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Providers’ perceptions of monitoring process for pregnancy category D or X medications in women of childbearing age

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Key words: pregnancy, monitoring, medications, resident education, clinical pharmacy

Abstract
BACKGROUND AND OBJECTIVES: A process for monitoring the prescribing of common pregnancy category D or X medications in women of childbearing age (ages 12 to 50) was developed and implemented by clinical pharmacists within a residency clinic. The project goals were to determine 1) if providers value the monitoring of their prescribing practices, 2) if they value the process used by the clinic, and 3) if providers report changing prescribing practices or note increased awareness when prescribing pregnancy category D or X medications in women of childbearing age as a result of the monitoring process. METHODS: An electronic survey was distributed to the 43 providers currently practicing in the clinic. Survey questions covered topics including value of monitoring prescribing practices for pregnancy category D or X medications in women of childbearing age, value of the specific monitoring process used at the clinic, frequency of consideration of pregnancy status and contraception use when prescribing medication, and suggestions for improvement on the monitoring process. RESULTS: The response rate was 81.4% (n=35). Results showed all responders valued the monitoring of their prescribing of pregnancy category D or X medications and the monitoring process used by the clinic. Providers reported the monitoring process increased how often they thought about a patient’s pregnancy status and contraception use when prescribing medications. CONCLUSIONS: The monitoring process is valued by providers and impacts prescribing practices. It is a quality process that could be implemented by clinical pharmacists in other primary care practices to enhance the safe prescribing of medications for women of childbearing age.

Introduction
In 2008, about half (51%) of pregnancies in the United States were unintended.1 Prescription medication use is common and increasing during pregnancy. In 2006-2008, 93.9% of women reported taking at least one medication during pregnancy.2 The average number of medications used at any time during pregnancy increased from 2.5 in 1976-1978 to 4.2 in 2006-2008.2 Two of the top 10 drugs by monthly prescription in the United States are pregnancy category D or X.3 Pregnancy categories indicate the potential of drugs to cause birth defects if used during pregnancy, with D and X having positive evidence of human fetal risk.

A process for monitoring the prescribing of common pregnancy category D or X medications in women of childbearing age (ages 12 to 50) was developed and has been implemented by clinical pharmacists within a family medicine residency clinic since October 2011. The clinic serves a young, urban, underserved patient population, which includes a significant number of women of childbearing age. These women often have a higher incidence of chronic diseases at younger ages than expected with the general population4,5 and have high numbers of unplanned pregnancies.1 The intent of the monitoring process was to identify women of childbearing age without documented contraception or sterilization who were prescribed pregnancy category D or X medications. The monitoring process was conducted about every six months.

As a result of creating and implementing this monitoring process, it was necessary to determine providers’ perceptions of the monitoring process. The goals were to determine 1) if providers value the monitoring of their prescribing practices, 2) if they value the process used by the clinic, and 3) if providers report changing prescribing practices or note increased awareness when prescribing pregnancy category D or X medications in women of childbearing age, as a result of the developed monitoring process.
Methods
A survey was developed to determine providers’ perceptions of the monitoring process of prescribing practices for pregnancy category D or X medications in women of childbearing age. Demographic information was collected, including gender and provider type: first-year resident (G1), second-year resident (G2), third-year resident (G3), faculty physician, or nurse practitioner (NP). Not all providers may have had patients who qualified for monitoring (i.e. on a pregnancy category D or X medication without documented contraception, postmenopausal status, or sterilization). A screening question assessed whether or not the provider received a patient list of women of childbearing age taking pregnancy category D or X medications, either in January 2012 or January 2013. For those who did not, a final question asked if they would value this type of monitoring and to explain why or why not. For those who did receive a patient list, questions on the value of this type of monitoring and the specific monitoring process used at the clinic were assessed on a 5-point Likert-type scale (strongly disagree to strongly agree). Using the same scale, these respondents were also asked to assess change in prescribing practices as a result of the monitoring process used at the clinic. These respondents were asked to assess the frequency of their consideration of pregnancy status and contraception use of a woman of childbearing age when prescribing medication using a 5-point Likert-type scale (never to always). Finally, respondents who did receive patient lists were asked three open-ended questions on how the monitoring process changed their prescribing practices, what is valued about the process, and suggestions for improvement on the monitoring process used by the clinic.

The survey was distributed to the 43 providers currently practicing in the clinic using Research Electronic Data Capture (REDCap Software, Version 4.13.18). Providers were sent an e-mail announcement and link to the survey. Reminder e-mails were sent to non-responders after one week and again five days later, with data collection concluding two weeks after initial distribution.

The University of Minnesota Institutional Review Board Human Subjects Committee determined review was not required.

Results
The response rate to the survey was 81.4% (n=35). Demographics are shown in Table 1. Thirty-one (88.6%) respondents reported receiving a patient list. Of those respondents, all strongly agreed or agreed that the monitoring of their prescribing of pregnancy category D or X medications in women of childbearing age and the monitoring process used by the clinic was valuable (Table 2). The majority of providers reported agreement with statements that they plan to change (83.9%) or have changed (64.5%) how they approach prescribing pregnancy category D or X medications as a result of the clinic’s monitoring process (Table 2). Eight providers (26.7%) reported they frequently and zero always thought about a patient’s pregnancy status and contraception use before the monitoring process. Twenty (64.5%) reported they frequently and four (12.9%) always thought about it after the monitoring process was implemented (Table 3). Most of the responses to the open-ended questions noted the monitoring increased awareness when prescribing pregnancy category D or X medications (Table 4). All respondents who did not receive a patient list reported they thought it would be valuable to have their prescribing of pregnancy category D or X medications in women of childbearing age monitored.

Discussion
The survey showed providers value the monitoring of their prescribing of pregnancy category D or X medications and the monitoring process used by the clinical pharmacists within the clinic. It also highlighted the impact of the monitoring process on providers; after implementation, 24 providers frequently or always considered pregnancy status before prescribing compared to 8 providers before the monitoring process. Based on the results of the provider survey, the clinic decided to continue the monitoring process.

The monitoring process highlights an important role for clinical pharmacists to support patient safety and resident education through quality improvement processes. Pharmacists have been demonstrating their impact in these areas for many years. The monitoring process also led to additional provider education on the use of medications in women of childbearing age, particularly for those who have a greater likelihood of having an unplanned pregnancy. Clinical pharmacists provided extra didactic presentations within the pharmacotherapy curriculum for the family medicine residency program.

Different providers in the clinic during the span of the monitoring process created a barrier to surveying the providers. The G3 resident class from the previous year was no longer at the clinic at the time the survey was distributed, but may have received patient lists in January 2012. One G2 resident who received patient lists left the program before the survey was distributed. This represents potentially missing data from the 10 residents who graduated and the one resident who left.
This monitoring process highlights one model of ongoing surveillance and aids in active panel management. This type of monitoring process could also be applied to medication alerts and major drug label changes, such as new restrictions, contraindications or dose limitations. It is a quality process that could be implemented by clinical pharmacists in other primary care practices to enhance the safe prescribing of medication for women of childbearing age.

References
Table 1. Demographics (n=35)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider type</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G1</td>
</tr>
<tr>
<td></td>
<td>6 (17.1)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12 (34.3)</td>
</tr>
<tr>
<td>Female</td>
<td>23 (65.7)</td>
</tr>
</tbody>
</table>

Table 2. Provider Agreement with Value and Change Statements

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree, n (%)</th>
<th>Disagree, n (%)</th>
<th>Neither Disagree nor Agree, n (%)</th>
<th>Agree, n (%)</th>
<th>Strongly Agree, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The monitoring of my prescribing of pregnancy category D/X medications in women of childbearing age is valuable (n=31)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10 (32.3)</td>
<td>21 (67.7)</td>
</tr>
<tr>
<td>The monitoring process used by the clinic is valuable (n=30)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>12 (40.0)</td>
<td>18 (60.0)</td>
</tr>
<tr>
<td>As a result of the monitoring process, I plan to change how I approach prescribing pregnancy category D/X medications in women of childbearing age (n=31)</td>
<td>0</td>
<td>1 (3.2)</td>
<td>4 (12.9)</td>
<td>19 (61.3)</td>
<td>7 (22.6)</td>
</tr>
<tr>
<td>As a result of the monitoring process, I have changed how I approach prescribing pregnancy category D/X medications in women of childbearing age (n=31)</td>
<td>0</td>
<td>1 (3.2)</td>
<td>10 (33.3)</td>
<td>12 (38.7)</td>
<td>8 (25.8)</td>
</tr>
</tbody>
</table>
Table 3. Frequency Provider Considered Pregnancy Status and Contraception Use

<table>
<thead>
<tr>
<th>How often did you think about the pregnancy status and contraception use of a woman of childbearing age when prescribing medication</th>
<th>Before Monitoring Process (n=30), n (%)</th>
<th>After Monitoring Process (n=31), n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>0 (0.0)</td>
<td>4 (12.9)</td>
</tr>
<tr>
<td>Frequently</td>
<td>8 (26.7)</td>
<td>20 (64.5)</td>
</tr>
<tr>
<td>Sometimes</td>
<td>17 (56.7)</td>
<td>6 (19.4)</td>
</tr>
<tr>
<td>Rarely</td>
<td>4 (13.3)</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>Never</td>
<td>1 (3.3)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Table 4. Open-Ended Questions and Responses

How has the monitoring of pregnancy category D and X medications in women of childbearing age changed your prescribing practices?

- “Better counseling of women of child bearing age on importance of contraception when on certain medications.”
- “Great reminder to keep this in mind with all young women.”
- “I am mindful of my practice when prescribing medications to woman of childbearing age.”
- “I am more likely to ask about contraception when managing chronic medical conditions in women of child bearing age.”
- “I am more mindful of category of a medication when providing it to women of childbearing age.”
- “I now think about a reliable birth control more.”
- “I think that I am often cognizant when in clinic or precepting residents of a women’s age and fertility status. This process has taught me that there are a few women that have slipped through the cracks, whether by my own prescriptions or by another physicians. This process served as another reinforcement of good medical practice.”
- “It made me realize that many of my patient’s of child-bearing age are on D/X medications- it made me aware of the volume of potential risks for many patients. I now think about warning women of the risks in pregnancy- which I did not before. Previously I had only thought about pregnancy risks really in women who were already pregnant or trying.”
- “It triggered me to think about it before prescribing certain BP meds.”
- “More cautious that they are on a reliable method.”

What do you value about this monitoring process?

- “Easy to use.”
- “Getting the list of patients where it is not clear about their contraception status.
- “Improved patient care.”
- “It’s a reminder system and allows me to review patients and contact them if I feel it is appropriate.”
- “Keeping my patients safe. Also, this process has made it easy for me to review my patients and make changes very quickly and efficiently.”
- “Reminders are great.”
- “The lists were created for us so it was easy to review the charts.”

What suggestions for improvement do you have for the monitoring process used at the clinic?

- “Have the medications in our faces, like on a small laminated card.”
- “More frequent monitoring!”
- “None.”
- “Please keep monitoring, don’t stop!”
- “The patients on our list were ones that we don’t see frequently. I think this is why they were on the list because when I see them more often, I remember to ask about contraception. It was very challenging to contact these patients. I sent a letter to one, but am not sure if she got it as both numbers in the chart were not working.”