

**A Quality Improvement Initiative to Increase Counseling and Referral
for Contraception Among Adolescents on Teratogenic Medications**

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Author Testimony

Submitting this assignment confirms this is the sole work of the author as required by
the student code of conduct

Abstract

In the pediatric kidney transplant population, many patients are prescribed at least one teratogenic medication. Despite the potential dangers of unintended pregnancy with concomitant use of these medications, clinicians do not often assess or address these risks. The aim of this project was to 1) Conduct a chart review within a kidney transplant clinic to examine baseline practices on counseling around teratogen risks and referral to a specialist for contraception 2) Implement a standardized “smart-phrases” template within the electronic medical record to prompt a discussion about teratogenic risk, remind the provider to consider a referral to a subspecialist for contraception counseling/provision, and help standardize documentation in all female pediatric patients 3) Conduct a post-intervention chart review to assess the outcomes of the quality improvement initiative. We found that while the implementation of a smart-phrases standardized documentation in the kidney transplant clinic, it did not increase the incidence of teratogenic risk counseling. Instead, we found that providers often used the smart-phrases to document why counseling did not occur at a given visit. However, this significant uptake in smart-phrases use suggests that providers are prompted by the phrase to think and document about this topic. Future considerations for this clinic include conducting chart review at 6 months to see if actual counseling increases over the course of a longer follow-up period. Additionally, by conducting further intervention-assessment cycles, the intervention can be further optimized to increase clinical change.

A Quality Improvement Initiative to Increase Counseling and Referral for Contraception Among Adolescents on Teratogenic Medications

Adolescents living with chronic disease face many challenges and unique obstacles in managing their health. Specifically, adolescents who have undergone kidney transplant are on lifelong treatment regimens to support kidney function and prevent transplant rejection. Many medications used to treat renal conditions have known or suspected teratogenic effects, including one of the most commonly prescribed medications after kidney transplant, mycophenolate (Pape, 2019). Teratogenic medications can increase the risk of miscarriage and/or poor fetal outcomes, and birth defects related to prenatal exposure of teratogens are considered preventable (Mody et al., 2015). Researchers have found that women are more likely to use contraception when they have been counseled about teratogen risks by their primary care provider compared to women who receive no counseling (Schwarz et al., 2013). More specifically within transplant population, contraception counseling pre-transplant significantly increases post-transplant use of an effective method of contraception (Szpotanska-Sikorska et al., 2014). Thus, it is important that kidney transplant patients who are reproductively capable receive counseling and/or referral to a specialist who can provide this service to help prevent unintended pregnancy and minimize the risk of birth defects.

Adolescents with kidney disease are especially vulnerable to unintended pregnancy due to their age, development, and serious underlying medical condition. Adolescents with kidney disease often falsely believe they are infertile due to their diagnosis and medication regimens, making contraception a low priority and unintended pregnancy a likely consequence (Ashoor et al., 2015). One research group in Sweden

found that adolescents living with chronic conditions exhibit fewer protective factors (i.e. high self-esteem, good relationships with friends and family, etc.) and report more risky behavior compared to healthy peers (Nylander et al., 2014). Adolescents who have received a kidney transplant are especially at risk for adverse pregnancy outcomes for both the mother and baby. Complications of pregnancy after kidney transplant include adverse effects from immunosuppressive medications, preeclampsia, and hypertension (Chambers et al., 2001; Coscia et al., 2014; Shah & Verma, 2016). While pregnancy is often considered rare in the pediatric population, one survey of pediatric subspecialists found that that 18% of providers had cared for an adolescent or young adult woman who became pregnant while taking a teratogenic medication (Kirkpatrick et al., 2021). Given these factors, it is imperative that adolescents with kidney transplant receive timely and adequate counseling about the risks associated with unintended pregnancy.

While the majority of providers understand the importance of pregnancy prevention among this population, researchers have identified common barriers that prevent clinicians from discussing this information with patients. Research suggests that limited time during visits and inadequate clinician training/knowledge on contraception and teratogens were among the top barriers to providing adequate counseling (Eisenberg et al., 2010). Yet despite these knowledge limitations, specialists may not be adequately helping their patients access other clinicians with family planning expertise to address this topic. In a survey of pediatric nephrologists, only 54% routinely or always discussed contraceptive options and 51% routinely or always referred their patients to another specialist for contraceptive counseling and provision (Ashoor & Dharnidharka, 2015). Thus, current evidence suggests there is opportunity for improving counseling on

the risks of teratogenic medications in the pediatric kidney transplant population. This project aims to improve counseling on risks of teratogenic medications and provide consistent referral options for contraception counseling among adolescent patients in the Kidney Transplant Clinic (KTC) at a children's hospital in the pacific northwest.

Literature Review

This literature review examines current clinical issues associated with providing contraception counseling in pediatric nephrology practices, clinician perspectives of contraception counseling, existing resources and interventions in improving this area, and limitations in current research. This review was conducted using PubMed and CINAHL databases, primarily focused on studies from within the last five years, however older publications were included due to limited research on this topic. Key words included: contraception, nephrology, adolescents, contraception counseling, chronic disease, renal transplant, chronic kidney disease, and primary care provider.

Current Clinical Issues

While primary care providers often follow patients over long periods of time and routinely provide preventative healthcare, it is becoming increasingly common for specialists to also deliver these services. An increasing numbers of visits with medically complex patients are conducted with specialists for preventative care and routine health maintenance (Fryer et al., 2004; Hashim, 2020; Valderas et al., 2009). Despite this trend being potentially more convenient for patients who are already routinely visiting specialists, there is concern that specialists may not address preventative health issues as thoroughly as traditional primary care providers. Similarly, primary care and health maintenance concerns are overly demanding for specialists to address during their

already time-limited visits with complex patients (Valderas et al., 2009). Finally, a lack of coordination between primary care providers and specialist could also mean that important medical issues are not being addressed, under the assumption that it is within the other provider's scope (Starfield, 2003; Stille et al., 2003). Thus, it is important for specialists to routinely assess if their patients have received contraception counseling and/or provision, and provide this service or referral to another physician if this area of care has not been addressed.

Evidence also suggests that contraceptive counseling is inadequate in the pediatric kidney transplant population. In this population, many patients are on at least one teratogenic medication (Pape, 2019). Renal specialists rank fifth highest in frequency of prescribing teratogenic prescriptions among all specialist clinicians (Stancil et al., 2016). Yet despite the potential dangers of unintended pregnancy with concomitant use of these medications, clinicians are not adequately addressing and preventing these risks. In a large chart review of over 4,000 encounters with pediatric specialists who prescribe teratogenic medications, contraceptive counseling was only documented 28.6% of the time, and only 11% of encounters had documentation of current use or a new prescription for contraception (Stancil et al., 2016). In another study specific to adult kidney transplant patients, only 26% of patients reported they were counseled on the importance of contraception pre-transplant, and 34% were counseled about contraception post-transplant. Even among women who were effectively counseled on contraception post-transplant, only 30% reported effective birth control compliance (Szpotanska-Sikorska et al., 2014). While research is lacking specifically in the pediatric population, there is one survey of pediatric nephrologists

regarding adolescent sexual health. In that study, researchers found that only slightly more than half of pediatric nephrology specialists (55%) asked adolescents about sexual intercourse (Hergenroeder & Brewer, 2001). These low counseling and discussion rates place a vulnerable population at risk for poor pregnancy and fetal outcomes.

Clinician perspectives of contraceptive counseling

One of the major perceived barriers among clinicians in providing teratogen risk and contraception counseling includes a lack of time during clinic visits. In a survey of 110 primary care providers, over half (61%) reported time limitations as a top barrier in providing contraception counseling and provision to patients on a teratogenic medication (Eisenberg et al., 2010). Another challenge to increasing the frequency of contraceptive counseling and provision in the pediatric kidney transplant patient is that providers may not be comfortable with having conversations around sexual health. Many providers feel uncomfortable bringing up sexual health, especially with adolescents (Akers et al., 2010; Miner et al., 2017; Sauer et al., 2013). Additionally, nephrologists may feel reproductive health issues are largely outside their scope of practice. In a survey among adult nephrologists, 65% of respondents lacked confidence in women's health issues (Hendren et al., 2019). Providers reported they did not counsel patients on reproductive issues due to a perceived lack of training, limited knowledge and confidence on the topic, and a lack of evidence for the specific patient population (Hendren et al., 2019). In another survey of fellowship-trained nephrologists, only 45.9% of respondents felt they were "well trained" in renal complications of pregnancy, and 46.6% reported they had "some training but not enough to feel

competent” (Berns, 2010, p. 493). While discussions about contraception for most patients take place in a primary care setting (Papas et al., 2017), primary care physicians may not feel comfortable prescribing or offering contraception to medically complex patients, especially those on multiple medications (Kang et al., 2019; Manze et al., 2020). Thus, it may be most appropriate for pediatric subspecialists to refer patients to contraceptive specialists in departments such as family planning or adolescent medicine as opposed to primary care providers due to the complexity of their patients.

Existing Resources and Interventions

There are a number of resources and tested interventions for improving contraceptive care delivery. One approach is to provide guidance through clinical resources for clinicians. The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have produced evidence-based guidelines to help providers with the provision of contraception for medically complex patients (Curtis et al., 2016). These organizations have created Medical Eligibility Criteria for Contraceptive Use (USMEC) charts and reports to categorize the safety and risks of various methods of contraception for patients with specific medical conditions (Curtis et al., 2016). The classification of “Category 1” designates that the method of contraception can be used without restriction, while “Category 4” warns the method could pose major health risks and should not be used within a specific population. While the intention of these guidelines is to provide guidance to clinicians and decrease barriers for patients, it is unclear if specialists feel confident in providing these resources.

Instead of increasing training and education among providers as a means to improve contraception counseling, an alternative would be to improve the referral process to contraceptive specialists who are trained specifically in the delivery of this care. In a survey of pediatric neurologists who frequently prescribe teratogenic medications, providers largely believed that reproductive healthcare should be comanaged with primary care or women's healthcare providers (Kirkpatrick et al., 2020). These researchers found that comanagement of adolescent patients helps overcome many of the barriers that specialists face in providing contraception counseling, such as lack of time and expertise (Kirkpatrick et al., 2020). In a survey among pediatric subspecialists, 92% believed that a "quick referral process to sexual and reproductive healthcare providers" would have the greatest potential for reproductive healthcare provision (Kirkpatrick et al., 2021). Models for streamlined referral to family planning specialists have already been suggested in medically complex adult populations and show promise in connecting patients with the care they need (Jatlaoui et al., 2016; Rafie et al., 2014).

Another possible intervention for improving contraception counseling and provision involves using standardized documentation for electronic medical records. In one study, researchers examined how to improve the safety of teratogen prescribing practices within a pediatric rheumatology clinic. These researchers conducted multiple Plan-Do-Study-Act (PDSA) cycles to determine effective ways to improve their practices. In one PDSA cycle they created a standardized template for documentation which included prompts for contraception and sexual health questions. They found that this change in documentation significantly increased the prevalence of teratogenic risk

education within the clinic (Cooper et al., 2019). The additional implementation of a standardized electronic template further increased documentation of education from 87% to 95%. Investigators found that implementation of this template standardized documentation of education in the patient's electronic medical record and helped ensure that patients were receiving accurate and consistent information. This study emphasizes the complexity of this topic and the need for multiple types of interventions to impact change in this area. Thus, the plan is to take a similar approach using PDSA cycles to introduce one intervention first, examine the effectiveness of that intervention, and then complete additional interventions to ultimately make significant changes to clinical practice (Christoff, 2018).

Limitations in Current Research

Overall, there is limited information and research on specific practices among nephrology and specialty providers in conducting teratogen risk and contraceptive counseling among adolescent patients. While many nephrology patients are prescribed teratogenic medications and remain at risk for fetal anomalies and adverse outcomes, historically this has not been an area of emphasis in nephrology care (Stancil et al., 2016). Limited current evidence confirms that nephrology providers are not routinely and consistently providing this care (Ashoor & Dharnidharka, 2015). Additionally, there are no clinical trials in this setting to guide evidence-based practice and interventions. Thus, a quality improvement approach for this project was most appropriate to use the limited evidence that is available from nephrology and other subspecialty research to initiate an intervention among this population.

Purpose/Aims of project

The purpose of this project was to assess and improve contraception counseling and referral for adolescent female patients on teratogenic medications who are seen in a KTC in the Pacific Northwest. The specific aims were as follows: 1. Conduct a chart review to record and examine pre-intervention practices on education, counseling, and referral to a specialist for contraception counseling and provision. 2. Implement a standardized template within the electronic medical record to prompt a discussion about contraceptive use in all female pediatric patients 13 years of age and older and offer referral for counseling by an adolescent medicine or family planning provider. 3. Conduct a post-intervention chart review to assess the success of the quality improvement initiative.

Thus, the overall aim of this project was that by April 2021, all female adolescent patients ages 13 through 21 who are seen in the KTC are consistently informed about the risks of teratogenic medications and receive referral to an Adolescent medicine or Family planning provider for contraception counseling and/or provision when appropriate. This information will be consistently documented in each patient's electronic medical record by nephrology providers, including doctors and the nurse practitioner in the practice.

Methods**Setting**

We conducted a prospective quality improvement initiative in a Pediatric Nephrology clinic in the Pacific Northwest. The pediatric nephrology clinic is a tertiary referral clinic situated in a large, urban, pediatric medical center. The clinical providers

within this department include six pediatric nephrologists and one Family Nurse Practitioner. The clinic cares for children with a wide range of renal disorders as well children who have undergone kidney transplantation through the only pediatric kidney transplantation program in the state. This project occurred within the KTC, which serves patients who have undergone at least one kidney transplant in their lifetime. This setting was specifically chosen for the project, as all patients who are seen in this clinic are prescribed at least one immunosuppressive medication that is considered to be teratogenic. Thus, patients did not have to be individually identified as being on a teratogen in order to be eligible for the intervention.

Readiness to change

Pediatric nephrology providers and staff who work in this clinic expressed readiness for a practice change in this area through divisional meetings and pre-intervention surveys. The implementation of this quality improvement project was part of a larger research study being conducted called “Preventing unplanned pregnancies in female adults and adolescents with high-risk medical conditions and medications: an evaluation of quality improvement interventions in subspecialty clinics.” In the first phase of this research study, specialty providers at this hospital were surveyed voluntarily on their reproductive counseling practices. In the survey results, nephrology providers consistently answered questions endorsing the need for improving contraception counseling and provision among their medically complex patients on teratogens. For example, when asked “how important do you view reproductive life planning (contraception and pregnancy planning) for your female patients of reproductive age who are prescribed teratogenic medication?” all seven nephrologists that were surveyed

(including both adult and pediatric providers) answered “very” in their response. When asked “does your clinic have a standard way of assessing and documenting contraception for females with high risk medical conditions or prescribed teratogenic medications?” all seven providers responded “no.” Finally, when asked “Do you feel there is a need to improve the way contraceptive needs are assessed and documented in your subspecialty clinic?” all providers answered “yes.”

This project was implemented in conjunction with one of the pediatric nephrology providers. The provider helped facilitate communication with the other faculty members and provide insight into anticipated strengths and weaknesses of various interventions knowing the culture and current practices within the department. The initial concept of this project was proposed to the group of pediatric nephrology providers during their monthly faculty meeting in August 2020. All providers who participated in the meeting expressed the need for more consistent counseling and documentation on this topic and expressed their willingness to participate in the project.

Barriers anticipated prior to start of intervention

An anticipated barrier to the success of this project included the implementation of the intervention during the COVID-19 pandemic and resulting clinical changes due to modified operations. At the start of the pandemic in March 2020, many face-to-face visits within the KTC were changed to virtual visits and practice changes were made for social distancing that ultimately resulted in fewer follow-up visits and direct provider-patient communications. In response to these clinical changes, we designed an intervention that could be implemented regardless of whether the visit was face-to-face or virtual. Additionally, instead of conducting our pre-intervention chart review in the

immediate proceeding period prior to the intervention, we used charts from January 1-December 31st 2019 in order to capture baseline practices of clinicians in the KTC prior to pandemic changes.

Participants

Participants in this project included all female adolescent patients ages 13-21 in the KTC. We excluded males since the focus of this study was in preventing pregnancy among reproductively-capable females. While there were no identified transgender patients being seen in this clinic, patients would have been included in the study if they were biologically female and at risk for pregnancy. There were exactly 16 patients who met inclusion criteria as of 2019 for the pre-intervention chart review, and 13 patients who met inclusion criteria for the post-intervention chart review. Between the year of 2019 (the year in which the pre-intervention chart review was conducted) and 2021 (the year in which the post-intervention chart review was conducted), one of the eligible patients passed away, and three additional patients joined the clinic due to a transplant since 2019.

All procedures in this study were approved by the Institutional Review Board (IRB) as part of the larger study of subspecialty clinics mentioned above (PI Bayer). The retrospective chart review was conducted under a HIPAA Waiver of Authorization. Patient information collected through retrospective chart review was de-identified and stored securely through the REDCap system, a secure web application for collecting and managing data in a HIPAA and IRB-compliant manner. Patients were assigned a study code and electronic files for data analysis only contained the subject code and did not contain any HIPAA identifying information. The key associating the codes and

subjects was kept in a secure, limited-access, encrypted drive that is only available to study members who are on the IRB and will be deleted within one year of completion of the project.

Intervention procedures

The first step of this project was a retrospective chart review of visits that female adolescent patients who met inclusion criteria attended between the dates of January 1, 2019 through December 31, 2019. The purpose of the chart review was to collect baseline information about practices within the clinic prior to the implementation of the intervention. The specific variables that were collected from the chart review included the following demographic information: the age at time of documented visit, race, ethnicity, etiology of diagnosed renal disease (glomerular versus non-glomerular), and age at most recent kidney transplant. The outcome variables that were collected included: documentation of teratogen counseling at visit, referral for contraception, current use/prescription of teratogenic medication, current use/prescription of contraception, and documentation of whether “patient on teratogenic medication” was present on the patient’s problem list within the electronic medical record.

Our primary intervention was to design and input a “smart-phrase,” to the KTC note template that providers use to document visit details. A “smart-phrase” within the EPIC electronic medical record system is a method of documentation that allows clinicians to rapidly document using pre-written pieces of text. Smart-phrases can expand based and incorporate logic based on selections to then populate additional text or choices relevant to the patient visit. Our smart-phrase for this project was as follows:

1. This patient is between the ages of 13-21 and eligible for contraception counseling:

(drop-down options: yes, no, or not applicable). If yes, the next phrase populates: This patient is taking (drop-down options: mycophenolate (Myfortic) mycophenolate mofetil (Cellcept), ACE inhibitor, Angiotensin Receptor Blocker, or Other), a medication that is contraindicated during pregnancy and carrier the potential for birth defects and adverse pregnancy outcomes. 2. Risks were discussed as well as the importance of appropriate contraception use and family planning (drop-down options: Yes, No, or Not Applicable). 3. Patient is currently using a method of birth control: (drop-down options: yes, no). 4. Method of contraception: (drop-down options: no contraception, cyclic OCP's, continuous OCP's, progestin only OCP's, contraceptive ring, contraceptive path, Mirena IUC, Paragard IUC, Skyla IUC, Liletta IUC, DepoProvera, Bilateral Tubal Ligation, Essure, Vasectomy, Condoms, Diaphragm). 5. Referral to (drop-down options: Adolescent medicine, Family planning) for contraception counseling/provision: (drop-down options: Yes, No, Not Applicable).

We believed there were three potential benefits of implementing a smart-phrase:

1. By adding it to the documentation template that providers use in this clinic, it would help remind clinicians to discuss this topic.
2. The phrase details would additionally provide the clinician a list of both discussion points and treatment options and
3. streamline documentation of this discussion in to the medical record.

After the smart-phrase had been implemented for seventy-five days, the same chart review variables that were collected during the baseline chart review were re-collected in the post-intervention period. The post-intervention chart review included one additional data point: whether or not the smart-phrase had been used by the provider. The intervention occurred over a seventy-five-day timeframe in an attempt to capture at least one visit

with each eligible subject since patients are typically seen at least quarterly for a visit within the KTC.

Pre-and Post-Chart Review and Data Collection

Documentation of teratogen/contraception counseling was considered to have occurred if the provider who saw the patient documented that counseling on the risks of teratogens and importance of contraception were discussed and documented within the medical record. Referral for contraception was considered to have occurred if a referral to a primary care, adolescent health, or family planning provider was present in the chart. A patient was considered to actively be on a teratogenic medication if they had at least one known teratogenic medication listed under their medications list within a chart visit. Documentation of current prescription/use of contraception was considered “yes” if contraception was listed on their active medication list or elsewhere in visit documentation. Each patient’s “problem list” within their medical record was examined to see if “patient on teratogenic medication” was present as a documented “problem” on the list or not.

Ethical Considerations

There are notable ethical considerations regarding the topic of contraception and women’s reproductive healthcare in the United States today. While many insurance and government entities have attempted to control these services, contraception counseling and guidance is ultimately the responsibility of providers of reproductive-aged females. Patients should receive accurate and current information to make informed decisions about if and when they want to become pregnant given their high risk for complications and poor outcomes compared to people without kidney disease (Wiles et al., 2018). It is

especially important that providers discuss the impact of becoming pregnant with patients who are prescribed teratogenic medications, as these women must be aware of the increased risk for fetal harm and Federal Drug Administration (FDA) warnings to pregnancy while on these medications (Stancil et al., 2016). There are also equity issues among adolescents who are prescribed teratogenic medications. Researchers have found that contraceptive provision occurs at a significantly higher rate among White compared to non-White populations (Stancil et al., 2016). Thus, it is crucial to recognize groups who are at higher risk of not receiving adequate contraceptive counseling to ensure interventions address reproductive needs for all female adolescents. As part of this project, we collected demographic information about race and ethnicity from chart review data, which could potentially be used to determine if there are any differences in contraception counseling and referral between patients from various backgrounds. If a patient is uninsured or has concerns about the costs or coverage associated with being referred to another specialist, the clinic RN could connect them to the social worker who can further discuss this information with them.

Implementation of Project

Evolution of Project

As with many quality improvement initiatives, this project changed over time as barriers were encountered and unexpected changes were made to clinic flows and procedures. After initially introducing the idea of this project to the nephrology providers in August 2020, the plan was to have the clinic RN who sees all patients at the beginning of each visit to be the point-person for implementing the intervention. This would have ensured that each provider would not need to make an individual practice

change, but instead the clinic RN could do the teaching and education on this topic to ensure consistent messaging. In this model, the RN would discuss the risks of teratogens with patients, inquire as to whether they were already using a method of contraception, and ultimately send a referral to the family planning or adolescent medicine department for the provider to sign if the patient was interested. However, after several meetings with the clinic RN in the fall of 2020, it became apparent that these additional processes would be too burdensome and we agreed to pursue an alternative implementation strategy.

Beginning in January 2021, we made a change so that each individual provider would be responsible for having this conversation with patients and documenting their discussion in the electronic medical record. The smart-phrase was added to the clinic note template that the providers use in January 2021 and a meeting was held a week later to clarify the use of the new smart-phrase and answer any questions or concerns about this practice change. An email was sent out to all providers in this clinic 6 weeks post implementation of the smart-phrase to inquire if there were any issues or concerns. There were no issues with the use of the smart-phrase documentation that were brought forth at that time. After the intervention had been running for 75 days, a post-intervention chart review was conducted to determine if there was a change in practice.

Unintended Changes

The intention of this project was to do a pre-intervention chart review that reviewed the visits of all eligible subjects during the year of 2019 and then to recapture these same individuals in the post-intervention. However, we found multiple reasons for

loss of follow-up during the post-intervention period, including: transition to an adult provider, no visits in the KTC during the post-intervention time period, and death.

We planned two primary outcomes for this project 1. documentation of a discussion of risk of teratogens and 2. Whether a referral was placed to a specialist for contraception counseling. However, we expanded inclusion of additional outcomes as we saw that while providers were using the smart-phase, they often used it to document why they were *not* choosing to discuss contraception at that visit. Thus, we collected additional data on reasons why contraception counseling did not occur.

Key findings

Chart Review

Between the dates of January 1, 2019 through December 31, 2019, sixteen individuals who were seen in the KTC met inclusion criteria for the pre-intervention chart review. A record was made in REDCap for each eligible patient and all visits within the stated timeframe were reviewed for documentation practices. Approximately one quarter of eligible patients in both the pre- and post-intervention chart review were already on a method of contraception, which leaves approximately 75% (n=12) of patients eligible for potential contraception counseling and provision.

Patients in the pre-intervention chart review ranged from 13 to 19 years of age; 13 subjects identified as white, two were not reported, and one identified as American Indian or Alaska Native. Despite 100% (n= 16) of patients being on at least one teratogenic medication, only one patient had documentation of “Patient on a teratogenic medication” within their electronic medical record problem list, and only three had received teratogenic risk counseling (Table 1).

Table 1*Pre-Intervention Chart Review Findings*

Response	Documentation of teratogen/contraception counseling at visit		Referral for contraception counseling		At least one teratogenic medication listed on medication list		Documentation of current prescription/use of contraception	
	N	%	N	%	N	%	N	%
Yes	3	(19%)	2	(13%)	16	(100%)	4	(25%)
No	13	(81%)	14	(88%)	0		12	(74%)

Post-intervention chart review included 13 subjects ranging from ages 15 through 20. Nine subjects identified as white, one identified as “other,” one identified as American Indian or Alaskan Native and two declined to answer. In the post-intervention period, approximately two thirds (n=9) of visits utilized the dot phrase. However, documentation of teratogen risk counseling (n=3) did not significantly increase, nor did referral to a subspecialist for contraception counseling (Table 2). Thus, of the nine charts where the smart-phrase was used, only in three visits did the provider actually choose to move forward with counseling. In the remaining six visits, the provider instead documented the reason for not providing counseling.

Table 2*Post-Intervention Chart Review Findings*

Response	Documentation of teratogen/contraception counseling at visit		Referral for contraception counseling		At least one teratogenic medication listed on medication list		Documentation of current prescription/use of contraception		Smart-phrase used	
	N	%	N	%	N	%	N	%	N	%
Yes	3	(23%)	2	(15%)	13	(100%)	3	(23%)	9	(69%)
No	10	(77%)	11	(85%)	0		10	(77%)	4	(31%)

Two out of three times when providers had a conversation with their patient about teratogen risks, a referral was placed for further counseling and provision. No referrals were placed without having a discussion of teratogen risks documented in the medical record. The primary documented reason referral was not made was that the patient was already on contraception (n=3). Other documented justification included: patient not medical ready due psychological/developmental state and referral not indicated due to patient developmental delay.

Implement a standardized template

The standardized smart-phrase that was created for this project was used in nine out of the 13 charts that were reviewed during the post-intervention period. While the providers who work in the transplant clinic used the smart-phrase the majority of the time, they did not always affirm that they were actually providing counseling. Thus, the smart-phrase provided consistent documentation around the subject of teratogens and

contraception, but the provider only affirmed conducting the recommended counseling in three of the 13 charts that were reviewed post-intervention. Thus, the remainder of the time, the smart-phrase was used to explain that they did not provide counseling on the topic of teratogens and contraception.

Outcomes/Discussion

Comparison of findings to expected results

Our primary goal was that by the conclusion of the observation period, April 2021, all female adolescent patients ages 13 through 21 seen in the KTC would be consistently informed about the risks of teratogenic medications. In our study we found that at the post-intervention period, only 23% (n=3) of visits documented clinical counseling around teratogenic risks and contraception use, the same number as during the pre-intervention. A secondary goal of this project was to offer consistent referral to adolescent medicine or family planning providers for contraception counseling and/or provision when appropriate. Again, in the scope of this project, we did not see high numbers of referral and rates were similar pre 13% (n=2) and post 15% (n=2). The final goal of this project was to increase and improve documentation of teratogenic counseling in the patient's electronic medical record by nephrology providers. With respect to this endpoint, we achieved relatively successful results. In the pre-intervention period only three charts included documentation of counseling. However, in the post-intervention, while only three charts documented that counseling took place, an additional 6 charts documented why counseling did not occur or why it was not indicated. Thus, overall documentation of clinical reasoning around the topic improved in the post-intervention period.

While it appears that the intervention did not improve the measured outcome of increased counseling and referral, this may be because teratogenic/contraceptive counseling may not have been indicated at all of the visits. Similarly, referral to a subspecialist typically only needs to occur once and our study period may not have captured the specific visit when this was most indicated.

Comparison of Findings to the Literature

In analyzing the baseline practices of the providers within the KTC prior to the intervention, findings from our pre-intervention chart review showed very low rates of counseling compared to findings in current literature. In a survey of 200 pediatric subspecialists who prescribe teratogens, 58% reported having sexual and reproductive healthcare discussions at least annually with their adolescent patients who are prescribed teratogenic medications (Kirkpatrick et al., 2021). In another study among pediatric specialists who prescribe teratogens, contraceptive counseling was documented 28.6% of the time (Stancil et al., 2016). Thus, conversations regarding sexual health topics occurred at relatively low rates within the KTC compared to current practices elsewhere, which reaffirmed the importance of this quality improvement work.

We did, however, find the implementation of a smart-phrase increased the frequency of documentation and made it more consistent across encounters, which is similar to findings in the literature. The implementation of a novel smart-phrase within a pulmonary fibrosis clinic increased documentation by 50 percent, and we similarly found that introducing a smart-phrase significantly increased rates of documentation within the patient's medical record (Anderson et al., 2020).

We found that approaching this issue from a single angle (i.e. solely introducing the use of a smart-phrase) did not entirely improve counseling practices about teratogen risks within the KTC clinic. Thus, additional PDSA cycles and improvement initiatives are needed to improve counseling and referral rates. Multiple studies have shown that a multipronged intervention strategy can be more successful in improving teratogen risk counseling than a single intervention alone (Cooper et al., 2019; Shroff et al., 2017). In one study that aimed to improve the safety of teratogen prescribing practices, researchers conducted seven PDSA cycles to ultimately make significant improvements in counseling and documentation practices (Cooper et al., 2019). In another study, a computerized alert was triggered whenever a clinician prescribed a teratogen to remind them to discuss risks. While this was mostly successful, 40% of women in the study still did not receive appropriate counseling when they were prescribed a teratogen (Schwarz et al., 2013). Thus, even successful interventions could benefit from additional PDSA cycles to further improve clinical practice.

Impact of Project on System

The major impact that this project has on the current system is adding additional time that providers spend discussing this topic with patients and with proper documentation. While time can be a significant barrier to providing counseling as noted in previous studies, the implementation of the smart-phrase streamlines the documentation process (Eisenberg et al., 2010). By having drop down documentation options available, providers simply have to click on pre-populated text that fits their needs rather than free-type in a patient's medical record. While many providers within the clinic incorporated the smart-phrase into their practice and embraced this new

change, not all providers participated in this change. There are multiple reasons why providers may not have conducted a discussion around teratogen risk and documented on this topic. Possibilities for non-compliance with this intervention include discomfort in discussing this topic with patients, lack of time, unfamiliarity with using smart-phrases, and resistance to change. There are no monetary costs or additional resources associated with this intervention making it sustainable as a long-term practice change.

Practice-related Implications/Recommendations/Limitations

Implications

The implications of this project are broad and have the potential to significantly improve the care that adolescents receive through the KTC. From the pre-intervention chart review data, it is clear that providers were not often initiating conversations about teratogen risks or documenting it consistently in the past. It is likely that with the significant uptake of the use of the smart-phrase among clinician, teratogen risk counseling will be a topic that is more widely thought about now among providers within the KTC. Although discussion rates about teratogen risks remained low post-intervention, providers were documenting reasons as to why they were choosing to have or not have this discussion at a given visit. Developing and implementing a smart-phrase was a worthwhile endeavor for this clinic as it streamlined and standardized documentation, however, further investigation is needed in engaging the providers in the planning phase of the next PDSA cycle to determine future interventions.

Recommendations

Next, this project will be presented to the faculty and staff who work in the KTC to share results and gain feedback on the provider experience of using the smart-phrase.

Other future steps include completing a chart review at six-months post-intervention to determine if there has been further increase in discussions about teratogen risk and documentation. Literature supports a multipronged approach and additional PDSA cycles to successfully incorporate teratogen risk counseling into practice. The next PDSA cycle could include an intervention such as a teratogen medication alert within the electronic medical record whenever a teratogen is prescribed or refilled to remind the provider that risk counseling should occur (Shroff et al., 2017). Additionally, findings from this work indicated that pediatric subspecialists have limited time and presence of family during office visits were two of the main barriers in providing counseling on this topic. Therefore, developing a process where adolescents are seen independently for a longer visit at least once a year to address these sensitive topics may improve counseling and referral rates as well (Kirkpatrick et al., 2021). It would be prudent to further engage providers in this project and elicit their input and feedback thus far to create more successful interventions in the future.

Limitations

There are multiple factors that were limitations in this project. Initially, a lot of time was spent coordinating an intervention that would be implemented by the clinic RN. When this element of the project did not progress as planned, it took extra time and coordination to determine the next best steps limiting the ability to implement further PDSA cycles. Creating a new process delayed the start of the intervention and decreased the timeframe for data collection and the longer to implement the intervention than initially planned. The initial intention was to have the intervention run for three months, as kidney transplant patients are typically seen at least quarterly and this

timeframe would ideally capture at least one visit with each eligible subject. However, the intervention only ran for 75 days and as a result there were four eligible subjects who did not have a visit within that timeframe.

Conclusion

Overall, the findings of this quality improvement initiative are encouraging and show promise in improving teratogen risk counseling and referral for adolescents within the KTC. While counseling and referral rates did not greatly increase between the pre- and post-intervention periods, we found that providers utilized the smart-phrase consistently in their documentation.

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