Perspectives of Primary Care Clinicians on Teratogenic Risk Counseling

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BACKGROUND: Women of childbearing age are commonly prescribed medications by primary care providers (PCPs) that may cause birth defects if used during pregnancy. **METHODS:** To identify what PCPs perceive as barriers to and potential facilitators of providing counseling to women of childbearing age when teratogenic medications are prescribed, we conducted eight focus groups with 48 PCPs recruited from four clinical settings in Pittsburgh, Pennsylvania. We explored PCPs' experiences counseling women about teratogenic medications. Each focus group was audio-recorded, transcribed, and coded using a grounded theory approach by three independent coders. **RESULTS:** PCPs feel responsible for counseling women when they prescribe medications that may cause birth defects, but note difficulties identifying clinically relevant sources of information on teratogenicity. Other barriers to providing counseling include limited visit times and lack of reimbursement for preconception or teratogenic risk counseling. PCPs find it challenging to identify patients who may become pregnant and who therefore need contraceptive and/or teratogenic risk counseling. PCPs expressed a desire for online resources that could be used when explaining medication risks to patients. PCPs feel that the development of patient information materials, electronic decision support tools, clinical care systems that routinely assess patients' pregnancy risk, and changes in the reimbursement structure may facilitate counseling patients about teratogenic risks. **CONCLUSIONS:** PCPs perceive themselves as playing an important role in providing their patients information on risk of medication-induced birth defects. To ensure safe prescription of teratogenic medications, PCPs suggest interventions at both the clinic and healthcare system levels. *Birth Defects Research (Part A) 85:858–863, 2009.* © 2009 Wiley-Liss, Inc.

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INTRODUCTION

Each year in the United States, 150,000 infants (1–3% of all births) are born with some form of physical or mental birth defect (Centers for Birth Defects Research and Prevention, 2004). Although the causes of most birth defects remain unknown, exposures such as radiation, alcohol, and certain medications are known to increase rates of birth defects. As such, the U.S. Department of Health and Human Services, the Office of the Surgeon General, and the Institute of Medicine have identified the prevention of birth defects as one of six priorities for the nation's health (U.S. Department of Health and Human Services, 2004).

In the late 1950s and early 1960s, women's use of thalidomide resulted in the birth of more than 10,000 children with significant birth defects (Leck and Miller, 1962). More recently the teratogenic effects of isotretinoin (Accutane, Hoffmann–La Roche Inc.) have received widespread attention (Garcia-Bournissen et al., 2008). However, multiple other medications have been associated with increased risks of birth defects. To protect women and their families from adverse outcomes associated with use of certain medications, the U.S. Food and Drug

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Administration (FDA) instituted a drug classification system in 1979 in which drugs classified as category D or X indicate potentially teratogenic medications (FDA, 2003). More than 100 prescription medications used to treat conditions ranging from hypertension to seizures were labeled as class D or X. In addition, there are numerous examples of drugs with other ratings that, depending on the timing and dose of the exposure, may also cause fetal harm (Briggs et al., 2008). It has been estimated that each year in the United States 11.7 million women of childbearing age are prescribed a medication that has been labeled by the FDA as increasing risk of birth defects if used during pregnancy, and that these potentially teratogenic medications are most frequently prescribed by primary care providers (PCPs) (Schwarz et al., 2005). Because comparably effective medications that are not teratogenic do not exist for some medical conditions, it is sometimes necessary to treat women of reproductive age with medications that are known to induce birth defects.

With use of effective contraception, birth defects associated with teratogenic medications can be prevented. This requires that PCPs counsel women about risks associated with use of a medication during pregnancy and their contraceptive options. National data indicate that ambulatory physicians provide contraceptive counseling only 5–20% of the time that they document use of a potentially teratogenic class D or X medication by a woman of childbearing age (Schwarz et al., 2005). Moreover, approximately 6% of pregnancies in the United States are exposed to potentially teratogenic class D or X medications (Andrade et al., 2004, 2006, 2008). In situations in which pregnancy is desired and untreated maternal disease poses a greater risk to a fetus than the medications used to treat the disease, proactive counseling about the irrelevance of information contained in package inserts may prevent women from stopping needed medications when they become pregnant.

Understanding how patients and physicians communicate about pregnancy and risk of medication-induced birth defects is an important first step in preventing adverse birth outcomes. Although PCPs frequently prescribe medications to women of childbearing age that have been labeled by the U.S. FDA as potentially teratogenic (Schwarz et al., 2005, 2007), little is known about how PCPs obtain information about teratogenic risks or convey this information to their patients. The objective of this qualitative study was to understand how PCPs can be supported in their efforts to provide information about teratogenic risks to their patients. Specifically, we investigated what clinicians perceive their role to be in providing information about potentially teratogenic medications. In addition, we explored perceived barriers to providing information about potentially teratogenic medications and elicited what factors PCPs believe might facilitate the provision of information about teratogenic risks in primary care settings.

METHODS

Study Participants

We conducted eight focus groups with 48 English-speaking, primary care clinicians. Clinicians were recruited by e-mail and by U.S. mail sent to six clinical offices affiliated with the University of Pittsburgh and the University of Pittsburgh Medical Center. These clinics included three family practice clinics, an academic general internal medicine clinic, a university student health clinic, and an adolescent medicine clinic. Clinicians were selected to ensure that focus groups contained a spectrum of academic and community-based clinicians, men and women, nurses, physicians, and pharmacists, and clinical faculty and trainees.

Focus Group Procedures

Focus groups (FGs) were conducted between November and December 2007. All participants provided written informed consent, in accordance with a protocol approved by the institutional review board of the University of Pittsburgh.

Before each FG, participants were asked to complete an anonymous single-page survey to provide demographic information (age, gender, race/ethnicity, clinical training), number of hours spent providing direct patient care per week, number of women of reproductive age seen per week, and experience using an electronic medical record (EMR).

Each FG involved 6–10 participants who received a $100 incentive and dinner during the discussion. Each FG lasted 1.5–2 hours and was conducted in a clinic conference room during evening hours. FGs were moderated, using a standardized interview guide, by a facilitator who shared no clinical responsibilities with any FG participants. The interview guide was developed using a conceptual framework that combined knowledge, beliefs, and perceived self-efficacy in counseling. Questions explored three topics: (1) primary care clinicians' perception of their role in providing teratogenic risk counseling, (2) barriers and facilitators of teratogenic risk counseling, and (3) possible targets for intervention. The interview questions were open-ended with prompts designed to provide more information (guide available on request).

Data Analysis

All FGs were audio-recorded and subsequently transcribed. Transcripts were entered into ATLAS.ti (Scientific Software Development, Berlin, Germany), and a grounded theory approach (Krueger and Casey, 2000; Strauss and Corbin, 2000) was then used for content analysis. We used an a priori, semistructured thematic template using the three thematic areas covered in the moderator guide. Thematic codes were refined using an iterative process. Themes were identified by open coding of the text, which were then compared within and across FGs. Codes were combined and synthesized into broader, recurrent themes based on consensus of two investigators (M.A.G. and C.N.) with further input from a third investigator (E.B.S.) producing a final codebook. The codebook was used by two team members (M.A.G. and C.N.) to independently code each transcript. Coded transcripts were reviewed by the principal investigator (E.B.S.), and discrepancies in transcript coding were resolved via discussion until consensus was reached by the research team. The independent coders applied similar codes to the transcripts 85% of the time. Thematic saturation was reached, and only minimal edits were made to the codebook by the time the fifth transcript was reviewed. However, all eight FGs were coded in their entirety and are referenced in this article.

Table 1
Characteristics of Primary Care Providers Participating in Focus Groups

Characteristic	
Age in years (mean ± SD)	49 ± 9
Current postgraduate trainee (%)	8
Gender (% female)	88
Race/ethnicity (% Caucasian)	93
Prescribe contraception	73
Direct patient care, median (range) hours per week	33.5 (4–60)
Women of reproductive age seen each week	50 per week (1–300)
Experience using an electronic medical record (%)	68

Data not available for 7/48 participating clinicians.

Once the transcripts were coded, patterns of responses, both within and between concepts, were explored across the various FGs. We initially treated each FG as the unit of analysis. We then used a data matrix to compare responses across the groups. This matrix divided clinician participants into groups based on gender, training status, and practice setting. This type of data display helped delineate variations and similarities among each participant type. Such analysis allowed insights to emerge about the ways different groups of people look at the same issue and provided a means of ensuring that all perspectives were appropriately represented.

RESULTS

The 48 primary care clinicians who participated in these FGs included general internal medicine faculty and residents, adolescent medicine faculty, family practitioners, nurse practitioners, registered and licensed practical nurses, and a pharmacist. Demographic characteristics of participants are shown in (Table 1).

Primary Care Clinicians' Role in Providing Teratogenic Risk Counseling

In general, PCPs described feeling responsible for counseling women about the teratogenic risks associated with medications they prescribe. As one clinician said, ''If you prescribe it, you should provide the counseling about it''; another said, ''I think the ultimate is on the physician because they're the one who's prescribing the medication and telling them to take it.'' PCPs also described feeling responsible for following up on clinical issues addressed by specialists. In the words of one provider:

''I've actually had some patients...I don't know how many but at least a handful of patients who specifically come with a question about a medication because they're pregnant or are gonna be getting pregnant. So that's the sole reason why they're...coming. So it might be like someone else—like, one of the specialists—is putting them on a medication that they wanna come ask primary care [about]...So I've had a fair number of them like that.''

PCPs recognized that patients seek their guidance about the impact of medications on pregnancy. As one PCP stated, ''When I had my children, it was that you called your obstetrician...Now everything gets punted back to the PCP.''

PCPs recognized the potential liability related to prescribing potentially teratogenic medications. They described concerns of facing malpractice claims if they do not ensure that patients are not pregnant before starting a teratogenic medication, and possibly if a patient were to become pregnant while taking such a medication. As one clinician said,

''If we're giving them...[a potential teratogen]...you have to ask them if they're pregnant and even if they say, 'There's no possibility that I could be pregnant,' you're still supposed to test them because we don't know. They might say that, but that may not be the case. And then we have to also tell them that they can't get pregnant within four weeks. If they're of child-bearing age, they could go out and get pregnant next week...So you have to think about the immediate problems that could possibly occur and there's always law suit issues and well, that's a safety thing for the patient too though.''

A number of PCPs had encountered clinical situations in which one of their patients had become pregnant while taking a potentially teratogenic medication. They discussed the clinical and emotional difficulty of providing care to women whose pregnancies had been exposed to potentially teratogenic medications:

''I had a situation where this young girl was taking medication for a condition that she had...and she got pregnant. And when she found out she was pregnant, she was still taking this medication that would have been absolutely devastating to a growing fetus. So we helped her to set up an abortion, which was rough...I was angry because I had to help her. And it's not, I mean, I'm very much pro-choice...but it just made me mad that this was something that...could have been avoided, you know...And it was sad. You know, it was a sad situation.''

Barriers to Provision of Teratogenic Risk Counseling in Primary Care Settings

Clinicians identified five barriers to routinely counseling women about teratogenic risks in their primary care settings: limited clinical time, lack of reimbursement for time spent counseling, difficulty finding clinically relevant information on medications' teratogenicity, concern that patient anxiety related to information about teratogenic risk will lead to medication non-use, and difficulty identifying patients' pregnancy plans (Table 2). Below are representative quotations describing the assortment of challenges PCPs face:

Table 2
Barriers to Provision of Teratogenic Risk Counseling in Primary Care Settings

Time
Lack of reimbursement
Finding clinically relevant information on teratogenic medication is difficult and time consuming
Nonuse of needed medications due to anxiety about teratogenic risks
Difficulty identifying patients' pregnancy plans

Time

PCPs reported that the limited amount of time allotted for clinic visits makes it difficult to provide counseling about teratogenic medications. Challenges related to limited clinical time were frequently placed in the context of competing medical priorities. In the words of one PCP, ''I think time is the biggest factor. There is no time. Sometimes there's so many more pressing issues at a visit that must be addressed so it always comes down to time.'' Another PCP echoed these concerns saying, ''Time would be the biggest thing. You have twenty minutes to see the patient. You know…There's a couple other issues like are you going to keep them alive next week.''

In addition, PCPs noted that the complexity of discussions of risks during pregnancy makes them inherently time consuming. As one PCP put it, ''It's such an intense subject that most doctors don't want—I mean, they're on a limited schedule so when that person comes in, the last thing they are going to do is get into an intense discussion about conception and preconception and birth control and the ins and outs because they just don't have the time.''

Lack of Reimbursement

Lack of reimbursement for providing teratogenic risk or preconception counseling was another commonly cited challenge. One PCP made this very explicit, stating ''I don't get paid to do it. That's, sort of, the nutshell. That's it.'' A number of PCPs expressed frustration with the way reimbursement issues impacted their clinical care, and made statements such as the following:

''I guess the difficult thing is there's the difference between what you would like and what reality is…I mean, it would be nice to have more time and frankly reimbursement to counsel people. You know, because that's the enjoyable part…But the fact is, number one, we don't have time to do it and so we're many times, we just have to put out fires first. And number two, frankly the reimbursement doesn't work that way. I think it's quite important. But the actuality—it just falls by the wayside.''

''I'm sorry. I just don't have fifteen minutes to sit down and deal with this and try and bill an insurance company who will reject the payment because they do not cover that. And this is a problem. When you have things like this…you are touching on a nerve here, a big nerve. Yes, in the best of all possible worlds, it should be done. It could be done, and we'd be happy to do it, but it's not being done. It's not because we're not…because we're not good physicians.''

Finding Clinically Relevant Information on Teratogenic Medication

PCPs spoke about difficulty identifying clinically relevant information about a medication's effects on a pregnancy. They described awareness of resources (primarily the Briggs text (Briggs et al., 2008) that provide information about potentially teratogenic medications but raised concerns about access to these resources in their examination rooms, and the variable quality of information that they encountered online. In addition, they described the process of seeking information about a medication's potential teratogenicity as often tedious and time consuming:

''In a pinch, you can practically always Google a drug name plus pregnancy category and that is practically always helpful…but it takes a lot of time to do that. And then a lot of times you have to say to the patient well, I'll call you back once I research the information. And sometimes it even takes you to the next day before you actually get back with the patient.''

PCPs spoke about challenges identifying resources that had the level of detail they felt was necessary for communicating with their patients. Statements made about this issue included the following: ''If you really need details—if a woman is on an SSRI and you really wanna go over the common birth defects that are possible and what the actual, you know, rate, you need to go to a source that's gonna give you that kind of information…I don't know that Micromedex is gonna give the kind of detail I need.''

PCPs expressed a desire for resources that would provide more specific numerical information that they could use when explaining a medication's risk of teratogenic side effects to a patient. In the words of one clinician, ''I know there are textbooks about pregnancy and lactation and drugs and, you know, they give you a little bit more but still they are laundry lists of what can potentially happen and not, how much of the time like 1 in 2000 or 1 in 20?''

PCPs also spoke of the challenges they faced in communicating risk of teratogenicity in a way that would be meaningful to their patients. Ideally, they would like references that provided information the same way they intended to convey that information to their patient: ''I talk about numbers for ten thousand because that's how I learned the numbers…I mean, there's a relative risk—so I try to get the attributable risk component in there 'cause if you talk relative risk…it sounds terrible. You know, if you talk…attributable risk or, you know, population-based risk, it's very different.''

No FG participant mentioned the option of referring their patients to a teratology information specialist.

Nonuse of Clinically Indicated Teratogenic Medications

Another issue that PCPs raised was their concern that discussions of a medication's risks might result in nonuse of a needed medication. As one clinician stated, ''For me, it's a big fear they're not gonna wanna take the medicine, that they're gonna be too worried…So then they won't even benefit from it…A lot of them don't understand that this is .001%…and then they refuse to think it really might help them or improve their quality of life or their general health…That's my biggest fear.'' Clinicians spoke of the importance of balanced discussions of medications' potential risks and benefits, and the need to place these discussions within the context of the woman's disease process.

Difficulty Identifying Patients' Pregnancy Intentions

A final challenge clinicians raised was the fact that they generally depend on their patients to raise questions

Table 3
Potential Facilitators of Teratogenic Risk Counseling in Primary Care Settings

Online references
Computerized decision support
Assistance in identifying patients' pregnancy plans
Patient education materials

about pregnancy, though they are aware that many women have difficulty volunteering this information:

''A lot of patients don't talk to their doctors. Some people...just talk to their OB/GYN about it...but they don't tell their internist, too, so I think there are probably a lot of people out there trying to get pregnant...who wouldn't necessarily tell you. Why would they tell you?—You're their [internist]''

Despite acknowledging that they frequently lacked information about their patients' plans for pregnancy, few described routinely asking patients about their pregnancy intentions.

Ways to Facilitate Counseling about Risk of Medication-Induced Birth Defects

Clinicians provided several suggestions for ways to facilitate counseling about medications' teratogenic risks in their primary care settings (Table 3). These included assistance in identifying medications that pose teratogenic risks, assistance in identifying women's pregnancy intentions, and access to educational materials for patients. Below are illustrations of each suggestion.

Online References

Clinicians made frequent mention of the Internet as a preferred source of information. A number of PCPs expressed concerns that books and other hard-copy references might be of date by the time they were published and distributed. This seemed to be a particular concern for resources regarding risk of teratogenicity because of the need for ongoing studies in this area, especially for newer medications. In the words of one clinician, ''Maybe online references ...I ain't read a book in five years. Honest to God. I gave my PDR away.''

Computerized Decision Support

A number of PCPs felt that decision support built into electronic medical records could be helpful if it was timed to coincide with computerized order entry of prescription medications. As one clinician said, ''I'd like it if it would pop up when you put the drug in the computer. Because then even if you're not thinking about it, it would be right there.'' Another clinician added, ''It would be nice if we had a resource where, as we're prescribing a drug, to have a tab off of that drug name that would tell us things like side effects in pregnancy, category, and all the other things.''

Assistance Identifying Chance of Pregnancy

Some clinicians stated that they would appreciate more assistance in identifying their patients' plans for pregnancy. They proposed a variety of ways in which this information could be routinely collected by clinic staff. For instance, ''If the person who's coming in and saying, 'What meds are you on, any allergies, [asked] are you pregnant or do you plan to become pregnant?' That would be sort of...normal, if you could sort of trust that that got screened...Like, if you go to get an x-ray they always do that. But in the doctor's office, they don't.''

Similarly, PCPs proposed systems that could be used to assure that a patient was not pregnant before a potentially teratogenic medication was prescribed. Interest was again expressed in harnessing dimensions of the electronic medical record. As one PCP suggested, ''Another thing might be if somehow it prompts the prescriber to do a pregnancy test. You know, if you have to stop and do a pregnancy test that would prompt you to think 'Oh, why do I have to do a pregnancy test on this?'''

Patient Education Materials

Finally, PCPs expressed interest in access to patient education materials that would allow them to efficiently convey information about teratogenic risks to their patients. In the words of one clinician, ''I think that in the perfect world, it's something that you should be able to discuss with everyone, but the reality is that'd probably be brought down to a hand out, where you at least have that information together, so that you could present it, but whether we'll be able to personally present it each time? Probably not.''

Here again, PCPs proposed harnessing the electronic medical record. One clinician described the possibility that ''with our electronic medical record [we could] have it print in the patient instructions, and just hand it to them at the end...So it covers all that stuff. And it talks about this, that, and the other, and if you do get pregnant, you should do this, etc.''

Many clinicians, however, acknowledged that they would find it difficult to find the time and resources required to implement many of the interventions they proposed.

DISCUSSION

This qualitative study found that participating PCPs feel responsible for providing their patients with information about the possibility of medication-induced birth defects. However, PCPs acknowledge that their current practices generally fall short of their own standards for ideal care. PCPs identified five key challenges in helping their patients safely use teratogenic medications and suggested several opportunities for improving counseling about teratogenic medications in primary care settings. Of note, while PCPs do not hesitate to refer patients to specialists if they have complex disease, few were aware of the option of referring their patients to a teratology information specialist.

Efforts to inform primary care providers of referral options, including the toll-free information service (1-866-626-6847) operated by the Organization of Teratology Information Specialists, may be of benefit. Other targets for intervention identified by PCPs included several that can be implemented in most clinical settings. These include the development of patient information handouts and systems to routinely assess patients' plans for pregnancy. As half of U.S. pregnancies are unplanned (Finer and

Henshaw, 2006), and many PCPs expressed a hesitancy to raise this issue with their patients, the development of such systems may be of particular importance. While more resource intensive, PCPs also felt that clinical decision support built in to electronic medical records holds great promise as a way to help PCPs identify medications that pose teratogenic risks and patients in need of counseling. While use of EMRs has been increasing rapidly, it will likely be some time before decision support will be available to aid in provision of teratogenic risk counseling in most primary care settings. In 2005 data from the National Ambulatory Medical Care Survey indicated that one-quarter of office-based physicians were using some form of EMR systems (National Center for Health Statistics, 2006). However, only 9% of these physicians had a ''complete EMR system,'' with computerized prescription, orders for tests, reporting of test results, and physician notes.

Clinicians also suggested the development of a comprehensive online reference as a way to enhance clinicians' ability to provide meaningful information on medications' teratogenic risks. However, developing and maintaining such a web-based database will require a significant amount of funds and attention to ensure that it remains free from bias resulting from pharmaceutical sponsorship. Finally, PCPs felt reimbursement for time spent providing teratogenic risk counseling is needed to support clinicians in the provision of this important aspect of care. Other studies have noted that lack of reimbursement limits provision of primary prevention services (Burack, 1989).

A major strength of this study is the open-ended structure of the interview guide, which allowed us to explore clinicians' perceptions of their role in providing information about teratogenic medications, barriers to the provision of this information, and suggestions for ways to improve the provision of this information. There was diversity in terms of FG participants' practice settings (general internal medicine, family medicine, university student health service, and adolescent medicine setting) as well as training (e.g., medicine, nursing, and pharmacy). Of note, statements made by older PCPs were similar to those made by younger PCPs, who were residents currently training in primary care.

A limitation of the study was that it was a convenience sample drawn from a single region. Despite efforts to recruit a sociodemographically diverse sample, most participants were female and white, which may limit generalizability to PCPs who are male or from different ethnic or racial backgrounds. We suspect that our sample was mostly female because the majority of individuals currently training in primary care are women (Brotherton et al., 2005), and nursing has long been a predominantly female profession. There is the possibility that social desirability bias may also play a role in our findings. In addition, the qualitative focus of this work does not yield estimates of the prevalence of specific responses, but rather reports on the range of answers that were elicited.

In summary, PCPs perceive themselves as playing an important role in providing their patients information on risk of medication-induced birth defects. Understanding the challenges clinicians face in providing information on teratogenic risks as well as their suggestions for ways to improve provision of such information may help to ensure that women of reproductive age receive appropriate counseling about risks of medication-induced birth defects.

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