

# COUNSELING REGARDING PREGNANCY- RELATED DRUG EXPOSURES BY FAMILY PHYSICIANS IN ONTARIO

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## ABSTRACT

### Background

Family physicians may play a significant role in providing information to their patients on the effects of medication exposure during pregnancy. Women must receive accurate information, as unrealistic perception of teratogenic risk may lead to inadequate treatment of maternal disease or termination of otherwise wanted pregnancies.

### Objectives

To collect data on the current practices of family physicians in providing information regarding pregnancy-related drug exposures, in particular, their confidence in providing counseling and their sources of information.

### Methods

A mailed survey was sent to a random sample of family physicians in Ontario. Outcome measures included the proportion of family physicians that feel confident in providing counseling regarding drugs in pregnancy, most common resources, barriers to counseling and preferences for future educational programs.

### Results

Of the 756 surveys, 400 (53%) were returned, 265 (66%) by practicing physicians caring for women of childbearing age. Most (80.3%) felt confident in providing counseling, though a majority (56%) stated that available sources of information are not adequate. The most commonly consulted source was the Motherisk Program (62%). Lack of evidence-based information was cited as the major barrier.

### Conclusions

Although family physicians were confident in providing counseling to pregnant patients with regards to drug use, more than one-half thought that the available sources of information are not adequate. The dissemination of more evidence-based information in this field is needed.

**Key Words:** *Family physicians, counseling, information, drugs, pregnancy*

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**D**rug use during pregnancy is a common scenario as many women expose their fetuses to drugs during pregnancy for a variety of reasons. Exposure may be inadvertent, as half of all pregnancies are unplanned<sup>1</sup> or may be unavoidable in women requiring treatment of chronic disease. In a study of women interviewed

within 2 weeks after delivery, 40% had had one or more questions about drugs during their pregnancy and a similar proportion said it was important to consult a health professional before using any medication. The physician was most frequently mentioned as a source of drug information.<sup>2</sup> Additionally, thirty-nine percent of

women reported non-compliance, predominantly due to hesitation to use drugs during pregnancy.<sup>2</sup> Similarly, in an Australian study, women reported that general practitioners (GPs) were the most frequently used formal source of advice about medication use during pregnancy.<sup>3</sup> Women must receive accurate information, as unrealistic perception of teratogenic risk may lead to inadequate treatment of maternal disease or termination of otherwise wanted pregnancies.<sup>4</sup>

Prescribing medications for pregnant patients can be extremely challenging for any physician.<sup>5</sup> Family physicians need to be aware of the possible effects of *in utero* medication exposure, or at least be familiar with and readily able to access the available sources of information, as they often care for women between pregnancies or early in pregnancy. However, as there are many ethical complexities involved in conducting randomized controlled drug trials in pregnant women, there is a relative lack of evidence-based information. Physicians may feel inexperienced and unprepared to deal with these kinds of concerns<sup>6</sup>, as they must decide whether the benefits to the mother outweigh the risks to the fetus based on little research data. Women often report their physicians have encouraged them to undergo terminations of otherwise wanted pregnancies just to be on the safe side.<sup>1</sup>

Despite the potentially significant role that family physicians may play in providing this information to pregnant women, we were not able to locate any published studies examining their counseling practices in this field. The objective of this study was to collect data on the current practice of family physicians in Ontario with respect to counseling of their patients on the effects of drug exposure during pregnancy, in particular their confidence in providing this counseling and their sources of information.

## METHODS

A descriptive study using a cross-sectional design was conducted. The sample of family physicians in Ontario was selected from the 2003 Canadian Medical Directory (*MD Select Profiler – Ontario*) by simple random sampling using a computer-generated table of random numbers. The initial questions of the survey screened for the following inclusion criteria: family physician (including

general practitioners), currently engaged in clinical work in family medicine in Ontario, and caring for female patients of child-bearing age. Physicians who did not meet these criteria were instructed to indicate their ineligibility on the questionnaire and to return the uncompleted survey.

A mail survey was sent out in August 2003. A modified version of the Tailored Design Method for mail surveys, as described by Dillman, was used to maximize response rates.<sup>7</sup> A brief pre-notice letter was sent a few days prior to the questionnaire. A reminder postcard was mailed one week after the questionnaire mailing. Three weeks after the initial questionnaire mailing, a replacement questionnaire was sent to non-respondents.

As there were no published standardized instruments, a new self-administered questionnaire (Appendix 1) was developed and pre-tested by eight volunteers. Items on counseling of patients regarding the effects of drug exposure during pregnancy and sources of information were included. With respect to counseling practices, the questionnaire focused on physicians' behaviour and opinions. For most questions, respondents were given a list of answers to choose from with an option to answer other and specify, if appropriate. Demographic information about the physicians' previous training and education regarding drug use during pregnancy was also requested.

Returned questionnaires were reviewed and data was entered into SPSS 12.0. The primary outcome measure was the proportion of family physicians that felt "very confident" or "somewhat confident" counseling women regarding drugs in pregnancy. Frequency of responses with 95% confidence intervals, were calculated. Sub-group analyses using Chi-squared and independent sample t tests were performed to compare confidence and response rates based on gender, number of years practicing and country in which medical training occurred. The required sample size for a cross-sectional (one group) design (assuming a 95% CI) and an estimate of the primary outcome measure of 50% was 385. Assuming a 60% response rate and a 15% ineligibility rate we arrived at a mailing list of 756. The study requested the voluntary participation of family physicians. The Research

Ethics Board for Health Sciences Research Involving Human Subjects at the University of Western Ontario approved the protocol.

### RESULTS

Of the 756 surveys mailed out, 400 (53%) were returned. Of the 400 returned surveys (herein referred to as respondents), 265 (66%) were completed by practicing family physicians caring for women of childbearing age. Of the 265 eligible respondents, 62.3% were male; mean age was 47.5 years (range 29 to 80 years); mean number of years practicing was 18.9 (2 to 52) and the majority (88.3%) had office-based practices and had graduated from Canadian medical schools (79.6%).

Respondents did not differ significantly from non-respondents (those who did not return the survey) in terms of mean number of years practicing (22.97 vs. 23.21,  $p = 0.79$ ), Canadian vs. non-Canadian medical training (80.8% vs. 80%,  $p = 0.78$ ), and gender (35.6% female and 64.4% male for responders vs. 29.3% female and 70.7% male for non-responders respectively,  $p = 0.07$ ).

With regards to counseling regarding drugs in pregnancy in their practices, 28% (95% C.I. 24%, 35%) indicated that 16 to 20% of their patients were women of childbearing age. Most

(67%, 95% C.I. 62%, 73%) estimated the proportion of their pregnant patients taking drugs to be 0 to 20%. About one-half (50.4%, 95% C.I. 44%, 57%) indicated that they counsel 80 to 100% of their patients with regards to the specific effects of drugs during pregnancy. Ninety-one percent (95% C.I. 87%, 94%) answered “yes” to whether or not they thought they were likely to be effective in relieving the anxiety of their patients regarding the effects on the fetus of a drug (excluding known teratogens).

The majority of respondents reported feeling “very confident” (16%, 95% C.I. 0.12, 0.21) or “somewhat confident” (64%, 95% C.I. 0.58, 0.70), for a total of 80%, in providing counseling to pregnant women regarding drug use. No significant differences were found in confidence based on gender, number of years practicing, rural versus urban practice location, or Canadian versus foreign medical training.

When asked whether or not they thought the available sources of information on the effects of drugs in pregnancy were adequate, the majority (54%, 95% C.I. 50%, 62%) of respondents answered that they did not think they were. The most commonly cited source consulted for obtaining information on drug use during pregnancy was the Motherisk program (62%), followed by the Compendium of Pharmaceuticals and Specialties (CPS) (25%) (Table 1).

**TABLE 1** Sources most commonly consulted by family physicians for information regarding the effects of a specific drug in pregnancy (can be more than one source).

SOURCE OF INFORMATION	FAMILY PHYSICIANS (%)
Motherisk Program	62
Compendium of Pharmaceuticals and Specialties	25
Textbooks	13
Electronic Sources	7
Obstetricians	4
Pharmacists	4
Peer-reviewed Journals	1

The majority of respondents indicated that the major barrier to providing effective counseling in this area was a lack of evidence-based information (64%), followed by a lack of personal knowledge (21%), and not having enough time (11%).

Most respondents indicated that they had received “a little” teaching on the effects of drugs in pregnancy during their undergraduate (69%) and postgraduate (65%) medical education (Table 2). With regards to future development of

educational programs in this field, the largest proportion indicated that they would prefer electronic means; while 27% (95% C.I. 25%, 37%) selected software programs, and another 8% (95% C.I. 5%, 12%) selected web-based teaching programs for a combined total of 35%. This was followed by 32% (95% C.I. 27%, 39%) indicating that they would like to see continuing medical education workshops and another 28% (95% C.I. 23%, 35%) stating a preference for reading materials.

**TABLE 2** Rating of amount of teaching on the effects of drugs in pregnancy received during medical education

AMOUNT OF TEACHING	% OF FAMILY PHYSICIANS (95% CI)
Undergraduate	
A Lot	2 (1,4)
A Moderate Amount	16 (12,21)
A Little	69 (65,77)
None	11 (8,16)
Postgraduate	
A Lot	2 (1,5)
A Moderate Amount	19 (15,25)
A Little	65 (57,76)
None	11 (8,16)

## DISCUSSION

Most respondents felt confident counseling women with regards to drug use in pregnancy. However, the majority also felt that current resources are not adequate and that they received little teaching on this subject during both their undergraduate and postgraduate medical education. This discrepant finding was also contrary to our expectation that the lack of readily accessible, evidence-based information in this area would undermine the confidence of physicians in their counseling practices. This confidence, despite reporting inadequacy of information resources and little education in this area, is difficult to explain. This study did not examine the appropriateness of this confidence. It is possible family physicians acknowledge the lack of available information as the standard and are confident counseling within that context, perhaps indicating this lack of data to their patients. As well, most who felt confident were

“somewhat confident” rather than “very confident”.

With regards to counseling practices, it is comforting to note that when drug counseling was required, the majority of family physicians reported that they counseled 81 to 100% of their pregnant patients with regards to specific effects of drugs during pregnancy. Additionally, a majority not only felt confident during the counseling process but also felt that they were likely to be effective in relieving patients’ anxiety. This is extremely encouraging, as it seems that the perceived lack of evidence-based information in this field has not had a negative impact on the reported clinical practices of most of our respondents. Of currently available resources, the Motherisk program was by far the most commonly cited source followed by the CPS, textbooks, electronic means, obstetricians and pharmacists. Several respondents listed multiple most commonly used resources confirming the findings of a study, which found that physicians

consult, on average, at least 3 sources before adopting a practice.<sup>8</sup> The Motherisk program is a teratogen information service that provides information about the safety or risk to the developing fetus or infant, of maternal exposure to drugs, chemicals, diseases, radiation and environmental agents.<sup>9</sup> The fact that Motherisk was overwhelmingly the most commonly relied upon resource is in accordance with a recent Motherisk survey study, which found that 100% of physicians who used Motherisk found the information to be sufficient.<sup>10</sup> However, in spite of its popularity, many respondents indicated that getting through to Motherisk by telephone can be time consuming and that a web-based, easily accessible, and frequently updated resource with the same quality of information would prove tremendously useful.

Though some internet-based resources currently exist, they may be either too expensive, otherwise not readily accessible, or not considered as reliable as Motherisk and therefore, are not commonly used. Our study found only 7% of respondents consulted any electronic resources. Similarly, in the previous Motherisk study only 8% of respondents used Medline for gathering information.<sup>9</sup> Electronic resources would, however, lack the “human touch” that Motherisk now allows via telephone contact. Though the CPS was also listed as a commonly consulted resource, it often gives vague disclaimers regarding use of specific drugs during pregnancy. Results of animal studies may be provided in the CPS, the significance of which may be difficult for most physicians to interpret. Textbooks have the problem of not being readily updateable and may often be cumbersome to transport. Interestingly, peer-reviewed journals were only listed by 1% of respondents, though they were cited as being in the top four resources by another survey study.<sup>10</sup> This discrepancy may be due to the fact that our study looked exclusively at family physicians as opposed to physicians in general who had contacted Motherisk.

In terms of future improvement in the counseling practices of family physicians with regards to drug use in pregnancy, the development of educational programs and the dissemination of

information on this topic would be useful; particularly in readily accessible, reliable and easily updateable formats such as PDA (Personal Digital Assistant) or web-based programs. Continuing medical education seminars and reading materials (e.g. widely distributed pamphlets) would further supplement the electronic resources. Additionally, increasing the amount of teaching received during undergraduate and postgraduate medical education could further improve physicians’ knowledge and confidence levels, as most respondents indicated that they received little to no teaching in this area; and though they may have indicated that they were confident, the majority was “somewhat” as opposed to “very” confident. Pharmacists trained in this area may also play a role in providing this education.

There are several limitations to our study. Our response rate was less than desired (53%); however, strong trends were found in many of the proportions calculated. As well, there may have been a response bias, though not present in the few variables for which information on non-respondents was available (number of years practicing, gender and country of graduation). However, it is possible that only those who were more confident responded to our survey or that those who did respond were less busy and would have more time to consult available resources (and thus are more knowledgeable in this field) and thoroughly counsel their patients with respect to drug use in pregnancy. Also, potential inaccuracies related to self-reporting must be considered, though in a previous study using a counseling questionnaire, the validity of self-report provided by physicians was demonstrated.<sup>11</sup>

The results of our survey indicate that although family physicians were confident in providing counseling to pregnant patients with regards to drug use, more than one-half thought that the available sources of information are not adequate. Electronic resources supplying the same quality of information as teratogen information services such as Motherisk, may aid in filling the information void, assisting family physicians in counseling their patients regarding drugs in pregnancy.

**APPENDIX 1:**

Survey # \_\_\_\_\_

**COUNSELING REGARDING DRUGS IN PREGNANCY BY FAMILY  
PHYSICIANS IN ONTARIO**

Department of Paediatrics, University of Western Ontario

Please return your completed survey in the envelope provided to:

Dr. Doreen Matsui  
Children's Hospital of Western Ontario  
800 Commissioners Road East  
London, Ontario N6C 2V5

**Counseling Regarding Drugs in Pregnancy by Family Physicians in Ontario**

The purpose of this study is to determine the current practice of family physicians in Ontario with respect to counseling on the effects of exposure to drugs during pregnancy. This information will be useful in the development of programs designed to assist family physicians in providing this information to their patients. Please answer each question as accurately as possible by placing an "x" in the appropriate box or filling in the blanks.

*For the purpose of this survey, "practicing family physician" refers to a family physician (including general practitioners) currently engaged in clinical work in family medicine in Ontario.*

1. Are you currently a "practicing family physician"?

- Yes → PLEASE CONTINUE WITH SURVEY.
- No → PLEASE GO TO THE END OF THE QUESTIONNAIRE AND  
RETURN IT IN THE ENVELOPE PROVIDED.

2. Does your practice involve the care of female patients of child-bearing age?

Yes → PLEASE CONTINUE WITH SURVEY.

No → PLEASE GO TO THE END OF THE QUESTIONNAIRE AND  
RETURN IT IN THE ENVELOPE PROVIDED.

### Drugs in Pregnancy

*For the purpose of this survey “drugs” refers to both prescription and non-prescription medication. The following questions focus on the use of drugs during pregnancy.*

3. Which of the following is the best estimate of the baseline risk for major malformations, detected at the time of birth, in the general population?

0%

3%

6%

9%

4. For each of the following drugs indicate whether or not there is evidence supporting an increase in the risk for major malformations in offspring when taken by women during pregnancy:

Drug	Increases Risk	Does not increase risk	Unknown
a) Fluoxetine (Prozac <sup>®</sup> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Misoprostol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Carbamazepine (Tegretol <sup>®</sup> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Diphenhydramine (Benadryl <sup>®</sup> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Metronidazole (Flagyl <sup>®</sup> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Lorazepam (Ativan <sup>®</sup> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### **Counseling Regarding Drugs in Pregnancy in Your Practice**

The next section contains questions about counseling patients regarding drugs in pregnancy in your practice. Think about the past year when you answer these questions.

5. Approximately what proportion of your patients are women of child bearing age?

- 0 to 5%
- 6% to 10%
- 11% to 15%
- 16% to 20%
- >20%

6. Of your pregnant patients, what proportion do you estimate take drugs, either prescription or non-prescription (excluding vitamins), during pregnancy?

- 0 to 20%
- 21% to 40%
- 41% to 60%
- 61% to 80%
- 81% to 100%

7. Of your pregnant patients who have taken a drug during pregnancy, what proportion do you counsel with respect to the specific effects of the drug in pregnancy?

- 0 to 20%
- 21% to 40%
- 41% to 60%
- 61% to 80%
- 81% to 100%



8. Do you think that you are "likely to be effective" in relieving the anxiety of your patients regarding the effects on the fetus of a drug (excluding known teratogens) that they have taken during pregnancy?

Yes

No

9. Based on the information you have on the effects of exposure to drugs in pregnancy, how confident are you in providing counseling to your patients regarding drugs in pregnancy?

Very confident

Somewhat confident

Somewhat unsure

Very unsure

10. What do you perceive to be the major barrier to you providing effective counseling to your patients regarding drugs in pregnancy? (Please select only one answer.)

Not the role of the family physician

Lack of personal knowledge

Lack of evidence-based information

Don't have enough time

Lack of reimbursement

Other (please specify): \_\_\_\_\_

### Sources of Information

11. Please rate each the following sources of information as to their usefulness as a source of information on the effects of drugs in pregnancy where 1 means not at all useful and 5 means extremely useful.

Source of Information	Not useful					Extremely useful				
	1	2	3	4	5	1	2	3	4	5
a) Pharmacist .....	1	2	3	4	5					
b) Obstetrician .....	1	2	3	4	5					
c) Teratogen Information Service (e.g. Motherisk).....	1	2	3	4	5					

d) Compendium of Pharmaceuticals and Specialties(CPS).....	1	2	3	4	5
e) Textbooks .....	1	2	3	4	5
f) Peer-reviewed journals .....	1	2	3	4	5
g) Web pages .....	1	2	3	4	5
h) Drug company.....	1	2	3	4	5

12. Which source do you MOST COMMONLY consult for information regarding the effects on the fetus of a specific drug in pregnancy?

Source: \_\_\_\_\_

13. Do you think that the available sources of information on the effects of drugs in pregnancy are adequate?

- Yes
- No

### Demographic and Training Information

The following questions will allow us to compare your responses with those of other respondents, that is, they will be used for classification only.

14. Year of Birth: \_\_\_\_\_

15. Sex: Male  Female

16. How many years have you been a "practicing family physician"?: \_\_\_\_\_years

17. Population size of town or city where current practice is located: \_\_\_\_\_

18. Type of current practice:

- Mainly office-based
- Mainly hospital-based
- Other (please specify): \_\_\_\_\_

19. Does your practice include performing obstetrical deliveries?

- Yes
- No

20. MD graduation:

a) Year: \_\_\_\_\_

b) Country:  Canada

Other (please specify): \_\_\_\_\_

21. Did you complete an internship?

Yes → Country:  Canada

Other (please specify): \_\_\_\_\_

No

22. Did you complete a family medicine residency?

Yes → Country:  Canada

Other (please specify): \_\_\_\_\_

No

23. During your undergraduate medical education, how much teaching on the effects of drugs in pregnancy did you receive?

A lot

A moderate amount

A little

None

24. During your postgraduate medical education, how much teaching on the effects of drugs in pregnancy did you receive?

A lot

A moderate amount

A little

None

25. If educational programs on the effects of drugs in pregnancy were developed for practicing family physicians, which format would you prefer? (Please select only one answer.)

- Reading material (journal articles, pamphlets, etc.)
- Software programs (for computers including handheld devices)
- Web-based teaching program
- Continuing medical education workshop or seminar
- Other (please specify): \_\_\_\_\_

### Further Comments

Please provide any further comments that you wish to make:

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Thank you for taking the time to complete this questionnaire. Your participation in this survey is very much appreciated. Please return your completed survey in the envelope provided to:

Dr. Doreen Matsui  
Children's Hospital of Western Ontario  
800 Commissioners Road East  
London, Ontario N6C 2V5

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