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Using the Electronic Medical Record to Refer Women Taking Category D or X Medications for Teratogen and Contraceptive Counseling

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Abstract

Background—Women taking teratogens may not receive teratogen and contraceptive counseling. The objective of this study is to explore the feasibility of an electronic medical record (EMR) alert and referral system to improve teratogen and contraceptive counseling.

Methods—We conducted a descriptive study in an academic outpatient setting to evaluate the feasibility of an EMR alert and referral system. Reproductive age women taking category D or X medications seen in family medicine clinics were referred by means of an EMR alert for teratogen and contraceptive counseling. A subset of these women consented to follow-up surveys assessing contraceptive usage before counseling, intended contraceptive method after counseling and satisfaction with the counseling. Participants were contacted at 1 and 3 months to assess contraceptive usage.

Results—A total of 354 women were prescribed category D or X medications by clinicians who received the EMR alert, 170 women were referred, 59 women received counseling, and 33 participants enrolled in the study. One participant did not use any contraception. Among the 32 participants using contraception, 12 (37.5%) used oral contraceptives, 11 (34.4%) used condoms, 3 (9.4%) used withdrawal, 3 (9.4%) used intrauterine devices, 2 (6.3%) used contraceptive rings, and 1 (3.1%) used the diaphragm. After counseling, one-third of participants were considering more effective contraception. Almost all participants strongly agreed or agreed that the counseling was helpful.

Conclusion—Creating an EMR alert and referral system for women prescribed category X or D medications is feasible. Counseling on teratogen exposure and contraception may improve the acceptability of more effective contraception.

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Keywords

teratogen; contraception; electronic medical records; medication safety; collaboration

Introduction

Approximately 6% of pregnancies in the United States are exposed to potentially teratogenic medications (Andrade et al., 2006). Birth defects due to prenatal exposure to teratogenic medications are among preventable types of congenital anomalies. Previous studies have revealed that women want more counseling regarding a potentially teratogenic medication when it is prescribed (Santucci et al., 2010). In addition to desiring more teratogen counseling, these women may benefit from more contraceptive counseling to more effectively prevent an unintended early pregnancy exposure.

A cross-sectional study to assess contraceptive usage among women prescribed potentially teratogenic category D or X medications found that despite the importance of avoiding an unintended pregnancy in women taking teratogens, the contraceptive usage rate was similar to the national average (38% reported not using a contraceptive method) (Jones et al., 2012; Mody et al., 2013). In addition, among the women using contraception, the most common contraceptive method was oral contraceptives, with a typical use failure rate of 9% (Trussell, 2011). In fact, the oral contraceptive adherence rate for women taking teratogens is the same as the national adherence rate (Steinkellner et al., 2010).

The primary care physicians who prescribe the potential teratogens should ensure patients know about highly effective contraceptives. However, a study by Eisenberg identified that time constraint is a major barrier to adequate contraceptive counseling. Internists in the Eisenberg study believed that an electronic medical records (EMR) alert would be worthwhile. In addition, two-thirds of the internists agreed that “a referral or telephone consultation service for assistance in providing appropriate contraception for women on potential teratogens would be useful” (Eisenberg et al., 2010).

The EMR provides an opportunity to identify women taking potentially teratogenic medications and offer teratogen and contraceptive counseling. These women specifically may benefit from more counseling about longacting reversible contraception. The purpose of this study was to explore the feasibility and patient satisfaction with an EMR alert, and a referral system for teratogen and contraceptive counseling.

Methods

We conducted a descriptive pilot study in an academic outpatient clinic from April 2012 to October 2013 to evaluate the feasibility and patient satisfaction with an EMR alert and referral system for teratogen and contraceptive counseling. Women taking U.S. Food and Drug Administration category D or X medications seen in the family medicine clinics at the University of California, San Diego Health System were referred by means of an EMR alert for teratogen and contraceptive counseling conducted on the telephone by teratogen counselors located at the California Teratogen Information Service (CTIS) Pregnancy

Health Information Line. The alert appeared once for each potentially teratogenic medication that was prescribed or confirmed as current medication for women aged 18 to 45 years. We selected the medications that generated an EMR alert using the U.S. Food and Drug Administration letter category system because it was used by clinicians and patients during the study period. We did not include category D or X medications that are not considered potential teratogens such as oral contraceptives. The alert said, “This patient may benefit from a referral to the CTIS Pregnancy Health Information Line for teratogen and contraceptive counseling,” click “Accept.” If the physician decided a referral was appropriate, he/she clicked “Accept” and informed the patient that she would be contacted by a CTIS counselor. The physician could decline the referral if it was not appropriate.

After the referral was placed, a CTIS counselor contacted the patient and reviewed the category D or X medication and its potential teratogenic effect if the patient were to become pregnant and contraceptive options. Ineligibility for contraceptive counseling was determined by the CTIS counselor using screening questions to assess the potential of becoming pregnant. The counselors were trained to do contraceptive counseling by a family planning specialist. The contraceptive counseling focused on efficacy of the methods, but also was tailored to each patient’s medical conditions, based on United States Medical Eligibility Criteria for Contraceptive Use created by the Center for Disease Prevention and Control (MMWR, 2010). Patients were instructed to consult their Family Medicine physician for contraceptive service delivery. The Family Medicine physicians were informed of the referral outcome by means of the EMR. At the end of the counseling, the women were asked if they would be willing to participate in a phone follow-up survey. If they agreed, they were contacted within 1 week and verbally consented to participate in the study. Follow-up surveys were performed after the counseling at 1 week, 1 month, and 3 months to assess current contraceptive usage and motivation to improve to a more efficacious method. Contraceptive usage was assessed using a modified version of the Behavioral Risk Factor Surveillance System, Module 5 (CDC, 2011). A Likert scale was used to measure participant satisfaction at the 1 week follow-up call. The study was approved by the Institutional Review Board at the University of California San Diego. Statistical analysis was conducted using SPSS.

Results

During the study period, 354 women were prescribed category D or X medications by clinicians who received an EMR alert. Among these women, 170 women were referred for teratogen and contraceptive counseling. We were unable to contact 26 women. Fourteen declined counseling and 71 women were ineligible for counseling. Reasons for ineligibility for study participation included not sexually active with a male, prior history of sterilization, history of hysterectomy, discontinuation of the potentially teratogenic medication, or planning to become pregnant. The remaining 59 women received teratogen and contraceptive counseling. During the consenting process for the study, 3 women did not meet the eligibility criteria for the study and we were unable to contact 3 women. Of the remaining 53 potential study participants, 33 women consented to participate in the study (Fig. 1). The most common medications that resulted in referrals included: alprazolam, depakote, carbamazepine, isotretinoin, lisinopril, lorazepam, paroxetine, simvastatin,

valsartan, and warfarin. There was not a statistically significant difference in the participants and nonparticipants with respect to category D or X medication use.

The mean age of follow-up study participants was 33 years (±6.8) with an age range of 23 to 45 years. The primary language for the majority of participants (93%) was English. The distribution of race/ethnicity of the participants was non-Hispanic White 21 (72.7%), Hispanic 7 (21.2%), Black 3 (9.1%), and Asian 2 (6.1%).

Among the 33 participants, the majority (84.8%) stated that none of their health care providers educated them about preparations for a healthy pregnancy. One participant reported not using any contraceptive due to not liking the hormonal side effects. Among the 32 participants using some contraceptive, 12 (37.5%) used oral contraceptives, 11 (34.4%) used condoms, 3 (9.4%) used withdrawal, 3 (9.4%) used intrauterine devices, 2 (6.3%) used the contraceptive ring, and 1 (3.1%) used the diaphragm. Most of the women using oral contraceptives underestimated the typical failure rate. Most participants indicated that they were not currently planning a pregnancy, specifically 9 (27.3%) were sure that they had completed their child bearing and 16 (48.5%) indicated they wanted a child within 2 to 5 years. Among the women using contraception, when asked the biggest influence on their contraception method choice: 1 (3.1%) participant indicated cost, 2 (6.2%) participants indicated easy to obtain, 4 (12.5%) participants indicated efficacy of preventing pregnancy, 11 (34.3%) participants indicated safety for medical condition and 14 (43.8%) participants indicated other reason. The most common other reason was ease of use.

After receiving teratogen and contraceptive counseling, approximately one-third of participants in the follow-up interviews said they considered using a more effective contraceptive. Among the 7 participants using withdrawal or condoms, 3 were considering IUDS, 1 was considering oral contraceptives, and 3 were not sure which contraceptive they wanted. Among the 3 participants using oral contraceptives or the contraceptive ring, 1 was considering the IUD and 2 were not sure which contraceptive they wanted. At the 1- and 3-month follow-up phone interviews, all 33 participants stated that they were using the same contraceptive method they were using at study enrollment. On the satisfaction survey, all of the participants strongly agreed or agreed that the teratogen counseling was helpful. Approximately 97.0% of participants strongly agreed or agreed that the contraception information was helpful. With regards to the EMR referral system, 90.0% of participants strongly agreed or agreed that it was beneficial.

Discussion

This descriptive pilot study demonstrates that it is feasible to create an EMR alert and referral system for teratogen and contraceptive counseling. In this study, only a small proportion of women (12.5%) were choosing contraceptive methods based on efficacy. Approximately a quarter of the participants indicated that they did not want children in the future, indicating an unmet need for sterilizations among women taking potential teratogens. In addition, almost half the participants indicated that they wanted a child in 2 to 5 years, therefore promoting long-acting reversible contraception among this population is warranted.

The major strength of this study is that it displayed the feasibility of using an EMR alert and referral system as a mechanism to educate women about the possible effects of those medications in pregnancy, and on contraceptive options. Although this study used the category D or X medication system that will be replaced by a more descriptive labeling system, a similar EMR alert system could be established based on a list of medications that are potential teratogens. A EMR alert and referral intervention has been proposed in the past, but this is one of the first studies to implement an EMR alert and referral system for teratogen and contraception counseling. In a study by Schwarz, women who saw clinicians who received the more in-depth computerized clinical decision support system reported a higher rate of receiving counseling about risk of birth defects or contraception compared with women who saw clinicians that received the simple alert (Schwarz et al., 2013).

A second major strength of this study is linking primary care physicians prescribing potential teratogens and teratogen counseling resources. A qualitative study by Schwarz revealed that primary care physician are willing to refer women for more in depth teratogen counseling however are often unaware of services like Organization of Teratogen Information Specialists now named Mother-ToBaby (Schwarz et al., 2009).

One limitation of the study is the small sample size. The low referral rate and low participation rate resulted in a convenience sample. Approximately half of the women taking a category D or X medication by a clinician who received the EMR alert were referred which may be due clinician EMR alert fatigue. The decline from the 170 referrals to 59 women eligible for counseling may be due to the EMR alert and referral system being “opt out.” Although “opt out” approach resulted in some inappropriate referrals, this approach likely lead to greater number of appropriate referrals as well.

This study highlights the importance of physician education regarding EMR alerts/referral systems to encourage usage. In this study we are able to increase acceptability of more effective contraception among participants. However we did not improve usage of more effective contraception. A future study could be a randomized controlled trial in which all participants receive the teratogen and contraceptive counselling but then participants are randomized to a follow-up contraceptive provision appointment or no appointment.

CONCLUSIONS

This descriptive pilot study revealed that teratogen and contraceptive counseling can be facilitated by means of EMR referrals. It also revealed that women of childbearing potential who are taking potentially teratogenic medications are often using the least or moderately effective contraception and after the intervention they are motivated to use more effective contraceptives. The women in this sample did not appear to change contraceptive behavior, despite that motivation. This lack of behavior change may be due to short follow-up time. It may take longer than 3 months before a woman can see a health care provider for contraception. In addition, there may be other barriers to pursuing more effective contraception such as insurance coverage. This pilot study still demonstrated that it is possible to educate women about using more effective contraception using EMR referrals to telephone teratogen and contraceptive counseling. A similar EMR alert and referral to

contraceptive counseling could be established for other medical conditions that make pregnancy contraindicated.

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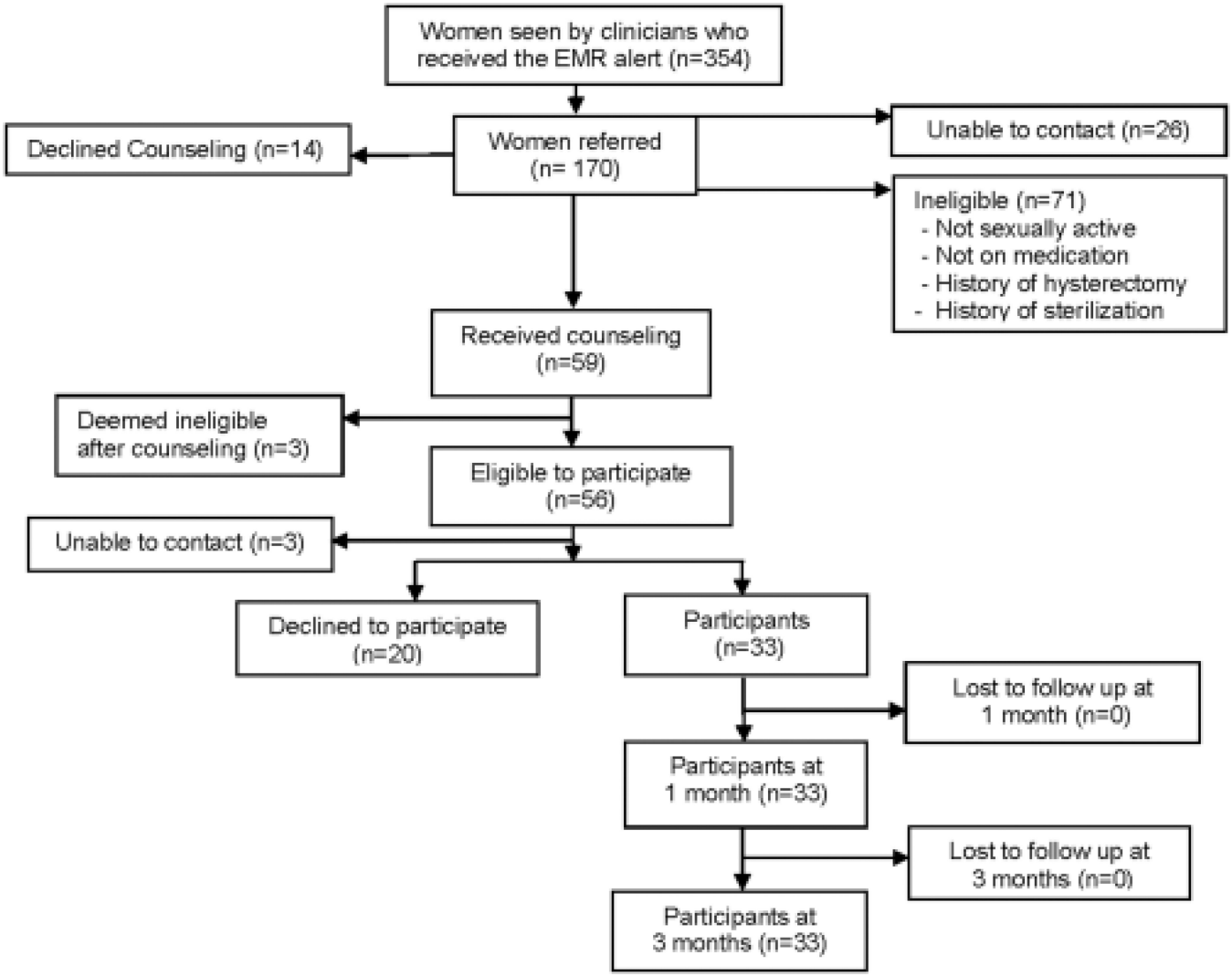

FIGURE 1.
Participant flowchart.