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"Implementation of an Outpatient Iron Infusion Clinic: Alternative Approach to Treat Iron Deficiency Anemia in Pregnancy"

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"Implementation of an Outpatient Iron Infusion Clinic: Alternative Approach to Treat Iron Deficiency Anemia in Pregnancy"

A Scholarly Project Presented to the Faculty of the
Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice

By

Melissa Barrera, MSN, APRN, FNP-BC

Supervised By

Dana Sherman, DNP, APRN, ANP-BC, FNP-BC

Approval Acknowledged: _____, DNP Program Director

Date: _____

Abstract

Iron deficiency anemia in pregnancy is a common and treatable condition that can potentially affect pregnant women and their unborn fetus. In pregnant women, iron deficiency anemia can lead to complications such as preterm labor, preeclampsia, and even sepsis. In children, iron deficiency anemia could affect the neurodevelopment of the fetus. This could potentially result in poor school performance, behavioral problems, or cognitive deficits. In addition, iron deficiency anemia in pregnancy could lead to intrauterine growth disturbances and potential fetal loss. In order to address this problem, an outpatient intravenous iron infusion clinic has been implemented at a Women's Hospital to allow for access to an alternative approach to treatment. Oral iron supplementation, the traditional treatment of iron deficiency anemia, is most often poorly tolerated by patients. As a result, many patients exhibit poor compliance with treatment for iron deficiency anemia. The goal of this quality improvement project is to provide patients and providers with an effective and efficient outpatient alternative approach to treat iron deficiency anemia in pregnancy.

Keywords: iron deficiency anemia, pregnancy, fetus, intravenous, iron infusion

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I. Introduction

Anemia is the most common condition worldwide and it is estimated that more than 1.5 billion people are affected (Api, Breyman, Çetiner, Demir, & Ecder, 2015). Iron deficiency anemia accounts for approximately 50% of these cases (Api, Breyman, Çetiner, Demir, & Ecder, 2015). In pregnancy and postpartum patients, iron deficiency anemia is one of the most common conditions (Bhavi & Jaju, 2017). The estimated global prevalence of iron deficiency anemia in pregnancy is about 25% (Bhavi & Jaju, 2017). The prevalence is higher in developing countries at 51% and lower in developed countries at 14% (Bhavi & Jaju, 2017). Iron deficiency anemia could put pregnant women at increased risk for preterm labor, sepsis, and preeclampsia (Bhavi & Jaju, 2017). Iron deficiency anemia is a treatable condition that when addressed, could make a difference in the outcomes of obstetrical patients.

Iron deficiency anemia is not only a concern for the mother but also a potential problem for the developing fetus. Anemia could cause intrauterine growth disturbances and even fetal loss (Bhavi & Jaju, 2017). In addition, one recent study reports that iron deficiency anemia could have an impact on fetal neurodevelopment (Basu, Kumar, Anupurba, et al., 2018). This could potentially lead to children exhibiting poor school performance, developing behavioral problems, and even developing cognitive deficits (Basu, Kumar, Anupurba, et al., 2018). As a result, iron deficiency anemia is an important problem that needs to be addressed.

The current obstacles faced in the treatment of iron deficiency anemia include access to care. Obstetrical patients with iron deficiency anemia are either treated with oral iron supplements or intravenous iron sucrose. At the Women's Hospital, it is challenging for these patients to access the care they need. In order to receive an iron sucrose infusion, the patient is required to essentially spend all day at the hospital. Based on the review of prior data, it takes

about an average of 7 hours from start to finish to receive an iron infusion as an inpatient. The steps of the current process include the following. First, the patients are admitted through the OB Triage unit and then transferred to the High-Risk Antepartum unit. They could then potentially wait several hours for the admission process, the medication to be delivered from the pharmacy, the intravenous infusion of iron sucrose, and the discharge process. For some women, this is not feasible and as a result, they decline the treatment that would be more effective for their condition.

To address this problem, the Women's Hospital is working towards the implementation of an outpatient iron infusion clinic. It is proposed that this clinic will be part of the solution in treating iron deficiency anemia in pregnancy. It will allow these women easier access to the care they need and hopefully improve the outcomes of high-risk obstetrical patients with iron deficiency anemia.

II. Summary of the Literature

Anemia is one of the most prevalent conditions around the world. Iron deficiency anemia is the most common form of anemia. It is also a very common medical condition among pregnant women. The World Health Organization estimates that in 2011 there were approximately 32 million pregnant women diagnosed with anemia and 50% of those cases were attributed to iron deficiency (Govindappagari & Burwick, 2019). Iron deficiency anemia screening should be conducted in the first trimester by checking the serum ferritin and then monitoring the hemoglobin in the remaining two trimesters (Breymann, Honegger, Hösli, & Surbek, 2017). If iron deficiency anemia is not addressed, it could potentially negatively affect the outcomes of pregnancy. This could not only cause maternal complications, but also fetal developmental concerns. To address this issue, it is proposed

that the implementation of an outpatient iron infusion clinic will provide better access for pregnant women and as a result, improve the outcomes of obstetrical patients with iron deficiency anemia.

To conduct a thorough review of the literature, the database CINAHL Plus was utilized. The search terms and Boolean phrases used were “iron deficiency anemia” AND pregnan* AND “intravenous iron” OR “IV iron”. At first, the search yielded 46 results. Once the limitations were set the results were condensed. The limitations used include the publication year from 2015-present, full-text, scholarly peer-reviewed, pregnancy, and available in English. The search results were then reduced to 25 articles. Of those search results, 18 articles were reviewed.

The articles were then screened for research conducted in the United States. Finally, 8 articles met all of the criteria for the purpose of this literature review. The most common themes presented throughout the articles selected include the comparison of treatment with oral iron and intravenous iron, maternal complications, and the outcomes of fetal development.

Oral Iron vs. Intravenous Iron

The most common debate presented in the articles for the literature review is the treatment of iron deficiency anemia with oral iron versus the administration of intravenous iron. According to Govindappagari & Burwick 2019, supplementation with oral iron is the first-line of treatment for pregnant women suffering from iron deficiency anemia (Govindappagari & Burwick, 2019). The Institute of Medicine reports that the recommended dose of elemental iron is 30-120mg daily for pregnant women (Govindappagari & Burwick, 2019). The issue, however, is that about 40-50% of pregnant women report side effects from

oral iron consumption (Bhavi & Jaju, 2017; Govindappagari & Burwick, 2019; Sultan, Bampoe, Shah, Guo, Estes, Stave, et al., 2019). The most common side effects reported from oral iron are gastrointestinal in nature. These side effects include constipation, nausea, vomiting, epigastric discomfort, bloating, diarrhea, heartburn, and dark stools (Bhavi & Jaju, 2017; Govindappagari & Burwick, 2019; Lewkowitz, Gupta, Simon, et al., 2019; Breymann, Honegger, Hösli, & Surbek, 2017; Jose, Mahey, Sharma, Bhatla, Kriplani, Saxena, et al., 2019; Sultan, Bampoe, Shah, Guo, Estes, Stave, et al., 2019). As a result of this intolerance or noncompliance with treatment, providers may choose to consider treatment of iron deficiency anemia with intravenous iron.

In comparison to oral iron, intravenous iron is more effective in the treatment of iron deficiency anemia and usually, it is well tolerated. The only rare potential side effects of intravenous iron include burning or swelling at the injection site, and hypersensitivity reactions (Bhavi & Jaju, 2017; Lewkowitz, Gupta, Simon, et al., 2019; Breymann, Honegger, Hösli, & Surbek, 2017; Govindappagari & Burwick, 2019). In addition to better tolerance, treatment with intravenous iron has demonstrated a more rapid improvement in levels of serum ferritin and hemoglobin in pregnant women at the time of delivery (Bhavi & Jaju, 2017; Lewkowitz, Gupta, Simon, et al., 2019; Sultan, Bampoe, Shah, Guo, Estes, Stave, et al., 2019; Govindappagari & Burwick, 2019). One article states that pregnant women treated with intravenous iron will achieve target hemoglobin levels after four weeks of treatment (Govindappagari & Burwick, 2019). As a result of its efficacy, there is a decrease in the need for blood transfusions during the peripartum and postpartum periods (Bhavi & Jaju, 2017; Jose, Mahey, Sharma, Bhatla, Kriplani, Saxena, et al., 2019).

As for recommendations of treatment, researchers agree that intravenous iron should be utilized especially in the cases of advanced gestational age, severe anemia, placenta previa, Jehovah's Witness patients, and lack of response to oral supplementation after two weeks (Breymann, Honegger, Hösli, & Surbek, 2017; Govindappagari, & Burwick, 2019). Although it has been proven to be safe and effective, intravenous iron remains underutilized due to perceived risks and costs (Govindappagari, & Burwick, 2019; Juul, Derman, & Auerbach, 2019). With more research and education, providers will be able to appreciate the advantages of intravenous iron treatment for iron deficiency anemia of pregnancy.

Maternal Complications

If iron deficiency anemia is left untreated, it could potentially lead to maternal complications. The more prevalent complications include symptoms associated with anemia such as fatigue, headaches, dizziness, restless legs syndrome, and pica (Breymann, Honegger, Hösli, & Surbek, 2017; Juul, Derman, & Auerbach, 2019). Iron deficiency anemia of pregnancy is associated with higher rates of cesarean sections, greater need for blood transfusions, and increased risks of preterm labor (Bhavi & Jaju, 2017; Lewkowitz, Gupta, Simon, et al., 2019; Breymann, Honegger, Hösli, & Surbek, 2017; Govindappagari, & Burwick, 2019; Juul, Derman, & Auerbach, 2019). Three articles report that iron deficiency anemia of pregnancy is associated with increased risks of infection; poor wound healing, and sepsis (Bhavi & Jaju, 2017; Breymann, Honegger, Hösli, & Surbek, 2017; Juul, Derman, & Auerbach, 2019). Two articles discuss potential cardiovascular complications secondary to iron deficiency anemia of pregnancy. These cardiac issues include preeclampsia, cardiovascular distress, perinatal bleeding, placental abruption, and cardiac failure (Bhavi & Jaju, 2017; Breymann, Honegger, Hösli, & Surbek, 2017; Juul, Derman, &Auerbach, 2019).

Two articles discuss hormonal disturbances secondary to iron deficiency anemia of pregnancy. These include decreased milk production in the postpartum period, and poor maternal thyroid status (Breymann, Honegger, Hösli, & Surbek, 2017; Juul, Derman, & Auerbach, 2019). Lastly, two articles discuss psychological symptoms as a result of iron deficiency anemia. These symptoms include impaired cognition, depression, and reduced mental capacities (Breymann, Honegger, Hösli, & Surbek, 2017; Sultan, Bampoe, Shah, Guo, Estes, Stave, et al., 2019). In order to avoid potential maternal complications, it is important to properly treat iron deficiency anemia during pregnancy.

Fetal Developmental Outcomes

Iron deficiency anemia of pregnancy could not only lead to maternal complications, but also poor fetal developmental outcomes. Maternal iron deficiency could interfere with normal intrauterine growth leading to low birth weights, preterm births, higher perinatal mortality, more neonatal intensive care admissions, and disruptions in neural development (Bhavi & Jaju, 2017; Breymann, Honegger, Hösli, & Surbek, 2017; Govindappagari, & Burwick, 2019; Juul, Derman, & Auerbach, 2019; Lewkowitz, Gupta, Simon, et al., 2019). Research suggests that iron deficiency anemia of pregnancy could potentially affect fetal brain development, leading to cognitive deficits, poor scholastic performance, and behavioral problems (Bhavi & Jaju, 2017; Basu, Kumar, Anupurba, et al., 2018; Juul, Derman, & Auerbach, 2019). The hippocampus, which is especially vulnerable to iron deficiency, is responsible for learning, memory, and cognition (Basu, Kumar, Anupurba, et al., 2018). In addition, iron deficiencies can result in adverse effects on brain growth in terms of myelination, neurotransmitter synthesis, and brain programming (Juul, Derman, & Auerbach,

2019). To prevent these potential deleterious consequences, it is important to ensure proper correction of maternal iron deficiency anemia.

In conclusion, the reviewed literature suggests that intravenous iron for the treatment of iron deficiency anemia of pregnancy is a more efficacious and well-tolerated option. The first-line treatment of oral iron supplementation, on the other hand, is more likely to result in gastrointestinal adverse effects. The literature also emphasizes the importance of correcting iron deficiency as it could result in maternal complications and/or negative fetal developmental outcomes. It is proposed that the implementation of an outpatient intravenous iron infusion clinic for obstetrical patients will have a positive impact on the rates of iron deficiency anemia. By addressing the accessibility, increased costs, and disproving the misconceptions of adverse effects, intravenous iron infusions could help decrease potential maternal complications and improve fetal outcomes.

III. Purpose/ PICO Question/ Objectives

A. PICO: "Does the implementation of an outpatient iron infusion clinic improve the outcomes of high-risk obstetrical patients with iron deficiency anemia?"

B. Objectives

1. Improvement of anemia status.
2. Decreased need for blood transfusions during labor and postpartum.
3. Better patient satisfaction and access to care by decreasing the length of stay for treatment.

IV. Definition of Terms

A. Iron deficiency anemia - Iron deficiency anemia can be defined by any one of the following findings:

1. Serum ferritin < 30 ng/mL
2. Transferrin saturation < 19%, mostly used in patients for whom the ferritin is thought to be unreliable due to an inflammatory state
3. Anemia that resolves upon iron administration
4. Absence of stainable iron in the bone marrow

(Uptodate, 2019)

B. Anemia of pregnancy - The World Health Organization (WHO) and the American College of Obstetricians and Gynecologists (ACOG) define anemia in pregnancy as follows:

1. First trimester – Hemoglobin < 11 g/dL
2. Second trimester – Hemoglobin < 10.5 g/dL
3. Third trimester – Hemoglobin < 10.5 to 11 g/dL
4. Postpartum – Hemoglobin < 10 g/dL

(Uptodate, 2019)

C. High-risk obstetrical patients - refers to women with an intrauterine pregnancy that is considered high-risk according to the American College of Obstetricians and Gynecologists, this includes preeclampsia, gestational diabetes, maternal conditions complicating pregnancy, placenta previa, placenta accreta, placenta percreta, coagulation disorders, acute fatty liver of pregnancy, ARDS, maternal cardiac disease, autoimmune or hematologic disorders, severe pulmonary hypertension, and pregnant women who are unstable and may require an organ transplant. (ACOG, 2019)

D. Intravenous iron - refers to the intravenous form of iron replacement therapy; in the case of our facility iron sucrose (Venofer) is utilized for obstetrical patients.

V. Conceptual Underpinning and Theoretical Framework

The conceptual framework that will be utilized for the purpose of this DNP project is the Donabedian model (Appendix H). This conceptual framework focuses on three aspects that include structure, process, and outcome (McDonald, Sundaram, Bravata, et al., 2007). The structure of this project entails determining how it would be best to establish and implement an outpatient intravenous iron infusion clinic. The process would be the actual implementation of the outpatient intravenous iron infusion clinic. Finally, the outcome would include the positive outcomes of obstetrical patients that can receive intravenous iron infusions to treat iron deficiency anemia of pregnancy.

In addition to the conceptual framework, a nursing theory will be utilized to guide this DNP project. Lydia E. Hall's theory of The Care, Core, and Cure will be applied as a guiding principle for this project (Appendix H). Hall's theory involves three independent but interconnected circles of the care, the core, and the cure (Parker, 2005). The care refers to the caregiver (Parker, 2005). The registered nurse administering the intravenous iron infusion would be considered the care component. The core refers to the patient who needs medical care or attention (Parker, 2005). In this case, the core is the obstetrical patient with iron deficiency anemia. Finally, the cure refers to the medical treatment or attention given to patients (Parker, 2005). The intravenous iron treatment ordered by the provider would be considered the cure for the purpose of this quality improvement project.

VI. Methodology

A. Setting & Participants

1. Setting: Outpatient Infusion Clinic at a Women's Hospital
2. Participants:

a) High-Risk Perinatal APRN Coordinator
   - Oversee the clinic as a contact person for any issues
   - Develop and implement clinic policy
   - Follow-up with patients scheduled at the clinic

b) Registered Nurse from Antepartum unit
   - Check-in and Check-out patients
   - Establish peripheral intravenous access
   - Order or verify medication from the pharmacy
   - Assess patient upon arrival and discharge
   - Scan patient wrist band and medication
   - Infuse iron over 30 minutes or as indicated by pharmacy
   - Flush and remove intravenous access once complete
   - Patient education on iron-rich diet & follow-up instructions
   - Discharge process

c) Nurse Manager
   - Manager overseeing the unit and registered nurse assigned

d) Attending Physician
   - Oversee the clinic and the fellow/resident assigned

e) Maternal Fetal Medicine Fellow or Resident
   - Determine which patients need to be seen in the clinic using the intravenous iron algorithm
   - Input orders for patients

3. Hours of Operation: Mondays 8:00 AM – 12:00 PM

4. Schedule/ Workflow:

7:00 AM - 7:45 AM: RN attends unit huddle and breakfast break

8:00 AM - 8:30 AM: RN reports to iron infusion clinic for set-up

8:30 AM: Patient #1

9:30 AM: Patient #2

10:30 AM: Patient #3

11:30 AM: Patient #4

12:00 PM: Outpatient iron infusion clinic closed

5. Technology: computer, phone, OB ultrasound monitor, blood pressure monitor, thermometer, Cerner scheduling privileges/ access, new clinic to be added to the scheduling application.
6. Supplies: patient recliners (3), OB ultrasound/ BP machines (3), privacy curtains (5), IV poles & pumps (3), desk (1), office chair (1), omnicell with supplies for infusions, medication omnicell with IV iron, and phone.
7. Training: Tasks and workflow of the clinic will need to be taught to the registered nurse and nursing manager.
8. Potential Barriers/ Threats:
    a) Difficulty with intravenous access
    b) Access to supplies
    c) Delay in receiving medication from the pharmacy
    d) Late arrival of appointments
    e) Time management & appointment overlap

f) Waiting List for appointments/ too many patients for infusion

g) Ensuring the patient is financially cleared prior to appointment

h) Provider orders for infusion prior to appointment

B. Description of Approach and Project Procedures

The primary goal of this project is to successfully implement and establish an outpatient intravenous iron infusion clinic for obstetrical patients within our facility. The goal is to be able to treat pregnant women with iron deficiency anemia in an efficient outpatient setting. In doing so, the goal is to improve the outcomes of high-risk obstetrical patients with iron deficiency anemia.

Currently, high-risk pregnant women have to be admitted to the hospital for almost a half-day in order to receive the intravenous iron infusion. According to the pre-data collected, on average patients spend 6 hours and 51 minutes in the hospital for an iron infusion that only takes 30 minutes to administer. The goal is to be able to expedite this process and provide better access to care. The iron infusions will be conducted on an outpatient basis in a clinic run by a registered nurse. The patient would present at her given appointment time and check-in directly at the clinic. The registered nurse would then check vitals and establish peripheral intravenous access. The patient would then be given the iron infusion in a timely manner. Following infusion, the intravenous access would be discontinued, vitals checked, and the patient discharged.

To prepare the medical staff for this new process, the nurses will be given an in-service presentation during the unit huddle and the providers will be emailed an informational flyer. Any

questions or concerns regarding the outpatient clinic will be directed to the High-Risk Perinatal APRN Coordinator who will be overseeing the outpatient iron infusion clinic.

C. Protection of Human Subjects

1. Recruitment of subjects: High-risk obstetrical patients will be referred to the clinic by their obstetricians.
2. Consent to the procedure: Patients will be asked to consent to treatment.
3. Participant benefits and risks: Patients will be educated on the benefits and possible side effects associated with the intravenous iron infusion.
4. Safety: Material safety data sheets will be made available for medications used in the clinic.

D. Data Collection

Data will be collected with the help of the Nursing Informatics Specialist at the Women's Hospital. She will pull reports demonstrating which obstetrics patients have received iron infusions prior to the start of the clinic and after it is implemented. Then with the help of the High-Risk Perinatal APRN Coordinator, the demographics, length of stay, and hemoglobin levels of the patients will be reviewed and analyzed.

E. Data management and analysis plan

Data is available through the Cerner EMR system that the facility utilizes. Data will be provided by the Nursing Informatics Specialist thus ensuring privacy and HIPAA compliance. The data collected will then be analyzed by the researcher. The patients will be assigned a unique identification number to compare results. The file will be password protected and the computer used to analyze the data will be kept in a locked office.

VII. Results

The following results demonstrate the positive potential of the outpatient iron infusion clinic. An iron infusion that initially took an average time of almost 7 hours, now takes approximately 3 hours to complete outpatient. There is still room for improvement but the preliminary data are supportive of the clinic's efficacy and potential in treating iron deficiency anemia in pregnancy.

Table 1: Pre-implementation data

IV Iron Infusions through OB Triage/ Antepartum Inpatient				
PATIENT	**DATE**	**ADMISSION TIME**	**DISCHARGE TIME**	**TOTAL TIME (HOURS)**
5245	11/04/20	13:34	20:30	6:56
4546	11/02/20	12:10	19:11	7:01
4695	10/14/20	11:05	19:23	8:18
5273	06/10/20	11:38	18:04	6:26
4006	06/08/20	8:25	15:00	6:35
5260	06/04/20	11:17	17:10	5:53
5273	06/04/20	9:53	17:09	7:16
5247	02/07/20	9:41	18:11	8:30
5234	01/17/20	13:00	19:07	6:07
4929	12/20/19	11:56	17:30	5:34
			AVERAGE TIME (HOURS)	**6:51**

Table 2: Preliminary Post-implementation data

IV Iron Infusions through Outpatient Clinic				
PATIENT	**DATE**	**ADMISSION TIME**	**DISCHARGE TIME**	**TOTAL TIME (HOURS)**
4695	10/26/20	10:30	13:30	3:00
4546	11/09/20	12:08	15:05	2:57
5245	11/09/20	12:41	15:15	2:34
			AVERAGE TIME (HOURS)	**2:50**

VIII. Discussion

The Quality Improvement Project demonstrated the improvement of access to care for patients with iron deficiency anemia in pregnancy. The project showed that the iron infusion treatment length of stay decreased greatly when changed to an outpatient clinic setting. This decreased length of stay will ultimately increase patient satisfaction and compliance. With increased patient compliance, the outcomes of women and children affected by iron deficiency anemia in pregnancy will improve.

Although the data was only collected in regards to the patient length of stay, it demonstrates that this advancement could potentially lead to improved patient outcomes. The review of the literature shows the importance of treating iron deficiency anemia to reduce the risks of complications in women and children as much as possible. The literature also discusses how compliance is a major issue as many women are unable to tolerate oral iron supplementation. By providing more efficient access to care through means of the outpatient iron infusion clinic, patients will have access to a better treatment option for iron deficiency anemia in pregnancy.

IX. Limitations of the Project

Although this project has already shown great success, there are a few limitations that need to be addressed. The first limitations encountered during this project were the challenges that came along with the COVID-19 pandemic. Because this project took place at a major hospital setting, the timeline was affected by the COVID-19 pandemic. The start date of the outpatient iron infusion clinic was originally set for sometime in Summer 2020. Due to administrative concerns, the clinic start date was postponed several times. The outpatient clinic start date ended up being October 26, 2020. Due to the delayed start date, the data collected was not comparable to the goal sample size. In addition, only data on length of stay was collected due to timing constraints.

The next limitations of this project were the obstacles that presented from within the facility. The administration of this facility went through several changes during this project. For instance, the Director of the Women's Hospital changed three times during this project. This was a significant challenge because the High-Risk Perinatal APRN Coordinator and preceptor of this project reports to the director. Each time the director changed, the project

needed to be reintroduced and revised. In addition, there have been many challenges with the pharmacy department. There is a significant delay in the availability of the iron sucrose for the infusions. This delay could potentially cause a greater length of stay outpatient. The infusion itself only requires 30 minutes to administer. If the medication is made more readily available, the average length of stay could be further reduced.

Another potential limitation of this project is the sample population. The women referred to the outpatient clinic are patients seen by the physicians of this facility. A more accurate representation would include patients referred by obstetricians throughout the area.

X. Implications for Advanced Practice Nursing

The implications for advanced nursing practice would be to guide those working in obstetrics and maternal fetal medicine with alternative forms of treatment for anemia in pregnancy. It would demonstrate the efficacy and promise of utilizing intravenous iron as opposed to simply oral iron in the treatment of iron deficiency anemia in pregnancy. In addition, this project may serve as a blueprint for other organizations to create a similar outpatient iron infusion clinic for pregnant women. By doing so, patients would have better access to care and improvement of iron deficiency anemia status. This would as a result lead to better outcomes for mothers and their children.

XI. Conclusions

In conclusion, the implementation of the outpatient iron infusion clinic has been successful thus far. The length of stay from inpatient to outpatient treatment has been greatly reduced. With this improvement comes increased patient satisfaction, better patient compliance to treatment, decreased facility costs, reduced patient insurance costs, and improved patient outcomes.

XII. References

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XIII. Dissemination Plan

The next phase for this project would be dissemination by a poster presentation at a major conference. Since this quality improvement project focuses on obstetrical patients, the goal would be to present at a Nurse Practitioners in Women's Health (NPWH), Society of Maternal Fetal Medicine (SMFM), or American College of Obstetricians & Gynecologists (ACOG) conference in 2021 or 2022.

In addition, data will continue being collected to analyze both the length of stay and the improvement of anemia status of patients. Once sufficient data has been collected, the goal would be to submit for publication in an obstetrics journal or a publication for nurse practitioners.

XV. Appendix

A. IRB Approval Letter

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To:	Dr. Dana Sherman
CC:	Melissa Barrera
From:	Elizabeth Juhasz, Ph.D., IRB Coordinator
Date:	November 13, 2020
Protocol Title:	" "Implementation of an Outpatient Iron Infusion Clinic: Alternative Approach to Treatment for Iron Deficiency Anemia in Pregnancy" "

The Health Sciences Institutional Review Board of Florida International University has approved your study for the use of human subjects via the **Expedited Review** process. Your study was found to be in compliance with this institution's Federal Wide Assurance (00000060).

IRB Protocol Approval #:	IRB-20-0522	**IRB Approval Date:**	11/13/20
TOPAZ Reference #:	109049	**IRB Expiration Date:**	11/13/23

As a requirement of IRB Approval you are required to:

1) Submit an IRB Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved by the IRB prior to implementation.
2) Promptly submit an IRB Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Utilize copies of the date stamped consent document(s) for obtaining consent from subjects (unless waived by the IRB). Signed consent documents must be retained for at least three years after the completion of the study.
4) **Receive annual review and re-approval of your study prior to your IRB expiration date**. Submit the IRB Renewal Form at least 30 days in advance of the study's expiration date.
5) Submit an IRB Project Completion Report Form when the study is finished or discontinued.

HIPAA Privacy Rule: **Satisifed**

Special Conditions: **N/A**

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

B. Letter of Approval from Facility

The Women's Hospital
AT JACKSON MEMORIAL

September 9th, 2020

Florida International University
Nicole Wertheim College of Nursing & Health Sciences
11200 SW 8th ST
Miami, FL 33199

RE: Letter of Support for Melissa Barrera, DNP Student

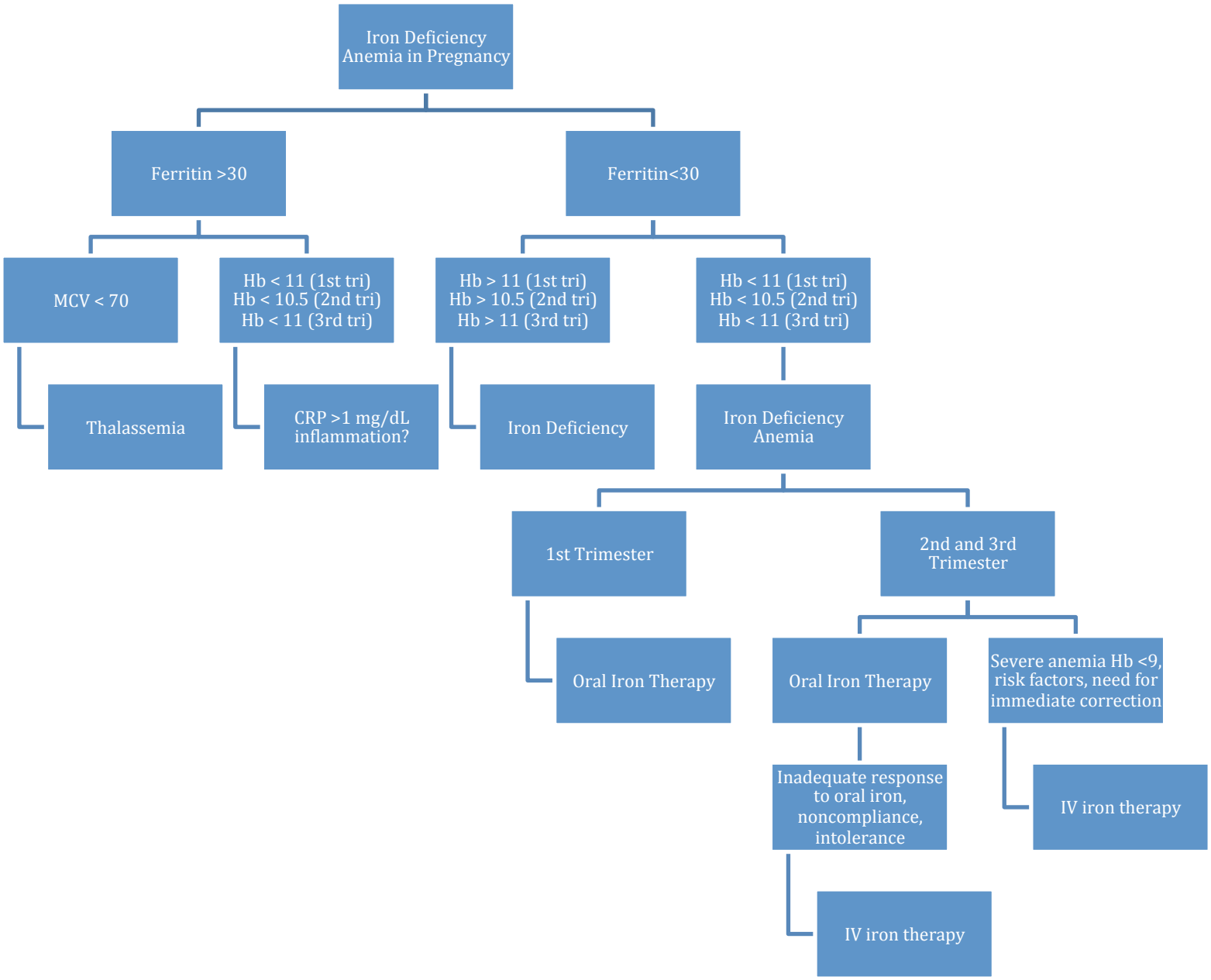
It is my pleasure to write this letter in support of Melissa's project entitled *"Implementation of an Outpatient Iron Transfusion Clinic: An Alternative Approach to Treat Iron Deficiency Anemia in Pregnancy"*. In collaboration with our nursing leadership team, it has been determined that this project is categorized as Quality and Performance Improvement.

At the Women's Hospital at Jackson Memorial Hospital, we are dedicated to providing the most up-to-date evidence-based care. Therefore, we highly value nursing contributions to organizational excellence. As such, supporting such projects allows for us to continue to achieve quality care and to improve patient outcomes.

Sincerely,

Jessica Saint Clair, DNP, APRN, FNP-BC
High-Risk Perinatal APRN Coordinator
The Women's Hospital at Jackson Memorial

C. Intravenous Iron Algorithm for Treatment



D. Provider Clinic Information Flyer

The Women's Hospital
AT JACKSON MEMORIAL

Antepartum Iron Infusion Clinic

Hours of Operation:

Mondays

8am – 12pm

Location:

Holtz ET 7th Floor, Antepartum Unit

Appointments:

Email requests to ObIron@jhsmiami.org with the following information:

1. Patient Name
2. MRN
3. EDD
4. Patient's Contact Number
5. Ordering Provider
6. Desired Date
7. Desired Amount of Doses
8. COVID symptoms or recent positive PCR test? Yes/No

For Uhealth patients, the referring office will be responsible for obtaining insurance authorization

E. Nursing In-service Presentation

OB Iron Infusion Clinic
RN In-service

Melissa Barrera, MSN, APRN, FNP- BC
Jessica Saint Clair, DNP, APRN, FNP- BC

Holtz Children's Hospital
UM/JACKSON MEMORIAL MEDICAL CENTER

The Women's Hospital
AT JACKSON MEMORIAL

Miracles made daily.

WHAT IS IRON DEFICIENCY ANEMIA?

- Iron deficiency anemia - Iron deficiency anemia can be defined by any one of the following findings:
  - Serum ferritin <30 ng/mL
  - Transferrin saturation <19 percent, mostly used in patients for whom the ferritin is thought to be unreliable due to an inflammatory state
  - Anemia that resolves upon iron administration
  - Absence of stainable iron in the bone marrow (providing that adequate staining controls are performed)

  (UpToDate, 2020)
- Anemia of pregnancy - The World Health Organization (WHO) and the American College of Obstetricians and Gynecologists (ACOG) define anemia in pregnancy as follows:
  - First trimester – Hemoglobin <11 g/dL
  - Second trimester – Hemoglobin <10.5 g/dL
  - Third trimester – Hemoglobin level <10.5 to 11 g/dL
  - Postpartum – Hemoglobin 10 g/dL

  (ACOG, 2020)

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BACKGROUND

- Iron deficiency anemia could put pregnant women at increased risk for preterm labor, sepsis, and preeclampsia (Young, et. al, 2019)
- Anemia could cause intrauterine growth disturbances, impact fetal neurodevelopment, and could even lead to fetal loss (Young, et. al, 2019)
- The current obstacles faced in the treatment of iron deficiency anemia include access to care.
- At Jackson Memorial, it is treated with oral iron or intravenous iron sucrose. Many women cannot tolerate the GI side effects related to oral iron. In order to get IV iron, the woman is required to essentially spend all day at the hospital as an admitted for observation patient.
- In order to address this problem, Jackson Memorial Women's Hospital is implementing an outpatient iron infusion clinic that will be staffed by Antepartum GYN/GYO nurses!

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OB IRON INFUSION CLINIC

Hours of Operation:
- Day(s): MONDAY
- Hours: 8:00 AM - 12:00 PM

Location: ET 4th/7th Floor

Schedule:
7:00 AM - 7:30AM: RN attends unit huddle
8:00 AM: Patient #1
9:00 AM: Patient #2
10:00 AM: Patient #3
11:00 AM: Patient #4
12:000 PM: Iron Infusion Clinic closed

Miracles made daily.

OB IRON INFUSION CLINIC

RN Responsibilities:
- ✓ Check-in and Check-out patients
- ✓ Establish IV access
- ✓ Check order/verify medication from the pharmacy
  - Iron Sucrose 200mg IV: should either be stocked in Omnicell to be mixed or in already prepared IV bags in the medication fridge.
- ✓ Assess patient upon arrival and discharge
  - Review any drug allergies
  - Vitals & fetal heart tone spot check before infusion
  - Vitals & fetal heart tone spot check after infusion
- ✓ Scan patient wrist band and IV iron medication
- ✓ Infuse IV iron sucrose over 30 minutes or as indicated by pharmacy
- ✓ Flush IV with 10cc NS once infusion is complete
- ✓ Document end-time of infusion in Cerner
- ✓ Discontinue IV access
- ✓ Add IV infusion charge through Ad-Hoc form
- ✓ Provide patient education on iron- deficiency anemia/iron-rich diet
- ✓ Give patient follow-up instructions; make appointments as necessary
- ✓ Print discharge paperwork and have patient sign
- ✓ Discharge patient from Cerner

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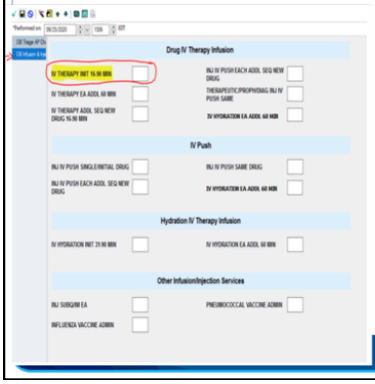
AD-HOC DOCUMENTATION



Ad Hoc
All Items
Women Services
Ob Triage Charges
Ob Infusion & Injection
IV Therapy Init 16 – 90 min

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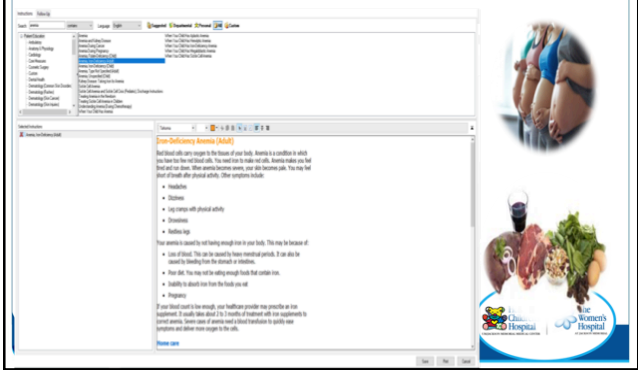
PATIENT EDUCATION



Challenges during clinic hours:

1. Antepartum Charge Nurse
2. APRN Coordinator: Jessica Saint Clair (85-5801)
3. MFM resident (pager #2125 or #9271)
4. Nurse Manager: Gustavo Rocha

Scheduling: Scheduling: Antepartum secretary or email ObIron@jhsmiami.org

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QUESTIONS?

Jessica Saint Clair, DNP, APRN, FNP-BC
Office #: 85-5801
Email: jessica.saintclair@jhsmiami.org

Melissa Barrera, MSN, APRN, FNP-BC
Email: melissa.barrera@jhsmiami.org

Miracles made daily.

THANK YOU!

Miracles made daily.

REFERENCES

American College of Obstetricians and Gynecologists (ACOG). (2019). Levels of Maternal Care. Retrieved from https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/08/levels-of-maternal-care

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Miracles made daily.

F. Outpatient Iron Infusion Clinic Policy Draft

The Women's Hospital
AT JACKSON MEMORIAL

Outpatient Iron Infusion Clinic Policy Draft

Table of Contents

I. Purpose

Treatment of iron deficiency anemia in the antenatal and postpartum period in order to improve maternal and fetal outcomes. Target population:

- Pregnant patients who have not responded to oral iron supplements.
- Pregnant patients with co-existing GI disorders and not candidates for oral iron.
- Pregnant patients with a history of bariatric surgery.
- Pregnant patients with anemia in the third trimester.
- Postpartum patients with anemia and significant blood loss during delivery.

II. Definitions

Anemia is an important risk factor for both maternal and fetal morbidity. Iron deficiency anemia is associated with higher rates of preterm birth, low birth weight, and small for gestational age newborns. (9) Maternal risks include fatigue, pallor, tachycardia, and poor exercise tolerance. (16)

Anemia in pregnancy is defined as:

- First Trimester: Hgb < 11 g/dL
- Second Trimester: Hgb < 10.5 g/dL
- Third Trimester: Hgb < 11 g/dL
- Ferritin < or = 30 mg/L
- MCV < 80-96 fL/red cell

III. Procedure

Materials:

- Normal saline 250mL for mainline IV
- 1 IV infusion set, 1 secondary line set
- IV catheter 18G or 20G
- Medication labels
- Antiseptic swabs
- Infusion pump
- Iron sucrose pre-mixed 100mL

Medication Administration:

1. Establish IV access
2. Prime infusion set with normal saline
3. Piggy back iron sucrose pre-mixed 100mL
4. Program infusion pump to deliver iron sucrose over 30 minutes
5. Follow infusion with remaining normal saline
6. Discontinue infusion
7. Discontinue IV access

Maternal/ Fetal Monitoring:

- Prior to infusion: Perform vital signs and fetal heart rate
- Following infusion: Perform vital signs and fetal heart rate
- If any concerns, escalate to OB team and transport to OB triage for further evaluation

Adverse Reactions:

- Immediately discontinue infusion and notify provider
- Administer Benadryl 25mg as ordered by MD for any adverse reactions

G. Material Safety Data Sheets

Venofer® Iron Sucrose Injection, USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision Date: 01/10/2019 Date of issue: 08/26/2014 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Colloidal Solution

Product Name: Venofer® (Iron Sucrose Injection, USP)

Product Codes: 0517-2340-01; 0517-2340-10; 0517-2340-25; 0517-2325-10; 0517-2310-05; 0517-2340-99

1.2. Intended Use of the Product

Use of the substance/mixture: An iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

1.3. Name, Address, and Telephone of the Responsible Party

Company

American Regent, Inc.
5 Ramsey Road
P.O. Box 9001
Shirley, NY
1-800-645-1706
www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Other Hazards: Exposure may aggravate individuals with iron overload. The most common adverse reactions are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, chest pain, and peripheral edema. Hemosiderosis has been observed following overdosage. Refer to package insert for more information.

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water for Injection	(CAS No) 7732-18-5	qs	Not classified
Saccharated iron oxide	(CAS No) 8047-67-4	2% w/v Iron (Fe)	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: Go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush affected area with water for at least 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical attention.

Hospira

SAFETY DATA SHEET

Product Name: Diphenhydramine Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Diphenhydramine Hydrochloride Injection
Synonyms	2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride.

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Diphenhydramine Hydrochloride Injection is a solution containing diphenhydramine hydrochloride, an antihistamine used for relief of symptoms associated with allergies or colds; it is also used for the treatment of symptoms associated with motion sickness. In the workplace, this material should be considered potentially irritating to eyes and the respiratory tract. Based on clinical use, possible target organs include skin, eyes, central nervous system, and gastrointestinal system.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word

Warning

Hazard Statement(s)

May cause damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray.
Wash hands thoroughly after handling.

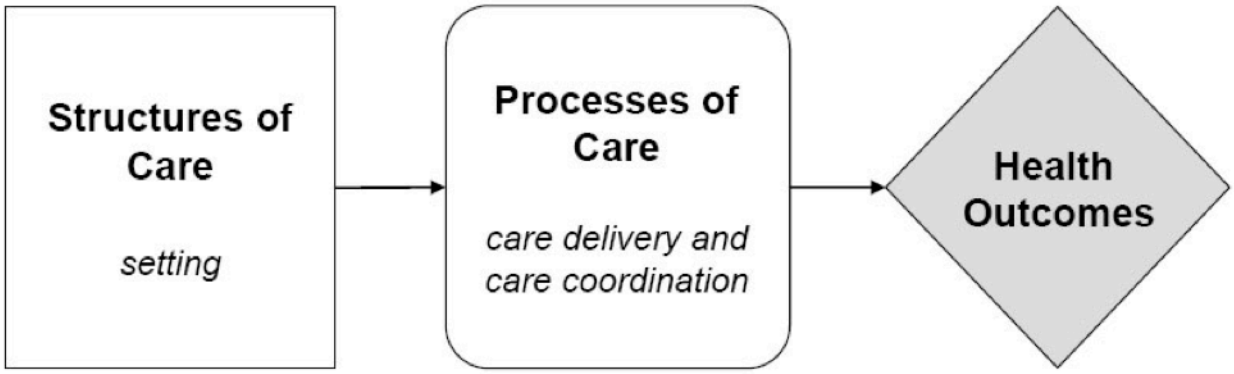
Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

H. Conceptual Underpinning & Theoretical Framework Diagrams

Donabedian Model



Lydia E. Hall Care, Cure, Core Theory

Diagram where Core and Care Predominate