Telephone-Based Teratogen Counseling to Improve Pregnancy Outcome - the OTIS Model

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TIS in North America

TERATOLOGY 61:314–317 (2000)

Mini-Review: History of Organized Teratology Information Services in North America

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ABSTRACT A history of the Organization of Teratology Information Services (OTIS) is presented in context of the history of teratology information services. During the late 1970s, teratology information services grew out of the need for current and accurate information about fetal effects of environmental exposures in pregnancy. Over the next decade, teratology information services networked and collaborated, developing their own professional organization. A description of the activities of OTIS is described. *Teratology 61: 314–317, 2000.*

backgrounds and training, including pharmacists, physicians, genetic counselors, poison control centers, and drug information centers (Buitendijk et al., '91). Buitendijk and colleagues ('91) documented that about 66% of women were exposed to prescription or over-the-counter medications during the first trimester, demonstrating how commonly these questions can arise. Resources available to practitioners regarding pregnancy exposures were often inaccessible, inadequate, difficult to interpret, and outdated (Elefant et al., '92; Ludowese et al., '93). Information resources for the general public were even more distorted: an analysis of

Mission of TIS

- Service:
  - Provide evidence-based risk assessment, individualized counseling and referral to callers regarding exposures in pregnancy
- Research
  - Conduct small exposure cohort studies of pregnancy outcome to help contribute to lack of adequate human data on most exposures, particularly new drugs


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OTIS - Find a TIS

http://otispregnancy.org/otis_find_a_tis.asp

otispregnancy.org

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Organization of Teratology Information Specialists

National Toll-Free Number:
(866) 626-OTIS
(866) 626-6847

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Find a Teratogen Information Service

Member programs of OTIS are located throughout the U.S. and in Canada. Each Teratogen Information Service listed below is designed to serve a specific population. If there is not a TIS for your area, the state list will direct you to which TIS to contact.

Please select an area:

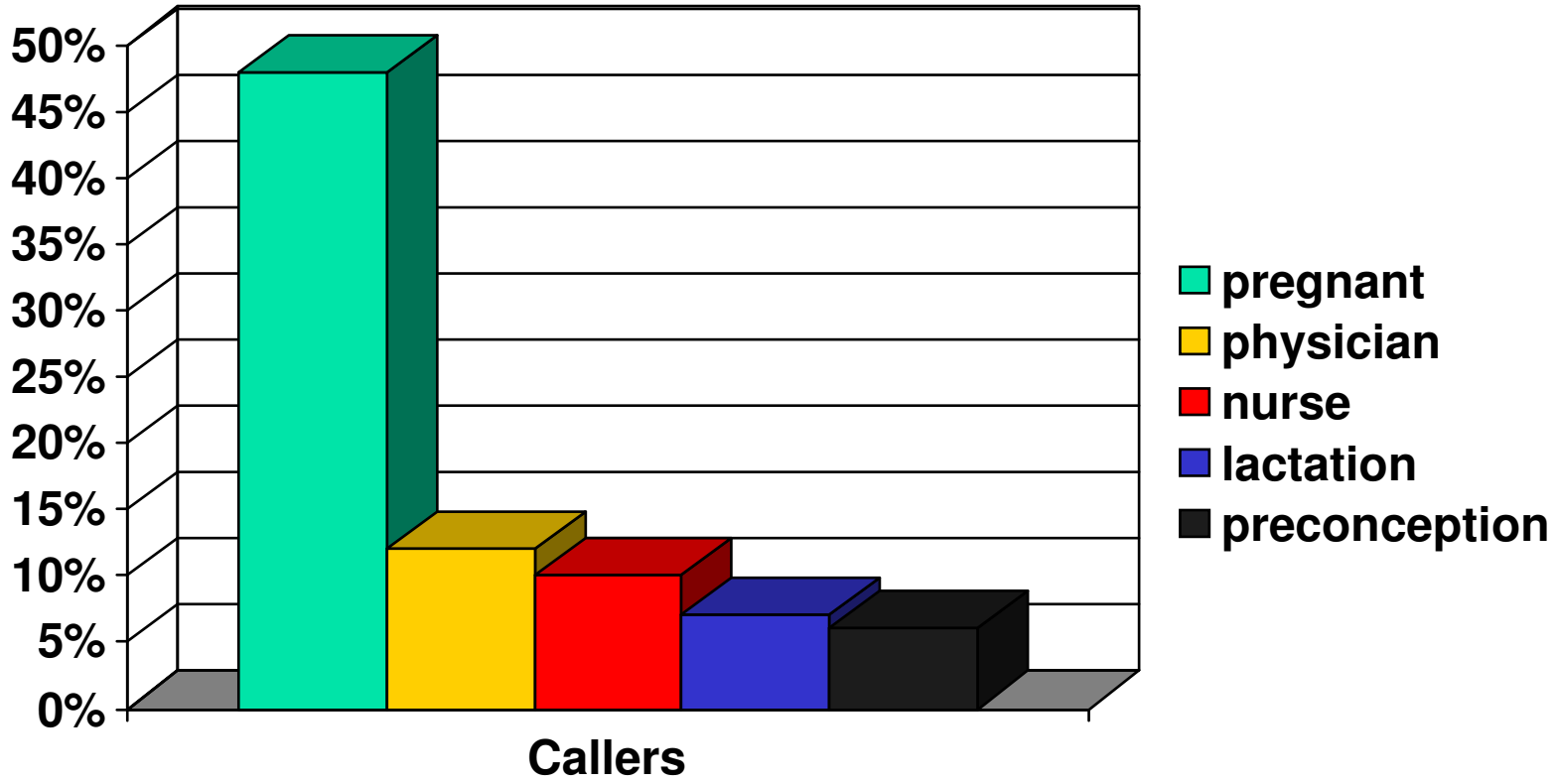
Please select place of residence

Done

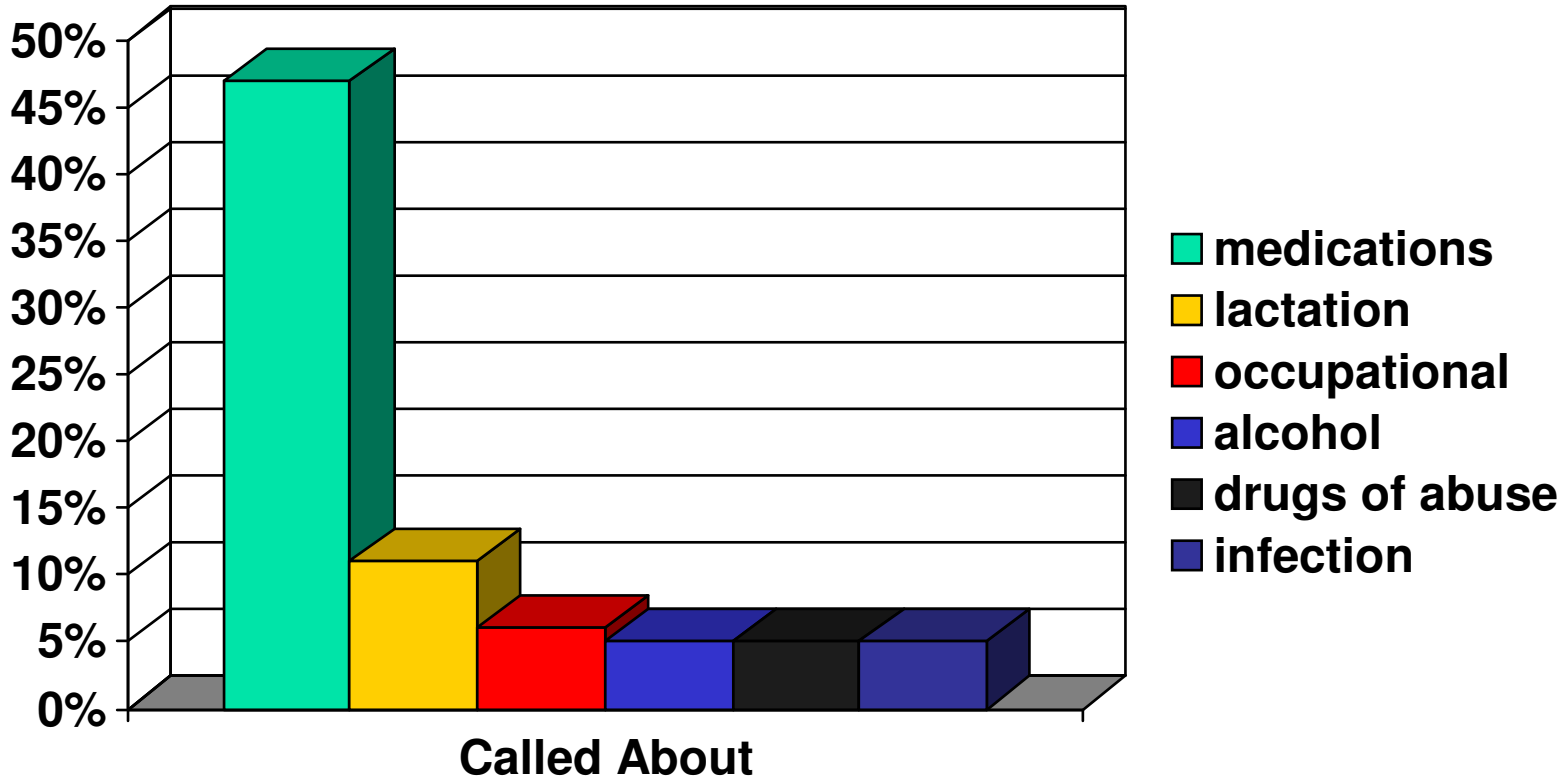
OTIS services & staffing

- 18 services in operation U.S. and Canada
- 70,000 annual caller contacts
- Staffed by genetic counselors, pharmacists, physicians, nurses, health educators

OTIS callers



OTIS exposures called about



OTIS exposures called about

Table 3
Broad Categories of Agents

Category	No. of inquiries by pregnant callers[a]	% of inquiries by category among pregnant callers[a]	Total no. of inquiries[b]
Central nervous system agents (including analgesics)	1664	21.5%	2703
Respiratory agents	942	12.2%	1394
Miscellaneous	906	11.7%	1165
Chemicals	711	9.2%	919
Recreational (including alcohol, cigarettes, caffeine, and illicit drugs)	689	8.9%	787
Systemic antiinfective agents	501	6.5%	869
Nutrients and nutritional agents	404	5.2%	507
Dermatological agents	393	5.1%	553
Biologic and immunologic agents (including vaccines)	369	4.8%	601
Endocrine/metabolic agents	342	4.4%	486
Natural and herbal products	264	3.4%	389
Gastrointestinal agents	226	2.9%	357
Diagnostic aids	162	2.1%	214
Cardiovascular agents	61	0.79%	125
Renal and genitourinary agents	44	0.57%	77
Hematological agents	25	0.32%	49
Ophthalmic and otic agents	23	0.29%	38
Antineoplastic agents	20	0.26%	32
Total	7746	100%	11,265

OTIS fact sheets

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Finasteride (Propecia®/Proscar®) and Pregnancy

This sheet talks about the risks that exposure to finasteride can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What is finasteride?

Finasteride is a medication used for the treatment and prevention of male pattern baldness. It inhibits a chemical in the body called 5-alpha-reductase. Finasteride has also been approved for treatment of benign prostatic hyperplasia. Finasteride is not approved at this time for use in women. Finasteride is marketed under the brand names Propecia® and Proscar®.

My partner is taking finasteride but is wondering if he should stop before I become pregnant. Is this necessary and if so, how long does it stay in the body?

The benefits of taking the medication and any possible adverse outcomes from not taking it should be taken into account and discussed with his healthcare provider before deciding to stop treatment. There is no known reason for him to stop taking this medication while planning a family. If he does decide to stop using finasteride, it takes on average two days for most of the drug to be eliminated from the body after the last dose.

If my partner decides to continue taking finasteride, will it be more difficult for me to become pregnant?

There is no evidence to say that if your partner is taking this medication it will make it more difficult for you to become pregnant. Animal studies suggest a temporary decrease in male fertility, however no adverse effect has been found in semen in humans. There are no reports linking this medication to human infertility or an inability to become pregnant.

Is there an increased risk for birth defects if the baby's father is taking finasteride when I become pregnant?

Studies in animals found that pregnancies sired by male rats that were given large doses of finasteride did not result in babies born with birth defects. There are no such studies in humans at this time.

Should my partner stop taking finasteride while I am pregnant?

There is a theoretical, although highly unlikely, risk for birth defects of a male fetus's sex organs if the couple has intercourse during the stage of pregnancy when the sex organs are developing (8 to 15 weeks of gestation). However, the amount of the drug found in the semen is very small and is not felt to be enough to harm a male baby.

If my partner stops using finasteride will there be side effects?

Finasteride must be used daily for three months, on average, before results can be seen. Continued use is recommended to sustain this benefit. There is no lasting benefit if treatment

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Paroxetine (Paxil®) and Pregnancy

This sheet talks about the risks that exposure to paroxetine can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What is paroxetine?

Paroxetine is a medication used to treat depression, social anxiety disorder, obsessive compulsive disorder, and panic disorder. Paroxetine belongs to the class of antidepressants known as selective serotonin reuptake inhibitors or SSRIs. A common brand name for paroxetine is Paxil®.

I am taking paroxetine, but I would like to stop taking it before becoming pregnant. How long does paroxetine stay in my body?

While everyone breaks down medication at a different rate, on average it takes four to five days for most of the paroxetine to be gone from the body after taking the last dose. There are case reports of people who have had withdrawal symptoms when suddenly stopping use of paroxetine. It may be preferable to gradually reduce the dosage before quitting completely. The benefits of taking the medication for your specific situation, and any possible adverse outcomes from not taking it, or any potential risks to the baby if you find out you are already pregnant, should be discussed with your health care provider before you decide to stop taking paroxetine.

Can taking paroxetine make it more difficult for me to become pregnant?

We do not know if taking paroxetine will make it harder for you to become pregnant. Animal studies suggest a reduced pregnancy rate with the use of paroxetine as a result of decreased male fertility. However, there are no reports linking paroxetine to human infertility or an inability to become pregnant.

Can taking paroxetine during my pregnancy cause birth defects?

Several studies have found no increased risk for having a baby with a birth defect when paroxetine is used during pregnancy. However, a study performed by the manufacturer of paroxetine and another study performed by a teratogen information service found that paroxetine use during the first trimester may increase the risk of having a baby born with a heart defect. The background risk for heart defects in the general population is one percent, and these studies showed that paroxetine use during pregnancy may increase this risk to two percent. More studies need to be performed to determine if paroxetine use during pregnancy increases the risk of birth defects over that of the general population.

I need to take paroxetine throughout my entire pregnancy. Will it cause withdrawal symptoms in my baby?

If you are taking paroxetine during the third trimester until the time of delivery, your baby may experience some complications for the first few days of life. Symptoms of withdrawal such as problems breathing, jitteriness, increased muscle tone, irritability, altered sleep patterns, tremors and difficulty eating may occur. Your baby may need to stay in a special care nursery for several days until the withdrawal symptoms go away. While these problems can occur at all doses of paroxetine, they may occur more often with higher doses of paroxetine.

Are there any other problems paroxetine can cause when used in the third trimester?

One study showed that babies whose mothers take SSRIs like paroxetine during the third trimester may be at an increased risk for pulmonary hypertension, a serious lung problem at birth. You should inform your obstetrician and your baby's pediatrician that you are taking paroxetine so that any extra care can be readily provided.

OTIS research

- Independent TIS studies
- OTIS Collaborative Research Group
  - Asthma and asthma medications
  - Autoimmune diseases and medications
  - Vaccines
  - Antidepressant discontinuation
  - West Nile Virus
    - http://www.fda.gov/womens/registries/

Do we prevent birth defects?

- Typical TIS caller is 7-10 weeks' gestation and has already had the exposure she is calling about
- TIS counselor's most common function is to reduce the caller's anxiety
- Low proportion of preconception calls

Opportunity for prevention

- Counseling on alcohol, tobacco, illicit drug, and some medications can benefit the pregnancy at any stage
- Counseling on importance of continuing needed medications can reduce adverse pregnancy outcomes due to undertreated disease

Opportunity for prevention

- Counseling can impact a future pregnancy
  - can lead to choice of more appropriate medication for treatment of chronic conditions during reproductive years
  - If TIS gathers complete exposure information from caller, can lead to advice to continue a pregnancy-related change in behavior (quit tobacco, alcohol, taking FA supplements) beyond the end of pregnancy

Use of folic acid supplements among TIS callers

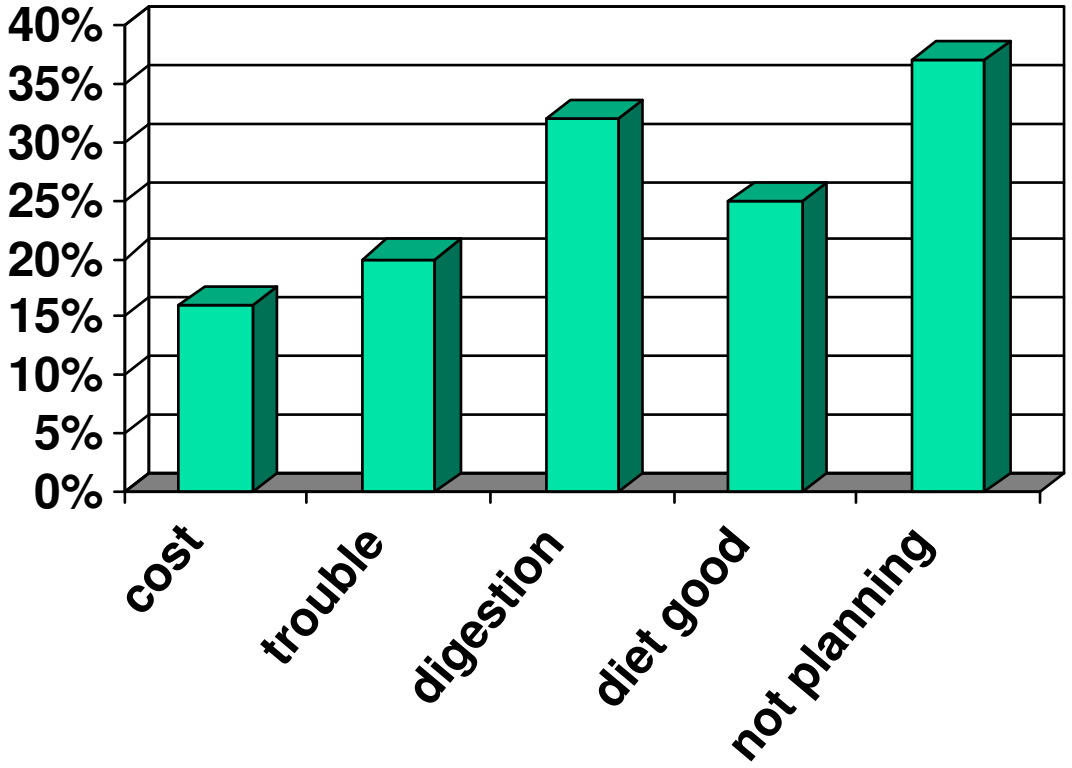
- 327 CA TIS callers surveyed 2003-4
- 53.2% not taking folic acid supplements in periconceptional period
- Predictors of no use
  - Higher BMI (>24.9)
  - Younger maternal age
  - Non-white race/ethnicity
  - Lower educational level
  - Unplanned pregnancy

- *Goldberg B et al, Birth Defects Research Part A, 2006*

Prevention in Next Pregnancy

- 25% of respondents who were not taking FA in periconceptional period said they would continue to take FA supplements in inter-pregnancy interval if advised by physician to do so

Barriers to continuation of FA supplements between pregnancies



Challenges in increasing preconception counseling

- High proportion of unplanned pregnancies (>50%) - woman/health care provider is not thinking about her possible exposure in pregnancy

Opportunity for prevention

- TIS can promote benefits of preconception counseling through partnership with
  - Diabetes programs like Sweet Success
  - WIC low-income nutrition support program
    - Testing self-administered web-based screening and referral
    - Tested ‘health educator’ model of screening and referral
  - Family planning clinics - Planned Parenthood
  - Specialty health care providers, e.g., neurologists, psychiatrists

Opportunity for prevention

- Alternative methods of delivering service
  - Increase web access through search terms on “women’s health”
  - Preconception section on website
  - Interactive web-site: “email a counselor”
  - Fact Sheet distribution via website

Conclusion

- TIS have a well-established and accepted role in counseling regarding pregnancy exposures
- The effectiveness of this model can be improved by
  - extending TIS educational intervention to benefit the next pregnancy
  - outreach to increase access to women prior to pregnancy