Health care providers' use of a drug information service for pregnancy-related inquiries

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Abstract

Objectives: To characterize pregnancy and lactation-related medication inquiries to a drug information center to identify classes of medications of most concern to providers. A secondary objective was to identify any trends in provider inquiries over the study period.

Design: A retrospective descriptive study of pregnancy and lactation-related inquiries to the University of North Carolina Health Care System Drug Information Center database between January 2001 and December 2010.

Setting: University of North Carolina Health Care System Drug Information Center.

Intervention: Provider inquiries and responses were extracted and characterized by indication for treatment and reason for inquiry. Comparison of the first and second 5-year periods was performed to delineate trends. Descriptive statistics, Fisher's Exact and χ^2 tests were used for analysis.

Main outcome measures: Inquiry origin, time, and subject.

Results: 433 inquiries were retrieved over the study period from physicians (50%), pharmacists (21%), and nurses (18%). Inquiries were most often made during the antepartum period (34%), followed by the postpartum (28%) and preconception (22%) periods. The most frequent indications for inquiry were psychiatry (15%) and infectious diseases (14%), which remained constant throughout the study period. Safety was the most common reason for inquiry (52%). The responses provided to callers were limited due to lack of information availability 37% of the time.

Conclusion: Psychiatry and infectious disease-related indications are the most frequent subjects of provider inquiry regarding medication use in pregnancy. Rates of inquiry remained constant throughout the past decade in most therapeutic areas. These findings are consistent with previous observations in other developed countries and suggest high-yield areas for pharmacist education.

Keywords: Pregnancy, drug information, psychiatric, teratology.

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In the United States, medication exposure in pregnancy is very common, with an estimated occurrence of 59%, based on a review of records from a consortium of eight health maintenance organizations.[1] Many medications are provided for treatment of medical comorbidities in pregnancy, including some with known teratogenic potential. In 1979, the U.S. Food and Drug Administration (FDA) instituted a risk classification system and labeling requirement to facilitate drug prescribing for pregnant patients.[2] Prior to this time, labeling practices included a standard disclaimer that safety in pregnancy had not been established, therefore risks should be weighed against benefits. In order to provide better guidance to prescribers, FDA required medications to be placed into one of five categories (A, B, C, D, X) based on their teratogenic potential and a risk/benefit assessment (Table 1).

Despite the efforts of FDA to assist health care providers in making informed prescribing decisions, the classification system left room for improvement. Critics cited prescribers' tendency to overestimate risk and often counsel or withhold necessary treatment from pregnant women.[2] Subsequently, FDA held a hearing on pregnancy labeling requirements in 1997 to address interpretation and application of the current system. They recommended changing the format and content of drug labeling to a narrative text in place of the letter category system. In May 2008, these changes were published as a Proposed Rule and opened to the public for comment.[3] As of February 2011, FDA was in the process of formalizing the proposed changes into a Final Rule after consideration of issues raised during the public comment period. Today, the pregnancy category labeling system is still in use while we await implementation of revisions to the Pregnancy and Lactation Labeling Rule.[4]

Table 1. FDA pregnancy drug labeling categories

Category	Teratogenic potential and risk/benefit
A	Adequate, well-controlled studies in pregnant women have not shown an increased risk of fetal abnormalities to the fetus in any trimester of pregnancy.
B	Animal studies have revealed no evidence of harm to the fetus; however, there are no adequate and well-controlled studies in pregnant women. OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.
C	Animal studies have shown an adverse effect and there are no adequate and well-controlled studies in pregnant women. OR No animal studies have been conducted and there are no adequate and well-controlled studies in pregnant women.
D	Adequate well-controlled or observational studies in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risk. For example, the drug may be acceptable if needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective.
X	Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities or risks. The use of the product is contraindicated in women who are or may become pregnant.

At a Glance

Synopsis: Many medications provided for treatment of medical comorbidities in pregnancy have known teratogenic potential. This retrospective descriptive study of pregnancy and lactation-related inquiries to the University of North Carolina Health Care System Drug Information Center database between January 2001 and December 2010 assessed types of questions asked by health care providers as well as resources used to generate responses. The evaluation determined that psychiatry- and infectious disease-related indications were the most frequent subjects of provider inquiry regarding medication use in pregnancy. Rates of inquiry remained constant throughout the decade in most therapeutic areas and were consistent with previous observations in other developed countries.

Analysis: *There is growing literature detailing the challenges of counseling on medication exposure in pregnancy. Although the FDA risk classification system has existed for more than three decades, patients and health care providers continue to struggle with their decisions around the use of medications with known teratogenic potential in pregnancy. The findings in this and other studies highlight the critical role drug information centers can play in evaluating use of medications in pregnancy as well as suggest a high-yield area for pharmacist education.*

Although the FDA risk classification system has existed for more than three decades, patients and health care providers continue to struggle with their decisions around the use of medications during pregnancy. Pregnant women have been found to commonly overestimate the teratogenic risk of medications and rely upon their medical providers for guidance.[5] This uncertainty is compounded by a perception among physicians that there is a lack of evidence-based guidelines from which they can counsel their patients.[6] When information is available, it is often passed on verbatim to patients.[7]

A growing body of literature details the challenges of counseling on medication exposure in pregnancy. Previous studies in Europe, Canada, and Australia have attempted to identify medications with the greatest perceived risk in pregnancy through an analysis of requests to established drug information services.[8–10] Using a