB

1.3.2025
IRB Chair 11-29-2024 Date

#5604202503

Appendix D

Mapping of DNP Project Outcomes to AACN DNP Essentials

AACN DNP Essential	Description	Application to DNP Project
Essential I: Knowledge for Nursing Practice	Integrates nursing science with knowledge from other disciplines for the delivery of advanced nursing practice.	Used current nephrology and anemia management evidence, including KDIGO guidelines, to create the ESA hyporesponsiveness checklist. Informed clinical judgment through interdisciplinary knowledge.
Essential II: Person-Centered Care	Provides individualized care that is respectful of and responsive to patient preferences, needs, and values.	Encouraged comprehensive and individualized assessments of ESA hyporesponsive patients, allowing providers to tailor interventions based on checklist findings.
Essential III: Population Health	Uses epidemiologic, genetic, and social determinants of health to improve care for populations.	Addressed a specific clinical issue—ESA hyporesponsiveness—prevalent in the hemodialysis population, with a focus on preventing complications and reducing disparities in anemia management.
Essential IV: Scholarship for the Nursing Discipline	Applies evidence-based practices and uses analytical methods to evaluate and improve outcomes.	Designed and implemented an evidence-based intervention; collected and analyzed data on ESA dosing, hemoglobin trends, and referrals to evaluate intervention impact.
Essential V: Quality and Safety	Promotes a culture of safety and continuous improvement.	Improved patient safety by promoting standardized evaluation for anemia-related risks; enhanced documentation, early referrals, and reduced variation in practice.
Essential VI: Interprofessional Partnerships	Collaborates with other disciplines to improve health outcomes.	Engaged nephrologists, nurses, and nurse practitioners in anemia management decision-making; fostered teamwork during implementation.
Essential VII: Systems-Based Practice	Uses knowledge of healthcare systems to improve care delivery and patient outcomes.	Integrated checklist into existing monthly anemia reviews; aligned with organizational goals to reduce high-dose ESA use and improve patient outcomes.
Essential VIII: Informatics and Healthcare Technologies	Uses technology to analyze data and improve care.	Manually collected and tracked patient outcomes; future iterations aim to digitize the checklist and integrate into EHR systems.
Essential IX: Professionalism	Upholds ethical standards and lifelong learning.	Reflected on gaps in practice and addressed them through a professional QI initiative; advocated for ongoing education and change management.
Essential X: Personal, Professional, and Leadership Development	Demonstrates leadership and resilience in implementing change.	Led planning, education, and implementation of the checklist project; used the ADKAR change model to guide sustainable adoption.