

Inherited Thrombophilias and Pregnancy

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INTRODUCTION

THROMBOEMBOLIC disease in pregnancy is seen in 0.2-0.3% of pregnancies. Increasingly, thrombophilias have been identified as underlying contributors to thromboembolic disease in pregnancy. Thrombotic events in pregnancy have not only been associated with poor maternal outcomes, but also with a myriad of fetal and obstetrical complications including: stillbirth, severe intrauterine growth restriction (IUGR), abruption, and severe, early-onset pre-eclampsia¹. The thrombophilias are divided into acquired and inherited forms. The most common acquired thrombophilia is the antiphospholipid antibody syndrome². Inherited thrombophilias refer to genetic disorders that increase the risk of thromboembolic disease. This paper will concern itself only with the inherited thrombophilias.

Coagulation is a complex process involving many factors (figure 1). In pregnancy, there are changes in many coagulation factors leading to a hypercoaguable state. Overall, there is an increased resistance to activated protein C, a decrease in Protein S activity, and an increase in fibrinogen, factors II, VII, VIII, X, XII, and fibrinolytic inhibitors. The inherited thrombophilias can compound this increase in hypercoaguability leading to adverse maternal and fetal outcomes². The placental sites in which thrombosis begins has

not been determined. Potential locations include the spiral arteries, intervillous space, and fetal vascular lumen.

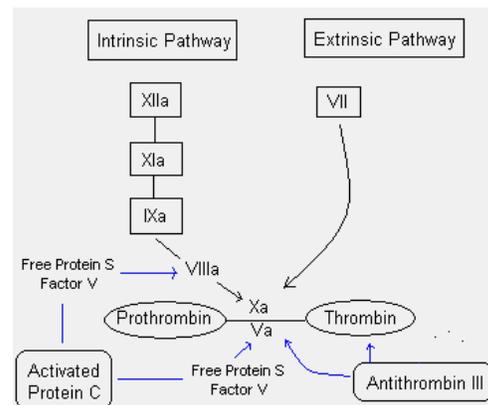


Figure 1 - Coagulation cascade

THE INHERITED THROMBOPHILIAS

There are six main inherited thrombophilias: factor V leiden gene mutation (FVL), prothrombin gene mutation, hyperhomocysteinemia, protein C deficiency, protein S deficiency, and antithrombin deficiency. (Cont'd)

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Table 1 – Prevalence of Inherited Thrombophilias

	General Population	Venous Thromboembolic Event Patients
Factor V leiden mutation	5%	25%
Prothrombin gene mutation	2%	6%
Hyperhomocysteinemia	3%	10%
Protein C, S, and antithrombin deficiency	<1%	10%

FVL gene mutation is the most common of the hereditary thrombophilias with a 1.0-8.5% heterozygous and 1.0% homozygous incidence. It is inherited in an autosomal dominant pattern. A guanine substitution for adenine at the 1691 position of the gene encoding for factor V renders it resistant to cleavage by activated protein C².

Prothrombin gene mutation heterozygosity is present in 2-3% of the general population. A mutation on the 3' untranslated end at nucleotide 20210 in the prothrombin gene causes a guanine to adenosine nucleotide substitution. This leads to an increase in prothrombin level resulting in a hypercoagulable state².

Homocysteine is produced by the metabolism of the essential amino acid methionine. Abnormalities of the enzymes in this pathway lead to hyperhomocysteinemia. This can be exacerbated by deficiencies in vitamins B₆, B₁₂, and folic acid. The most common mutation is that of the 667C-T MTHFR (methylene tetrahydrofolate reductase) thermolabile enzyme. The pathogenesis of hypercoagulability is potentially through direct endothelial injury through increased oxidative stress, impaired endothelial synthesis of vasodilatory substances, increased expression of procoagulants, increased platelet aggregation, impaired endogenous anticoagulant activity, and decreased fibrinolysis².

Proteins C and S are vitamin K dependent proteins synthesized in the liver. Deficiencies in both these proteins are through autosomal dominant inheritance. The incidence of each disease is 0.002-0.005% and 0.1% respectively².

Antithrombin deficiency is the most thrombogenic of the heritable coagulopathies. It is also inherited in an autosomal dominant

manner and has a prevalence of 0.5-1.0%. Antithrombin III is a major inhibitor of thrombin and other procoagulants (Factor IXa, Xa, XIa, XIIa)².

RECURRENT PREGNANCY LOSS

Recurrent pregnancy loss (RPL) is defined as three consecutive spontaneous pregnancy losses of an intrauterine pregnancy at less than 20 weeks. It has an incidence of 1-2%³. After standard gynecologic, hormonal, and karyotype investigations, 30-40% will remain unexplained⁴. It has been hypothesized that microthrombi in the placental bed can affect early placentation and, therefore, be a cause of RPL.

Rey *et al.* in 2003 published a meta-analysis examining RPL and thrombophilias. They defined RPL as ≥ 2 pregnancy losses, and no distinction was made between early or late pregnancy losses. A significant association was found between RPL and FVL mutation, prothrombin mutation, and protein S deficiency. Antithrombin deficiency had a low disease prevalence making it difficult to study and an uncommon cause of RPL. The authors concluded that there was insufficient evidence to include the hereditary thrombophilias in the initial evaluation of RPL. However, after excluding the more common causes of RPL, it was reasonable to assess for FVL mutation, prothrombin gene mutation, and protein S deficiency.

Carp *et al.*, 2003 conducted a prospective cohort study of 85 women with ≥ 3 consecutive pregnancy losses in the first or second trimester. These patients were included in the study only after other causes of RPL were excluded and they were found to be positive for one of the hereditary thrombophilias. 37 women were treated with Enoxaparin 40 mg daily, once the pregnancy was diagnosed until delivery. 48 controls were matched for number of previous pregnancy losses, age, and time to conceive. There were a significantly higher number of live births in the treated group (70.2% vs. 43.8% control). This effect was greatest in those women who never had a previous live birth (90.0% vs. 48% control). Although the effect was not significant in those women who had a previous live birth (47.1% vs. 39.1% control), the trend did show a benefit. Enoxaparin seems to have a role in preventing

RPL in patients with hereditary thrombophilias.

The 2001 ACOG guideline on RPL states that the role of heritable thrombophilias in RPL is uncertain at present. Tests for these thrombophilias are not required as part of the evaluation. Treatment with antithrombotics to improve subsequent pregnancies is uncertain⁵.

ADVERSE PREGNANCY OUTCOMES

Severe pre-eclampsia, abruptio placentae, IUGR, and stillbirth contribute greatly to maternal & fetal morbidity and mortality. Their causes are unknown, but may be related to abnormal placental vasculature and disturbances of hemostasis, leading to inadequate maternal-fetal circulation. Alfirevic *et al.* in 2002 published a review that examined these adverse pregnancy outcomes and inherited thrombophilias. Women were excluded from the study if they had a prior thromboembolic event or history of RPL in the first trimester. Many of the inherited thrombophilias were associated with adverse pregnancy outcomes (table 2).

Table 2 – Pooled Odds Ratio

	Placental Abruption	IUGR	Stillbirth	Pre-eclampsia
Factor V leiden mutation	6.7 (2.0-21.6)	-	6.1 (2.8-13.2)	1.6 (1.2-2.1)
Prothrombin mutation	28.9 (3.4-236.7)	5.7 (1.2-27.4)	16.2 (5.0-52.3)	2.4 (1.2-4.7)
MTHFR mutation	3.5 (1.5-8.1)	5.0 (1.8-13.8)	-	1.7 (1.2-2.3)
Protein C deficiency	-	-	-	21.5 (1.1-414)
Protein S deficiency	-	10.2 (1.1-91)	-	12.7 (4.0-39.7)
Antithrombin deficiency	-	-	-	-

Table 3 – Who should be tested

Testing for Inherited Thrombophilia Recommended
History of VTE < 45 y.o
Unusual manifestations of thromboembolism (eg. mesenteric thrombosis)
Strong family history of VTE
Recurrent pregnancy loss
Stillbirth assoc. with IUGR & placental infarcts
Severe or recurrent pre-eclampsia occurring in 2 nd trimester or early 3 rd trimester
Unexplained recurrent or severe abruption

TREATMENT

Several clinical trials have demonstrated a beneficial effect of aspirin and heparin in improving fetomaternal outcomes in women with antiphospholipid antibody syndrome, a type of acquired thrombophilia. However, similar information is lacking regarding the optimal treatment for the inherited thrombophilias. Kupferminic *et al.* in 2001 published a cohort study of 33 women with prior adverse pregnancy outcomes (eg. severe PIH, abruption, IUGR, IUFD). These women were subsequently found to have an inherited thrombophilia. In their next pregnancy, they were treated with Enoxaparin 40 mg daily (from 8-12 weeks GA to 6 weeks post-partum) and ASA 100 mg po daily (from 8-12 weeks GA to 37-38 weeks GA). There were only 3/33 adverse pregnancy outcomes observed. Mean GA at delivery improved in the treated group (32.1 ± 5.0 weeks index pregnancy, to 37.6 ± 2.3 weeks treated pregnancy). Likewise, birth weight also improved (1175 ± 590g to 2719 ± 526g).

Anyone who experiences a VTE event during pregnancy should be placed on therapeutic heparin for 4 months and then prophylactic therapy for the remainder of the pregnancy. Anticoagulation should be continued for at least 6 weeks post-partum¹.

Patients with antithrombin deficiency, homozygote or compound heterozygote for FVL, or prothrombin gene mutation are at high risk for VTE disorder. They should be on therapeutic heparin throughout pregnancy and anticoagulated with coumadin for 6 weeks post-partum or longer if there has been a prior VTE event¹.

Treatment of the lesser thrombogenic inherited thrombophilias (protein C or S deficiency, hyperhomocysteinemia) will depend on whether or not there is a history of

VTE event or adverse pregnancy outcome. If the history is negative for VTE or adverse pregnancy outcome, the risk of either is < 1%. These patients, therefore, do not require any antenatal treatment. Anticoagulation is recommended post-partum if delivery was by caesarean section or if they have an affected first degree relative because the risk of VTE is higher. If history is positive for a prior VTE event, prophylactic heparin is recommended in the antenatal period with post-partum anticoagulation for at least 6 weeks after. If history is positive for a prior adverse pregnancy outcome, prophylactic heparin is recommended in the antenatal period with post-partum anticoagulation only if delivery was by caesarean section or if they have an affected first degree relative¹.

MEDICATION DOSES⁹

Unfractionated Heparin

Prophylactic

5000-7500 units sc q12h in first trimester
7500-10,000 units sc q12h in second trimester
10,000 units sc q12h in third trimester

Therapeutic

target a PTT 1.5-2.5x normal baseline value 6h post-injection, q12h

Low Molecular Weight Heparin

Prophylactic

Dalteparin 5000 units sc q24h
Enoxaparin 40 mg sc q24h

Therapeutic

Dalteparin 200 units/kg sc q24h
Enoxaparin 1 mg/kg sc q12h
target anti-factor Xa levels of 0.6-1.0 units/ml 4h post-injection

Post-partum Prophylaxis

Warfarin to target INR of 2.0-3.0
Initial UFH or LMWH overlap until INR \geq 2.0 for 48h

SUMMARY

The inherited thrombophilias play a role in recurrent pregnancy loss and other adverse obstetrical outcomes. After excluding more common causes of RPL, it is reasonable to screen for FVL mutation, prothrombin mutation, and protein S deficiency. The

inherited thrombophilias not only increase the risk of a VTE event, but also of an adverse pregnancy outcome such as placental abruption, stillbirth, pre-eclampsia, and IUGR.

Treatment with LMWH is associated with the prevention of RPL and improved fetomaternal outcomes, but data from randomized control trials is pending. Current guidelines suggest treatment for inherited thrombophilias associated with a high risk of VTE events (prothrombin gene mutation, antithrombin deficiency, FVL). Treatment is also suggested for the lesser thrombogenic inherited thrombophilias (protein C or S deficiency, hyperhomocysteinemia) if there is a history of VTE event or adverse obstetrical outcome.

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The Multidisciplinary Collaborative Primary Maternity Care Project (MCP²) – A national initiative to address the human resource shortage in primary maternity care.

Anne L. Maranta, BIS (midwifery), BA
Associate Project Manager, Multidisciplinary Collaborative Primary Maternity Care Project

MOST reproductive health care providers are well aware that Canada as a whole suffers from a shortage of health care professionals providing maternity care to pregnant women; that this shortage is having a detrimental impact on the availability and quality of care made available to women throughout the country; that it is putting a significant strain on health care providers who must expend significant energy in an attempt to mitigate the effects of the shortages and maintain a quality provision of care to patients.

We have also heard the merits of multidisciplinary collaborative maternity care, a concept that is being advocated by many governments and stakeholders as a solution to the growing human resource shortages. The ***Multidisciplinary Collaborative Primary Maternity Care Project (MCP²)*** is an exciting initiative undertaken to address the key barriers to collaborative primary maternity care. The goal of ***MCP²*** is to develop means by which the availability and quality of maternity care services for Canadian women can be increased. The project's focus is on finding inter-professional collaborative solutions that will build capacity in primary maternity health care, will engage key stakeholders in considering alternate models of primary maternity care, will disseminate information and consider the development of catalogues of models, guides and implementation tools. Bringing such approaches forward should help to improve confidence amongst health care providers and the public about the benefits of developing collaborative services.

The strength of ***MCP²*** lies in the partnerships that have been established. Associations representing the full range of maternity care

providers are collaborating in this initiative, in order to collectively champion changes to the provision of maternity services and the move to more collaborative models of primary maternity care. They include: the Association of Women's Health, Obstetric and Neonatal Nurses Canada (AWHONN Canada), the Canadian Association of Midwives (CAM), the Canadian Nurses Association (CNA), the College of Family Physicians of Canada (CFPC), the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Society of Rural Physicians of Canada (SRPC). ***MCP²*** is funded by the Primary Health Care Transition Fund of Health Canada.

The legacy objective for the project is the development of a National Primary Maternity Care Committee that currently includes representatives from each of the partner associations, provincial government representatives and consumers. The members of the national committee are involved in one of five working groups established to focus on the topics of model development, public policy, research/ evaluation, harmonization/legal and communication. The national committee first met in Ottawa on January 12, 2005, and again on June 8, 2005.

The project has seven main objectives, listed on the project overview, which will be addressed by the working groups and consultants contracted to facilitate information gathering and development of implementation strategies including:

MODEL DEVELOPMENT:

With feedback from the working group, Dr. Malcolm Anderson facilitates a two phase consultation process focused on the objectives of developing guidelines for models, collaboration among professionals and

changing practice patterns. The consultation process will address knowledge generation and knowledge transfer and will include interviews with key stakeholders, focus groups with health care providers and consumers and decision support tools to assist with implementation of collaborative models. Kathy Herschderfer from the International Confederation of Midwives leads the international portion of project that includes describing and reviewing collaborative models in the UK, the Netherlands, Germany, France, Sweden and Australia.

PUBLIC POLICY:

Solugik Public Affairs (Solugik), a bilingual consulting company, has compiled background research that will be used to address harmonization of terminology, standards and scope of practice. Solugik conducted telephone interviews with care providers and focus groups with care recipients that will be used to develop information packages about the benefits of collaborative practice. They will be working with members of the working group to identify how to garner support for moving the project recommendations forward.

RESEARCH/EVALUATION:

Dr. Barbara Davies and Dr. Jennifer Medves are leading the evaluation portion of the project, and in particular they will be assessing the impact of the project on the knowledge, attitudes and beliefs about collaboration of health care providers and other stakeholders. This group will also be conducting surveys, focus groups and interviews.

COMMUNICATIONS:

The project will focus on the implementation of communication strategies to disseminate information to governments, consumers, health care providers and other relevant stakeholders.

HARMONIZATION /LEGAL:

The Harmonization Working Group has drafted a list of core competencies required by a multidisciplinary collaborative primary maternity care team. This list will serve a basis from which to identify the regulatory and/or legislative changes that may be necessary to facilitate collaborative care. This information has also been shared with the consultant working with the model development working group. The group is also continuing to identify regulatory and other documents that pose barriers to multidisciplinary primary maternity care. An action plan will be developed to identify which, if any, of these barrier documents to address.

Many individuals and organizations will be contacted by the consultants throughout the project. Copies of all reports and updates of the progress of the project will be posted on the project's website at www.mcp2.ca. If you have any questions or comments please contact Margaret McNamee (Project Manager) at mmcnamee@sogc.com or Anne Maranta (Associate Project Manager) at amaranta@sogc.com.

**For an overview of the project
See page 7**



MCP²

Multidisciplinary
Collaborative Primary
Maternity Care Project

Projet de soins
primaires obstétricaux
concertés

PROJECT OVERVIEW

Executive Committee

- Association of Women's Health, Obstetric and Neonatal Nurses (Canada)
- Canadian Association of Midwives
- Canadian Nurses Association
- College of Family Physicians of Canada
- Society of Obstetricians and Gynaecologists of Canada
- Society of Rural Physicians of Canada

Overarching Goal

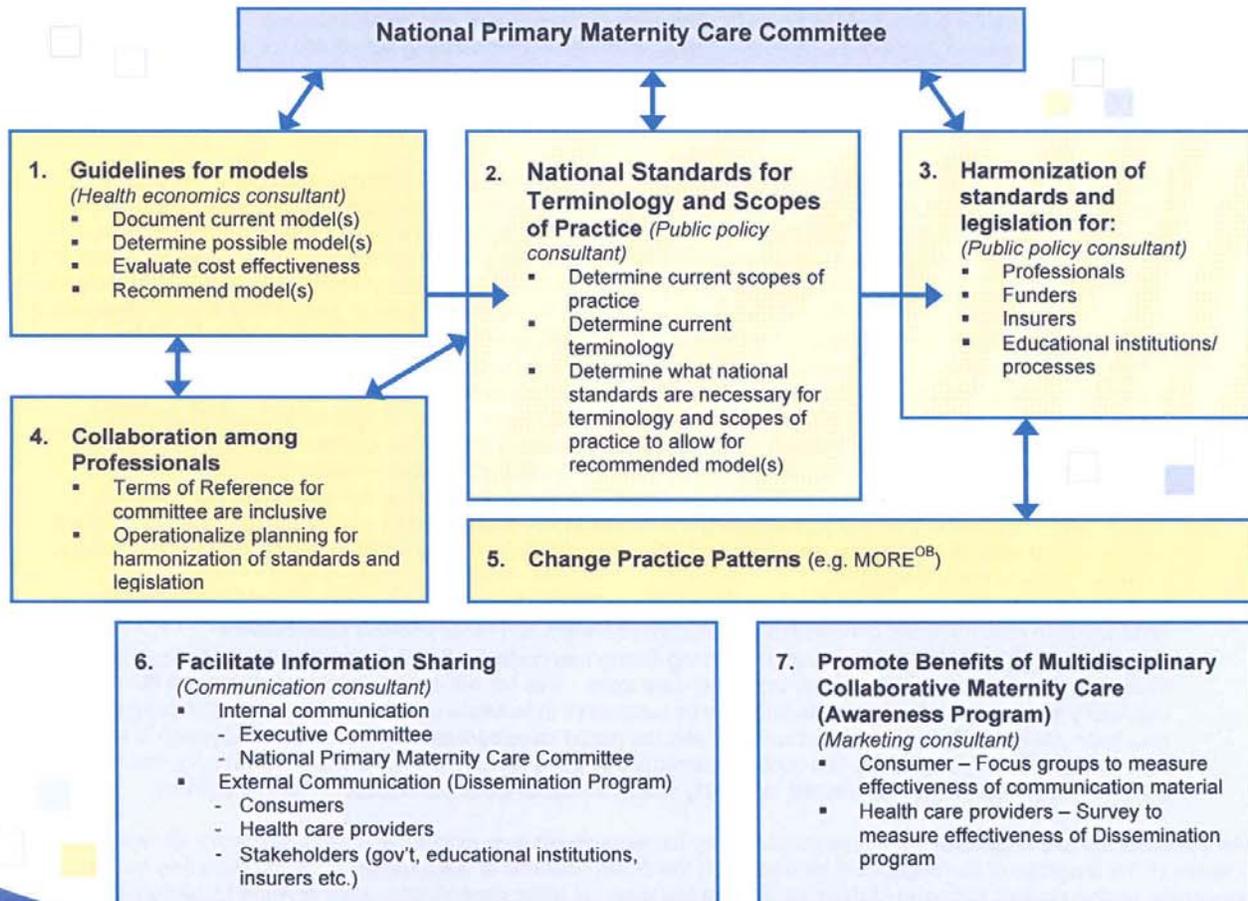
To reduce barriers and facilitate the implementation of national multidisciplinary collaborative primary maternity care strategies as a means of increasing the availability and quality of maternity services for all Canadian women.

Evaluation Framework

(Evaluation Consultant)

- Determine impact of project on care providers' knowledge, attitudes and beliefs about collaborative maternity practice
- Determine if project objectives are met
- Record lessons learned

National Primary Maternity Care Committee



FOR YOUR INFORMATION:

Welcome Welcome

We are extremely pleased to announce that beginning this fall, you will be seeing a new face when the Perinatal Outreach Program comes to your town! Dr. Kevin Coughlin, neonatologist, is now a member of the outreach team and will be assisting with visits to our community hospitals.



Kevin completed his MD degree at Queen's University following pre-med training in the life sciences program with postgraduate courses in immunology. He entered pediatric residency training in 1999 at the Children's Hospital of Eastern Ontario and in July 2001 undertook fellowship training in Neonatology at St. Joseph's Health Care London ending June 2004. He recently completed his Masters of Health Sciences in Bioethics from the University of Toronto. Dr. Coughlin will assume an active role in the NICU as an attending physician at St. Joseph's, but will also assist departmental specific teaching in Bioethics, primarily at CHWO.

Please join us in welcoming Kevin

TIME IS RUNNING OUT!!



DON'T FORGET TO REGISTER FOR ONE OF THE 5 CONVENIENT ACoRN WORKSHOPS NEAREST YOU

WHAT IS ACoRN?

ACoRN (Acute Care of at-Risk Newborns) is a systematic approach to the identification and management of babies requiring stabilization. The educational program and accompanying text aim to teach the concepts and basic skills of neonatal stabilization, and where necessary, preparation for transport to a referral facility. The ACoRN process applies to babies who need assistance in the transition from fetal life, and babies who become unwell or are at risk of becoming unwell in the first few hours or days after birth.

WHO SHOULD ATTEND?

For most health professionals, few events are more challenging or stressful than caring for a sick or preterm baby. It is, therefore, not surprising that the management and stabilization of these babies is repeatedly identified as a priority for new educational programs. The Acute Care of at-Risk Newborns (ACoRN) program was developed in response to this need. It is designed for any practitioner who may be called upon to care for at-risk babies and their families, regardless of experience or training in neonatal emergencies.

It will be of particular benefit to family physicians who attend birth, particularly when pediatric assistance is not readily available.

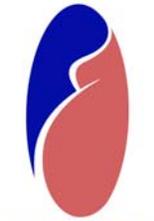
Obstetricians, nurses and midwives will also find the ACoRN process invaluable.

For dates and locations please see Upcoming Events.



ACoRN Editorial Board 2005

FYI: (CONT'D)



International Trial
of Antioxidants for the Prevention
of Preeclampsia

INTAPP is a 5-year study seeking to determine if supplements of Vitamin C and E can prevent preeclampsia. There are 55 centres through out the world

participating in the study. Twenty-one centres are located in Canada. Over 12, 000 women will be recruited to participate.

In the past, researchers in England found in one study that the incidence of preeclampsia was reduced in women who took supplements of Vitamin C and E in pregnancy. These vitamins act as “antioxidants” to reduce certain “oxidant molecules” that are believed to be increased in gestational hypertension.

Women are currently being recruited to participate in the study at St. Joseph’s Health Care London, Ontario. The research team is led by Dr. R. Gratton, Dept. of Obstetrics/Gynecology and will be recruiting 450 women at this site. Women who are between 12 and 18 weeks of pregnancy, and who plan to give birth at St. Joseph's Hospital, can be eligible.

Criteria for participation are:

Nulliparous women and multiparous women who have one or more of the following risk factors for preeclampsia:

- *multiple gestation*
- *chronic hypertension*
- *diabetes*
- *a previous pregnancy complicated by preeclampsia*

Participants will meet with the research nurse three times in the pregnancy and again in hospital following the birth of their baby. Each visit will include blood sampling, blood pressure measurement, urine testing for protein and a health assessment. Women participating in the study will also be asked to complete a nutritional assessment at the first and third visit. They will be asked to take two capsules daily, containing either Vitamin C and E or gelatin placebo. The study participants and researchers will not know if the capsules contain vitamins or if they are placebos.

It is hoped that this study will provide valuable information about methods to prevent preeclampsia, one of the most common complications of pregnancy. To receive more information about the study, or to inquire about participation, contact:

Ann Jarvie, MScN
Research Nurse
INTAPP Study
Dept. Obs/Gyn
St. Joseph's Health Care, London
519-646-6100 ext 65760



**Rubella Guidelines &
Physician Cover
Letter
Available**

[www.sjhc.london.on.ca/sjh/
profess/periout/educate.htm](http://www.sjhc.london.on.ca/sjh/profess/periout/educate.htm)

UPCOMING EVENTS:

Mark Your Calendar!



ACORN REGIONAL ROLL-OUT

~~Windsor – September 7-8, 2005~~
~~Owen Sound – October 5-6, 2005~~
~~Chatham – November 3-4, 2005~~
Stratford – November 17-18, 2005
London - January 19-20, 2006

Contact: Perinatal Outreach Office
(519) 646-6100, ext. 65859
Watch our webpage for further details:
www.sjhc.london.on.ca/sjh/profess/periout/periout.htm

FETAL HEALTH SURVEILLANCE WORKSHOP

October 21, 2005
Location: St. Joseph's Health Care London
Cost: \$60 (includes materials)
Contact: Perinatal Outreach Program
(519) 646-6100 x 65859

REGIONAL NURSE MANAGER'S MEETING
(for entire region)

Friday, October 28, 2005
Location: Shuttleworth Auditorium
Roney building
St. Joseph's Health Care London

Contact: Perinatal Outreach Office
(519) 646-6100, ext. 65859

PREGNANCY & BIRTH ANNUAL CONFERENCE
**Maternal, Infant & Reproductive Health
Research Unit (MIRU)**

Friday, December 9, 2005
Location: Marriott Toronto Eaton Centre
Contact: MIRU office
416-323-6501 mailbox 3781, or
miru@sw.ca

LUNCH & LEARN VIDEOCONFERENCE SERIES
"BABY TALK – LESSONS FROM THE NICU"

Dates and topics to be announced. For more information:

Contact: Perinatal Outreach Office
(519) 646-6100, ext. 65859

Watch our webpage for further details:
www.sjhc.london.on.ca/sjh/profess/periout/periout.htm

MATERNAL NEWBORN NURSE EDUCATION COURSE
London:

Mondays: March 27 – May 15, 2006
St. Joseph's Health Care, London
*Will be offered by Videocare to all our regional hospitals. For more details, or to register your site, please

Contact:
Gwen Peterek
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21ST ANNUAL PERINATAL OUTREACH CONFERENCE
TO BE ANNOUNCED

Fall 2006
Location: Lamplighter Inn, London

Contact: Perinatal Outreach Office
(519) 646-6100, ext. 65859
Watch our webpage for further details:
www.sjhc.london.on.ca/sjh/profess/periout/periout.htm



Did you know . . . that archived copies of this newsletter (1997 – present) can be viewed and/or downloaded from our website? Go to:
www.sjhc.london.on.ca/sjh/profess/periout/periout.htm
and choose the tab marked "Newsletter"



This newsletter is a publication of the Perinatal Outreach Program of Southwestern Ontario.

Letters, queries and comments may be addressed to:
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To have your name included on our mailing list, please contact the above, or
E-mail: gwen.peterek@sjhc.london.on.ca
www.sjhc.london.on.ca/sjh/profess/periout/periout.htm