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Using the Electronic Medical Record to Assess Contraception Usage among Women Taking Category D or X Medications

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Abstract

Background—The aim of this study is to investigate contraceptive usage among women prescribed or currently taking a category D or X medication using the electronic medical record.

Methods—This is a retrospective study assessing contraceptive usage among women prescribed category D or X medications. We obtained access to the electronic medical records of women seen in an academic Family Medicine Department between April 2011 and April 2012 who were prescribed a category D or X medication. Information was abstracted regarding the specific category D or X medication, demographics, sexual activity, sexual partner gender, and contraceptive usage.

Results—There were a total of 610 women included in this study. Among the 610 women, 72 (11.8%) of women had documentation that they were not asked about their sexual activity. Sexual activity with men was documented in 407 of the 610 women (66.7%). Of these 407 women, 132 (32.4%) had no contraceptive method documented. Among the women using contraception, the most common method used was oral contraception.

Conclusion—According to data obtained from the electronic medical record, women who are taking a category D or X medication are not always asked about sexual activity. Contraception usage among women taking category D or X medications and who were sexually active with men was similar to the general population. Contraception usage should be better in this population given the risk of an unintended pregnancy includes fetal exposure to a potential teratogen. The electronic medical record creates an opportunity for an intervention to increase contraception utilization in this population.

Keywords

Lacking

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Introduction

Birth defects remain one of the most common and most dangerous obstacles to healthy birth, with one in 33 babies born with a birth defect each year (Rynn et al., 2008). While many of these birth defects are due to unknown or unpreventable causes, exposure to teratogenic medications remains one cause of birth defects health care providers can prevent. An estimated 11.7 million women of reproductive age are prescribed Food and Drug Administration (FDA) category D or X medications annually (Andrade et al., 2006), which are medications that may cause harm to fetuses. Approximately 6% of pregnancies in the United States occur in women taking medications with known teratogenic risk, and the most commonly prescribed category D and X medications include anxiolytics, anticonvulsants, antibiotics (e.g., doxycycline) and statins. Prescription of these and other category D and X medications occur at approximately 1 in 13 office visits, and family medicine and internist primary care physicians are responsible for 45% of these prescriptions (Schwarz et al., 2005). Given the frequency of teratogen prescriptions among women of reproductive age it is important that these women receive teratogen counseling. This type of counseling may motivate these women to use contraception to avoid unintended pregnancy.

Forty-nine percent of pregnancies are unintended, with unintended pregnancies accounting for one out of three births (Mosher et al., 2012). All women, but especially those taking potential teratogens, would benefit from using highly effective methods of contraception to avoid unintended pregnancy. While there is little research on whether rates of highly effective long-acting reversible contraceptive (LARC) methods differ in women on potential teratogens compared with the general population, there has been investigation of adherence to oral contraceptive pills (OCPs) which have user-dependent efficacy. A study of prescription medication claims showed that 18% of women taking a long-term category X medication were prescribed oral contraceptives. In addition, this rate is similar to the overall population's use of OCPs (17%), and category X medication users did not have higher adherence rate to OCPs compared with the overall population, 57.1% versus 57.8%, respectively (Steinkellner et al., 2010).

Because contraceptive use may improve with better counseling (Lee et al., 2011), documentation of contraceptive counseling has been of interest to researchers. A study using the National Ambulatory Medical Care Survey to analyze outpatient visits approximates between 6 and 20% of outpatient visits had documented contraceptive counseling (Schwarz et al., 2005). Later studies in other groups of providers demonstrate slightly higher rates ranging from 40 to 51% of encounters with documented contraceptive counseling (Schwarz et al., 2010, Fritsche, 2011).

It is important that women are able to receive this teratogen and contraceptive information from the primary care providers who frequently prescribe their medications. Women who participated in focus groups of one qualitative study stated that they desire this information, even if they do not have immediate plans to become pregnant or are not sexually active (Santucci et al., 2010). In a survey of 322 premenopausal female veterans, 90% of women taking medication also have confidence that their physicians will provide this information if

they are taking potentially teratogenic medications, although only 24% received counseling about teratogenic risk (Schwarz et al., 2013).

With the advent and rapid integration of Electronic Medical Records (EMR) into clinical practice, there is growing opportunity to use notifications and reminders to increase the amount of counseling provided women. This study is specifically interested in how physicians use the EMR to document sexual activity and contraceptive use for women using category D or X medications.

Materials and Methods

STUDY DESIGN AND DATA SOURCE

This study was a retrospective study to investigate documentation of sexual activity and contraception use among 18- to 45-year-old women seen in family medicine at an academic institution. This study was approved by the University of California, San Diego (UCSD) Human Research Rights and Protection Program. Data was collected from the EMR of the UCSD Family Medicine Clinic from April 2011 to April 2012. This clinic initiated use of electronic medical records in 2005 with EpicCare Ambulatory Electronic Medical Record. The study collected the data by means of manual review of medical records determined to meet inclusion criteria, and patient information was de-identified during collection of social/sexual history and contraception prescribed in medication lists. Data was collected based on EpicCare Patient Snapshots which included information about surgical history, medication list and social history. The EMR options for sexually activity were not asked, not currently, no or yes. The EMR options for partner type were male or female. There were no questions regarding the number of sexual partners. The EMR options for birth control/protection were (1) abstinence, (2) condom, (3) diaphragm, (4) implant, (5) injection, (6) intrauterine device, (7) pill, (8) rhythm, (9) spermicide, (10) sponge, (11) surgical. There is also the options to write in comments. Because no personally identifiable data was recorded during collection of data, the review board waived requirement of consent for review of records and women were not consented.

CASE INCLUSION CRITERIA

Cases included in our analysis were female patients age 18 to 45 at time of their appointment in study interval who were prescribed a category D or X medication. There were a total of 610 women who met these criteria and were included in data analysis.

Category D or X medications were determined based on review of the category D and X medications in 2012 by a counselor for California Teratogen Information Specialists. Some category D and X medications were excluded by this specialist if they were determined to have low teratogenic potential (e.g., oral contraceptives) and the 15 most commonly prescribed medications screened for are listed in Table 1: Teratogen case inclusion list.

STUDY VARIABLES

Variables analyzed for primary outcome were EMR documentation of sexual activity, contraception use, and specific method used. Cases were considered to have documentation

of sexual activity if there was included in “social history” or “ob/gyn history” notation of no current sexual partners or number of current partners (with or without genders of partners).

Criteria for documentation of contraception use included the following: medication list including contraceptive method, immunization records documenting contraceptive injections, documentation in social history of contraceptive method, and surgical/procedure history including contraceptive procedures.

DATA ANALYSIS

Statistical analysis including descriptive statistics of demographics and primary outcomes was conducted using SPSS. We calculated simple frequencies.

Results

A total of 610 women prescribed a category D or X medication were identified. The number of women prescribed teratogenic medications increased with age, with the 18-to 24-year-old cohort having the fewest (77) women and the 40- to 44-year-old cohort having most (176) women. The most common potentially teratogenic medications were alprazolam (27.4%), lisinopril (11.9%), simvastatin (10.0%), minocycline (6.0%), and paroxetine (5.7%).

There was documentation of sexual activity in 434 (71.1%) of these women. In those women who did not have documented sexual activity, 72 (11.8%) were not asked about their sexual activity; 64 (10.5%) were not currently sexually active; and 33 (5.4%) were never sexually active. Of the 434 sexually active women, 407 were sexually active with males. Seventy-two of the 610 patients (11.8%) had documentation that they were not asked about sexual activity. Among the 407 women known to be sexually active with men, 267 women (65.5%) were using contraception. Oral contraceptives were the most commonly used method ($n = 103$). Sterilization was used by 53 women (13.0%) and condoms by 44 women (10.8%) men. All other contraceptive methods (16.5%) made up the remainder of women contraception, as shown in Table 2. The other contraceptive methods included abstinence, diaphragm, implant, injection, intrauterine device, rhythm, spermicide, and the sponge.

Discussion

Past research has shown that women are interested in receiving contraceptive counseling and information about teratogenicity of their medications (Santucci et al., 2010). In this study only 434 of the 610 reproductive aged women (71.1%) had documented of sexual activity.

Contraceptive usage among women taking potential teratogens should be more prevalent given that the risk of an unintended pregnancy includes fetal exposure to a potential teratogen. However, when we compare the rate of contraception use in the study population (65.5%) with the general population (62%) the rate of contraceptive use is similar (Jones et al., 2012). In addition, specific contraceptive method use such as condoms was similar to the national average (11% vs. 10%) (Jones et al., 2012). The typical use failure rate for condoms is 18% and, therefore, is not considered a highly effective contraceptive method (Trussell, 2011). The rate of oral contraceptive use was higher among the study population (25%)

compared with the general population (17%) (Jones et al., 2012). It is possible that the family medicine providers may feel more comfortable prescribing an oral contraceptive the same time they prescribe a Category D or X medications. However, oral contraceptive may not be an optimal choice for women taking potential teratogens because the typical pregnancy failure rate for oral contraceptives is approximately 9% and the adherence among women taking potential teratogens is comparable to the general population of women (Trussell, 2011). In addition, the adherence rate with oral contraceptive is no better than the general population (Steinkellner et al., 2010). Instead, the use of LARC methods may be better suited for this population. The contraceptive implants and intrauterine devices that comprise LARC methods have typical use rates of less than 1%, and they do not rely on patient adherence for their efficacy (Trussell, 2011).

IMPLICATIONS FOR USE OF EMR FOR INTERVENTIONS

The documentation of contraceptive utilization at this site is higher than the rates reported in other studies, with 65.5% of women who are sexually active with men having some form of contraception documented. This may be a reflection of a cultural shift toward using EMR in clinical practice, often with standardized note templates and data forms that act as reminders of important information to collect. Furthermore, this clinic had been using EMR for more than 5 years by the time the visits used for cases were analyzed. Still, with other studies showing an improvement of contraception counseling after additional physician training, this study's rate of documentation of assessment of sexual activity and contraceptive use could be improved further (Fritsche, 2011). When considering how EMR could be used to improve these rates of contraceptive counseling, this study demonstrates that assessing and implementing EMR tools is only as good as the information recorded. With this in mind, 99.1% of physicians who responded to a survey assessing attitudes and barriers agreed that an EMR alert would be worthwhile (Eisenberg et al., 2010).

The results from this study and the body of literature regarding education about contraceptives and potentially teratogenic medication informed the development of an EMR alert that brought provider's attention to the pregnancy risk category of a medication they were ordering for category D and X drugs (Mody et al., 2013). That study prompted physicians to order a referral to the California Teratology Information Specialists (CTIS) Pregnancy Health Information Line when writing a prescription for potential teratogens. This referral led to a CTIS counselor sharing information with participants about teratogenic potential of their medications, and contraceptive options. One in three women were considering a more effective contraceptive method, as determined by her stating an interest in a method with lower failure rates and her current method (e.g., moving from barrier only to hormonal/user-dependent, or from hormonal/user-dependent to LARC). Future areas of study would be to determine whether such expressed interest later translates into changes in contraceptive behavior, which was not assessed in that study.

LIMITATIONS

It is notable that this classification system was eliminated. However, when this study was conducted the pregnancy categories were still in place, therefore, may have impacted provider counseling and patient usage of contraception. With the advent of the FDA's new

Pregnancy and Lactation Labeling Rule (PLLR), drug labels will move from the traditional lettered risk classifications to a more narrative summary assessing risk versus benefit of use of a medication during pregnancy, along with the evidence base from which such summaries are based (Ramos and Patel-Shori, 2014). Despite this upcoming change, this study still analyzed category D and X medications specifically because it was the classification system during the study period. While not all category D or X medications are teratogens, they are categorized as such based on how their risks weigh against their potential benefits (Doering et al., 2002) and such shared decision-making by patient and physician about the use of potentially teratogenic medications must be informed by knowledge of a patient's reproductive goals and sexual activity.

Another limitation of this study is the use of EMR to gather data. While this tool is becoming increasingly useful, it still relies on clinician knowledge and commitment to documenting their encounters in a standardized way. Given that some Depo-Provera injections were documented under immunizations rather than medications, and not all intrauterine devices were listed under medications, it is unlikely that EMR chart reviews capture the entirety of contraceptive use that happens between providers and their patients. Another limitation of the documentation of contraception prescribing in the EMR is that it does not necessarily equate usage of the method. However, this issue also occurs with contraceptive studies that rely on with self-report of contraceptive use. For example, a participant may report use of condoms to a study team member but in fact not use condoms. A final limitation of this study is that we sequentially looked for documentation of sexual activity, partner type, and then if a method was listed under contraceptive. If sexually activity with a male was not documented we did not see if a contraceptive method was listed.

CONCLUSIONS

Although the majority of women who are taking potentially teratogenic medications are asked about their sexual activity, there are still a significant number who still need to be asked about sexual activity. This study successfully used EMR to identify the high usage of oral contraceptives and identified the low LARC methods. The EMR has the potential to improve physician and patient education about the importance of assessment of sexual activity, contraceptive use, and the prevention of pregnancy exposures to teratogenic medications.

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TABLE 1

Frequency of Use of the Most Frequently Used Potential Teratogenic Medications among Females Aged 18 to 45, University of California San Diego Family Medicine Clinic, April 2011 to April 2012

Teratogenic medication	No. of subjects
Alprazolam	473
Lisinopril	205
Simvastatin	172
Minocycline HCl	103
Paroxetine HCl	99
Atorvastatin calcium	75
Hydroxychloroquine sulfate	68
Warfarin sodium	65
Valsartan	55
Benazepril HCL	42
Temazepam	37
Carbamazepine	36
Enalapril maleate	35
TELMISARTAN	29
Lovastatin	26
38 Other medications	208

TABLE 2

Documentation of Sexual Activity and Contraceptive Methods among Females Aged 18 to 45, University of California San Diego Family Medicine Clinic, April 2011 to April 2012

	Number (N = 610)	Percent of total women (N = 610)	
Not asked about sexual activity	72	11.8%	
Not currently sexually active	64	10.5%	
Never sexually active	33	5.4%	
Sexually active	434	71.1%	
Left blank	7	1.1%	

	Number (N = 434)	Percent of women sexually active (N = 434)	
Female partners or not specified	27	4.4%	
Male partners	407	66.7%	Percent of women with male partners (n = 407)
No contraception listed	132		32.4%
Pregnant	1		0.2%
Hysterectomy	7		1.7%
Using contraception	267		65.6%
Sterilization	53		13.0%
Oral contraceptive	103		25.3%
Condoms	44		10.8%
Other methods	67		16.5%