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Women's Perspectives on Counseling about Medication-Induced Birth Defects

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Abstract

Purpose—This qualitative study explored women's experiences with counseling about medication-induced birth defects, as well as how and when they would like to receive information on medication-induced birth defects from their health care providers (HCPs).

Methods—We conducted 4 focus groups with 36 women of reproductive age (18–45 years) in Pittsburgh, PA. Twenty-one women were using medications to treat a chronic health condition, and two were pregnant. Content analysis was performed by 3 independent coders using a Grounded Theory Approach. Discrepancies were resolved by consensus.

Results—Women reported depending on their HCPs for information about the risks of teratogenic effects of medications on a pregnancy, but felt the information they had been provided was not always comprehensive. Women want HCPs to initiate discussions about potentially teratogenic medications at the time the medications are prescribed, regardless of whether the woman is sexually active or planning a pregnancy. Women want clear information about all potential outcomes for a fetus. Factors women reported as being critical to effective teratogenic risk counseling included privacy, sufficient time to discuss the topic, and a trusting relationship with their HCP.

Conclusions—Women of reproductive age feel provision of information about the possible teratogenic effects of medications could be improved by routine discussions of teratogenic risks at the time medications are prescribed.

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It is estimated that 6% of US pregnancies are exposed to potentially teratogenic medications (Andrade et al., 2004) and approximately 3% of U.S. pregnancies result in the birth of an infant with a physical or mental birth defect (Centers for Birth Defects Research and Prevention, 2004). Additionally, some medications which do not cause gross structural anomalies carry the risk, of growth impairment, behavioral teratology, neonatal toxicity, and intrauterine death (Wilson, 1977). Under ideal circumstances, no pregnancy would be exposed to a potentially teratogenic medication. However, for some medications only limited information is available about use during pregnancy, and for some medical conditions that affect women of reproductive age, effective, non-teratogenic medications do not exist, making it necessary at times to treat women with medications that may cause birth defects. For instance, in some clinical situations, untreated maternal disease poses a greater risk to a developing fetus than maternal use of medication would.

National guidelines recommend that primary health care providers (HCPs) routinely provide preconception counseling (PCC) to women of child bearing age (United States CDC/ ATSDR Preconception Care Work Group and the Select Panel on Preconception Care, 2006). As reproductive-aged women in the U.S. receive 11.7 million prescriptions for potentially teratogenic medications each year, (Koren et al., 1998; Schwarz et al., 2007) an important component of PCC is informing women about medications that are potential teratogens. This requires providing information about the frequency and severity of teratogenic effects as well as alternative therapies which may have less severe fetal effects. Two recent studies demonstrated that PCC can increase women's knowledge of pregnancy-related risks and change women's pregnancy-related behaviors, including reducing their exposure to potential teratogens during pregnancy (Elsinga et al., 2008; Schwarz et al., 2008). However, another study did not find PCC improved pregnancy outcomes (Winterbottom et al., 2008) while a fourth noted that PCC heightened women's anxiety (Griffiths et al., 2008). Additional information is therefore needed to refine the content and improve delivery of PCC within the constraints of limited information for some medications about pregnancy-specific risks.

Understanding how and when women want their HCPs to communicate with them about the risk of medication-induced birth defects is an important step in improving PCC and preventing adverse birth outcomes. The objective of this qualitative study was to understand how and when women of reproductive age have received information about risk of medication-induced birth defects and to explore their opinions about how the counseling provided by their HCP could be improved.

Methods

Study participants

We conducted four focus groups with thirty-six English-speaking women of reproductive age. Women aged 18 to 45 were recruited via flyers placed in local hospitals, shopping areas, and medical clinics. Participants were purposefully selected to ensure participation of women with a range of medical conditions and experiences with long-term medication use.

Focus group procedures

Focus groups were conducted between November and December 2007. All participants provided written, informed consent. Prior to each focus group, participants completed a

brief, anonymous survey that assessed demographic information (e.g. age, race/ethnicity, education, marital status), pregnancy and health history (e.g. medical problems, recent medication and contraceptive use). Each focus group lasted 1.5–2 hours, included 6–10 participants and was conducted in a clinic conference room during evening hours. Participants received a \$50 incentive and dinner during the focus group. Focus groups were moderated, using a standardized, semi-structured question guide (available on request), by trained facilitators. The facilitators initially asked questions that explored women's past experiences with teratogenic risk counseling, including what information they had received from HCPs and what other sources of information they had used. The facilitators then explored women's preferences regarding how and when they might have preferred to receive teratogenic risk information, and what specific information was most important to them. This study was approved by the University of Pittsburgh Institutional Review Board.

Data analysis

All focus groups were audio-recorded, transcribed and entered into ATLAS.ti (Scientific Software Development, Berlin, Germany), a qualitative data management program. Directive content analysis was performed in an iterative process that involved reading and rereading each transcript line-by-line to identify and explore emergent themes. Directive content analysis is generally performed when prior research exists about a topic and when the analytic goal is to validate or extend current knowledge. (Hsieh and Shannon, 2005) In this case, we used this approach to code words, phrases and passages related to two themes: 1) women's experiences with, and 2) women's preferences for teratogenic risk counseling. We then used a grounded theory approach to content analysis to identify sub-themes related to each of the primary coding categories. This inductive process involved re-reading the coded passages line-by line to identify and define relevant sub-themes. These sub-themes were organized into a codebook which was used to recode the transcripts. Each step of the coding process was performed independently by two team members (AKS and MAG), who then met to compare their codes. Coding discrepancies were resolved via discussion with the PI (EBS). The independent coders applied similar codes at each step in the coding process 85% of the time. Thematic saturation was reached by the third focus group, however all four focus groups were coded in their entirety and are referenced in this paper.

Results

Sample Characteristics

The majority of participants had one or more chronic medical conditions, including acne, diabetes, hypertension, multiple sclerosis, systemic lupus, migraines, and arthritis. Medications taken by participants included isotretinoin, antidepressants, anti-inflammatory medications, proton pump inhibitors, and antibiotics. All women had taken medications at some point during adulthood, for either chronic or acute health conditions, and identified as their primary care provider a physician who did not provide obstetric services. A number of participants had previously been pregnant, and some had used medication while pregnant. None of the participants disclosed having personal experience with an abnormal pregnancy outcome. In addition, none of the participants described ever having scheduled an appointment to specifically discuss medication risks or preconception counseling with their HCP. Additional sample characteristics are shown in Table 1.

Women's Experiences with Teratogenic Risk Counseling

Sources of information—Women reported receiving information about pregnancy-related risks associated with prescribed medications from a variety of sources. (Table 2) The most commonly reported sources of information were written materials (e.g., pamphlet inserts) which did not allow women the opportunity to ask questions, clarify content, or

explore the relevance of the information. However, a number of women also reported obtaining information from individuals from whom they could engage in a dialogue, ask questions, and receive additional clarification. Commonly cited sources included HCPs, friends or family members.

HCP Approaches to teratogenic risk counseling—Women reported that HCPs used several different approaches to providing teratogenic risk counseling (Table 3). Some providers directly cautioned women not to become pregnant while taking a particular medication while others were less direct. One woman described her provider giving direct counseling to avoid pregnancy: “My doctor has been pretty good. I guess, you know, since I’m a female, automatically that pregnancy question comes along every time he does something with me.” Another woman described her doctor’s less direct approach: “If you become pregnant, this medication could harm the baby – [but] they didn’t advise me to not become pregnant while using the medication.” Other women described having had a HCP indirectly tell them not to become pregnant while using a medication, by cautioning the woman to use a “backup” or second method of birth control.

A number of women reported never having received any teratogenic risk counseling from a HCP. These women described feeling concerned upon having discovering on their own that a medication could have teratogenic effects on a pregnancy. As one woman said, “I know the medication I’m taking right now causes problems [with a pregnancy] and my doctor has never told me it. I found out by accident, actually, from another person who was taking it. And then I researched it and there it was.”

For women who received information about teratogenic risks of medications, there were varying levels of satisfaction with the information received. While several women indicated that they were satisfied with the teratogenic counseling they received from their HCPs, other women expressed concern that the information they had received was not complete. As one woman expressed, “If they do tell you, they’re vague. Like oh, you know, just take some extra birth control. Tell me why I need to make sure I’m extra safe because what can happen. I want the whole picture all the time. I want to know why...why do I need to be extra careful...what will happen if I do get pregnant? Don’t just say -- Oh, just be careful. Use a second method of birth control.” This implies that in situations where information on the safety of use of a medication during pregnancy is not yet available, HCPs should share with their patients the need for ongoing data collection.

Women’s sense of their providers’ comfort with teratogenic risk counseling also affected their perceptions of the quality of their counseling experiences. Some HCPs were perceived as uncomfortable when introducing the topic of medication-induced birth defects to women: “[My gynecologist] seems like she’s actually kind of uncomfortable talking about it with me, and I’m just kinda like, “Well... you’re giving me this. Like, I need to know what this is.” Women also expressed that impersonal communication styles, or poor bedside manner, at times hindered communication about medication-induced birth defects.

Although women generally indicated that they trusted their HCPs, particularly when they had a long-standing relationship, many still directed follow-up questions to trusted friends or relatives, particularly those who worked in health care. In the words of one woman, “My mom is a nurse...so a lot of times I’ll ask her about different medications...I usually listen to her advice more than anything, or ask friends, but, put her at the top of my list.”

Women’s Preferences for Teratogenic Risk Counseling

Women overwhelmingly expressed the feeling that HCPs should initiate discussions and provide information about teratogenic risks of medications, regardless of a woman’s age,

pregnancy intentions, sexual orientation, or level of sexually activity. Although most women acknowledged that patients should play an active role in initiating questions about the safety of medications during pregnancy and providing accurate information about their current sexual activity, pregnancy plans, and contraceptive use, they uniformly expressed the opinion that it is primarily the responsibility of HCPs to proactively provide women with accurate and current information about pregnancy-related risks associated with medication use. This is illustrated by statements such as “If they gonna put you on a medicine, then they should tell you. If they puttin’ you on a medicine or something like that that may harm a fetus, then ask me am I planning pregnancy or just tell me the side effects if I am pregnant because I’m a woman, so you should tell the women the side effects of pregnancy and that medicine.” In the words of another participant, “Even if <someone> doesn’t wanna know– it’s still the doctor’s responsibility to give that information, just like it was the doctor’s responsibility to say, “Hey, you have lung cancer.” Even if you don’t wanna know that” Another common perspective among women in this focus group was expressed by one woman as: “if they’re going to wait for people to say oh, yeah, I’m planning to get pregnant, they’re going to get very little response from that-- because nobody’s planning!”

Women identified seven components of effective teratogenic risk counseling: 1) timely information, 2) data on all potential impacts on a fetus, 3) clear information, 4) repetition of important information, 5) avoiding assumptions about women’s pregnancy intentions, 6) explanations as to why HCPs are asking about sexual activity and pregnancy intentions, and 7) discussion of future consequences for reproductive health (Table 4).

Women also had preferences for how information about teratogenic risks should be communicated. Specifically, women spoke about: 1) a desire for privacy, 2) sufficient time to discuss the topic during a medical visit, 3) HCP bedside manner, and 4) a trusting patient-provider relationship (Table 5). Although women wanted timely information about pregnancy-related risks, this desire was tempered by a general concern that a HCP must build a trusting relationship with a patient in order for the patient to have confidence in the counseling she is receiving. Trust in a patient-provider relationship was identified as a critical factor to successful teratogenic risk counseling.

However, women felt that detailed information about pregnancy-related risks at the time of prescription was necessary to prevent unfavorable outcomes, and they preferred to receive this information regardless of whether the discussion might make either their HCPs or themselves uncomfortable. As one woman said, “I think I’d be more embarrassed if I had to go and have an abortion because I took this medication that was gonna prevent this baby’s kidneys from developing and I didn’t know the full extent of what it would do. I’d rather be embarrassed in the office than embarrassed in a situation like that down the line.”

Despite the above thoughts about the importance of teratogenic risk counseling, none of the women who participated in these focus groups reported having personally considered the possibility of teratogenic effects of a medication when they last filled a prescription. When women were asked what factors they had personally considered when deciding whether to take their current medication, participants described side effects, cost, interactions with other medications, and efficacy as their primary concerns. Only two women identified “interaction with contraception” as a concern, and none of the women suggested effects on a pregnancy or fetus as a concern without prompts from the moderator. This underscores the importance of HCPs introducing the topic of medications’ potential effects on fetal development.

Discussion

This qualitative study found that participating women wanted clear information about how health conditions and medications affect a pregnancy, and that they would like this information introduced to them by their HCPs when they are prescribed a potentially teratogenic medication regardless of their pregnancy intentions. This point is particularly salient given that few participants reported planning their pregnancies and none reported having personally considered the possibility of teratogenic effects of a medication when they last filled a prescription. This implies that the written information women likely received from their dispensing pharmacy was not an adequate way to alert women of a medication's potential teratogenic risk.

Ideally, women envision their HCPs serving as a primary source of information about teratogenic risks. They would like this information conveyed privately and with adequate time to discuss issues related to pregnancy-related outcomes. They also identified trust in the patient-provider relationship as an important factor. However, women also commonly sought information on medications and contraception from trusted friends and relatives, who they felt were knowledgeable. Other investigators have found that women frequently identify friends or relatives as more important than the counseling they received from an evidence-based teratogen information service to their decisions regarding use of medications during pregnancy (Bonari et al., 2005). As such, HCPs need to take an active role in routinely providing teratogenic risk counseling and be aware of these other sources of information, and be ready to address differences in opinion about potential risks to ensure that patients receive accurate information about teratogenic risks.

As a health care system, we need to ensure that our primary care providers have the support they need to function effectively in such clinical encounters. Increasing awareness among 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. Alternatively, increasing HCP use of web-based resources such as the ReproTox database offered by Micromedex or the national library of medicine's Toxnet may also be worthwhile. Other targets for intervention include the development of systems to routinely assess patients' plans for pregnancy and to encourage use of effective contraception by women who do not wish to become pregnant. In addition, more wide-spread distribution of patient information handouts such as those published by the Organization of Teratology Information Specialists. Finally, clinics with electronic medical records and computerized physician order entry, may find it advantageous to program computerized alerts for physicians prescribing potentially teratogenic medications.

A strength of this study is the open-ended structure of the interview guide which allowed us to explore women's desires for information about teratogenic medications and suggestions for ways to improve the provision of this information. However, 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. While participants were ethnically diverse and had a range of experiences with disease and medication use, all were from a single geographic region. In addition, there is the possibility that social desirability bias may have affected focus group discussions. While the target population for this study was purposefully sampled to include women with a range of pregnancy, disease, and medication use experiences, women who were interested in participating may differ from women who declined to participate resulting in a self-selection bias.

In conclusion, reproductive age women feel provision of information about the possible teratogenic effects of medications should be routine and is the responsibility of providers,

and that counseling should be accompanied by an assessment of women's pregnancy intentions and contraceptive counseling, if necessary. Currently, HCPs vary in their approach to providing teratogenic risk counseling to women. As prior studies have shown that most women seen in primary care settings could benefit from preconception counseling (van der Pal-de Bruinet al., 2008) the development and evaluation of systems to deliver this counseling in primary care settings should be a priority.

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Table 1**Demographic Characteristics of Focus Group Participants***

Characteristic	
Age in years (Mean \pm SD)	30 \pm 7
Range	18–45
18–34 (n)	25
35–45 (n)	10
Race/Ethnicity N (%)	
Caucasian	19 (54)
African American	14 (40)
Asian	2 (6)
Marital Status N (%)	
Single	23 (66)
Married/Committed Relationship	12 (34)
Education	
High school	3 (9)
Associate's/Trade School	9 (26)
Some college	2 (6)
College	13 (37)
Some graduate school	2 (5)
Graduate school	6 (17)
Has taken 1+ medication for >1 month	83%
Ever pregnant	46%
One or more chronic health conditions*	63%
Age 18–34	60%
Age 35–45	70%
Currently using contraception	91%

* N = 10 (17%) had more than one chronic health condition

* 36 women participated in these focus groups. However, one participant did not provide demographic information.

Table 2

Sources of Information about Teratogenic Effects of Medications

Package insert	"usually I read the little pamphlet...because there are so many things that you have to be careful with. So, it's mostly just reading up on my own."
Medication bottle	"When I was pregnant, I was looking at every bottle of anything I took, and usually it says on there, "Do not take while pregnant," or "Consult your physician before taking if you're pregnant." So I think that the actually bottle is pretty informative"
Teratogen hotline	"I know [local women's hospital] has a teratogen helpline that you can phone in on...So you can phone in and it doesn't have to be a specific, "You know, I've been taking cocaine, how will it affect my child?" It's more like, "I've been prescribed such and such a medication. Will this affect my pregnancy?"
Websites	"I use the internet for everything so I always go to check. And actually they have a website. I think it's called safefetus.com. I can look up a bunch of medications and see like what category it is during pregnancy and what effects it might have on the fetus."
Television commercials	"sometimes you hear 'not for women who are breast feeding or trying to get pregnant'. You hear that a lot. Just like with the commercial. They always put that right out there."
Friends/Family members, especially those in healthcare	My sister's a physician so I ask her a lot of questions.
Health care Providers	"Physicians will give you information...let them know that you're on a medication so they can adjust that or take you off of it because of the side effects or birth defects."

Table 3**Health Care Provider Approaches to Teratogenic Risk Counseling**

Directly inform women that medications pose risks to a fetus	"If you're trying to conceive, he's going to tell you automatically that you cannot take this medication because this could happen to your unborn child -- so it comes from the physician when you tell him that you're trying to conceive." They just said, "If you become pregnant, this medication could harm the baby."
Standardized pre-prescription procedures	"By what they ask you to do prior to taking the medication, like, if it requires you having a negative pregnancy test, for some acne medications, like Accutane, for example, they make you do that because of the severe birth defects that could have upon your child. So, that's just one of the reasons that it's red-flagged. If there's some kind of procedure I have to do ahead of time"...
Recommendations to use a "backup" method of contraception	they're vague. Like oh, you know, just take some extra birth control. they'll be like, "You need to use another means of contraception."
Nonspecific advice not to become pregnant	"I was considering taking a medicine, Accutane, that would cause birth defects... I had talked to a friend who was on the medication and she said that her physician made her... made everyone use two birth control methods, and then my physician just told me not to get pregnant. I mean, it was just kind of weird that her physician had said, "Okay, well, I need to know the two that you're taking," and mine was just like, "Well, don't get pregnant."
Not communicated	"they didn't advise me not to become pregnant while using the medication; but on the bottle it says, "do not use this if you are pregnant, think you may be pregnant, or breastfeeding." They never asked me if I planned on becoming pregnant soon, unless it was for, like, a research study. No, they never really have, and I just wonder how much it has to do with me being single.

Table 4

Desired components of teratogenic risk counseling

Timely information	With every prescription, they [physician] always check for interactions. They check for allergy. And they check your family history and stuff like that. Pregnancy or planning for pregnancy should be on the list. You know, in the top five things that they should check as long as you're of child bearing age, they should ask that question. You ask me if I'm pregnant and I said 'no'... That doesn't mean I might not get pregnant next week on accident. You know what I mean? And so could you tell me what might happen if I do get pregnant?
No assumptions about pregnancy intentions	You don't know what somebody's circumstances is. Most of us go in there as single people... by ourselves. You don't know our situation all the time
Explain rationale for sensitive questions	Ideally, when they ask – “Are you having intercourse?” maybe explaining why they're asking that question. You know, “I'm asking this because if you're thinking about getting pregnant...it could affect what I prescribe.”
Clear information	He could've made it a little bit clearer... what exactly it would do to a fetus if I got pregnant and didn't know about it and was still taking my medication... they didn't go into details like if it would cause a miscarriage or if the baby would have to be aborted or if as soon as I stopped taking it, the baby would develop normally.
Comprehensive information on all potential fetal outcomes	I would want to know everything. I would want to know all Everything. I want to know everything.
Information on future consequences for reproductive health	I think that the way any drug is gonna affect any part of your reproductive system should be addressed because, you know, I don't wanna be pregnant now, but in ten years, sure. So, is it gonna affect, you know, anywhere from my fallopian tubes – any effect that it's gonna have on any part of it
Repetition of information from multiple sources	I think the repetition is important. I think actually when I've been to my doctor and the doctor says, “This antibiotic may or may not reduce the effectiveness of your birth control pill,” and then the pharmacist tells me again, it's sort of like, “Yeah... I really need to watch that.” For me, it's good to have that repetition... It just puts it in my head a little bit stronger. in the clinic, time is very limited. Even if they touch on even the most serious or the most frequently experienced side effects... but also providing some kind of backup literature or saying go to such and such and you can read more about it

Table 5

Desired characteristics of teratogenic risk counseling

Privacy	I wouldn't want somebody to say something embarrassing when there was people around me. Just because that's my private business, you know, so I wouldn't want anybody else to know.
Enough time to discuss topic in visit	Well, it's kind of hard for your doctor to go through all that because they have a limited time to see patients...but you want it from your physician. At least I do. Because they're the ones giving it to me. They're the ones that know what I need.
Good bedside manner	I could see him asking the question, "Are you planning a family?" or something like that. But everybody... don't want children! Everybody's not in the planning your family stage. And sometimes <if not presented properly> that might offend someone."
Trusting relationship	You know, by having the type of relationship with each other, I trust you...I speak to you...I'm more apt to listen to you as opposed to listening to somebody else. Maybe I'm the only oddball, but I think I put a lot of trust in my physician... You know, if <my primary care provider says> I need X, Y, and Z, I'm the type of person, I think, I just trust them. I put a lot of trust into the healthcare system