Improving Adherence and Satisfaction with the iPLEDGE Program

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Introduction

The iPLEDGE Program is the mandatory pregnancy prevention program associated with the acne medication, isotretinoin. Non-adherence to the iPLEDGE Program results in extra, unnecessary pregnancy testing and increased costs in terms of time and money.

Objectives

The purpose of this Quality Improvement (QI) project was to increase Female of Reproductive Potential's (FRP's) adherence to the iPLEDGE Program.
Aim #1: to increase FRP adherence to the iPLEDGE Program by delivering an educational handout and weekly text message reminders
Aim #2: to increase FRP satisfaction with practice management of the iPLEDGE Program.

Methods

Sample

Enrollment was determined by which FRPs attended their regularly scheduled appointments between August 1, 2018 and November 30, 2018.
All female patients between the ages of 12 and 55 who were seen at the site of interest, prescribed isotretinoin, and enrolled in the iPLEDGE Program were included in this QI project. For FRPs under the age of 18, a parent or guardian supplied the cell phone number.
Males, females of non-child-bearing potential, and all patients who were not enrolled in iPLEDGE and taking isotretinoin were excluded.

Design

This was a QI project with a pre-test/post-test design.

Measures

The data collected for Aim #1 were measured as adherent to iPLEDGE or not (yes or no) and compared to two historical data points: 2015 data which reflect pregnancy testing data from patients within this practice who visited multiple different providers, and 2018 data which reflect pregnancy testing data from only the primary author.
Satisfaction survey scores were collected using a 5-question section from the validated tool: "Pain Treatment Satisfaction Scale."

Summary and median satisfaction scores were collected for both pre- and post- intervention surveys.

Analysis

The outcome for Aim #1, increasing adherence to iPLEDGE, was the rate of adherence, and was measured as a percentage. Rates of adherence between groups were compared using a Pearson Chi-Square test.
There were two historical data groups, 2015 and 2018, and one intervention data group from 2018.
Historical data from 2018 included data from multiple providers' patients.
Historical data from May 1, 2018 through July 31, 2018 included data from only patients from the primary author
The outcome for Aim #2, increased satisfaction with iPLEDGE, was measured using a 5 question, 5-point Likert scale survey. It was taken from a larger survey utilized to measure pain.
Satisfaction scores were evaluated using summary and median scores.
Satisfaction scores were compared using a Wilcoxon Signed Ranks test.

Results

Adherence to the iPLEDGE Program			
	No	Yes	Percent (%)
Historic 2015 (N=806)	171	635	21.2%
Historic 2018 (N= 35)	5	30	14.3%
Intervention (N= 25)	3	22	12%
	Chi Square		**2.163**

A frequency table was used to illustrate adherence to the iPLEDGE Program (yes/no) between eight hundred and five historic FRPs from 2015, thirty-five historical FRPs from 2018, and twenty-five intervention FRPs. The historical sample from 2015 displayed a 21.2% (N= 171) rate of non-adherence, the historical sample from 2018 displayed a 14.3% (N= 5) rate of non-adherence, and the intervention group displayed a 12% (N= 3) rate of non-adherence.

A Pearson Chi-Square test was conducted to determine whether there was a difference in the number of pregnancy tests performed between groups. The result was not statistically significant (p= 2.163), there was no significant difference between the number of pregnancy tests performed during the intervention period and the historical data.

Satisfaction Survey Results			
	Minimum	Maximum	Median
Pre-Intervention	10	16	15
Post-Intervention	12	15	15
Wilcoxon Signed Ranks			**0.705**

AIM #2:

The table displays the results from Aim #2: increased satisfaction with iPLEDGE Program management. Pre-Intervention satisfaction results ranged from 10 to 16, with a median satisfaction score of 15.
Post-Intervention satisfaction ranged from 12 to 15, with a median satisfaction score of 15.
A Wilcoxon Signed Ranks test was performed to evaluate improvement in satisfaction. Satisfaction showed no improvement after intervention; therefore, it was not statistically significant (p= 0.705).

Discussion

The use of text messaging reminders did not result in statistically significant improved adherence to the iPLEDGE program. Neither comparison (2015 vs. intervention NOR 2018 vs intervention) resulted in a statistically significant Chi Square result. One reason for the deviation from the evidence may be variation in comprehension and familiarity among providers with the iPLEDGE Program. Older historic data from this practice suggest a rate of nonadherence of 21.2% which may be closer to the true historic rate of adherence for the entire practice than historic data from 2018 which is from the author's own patient list.

Unfortunately, FRP understanding, or lack thereof, is not the only barrier to adherence to the iPLEDGE Program. One FRP fell outside her 7-day prescription window due to pharmacy error- not a misunderstanding on her part.
The patient satisfaction surveys indicated no change in satisfaction with the iPLEDGE Program. This may be because the iPLEDGE Program is challenging to navigate and is costly in both time and money.
This dermatology practice was sold to a venture capital firm in fall 2017. The new owners implemented a series of infrastructure changes, including administrative structure and staffing. These changes resulted in resignations from providers and staff. The structural changes and their impact on this project are immeasurable.

Conclusions

This project was inexpensive, sustainable, and patients responded favorably.
Statistically significant results may be possible with an increased recruitment time period. There was a clinical significance demonstrated- increase from 14.3% rate of nonadherence to 12%, a 16% increase in adherence.
Having more time to collect historical data from multiple providers would likely demonstrate a different rate of historical adherence, as the 2018 historical data merely demonstrate that the author is already promoting a higher rate of adherence than other providers.
Including multiple providers' patients would incorporate differing practice techniques and thereby address the limitation of an already heightened baseline knowledge level encountered in this study.
Measuring satisfaction with the interventions may require that the investigator provide more direction to FRPs.
The iPLEDGE Program is challenging for patients, providers, and healthcare workers, but it is an important program with a worthwhile purpose. Methods to facilitate adherence warrant further study.

Handout

iPLEDGE Program and Pregnancy Testing: *What You Need to Know*

First Appointment:

- Fill out consent paperwork and have first pregnancy test.
- From the date you are registered in the iPLEDGE program, you have 30 -60 days to have your next pregnancy test.
- Do not have your next pregnancy test prior to 30 days from your registration date or you will have to repeat it.
- You will receive a packet in the mail from the iPLEDGE program with your login information. Your provider does not have this information and cannot get it for you.

Second Appointment/Month 1 of isotretinoin:

- Additional counseling with your provider. Ask questions!
- Have your next pregnancy test close to this appointment.
- From the date of this pregnancy test you have 7 days to fill your prescription.
- If you do not pick up your prescription within 7 days you will be locked out for 19 days and have to repeat your pregnancy test before you can receive another prescription.
- After your pregnancy test and after your appointment, you must login to the iPLEDGE program and answer your comprehension questions prior to picking up your prescription, otherwise the pharmacist will not be able to give it to you.

Months 2-6 of isotretinoin:

- You will need to have a pregnancy test and an appointment with your provider before a new prescription can be given.
- Remember that your pregnancy tests must all be 30-60 days apart.
- If you have one closer than 30 days from the last one, you will have to repeat it.
- Additionally, if you do not pick up your prescription within 7 days of it being sent to the pharmacy, you will have to repeat it.

Final Appointment:

- Final counselling and discuss whether you and your provider think you should extend your therapy. You must have a pregnancy test at least 30 days from your last pregnancy test.

Last pregnancy test:

- There is one final pregnancy test required after your therapy has concluded. Please remember to have this done!
- ***Pregnancy tests may be urine or blood- discuss with your provider at each appointment***

EXPECTED iPLEDGE COURSE

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