Evaluation of Documentation of Contraception Education for Solid Organ Liver Transplant Recipients

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PART I: DNP PROJECT PROPOSAL

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Finally, I would like to thank my husband Eddy my kids Imani and Xavier for their patience and support throughout the period of my studies. I would not been able to finish my scholarly project without their uplifting words of encouragement.

Abstract

Background: Solid organ liver recipients who are of childbearing age are placed on immunosuppressive medications after receiving a transplant. These teratogenic immunosuppression medications are harmful to the developing fetus. Unplanned pregnancy in this patient population puts the recipient at high risk for fetal abnormalities and a high-risk pregnancy. Contraceptive education has scant published data for this population. Additionally, there is minimal data developed for low literacy educational interventions that would assist the transplant recipient to make informed choices. The purpose of this scholarly project was to determine documentation of the baseline occurrence of contraceptive counseling in a Florida clinic, and the evaluation of a low literacy contraceptive education brochure in the Miami Transplant Institute clinic liver patients.

Method: A retrospective chart review occurred to assess baseline documentation data of sexual education in these patients. This retrospective data was then presented to colleagues in the clinic and an intervention proposed for an educational brochure at the 8th grade literacy level. After establishing face and content validity a brochure was launched. The brochure includes the combinations of progestin-only (pills, implants, injections) and condoms which is considered the best options while on immunosuppressive medication. The patients were then surveyed to evaluate the usefulness of the brochure.

Results: Documentation of the contraception education counseling was absent in the 45 retrospective patient records. The 45 patients who were named in the review comprised the sample. Of those 45 patients, 17 (38 %) were consented to evaluate the brochure and 28 (62%) did not consent. The researcher selected this purposeful sample of the 17 that were seen by the medical doctors and the nurse practitioner in telehealth or clinic visits during a three-month period. These 17 completed a follow-up survey via telephone. The patients answered five nominal questions about contraception options while on immunosuppressive medications and optimal contraception. These questions validated the patient's ability to understand the information within

the brochure.

Conclusion: Contraceptive education for female solid liver transplant patients on immunosuppressive medications within the clinic should be documented in the electronic records. In order to both improve the occurrence and documentation a low literacy brochure was developed. The patients receiving the brochure evaluated the brochure as helpful and were also able to verbalize which contraceptive options would be optimally effective. This author will continue to raise awareness of this important patient and practioner conversation for the health and safety of mothers and children. Additionally, a one year evaluation of documentation of this intervention will occur post completion of the DNP program.

Introduction

One year after solid organ transplantation is the recommendation window for obligatory female contraception, due to tetragenic risks from the immunosuppressive pharmacology. (Paulen et al., 2010). Ovulation returns from sporadically from one to 10 months after transplant. Females of reproductive age who are solid organ transplant recipients need information and education in order to prevent unintentional pregnancy during the first-year post-transplant period (Krajewski et al., 2013).

Background

Solid organ liver recipients are placed on immunosuppressive medications after transplant. Teratogenic immunosuppression medications can be detrimental to the developing fetus. Additionally, the stress of pregnancy can have untoward effects on the recently transplanted liver leading to increased mortality and morbidity in the mother (Krajewski & Sucato, 2014). Unintentional pregnancy is common, and awareness of immediate contraception medications post intercourse has not been extensively studied within transplant recipients (Vricleea, Gawron & Louis, 2019). There is scant data upon which to develop educational interventions that would assist the transplant woman who is heterosexual active to make informed choices. The purpose of this scholarly project is to determine documentation of the baseline occurrence of contraceptive counseling in the University of Miami clinic liver patients. This retrospective chart review then would allow this nurse practitioner to have meaningful data with which to develop an action plan for education for this clinic population. After presentation of this retrospective data to colleagues in the clinic an educational brochure at the 8th grade literacy level will be developed for use in clinic visits. Then 30 days after the brochure launch there will be a follow-up survey via telephone to the patients who are 18 and older who visited the clinic and above to assist their understanding of birth control options.

Problem Statement

Pregnancy can be detrimental in young females who underwent liver solid organ transplants. Pregnancy increases cardiovascular demands and may decrease perfusion to the newly transplanted liver. To the developing fetus, immunosuppressive pharmacology can lead to congenital birth defects, malformation of the fetus, and increased susceptibility to infectious disease (Kelly et al., 2013). The US Food and Drug Administration (FDA) previously classified mycophenolate mofetil and azathioprine in pregnancy risk category D (positive evidence of human fetal risk) (Rafie et al., 2014). These two medications are commonly used in liver transplant patients to prevent liver rejection. When a woman is sexually active, preventive education is critical after having a liver solid organ transplant. There are various types of contraception that can be grouped by their effectiveness and by the medical eligibility criteria set by the United States Centers for Disease Control and Prevention (Al-Badri et al., 2017). A combination of two forms of contraception are recommended such as progestin-only and condoms. In order to address this problem, the following PICOT question is posed.

- (P) In female adolescent recipients before and after liver solid organ transplant
- (I) how important is educating and counseling of 2 forms of contraception is recommended while taking immunosuppression medication
- (C) compared to not receiving the education and counseling
- (O) affect including pregnancy with high risk for congenital birth defects and malformation of the fetus
- (T) over August 2019 to September 2020

Review of the Literature

The CINAHL and PubMed database were used to perform a literature review on contraception after solid-organ transplant. The following keywords were used during the search: *reproductive planning for women after solid-organ transplant*. The most comprehensive study was a metanalysis by four transplant physicians. Rafie, Lai, Garcia & Mody (2014) found that women of reproductive age make up 37% of the transplant recipients in the United States, with 10,817 women receiving organ transplants in 2013. Of these women, 35% were between 18 and 49 years old with a possibility of fertility. Multiple studies emphasize the importance of contraceptive education in this population.

It was also important to establish through evidence review, which contraception methods have optimal outcomes with liver transplant patients because contraceptive medications are metabolized by the liver. Parham, Gibson, and Coffin (2012) and Krajewski, Geetha, and Gomez-Lobo (2013) provide the only published guidelines for contraception management after solid organ transplant. These recommendations were evaluated by our Clinical Pharmacists for the University of Miami as being current best practice (Jebrock, 2019). Both sets of guidelines recommend progestin only medication can me use for example (pills, implants, injections), combined with condoms. Plan B can also be an option for unprotected intercourse or a known or suspected contraceptive failure (Vricella, Gawron, &Lewis, 2019). The chemical composition of Plan B is 1.5 mg of a single active steroid ingredient, levonorgestrel, a totally synthetic progestogen. Additionally, the author consulted with the clinic's clinical pharmacist to assure that the pharmacokinetics for immunosuppressive medications was not impacted by the contraception medications.

Low literacy recommendations and best practices were also evaluated in order to create the brochure for the study. The following keywords were used during the literature search: *low literacy, and education at eight grade level.* The definition to be used for health literacy in this study was developed by Chew (2004). When

teaching adult patients there are two factors that need to be addressed when developing patient information brochures. The first is literacy level and the second is cognitive load and suitability. Health literacy is the ability an individual has to obtain, communicate, process, and understand health information to make health decisions.

According to (Ryan et al., 2014) twenty-eight percent of the healthcare materials in their sample of 97 were at a 9th grade or higher reading level, and only 23% were 5th grade or below. As an additional step the study examined the face value of the brochures using a scale. The Suitability Assessment of Material (SAM) scale was developed as a rigorous and quantifiable measure of attributes of printed materials that go beyond the assessment of reading level, but that influence readability. The SAM ratings for not suitable, adequate, and superior were 11%, 58%, and 31%, respectively. Few materials were superior on both scales. The SAM scale was easy to use and required little training of reviewers to achieve interrater reliability. A more recent study is Moore & Cordero (2019) that is specific to Miami Dade County. This study looked at the health care literacy of 283 patients. The purpose was to evaluate printed health materials for legibility and appropriateness for patients with restricted overall health literacy skills. This study revealed that the younger the patient the less basic health care knowledge was measured. Clinicians require an understanding of their patients' health literacy to more effectively communicate health information, understand patient needs, and decide which treatment plans, services, or programs are most appropriate (Moore & Cordero, 2019). One aspect of suitability of written healthcare materials is also cognitive load. Cognitive load speaks to the amount of time the person will provide attention to information over the complexity of the task or change (Sewell, et.al, 2017). Providing simple and suitable information can reduce cognitive load. For example, pictures when added to brochures increased patient comprehension.

Study Intention: Develop Data for Practice Decisions

In order to assess the baseline electronic documentation of conversations about contraception and unplanned pregnancy consequences between the patient and researcher a chart audit was required.

Educational intervention would be provided to clinic healthcare providers to introduce the brochure. Then a brochure would be developed using the recommendations for low literacy written materials. The brochure would be evaluated by peers for face validity and content. Then the patients given the brochure would evaluate the information and useable of the information.

Objectives/Goals

1. Determine the baseline documentation of contraceptive education to the clinic's population of liver transplant patients.
2. Develop a CDC based brochure 8th grade literacy level targeted contraceptive information.
3. Evaluate the usefulness of the brochure by a follow-up survey via telephone to determine the impact on the patient's knowledge of birth control.
*4. Reevaluate the documentation of contraceptive education to the clinic's population of liver transplant patients. This will be completed one year after the brochure launch. This will be completed after the DNP project is complete.

Methods (Plan)

After approval was obtained from both the University of Miami and the University of Alabama IRB the following data collection process was started. All data was carefully encrypted and kept secure as instructed by the clinical administrators at the IRB in Miami. No personal patient identifiers were shared by the author to any other persons.

Part One and Part Four: (Pre and Post Provider Documentation)

Data collected from past medical records included age in years, date of transplant (month/year), race/ethnicity, immunosuppression medication and other medications, and documentation of contraception yes or no format. Retrospective analysis timeframe includes the medical records from January 2018 to December 2018. The Excel spreadsheet in which the data would be recorded is attached to this proposal. The data was

reported as an aggregate and descriptive statistics were used. One year later after getting consents and the initiation of the educational brochure, the same data will be collected to report if contraceptive education documentation has improved from baseline. The retrospective analysis timeframe is projected to be July 2020 to July 2021.

Part Two: (Intervention)

After presenting the data to the healthcare providers, the team members behind the study rolled out a low literacy contraception brochure for female patients 18-25. At the clinic visits either in person or remotely the patient consented to receive a follow-up phone call relevant to the flyer/brochure.

Part Three: (Survey Patients)

The phone call occurred within 30 days of the clinic visit. The phone call included the following four questions which are to be answered either yes or no:

1. Do you remember receiving a brochure at your last visit about contraception?
2. Do you realize having a baby can be dangerous to you and the baby with certain immunosuppression medications that you are taking?
3. Are you going to use two forms of contraception to prevent pregnancy?
4. Do you know you can use Plan B after an episode of unprotected sex?

Part Four: (Post educational intervention documentation)

A second retrospective chart review will be completed in the year following the initiation of the educational brochure to measure the impact on healthcare provider documentation. The projected date range is February 2020 to February 2021.

Project Design

The DNP project design that was a baseline assessment (provider documentation), intervention (use of low literacy brochure), and evaluation of the intervention by the patients (telephone survey about

contraception education material). It is type of pre-test, intervention, and post-test evaluation design. The design was impacted by the COVID 19 pandemic reducing the number of patients who were included and also the ability to reexamine the documentation at one year. The author plans to complete the additional provider chart audit after the conclusion of the DNP program.

Project Site and Population

Inclusion and Exclusion Criteria

Part One and Part Four

Retrospective chart review inclusion criteria: female adult liver transplant recipients, ages 18-25, who received a liver transplant at the University of Miami/Jackson Memorial Hospital who are English speaking only. The timeframe will be January 1, 2018, until December 31, 2018 (Approximately 50 charts). Baseline data to check if reproductive counseling was included in the clinic visit. Charts to be used would be identified by using the Active Liver Transplant Sheet that is maintained in the clinic. The action is performed by the clinical provider who is also part of the IRB submission. The personal protected information would only be included to validate that the charts reviewed were linked to eligible patients within the clinic. The critical data to be extracted is if the healthcare provider documented reproductive counseling. This chart review would occur again one year after the initialization of educational brochure for clinic patients. It is intended to raise awareness and accountability of this aspect of patient follow-up. It is a portion of the clinic's efforts to have optimal documentation.

Part Two

Part two includes an educational intervention with the clinic healthcare providers in order to introduce the brochure. This will be a part of the clinic's quality improvement process. All liver transplant providers will be included in the clinic's staff meeting.

Part Three

Part three includes a follow-up telephone call to patients who are given the low literacy brochure to determine if the information was helpful and remembered. Written consent will be asked for at the time the brochure is given to the patient. The consent will be used specifically to call the patient within thirty days with a survey. The purpose of the survey is to determine the use of the written information. **Exclusion**: The only patients to be excluded will be those who cannot read or write English. Additionally, there were some barriers due to the current pandemic of COVID-19. Remote consent process was added to the protocol due to the COVID-19 pandemic public health emergency. Once modification was done to the protocol it was approved by both IRB.

Data Collection Procedures

Part One: (Baseline documentation)

The retrospective charts were reviewed and identified through a clinic log that is maintained to promote continuum of care of the liver transplant patients. The records reviewed met the date range (January-December 2018), gender (F), and age range criteria (18-25).

Part Four: (Post educational intervention documentation)

A second retrospective chart review will be completed in the year following the initiation of the educational brochure to measure the impact on healthcare provider documentation. The projected date range is February 2020 to February 2021.

Part Two: (Intervention)

After meeting with staff to educate them and providing the brochures in English, the clinic healthcare providers rolled out the emphasis on contraceptive education. All eligible patients were given the flyer/brochure.

Part Three: (Survey)

The patients who were seen in clinic in-person or remotely met the study criteria and gave consent at the time of the visit for a follow-up phone call. An amendment was added to the IRB applications to allow for

consent to be obtained via telehealth since COVID 19 was in high prevalence in the Miami area. Once consent was given, then the follow-up phone call occurred within 30 days of the clinic visit. The phone call was be an informational survey. The phone call will include the following four questions which are to be answered either yes or no.

1. Do you remember receiving a brochure at your last visit about contraception?
2. Do you realize having a baby can be dangerous to you and the baby with certain immunosuppression medications that you are taking?
3. Are you going to use two forms of contraception to prevent pregnancy?
4. Do you know you can use Plan B after an episode of unprotected sex?

Data Management

Data was stored in the JHS Sharepoint environment. Research data collected will not be personally identifiable data because the data will be coded and listed as numerical cases.

Cost-Benefit Analysis/Budget

There was no external funding provided for by grant or release time for this study. The study is part of the quality assurance initiatives that occur to improve patient outcomes and enhance provider documentation. The costs of the study were the author's time and the expense of creating and producing the brochure.

Ethical Considerations/Protection of Human Subjects

The University of Alabama and University of Miami's Institutional Review Board (IRB) approval were obtained prior to initiating the project. There is minimal risk to the subjects because we are following the standard of care documentation of female patients post liver transplant. The patients will be given consent during clinic visit prior to participation. There is a minimal risk for breach of confidentiality since data will be locked in a cabinet and will only be discussed among research team members. Providing patients with

meaningful education about pregnancy prevention may improve the sexual health of the subjects. Low literacy materials are designed to provide information that can be easily understood. Miami Transplant Institute does see patients under 18, but they will not be included in this study. If the patient cannot read or write English, they were excluded from the study.

Data Analysis

The Chi-square test was utilized in this study for analysis of the data collection on the sample population. Chi-Square test involves calculating a metric called the Chi-square statistic which follows the Chi-square distribution (Yung-Pin, 2011). The P-value null hypothesis provides a probability framework against which to compare the data. Specifically, through the proposed statistical model, the P-value null hypothesis can be represented by a probability distribution which gives the probability of all possible outcomes if the null hypothesis is true.

MTI statistician created the Chi-square test that analysis of the data collection which included patients age, race, year of transplant, immunosuppression medication (yes or no), and documentation of contraceptive education (yes or no), and my four survey questions (yes or no). Because the sample size was small so he also incorporated the Fisher's exact test. Fisher's test meets all the assumptions on which basis the distribution of the test statistic is defined and relies on computing the p-value null according to the hypergeometric distribution using binomial coefficients (Yung-Pin, 2011).

Analysis of Effects Eligible for Entry

Effect	DF	Score Chi-Square	Pr > ChiSq
Age_in_years	1	0.8737	0.3499
age21	1	1.1233	0.2892
dot_year	1	0.1023	0.7491
dot2001	1	0.1147	0.7348
dot2005	1	0.0009	0.9756
agetx	1	0.0368	0.8479
agetx4	1	0.6627	0.4156
agetx5	1	1.1542	0.2827
agetx6	1	1.0642	0.3023
agetx7	1	1.4915	0.2220
agetx8	1	1.1214	0.2896
yrs_since_tx	1	0.1023	0.7491
yrs_since_tx10	1	1.4915	0.2220
yrs_since_tx12	1	1.0451	0.3066
yrs_since_tx15	1	0.3201	0.5716
yrs_since_tx18	0	.	.
black	1	0.2955	0.5867

NOTE: No (additional) effects met the 0.05 significance level for entry into the model.

Summary of Stepwise Selection

Step	Entered	Effect Removed	DF	Number In	Score Chi-Square	Wald Chi-Square	Pr > ChiSq
1	dot2003		1	1	6.5020		0.0108
2	white		1	2	4.2667		0.0389

Estimated Correlation Matrix

Parameter	Intercept	dot2003	white
Intercept	1.0000	-0.5072	-0.4634
dot2003	-0.5072	1.0000	-0.3357
white	-0.4634	-0.3357	1.0000

Conclusion

Of 45 retrospective records reviewed, 17(38%) screened and agreed to be in the study, and 28 (62%) were not consented. The researcher selected the 17 that were seen by the medical doctors and the nurse practitioner. The lack of documentation of the contraception education counseling was found in 100% of the retrospective records reviewed. This retrospective chart review then allowed this nurse practitioner to have meaningful data with which to develop an action plan for education for this clinic population. This information was shared in a staff meeting and support was asked for development of a teaching brochure to assist in starting the contraceptive education. The low literacy brochure was drafted and revised with input from the relevant stakeholders. The brochure was critiqued for readability, content, and face validity. Once the edits were complete the brochure was launched.

Then, 30 days after the brochure was introduced. there was a follow-up survey via telephone to the patients who are 18 and older who agreed to be in the study; 100% of the 17 who had consented had an understanding of birth control options which included combination of two forms of contraception such as progestin-only and condoms. First survey question 100% remember receiving a brochure about contraception. Second survey question 100% realize having a baby can be dangerous with certain immunosuppression medications that they are taking. Third survey question 100% will use two forms of contraception to prevent pregnancy. Final fourth survey question 100% know that they can use Plan B after an episode of unprotected sex. The patient survey data was very encouraging to the author because the information the patient needed was verbally validated. Knowing the message for self care was received is vital in patient and provider conversations.

In order to decide if this educational brochure has been helpful for our clinic patients chart audits will be done one year after this project completion. Because this study is a process improvement it is important to evaluate the impact of the intervention for this patient population.


We are here for you to stay protected!
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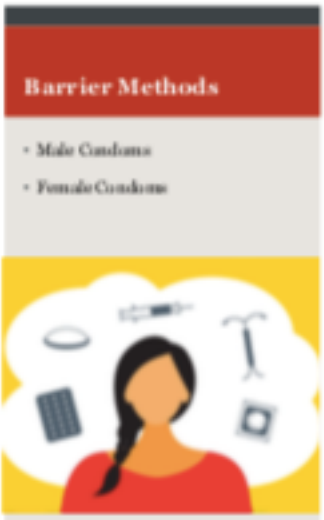
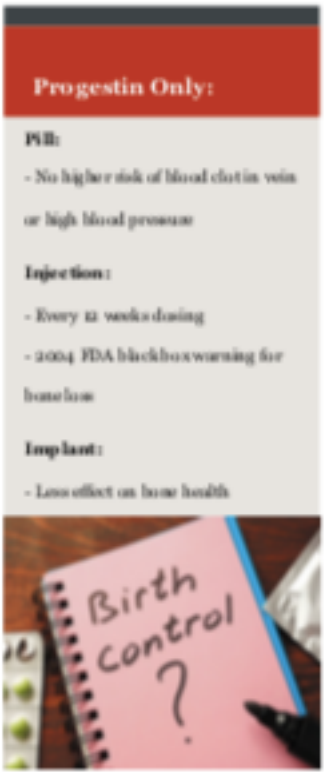
https://www.cdc.gov/reproductivehealth/contraception/mmwr/sp/summary.html
UHealth Jackson
Miami Transplant Institute
Ruth Dassas-Molin APRN
(305) 585-8574 Between 8 am – 4pm
Birth Control After Liver Transplant


Barrier Methods
• Male Condoms
• Female Condoms
The best practice is to use progestin only medication for example (pills, implants, injections, etc.) used combined with condoms.


Plan B
Plan B is also a progestin only backup birth control used for prevention of pregnancy following unprotected sex or possible birth control failure. The first tablet should be taken as soon as possible within 72 hours of having sex. The second tablet should be taken 12 hours later.


Progestin Only:
Pill:
- No higher risk of blood clot in vein or high blood pressure
Injection:
- Every 12 weeks dosing
- 2004 FDA blackbox warning for bone loss
Implant:
- Less effect on bone health
Birth control ?

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Graduation Criteria Statement

The DNP Project Proposal and DNP Final Project submitted, revised, and completed by the student and approved by the Faculty Advisor are criteria for graduation from the DNP program. All DNP students are strongly encouraged to revise the final project as a manuscript for publication in collaboration with the faculty advisor and submit to the student and Faculty Advisor's peer reviewed journal of choice. However, this is not a graduation criterion.