PREGNANT WOMEN AND HEALTH RESEARCH: AN ETHICAL IMPERATIVE

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An Unnecessary Risk

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When a clinical trial excludes pregnant women, we have no idea how the drug or vaccine will affect their fetuses.

In Canada, research involving humans is primarily governed out in the Tri-Council Policy Statement: Ethical Conduct for Humans. These guidelines are currently being [revised] (http://pre.ethics.gc.ca/eng/policy-politique/initiatives/reviewed/Default/) and the public consultation period ends M.

When the policy statement was published in 1998, it address problem of the day, namely the exclusion of women from research solely on the basis of sex or reproductive capacity. This salutary effect – the number of women research participants exponentially. However, problems with research involving w

Frequently, women of reproductive capacity (including nuns heterosexual women with infertile male partners, and women sexual activity) are required to use oral contraceptives as a participation. This is ethically offensive.

Another ethical problem is the common practice of excluding from research. This can harm pregnant women and undermi example, frequently there are no clinical trial data on which decisions about treatment or immunization. This can result i

Pregnant women deserve better

Clinical trials routinely exclude expectant mothers. This is unethical and unscientific, and regulators must mandate change, says Francoise Baylis, in the second of three related pieces on gender bias in biomedicine.

This is ethically and medically unacceptable for two reasons: pregnant women get sick, and sick women get pregnant. Patients who happen pregnancy — such as increased plasma volume, body weight, body fat, metabolism and hormone levels — make it impossible to calculate dose and safety information by extrapolating from data on men and non-pregnant women.

This means that when a pregnant woman has a health condition that requires treatment, her physician often has insufficient information to make an evidence-based recommendation.

International ethical guidelines drawn up by the Council for International Organizations of Medical Sciences clearly stipulate that pregnant women are eligible to participate in biomedical research. Yet they are routinely excluded from the vast majority of clinical trials of drugs, vaccines, nutraceuticals, natural health products and medical devices because of the harm the intervention might do to the fetus. This decision is both impractical and unethical.

This is problematic because it is not unusual for the same medication to have a different effect in pregnant women than in the general population. With this staggered approach, pregnant women and fetuses would not be exposed to any compounds that failed in phase I and II trials. Another option would be to allow pregnant women to join phase III trials once a drug has passed safely through phases I and II. This would need to include enhanced safety monitoring for pregnant women, similar to that done in a stand-alone phase I trial. As researchers and sponsors are unlikely to make such changes of their own volition, regulators will need to make the inclusion of pregnant women in such trials mandatory, and oblige drug companies to conduct follow-up studies to identify any short- or long-term effects of the drugs.

Persuading pregnant women to take part in research can be difficult because of the perception that trials are riskier than taking prescribed medication. Trial organizers should take pains to demonstrate that this is often a false belief, and that it is generally safer for pregnant women to use drugs in a trial under controlled
My starting assumptions

• Physicians should practice evidence-based medicine
  – Individual clinical expertise
  – External clinical evidence

• Pregnant women are capable of autonomous decision-making
  – trial participation
  – treatment

• Pregnant women should have access to sound information and advice on the basis of which to make medical decisions for themselves and their fetuses

• Pregnant women care about fetal well-being
My conclusions

• The **automatic exclusion** of pregnant women from research potentially **harms** women and their fetuses.

• The **responsible inclusion** of pregnant women in research potentially **benefits** women and their fetuses.
Children

“Children cannot be regarded simply as ‘little people’ pharmacologically. Their metabolism, enzymatic and excretory systems, skeletal development and so forth differ so markedly from adults' that drug tests for the latter provide inadequate information about dosage, efficacy, toxicity, side effects, and contraindications for children.”

Women

“Women are not simply ‘men with estrogen’. Women differ systematically from men in many ways, including in their genetics, metabolism, behavior, and social determinants of health. Female–male health differences may be due to ‘sex’ (ie, sex-linked biology), ‘gender’ (ie, socially-structured relations), or both.”

Pregnant women

“Pregnant women are not just women with bigger bellies. Physiological changes during pregnancy such as increased plasma volume, body weight, body fat, metabolism and hormone levels preclude the extrapolation of data about dosing and safety (from men and non-pregnant women) to pregnant women.”

Reasons for inclusion

- Develop effective treatment for women during pregnancy
- Promote fetal safety
- Reduce harm from suboptimal care
- Allow access to benefits of research participation

Lyerly, A.D., Little, M.O., and Faden, R.R. *Hastings Center Report* 2008; 8(6)
Outline

• Where are we?
• Where should we be?
• How can we get there?
• Where are we?
• Where should we be?
• How can we get there?
Some facts

- Most drugs are not studied in pregnant women
- Most drugs are not labeled for use during pregnancy
- Most pregnant women (64%) take one or more prescribed medications for chronic medical conditions or acute problems

Drugs: Not for use in pregnancy

- **OTC:** “If pregnant or breast-feeding, ask a health professional before use.”
- **Product monograph:** “The effect of pregnancy on the pharmacokinetics and pharmacodynamics of XXX has not been studied.”
- **Physicians' Desk Reference:** “Use in pregnancy is not recommended unless the potential benefits justify the potential risks to the fetus.”
The problem

• “Physicians caring for pregnant women have very little information to help them decide whether the potential benefits to the mother outweigh the risks to the fetus.”

Koren, Pastuszak, and Ito. NEJM 1998; 338:1128-1137
Exclusion from clinical trials

- Majority of information is from:
  - Animal studies
  - Case reports
  - Registries
  - Retrospective exposure studies
  - Meta-analysis
The problem

• “The effort to protect a small number of fetuses from research-related risks places a greater number of fetuses and women at risk from unstudied clinical interventions, and from lack of therapeutic options.”

SSRIs during pregnancy

• “The controversy surrounding antidepressants and pregnancy”
  Anne Kingston, April 20, 2013 Maclean’s
Bartram vs GlaxoSmithKline

- Faith Gibson (Surrey BC) prescribed Paxil (SSRI) in December 2002.
- Became pregnant, asked Dr about continuing Paxil during pregnancy; told “100 % safe”.
- Daughter, Meah Bartram, born September 2005 with hole in heart.
- 2 weeks later, Health Canada and GSK issued advisory: Paroxetine taken in first trimester may pose “an increased risk” of caridovascular defects.
Paroxetine

NEW SAFETY INFORMATION REGARDING PAROXETINE:
FINDINGS SUGGEST INCREASED RISK TO OTHER ANTIDEPRESSANTS: ON CONGENITAL MALFORMATIONS, FOLLOWING FIRST TRIMESTER EXPOSURE TO PAROXETINE

Dear Health Care Professional:

GlaxoSmithKline (GSK), following discussions with Health Canada, would like to inform you of important new safety information regarding the use of paroxetine during the first trimester of pregnancy.

- The preliminary report of a retrospective epidemiological study of 2,581 pregnant women exposed to paroxetine or other antidepressants during the first trimester indicates an increased risk for paroxetine compared to other antidepressants, of:
  - Overall major congenital malformations (2-fold increase)
  - Cardiac malformations (2-fold increase) with venous cardiac septal defects being the most frequent types of cardiac defects detected in this paroxetine-exposed group.
  - The prevalence of major congenital defects and cardiac defects in paroxetine-exposed pregnancies were 4% and 2% respectively in the study, as compared to 3% and 1% respectively in one estimate of the overall prevalence in the US general population (i.e., multiple of all births, regardless of drug treatment) (Monoson, 1998).

- Other independent studies of pregnancy outcome following first trimester exposure to antidepressants, including paroxetine, provide conflicting evidence regarding rate of birth defects.

- As currently stated in the Product Monograph, paroxetine should be used during pregnancy only if the potential benefit justifies the potential risks to the fetus. Prescriptions should carefully evaluate this new information when considering the use of paroxetine in women who are pregnant or planning pregnancy. This information should be discussed with the patient.

- Due to the potential for discontinuation symptoms, if the decision is made to discontinue paroxetine in a patient, please refer to the Discontinuation of Treatment with PAXIL/PAXIL CR subsection of the WARNINGS & PRECAUTIONS section in the Product Monograph for further information.

- GSK has posted the results of this study to its Clinical Trial Website where it can be read by anyone with Internet access. The website is http://www.gsk.co.uk/trials.asp

BACKGROUND

GSK initiated a retrospective epidemiological study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy from January 1996 to June 2003. The study was conducted in 2,581 pregnant women. A preliminary analysis has recently been conducted which has shown a 2-fold increase in adalposed congenital malformations (2.50% vs. 1.21%) for congenital malformations as a whole, and a 1.60 fold increase (2.00% vs. 1.23) for cardiovascular malformations alone, paroxetine compared to other antidepressants in the database. The prevalences of congenital malformations in a white and a non-white population were approximately 4% and 2%, respectively. Preliminary counts of the types of cardiac malformations suggest that of the 14 paroxetine-exposed infants with venous cardiac septal defects (4.11%) in comparison to 17/152 (11%) for the other antidepressants combined. Exposure to paroxetine in the mothers of these 14 infants may or may not have been accompanied by co-exposure to other antidepressants in the database.

SUMMARY OF FINDINGS

An independent epidemiological study of delivery outcome following maternal use of SSRI antidepressants in early pregnancy has been conducted using the Swedish national registry data (n=1,751 women). The findings were not appreciable. In a 1.6-fold increased risk of cardiac malformations in infants exposed to paroxetine compared to the total registry population (approximately 2% incidence vs. 3%, respectively).

- The above Swedish findings are similar to those from GSK-sponsored, U.S. epidemiologic study (n=1,751 women) in approximately 1.6-fold increased risk of cardiac malformations in infants exposed to paroxetine, as compared to exposure to other antidepressants (approximately 1.5% incidence vs. 3%, respectively).

- The majority of previously associated cardiac malformations were ventricular septal defect (VSD) and atrial septal defect (ASD) in the Swedish study and VSD in the U.S. study. In both, the combined data from these epidemiological studies, which use different methodologies, suggest that the increased risk of a cardiac defect in an infant with a cardiac defect following maternal paroxetine exposure is approximately 1.50, compared with an expected rate for all defects of approximately 1/100 infants in the general population. In general, asymptomatic defects occur in those who are asymptomatic and may require surgery, whereas those that are symptomatic and may require surgery, may involve spontaneous resolution. Information about the severity of the defect reported in the above database is not currently available.

RECOMMENDATIONS

- If a woman becomes pregnant while taking paroxetine, she should be informed of the current estimate of increased risk to the fetus with paroxetine over other antidepressants. Evaluation of additional databases, as well as updated analyses, may result in changes to the current risk estimates. Consideration should be given to switching to other treatment options, including another antidepressant or non-pharmacological treatment such as cognitive behavioral therapy. Paroxetine treatment should only be continued in an individual patient, if the potential benefits outweigh the potential risks.

- Due to the potential for discontinuation symptoms, doctors should inform patients that the drug should be stopped without first discussing it with their doctor. If the decision is made to discontinue paroxetine in a patient, please refer to the Discontinuation of Treatment with PAXIL/PAXIL CR subsection of the WARNINGS & PRECAUTIONS section in the Product Monograph for further information.

- For women who used to become pregnant, or use in their first trimester of pregnancy, initiation of paroxetine should be considered only after other treatment options have been evaluated.
Some facts

- Most of the time, drugs are not studied in pregnant women.
- Most drugs are not labeled for use during pregnancy.
- Most pregnant women (64%) take one or more prescribed medications for chronic medical conditions or acute problems.
- Animal studies dating to the early 80s link SSRIs with increased risk of birth defects.
- Pregnant women not allowed to participate in RCTs.
- Epidemiological, or population, studies show risk of harm.
- SSRIs not approved for use in pregnancy.
- SSRIs top-prescribed drugs in pregnancy.
Motherisk vs its critics

- Depression during pregnancy is a greater risk to pregnant woman and fetus than SSRIs
- Health Canada’s 2005 Paxil advisory “based on small non-peer reviewed, unpublished studies”
- 2010 Motherisk report found no increased risk of neonatal heart defects
- “the benefits of [SSRI] therapy far outweigh the potential minimal risks”
- There is no good data suggesting that untreated depression is more dangerous to pregnant woman and fetus than SSRIs
- Clinical depression during pregnancy is a serious concern, but there are less risky effective treatment options
Impact on pregnant women: H1N1 vaccine

• Public health authorities in Canada initially recommend adjuvanted H1N1 vaccine for everyone (including pregnant women)

• Change in plan – prior to 20 weeks should take unadjuvanted vaccine
Seasonal influenza
unadjuvanted vaccine

• Unadjuvanted seasonal flu vaccine has been used in the US and Canada in pregnant women since the 1950s.

• Recommended for use by all women who are or will be pregnant during the influenza season (based on observational data, not clinical trials)
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Study group</th>
<th>Control group</th>
<th>Follow-up period</th>
<th>Maternal outcomes</th>
<th>Infant outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zama et al. 2008</td>
<td>Prospective, randomized, double-blind controlled trial</td>
<td>172 pregnant women in third trimester</td>
<td>168 pregnant women who received 25-valent pneumococcal polysaccharide vaccine</td>
<td>7 d postvaccination; mother-infant pairs followed up to 24 wk of life</td>
<td>No serious adverse events or differences in pregnancy outcomes</td>
<td>No differences in gestational age, proportion with cesarean delivery, birthweight, or APGAR score</td>
</tr>
<tr>
<td>France et al. 2006</td>
<td>Retrospective, matched cohort</td>
<td>3160 infants born to vaccinated mothers</td>
<td>3769 infants born to nonvaccinated mothers</td>
<td>End of influenza season</td>
<td>Not assessed</td>
<td>No difference with regard to birthweight, gestational age, or length of stay for birth hospitalization</td>
</tr>
<tr>
<td>Munoz et al. 2005</td>
<td>Retrospective, matched cohort</td>
<td>225 pregnant women in second and third trimesters</td>
<td>826 nonimmunized pregnant women</td>
<td>42 d after immunization; birth to 6 mo of age</td>
<td>No serious adverse events or differences in pregnancy outcomes</td>
<td>No differences in outcomes of pregnancy (cesarean delivery and premature delivery) and infant medical conditions</td>
</tr>
<tr>
<td>Black et al. 2004</td>
<td>Retrospective cohort</td>
<td>3719 pregnant women immunized</td>
<td>45,866 women</td>
<td>Until delivery</td>
<td>No difference in cesarean section</td>
<td>No difference in cesarean section or preterm delivery</td>
</tr>
<tr>
<td>Yeager et al. 1999</td>
<td>Prospective cohort</td>
<td>319 pregnant women immunized in second and third trimesters</td>
<td>None</td>
<td>Next prenatal visit</td>
<td>No preterm labor or other serious events</td>
<td>Not assessed</td>
</tr>
<tr>
<td>England et al. 1994</td>
<td>Randomized, controlled trial</td>
<td>13 pregnant women in third trimester</td>
<td>13 pregnant women who received tetanus toxoid vaccine</td>
<td>Not specified</td>
<td>No significant adverse reactions, including fever, moderate or severe pain, or need to visit a physician noted in either group</td>
<td>Similar gestational ages in both groups; no health concerns in infants examined between 1-3 mo of age</td>
</tr>
<tr>
<td>Deinard and Ogbum. 1981</td>
<td>Prospective cohort</td>
<td>189 pregnant women (13 prior to conception; 41, 58, and 77 in first, second, and third trimesters, respectively)</td>
<td>517 nonvaccinated pregnant women</td>
<td>48 h after immunization; pregnancy outcome to 8 wk of life</td>
<td>No differences in maternal health, pregnancy outcome, or postpartum course</td>
<td>No significant differences in adverse pregnancy outcomes (congenital anomalies, neonatal mortality)</td>
</tr>
<tr>
<td>Sumaya and Gibbs. 1979</td>
<td>Retrospective, matched cohort</td>
<td>56 women in second and third trimesters</td>
<td>40 nonvaccinated pregnant women</td>
<td>24 h after immunization</td>
<td>No significant immediate reactions or differences in pregnancy course</td>
<td>No increased fetal complications associated with vaccine</td>
</tr>
<tr>
<td>Murray et al. 1979</td>
<td>Prospective, matched cohort</td>
<td>69 pregnant immunized women (5, 22, and 32 in first, second, and third trimesters, respectively)</td>
<td>27 nonpregnant vaccinated women</td>
<td>Not specified</td>
<td>No significant side effects after immunization in any women</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Heinonen et al. 1973, 1974 and 1977</td>
<td>Prospective cohort</td>
<td>2291 pregnant immunized women, up to 650 in first trimester</td>
<td>None</td>
<td>Up to 7 y of age</td>
<td>No suggestive associations for congenital malformations, malignancies, or neurocognitive disabilities</td>
<td>No association with fetal anomalies or miscarriage</td>
</tr>
<tr>
<td>Hulka. 1984</td>
<td>Retrospective and prospective cohort</td>
<td>225 pregnant immunized women (19 in first trimester)</td>
<td>44 nonpregnant influenza immunized; 104 pregnant and 25 nonpregnant immunized with placebo</td>
<td>Up to 3 d after vaccination and at delivery</td>
<td>Local pain at injection site and some systemic symptoms greater in women immunized with influenza vaccine</td>
<td>No association with fetal anomalies or miscarriage</td>
</tr>
</tbody>
</table>

Seasonal influenza: adjuvanted vaccine

- No pregnant women enrolled
- “No adverse outcomes” in pregnant women inadvertently immunized
- Retrospective analysis (1991-2009) MF59 exposure during pregnancy not associated with increased proportion of abnormal outcomes compared with unadjuvanted vaccines

_Vaccine_ 2010 28:1877-80
H5N1 influenza: adjuvanted vaccine

• Studies with several adjuvanted vaccines
  – Alum
  – MF59
  – AS03
• No pregnant women enrolled
• “No adverse outcomes” reported in pregnant women inadvertently immunized
At the time of H1N1 what did we ‘know’ about vaccines?

- Unadjuvanted seasonal vaccine
  - “safe and effective” (mostly observational data)

- Adjuvanted seasonal vaccine
  - (MF59) “no adverse outcomes” reported in pregnant women inadvertently immunized while pregnant
  - Retrospective analysis from 1991-2009

- Adjuvanted H5N1 vaccine
  - (Alum; MF59; AS03) “no adverse outcomes” reported in pregnant women inadvertently immunized while pregnant

- Adjuvanted H1N1 vaccine
  - (AS03) tested in 45,000 with no serious adverse events reported
H1N1 influenza

• “Unadjuvanted vaccine is recommended for use by pregnant women”
• “Although there is no evidence that adjuvanted vaccine is unsafe for pregnant women, this kind of vaccine hasn’t been tested in pregnant women, so unadjuvanted vaccine is the first choice for pregnant women.”
• Where are we?
• Where should we be?
• How can we get there?
Responsible inclusion

• If pregnant women are going to use drugs, then we need to study the drugs in this patient population.
• “Need to make reasoned decisions about risk in pregnancy”
• “Need to take responsible and calculated risks in order to garner evidence, lest we visit more risk on more people in the future.”
Responsible inclusion

• Wrong to tolerate the *status quo* where clinicians care for patients without evidence of safety and efficacy
• Need to include pregnant women in clinical trials, *including Phase I trials*
• Important to shift the burden of justification from inclusion to exclusion
It was suggested that the assumption should be one of inclusion, unless the sponsor of the drug has a compelling argument not to include them. Françoise Baylis, Professor at the Faculty of Medicine at Dalhousie University, made the observation that “[p]regnant women get sick and sick women get pregnant”, and that they deserve the same level of evidence-based healthcare as any other Canadian.
The committee feels it is necessary to require that drug developers test their drugs in a population that is reflective of who could reasonably be expected to consume that product, should it obtain market approval.
... greater emphasis must be placed on testing a candidate drug’s safety and efficacy in groups that reflect those who can reasonably be expected to consume the drug once it becomes marketed to the general population.
• Where are we?
• Where should we be?
• How can we get there?
Ending the knowledge gap

- Pursue innovative study designs
- Develop more nuanced research regulations
- Alter labelling to more effectively communicate evidence-based guidance to medication use in pregnancy
- Establish an Institute of Medicine working group to issue a report on the under-representation of pregnant women in research
- Create incentives for inclusion of pregnant women in biomedical research

http://secondwaveinitiative.org/Case_Statement.html
Ending the knowledge gap

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http://secondwaveinitiative.org/Case_Statement.html
Create incentives for inclusion of pregnant women in biomedical research
Barriers to inclusion

- Manufacturers (Pharma)
- Regulators (Health Canada, FDA)
- Research sponsors (CIHR, NIH, MRC)
- Oversight organizations (PRE, OHRP)
- Research ethics guidelines/legislation (TCPS-2; 45 CFR 46 Subpart A)
- Research ethics review committees (REBs)
- Researchers
- Clinicians
- Participants
- General public (beliefs, customs, practices)
Incentives for inclusion

- **Manufacturers:** Protect from tort liability. Provide data exclusivity. Prohibit off-label prescribing.
- **Regulators:** For research involving additional risks to the fetus, index levels of risk to the severity of need.
- **Research sponsors:** Make research in pregnancy a funding priority – expand funding for cohort registries, case-control surveillance studies.
Incentives for inclusion

• Oversight organizations: Presume inclusion and provide clear criteria for managing risk; clear criteria for exclusion
• REBs: No boiler-plates
• Researchers: Justify exclusion
• Clinicians: Educate about preventive medicine for themselves and their patients.
• Research participants: Increase public awareness.
• Public: Time ....
Develop more nuanced research regulations
Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding.
Application:
Researchers should not exclude women from research on the basis of their reproductive capacity, or their pregnancy, or because they are breastfeeding, unless there is a valid reason for doing so.

... REBs shall take into account foreseeable risks and potential benefits for the woman and her embryo, fetus or infant, as well as the foreseeable risks and potential benefits of excluding pregnant women from the research.
Risk/benefit assessment

- Nature and severity of the disease
- Availability and results of previous nonclinical data on pregnant and nonpregnant women
- Results from clinical data
- Availability of alternative therapies and knowledge of associated risks
- Stage of pregnancy in relation to overall development of fetus
- Potential for harm to woman, fetus, or child

Health Canada Guidance Document Jan 2012
CIOMS: Guideline 17

• “Pregnant women should be presumed to be eligible for participation in biomedical research. Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility.”
Researchers and trial sponsors should include **women in clinical trials** in order to verify safety and efficacy from their standpoint, including immunogenicity in the case of vaccine trials, since women throughout the life span, including those who are sexually active and **may become pregnant, be pregnant**, or be breast-feeding, should be recipients of future safe and effective biomedical HIV prevention interventions.
UNAIDS/WHO Guidance document: Guidance Point 9

• During such research, women should receive adequate information to make informed choices about risks to themselves, as well as to their foetus or breastfed infant, where applicable.

• ...women should be viewed as autonomous decision-makers, capable of making an informed choice for themselves and for their foetus or child.
Pursue innovative study designs
Two options

• Stand-alone Phase I trials concurrent with Phase III trials

• Phase I trials embedded into late Phase II or Phase III trials

Baylis, F. and Halperin S. *Clinical Investigation* 2012
Option 1
Phase 1 → Phase 2 → Phase 3 → Phase 4

Option 2

Novel Tech Ethics
Responsible inclusion of pregnant women in research

• Promote the inclusion of pregnant women in vaccine research among all relevant parties
  – Presumed eligible for research participation
  – Presumed autonomous (able to make informed decisions)

• Create incentives for inclusion
• Develop more nuanced research guidelines
• Pursue innovative study designs
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