



**ICAN**

International Cesarean Awareness Network, Inc.

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Dear Caroline:

On behalf of ICAN, I am writing to personally thank you for your initiative in pursuing a new research study comparing vaginal birth after cesarean (VBAC) with elective repeat cesarean (ERC).

The medical research of the last 20 years has consistently shown that VBAC is a safer option than major abdominal surgery, even when the low risk of uterine rupture is considered. Research studies point out that induction of labor dramatically increases the chance of rupture, yet this procedure is still widely practiced. Unfortunately, this is where research and reality are at odds, because ERC is the most common procedure offered or imposed on women having a baby after a previous cesarean.

ICAN has grown from 30 chapters in 2003 to more than 70 chapters in 2006, because of the strong commitment of our chapter leaders. Our expansion validates the need for support to the ever greater numbers of women that are cut by cesareans everyday.

ICAN wishes to support any organization or individual that wishes to enrich the body of research on VBAC and ERC, and we have some comments regarding the 'randomisation' aspect of this study. Please refer to the attached document on your *Birth After Caesarean Study Patient Information Sheet*.

Please do not hesitate to contact me with any questions. Thank you for the work you are doing in studying childbirth. Warmly,

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The International Cesarean Awareness Network, Inc. (ICAN) is a nonprofit organization founded by Esther Booth Zorn in 1982. ICAN's mission is to improve maternal-child health by preventing unnecessary cesareans through education, providing support for cesarean recovery, and promoting Vaginal Birth After Cesarean (VBAC).

## **ICAN Comments**

### **On The *Birth After Caesarean Study Patient Information Sheet***

Upon review of your *Birth After Caesarean Study Patient Information Sheet*, here are ICAN's comments on the study, for your careful consideration:

#### **1) Background:**

The information sheet, in the background section, reads:

**For women having a planned VBAC**, there is a very small risk of the uterus tearing leading to serious problems for the mother such as major bleeding or needing a hysterectomy. For the baby there is a small risk of them being unwell at birth and a very small risk of the baby dying. The chances of all these complications are less with a caesarean birth.

**For women having a planned elective repeat caesarean birth**, there is a small risk of needing a blood transfusion, having a temperature after birth needing treatment with antibiotics, and a very small risk of hysterectomy. The chances of a vaginal birth after a caesarean section may be reduced. For the baby there is a small risk that they may need to spend a short time in the nursery due to breathing problems.

ICAN is concerned that in your sheet women are asked to choose between their baby dying or losing their uterus. They are also asked to choose between major bleeding or having a temperature. Finally, they are asked to choose between having an unwell baby or the baby having a short visit to the nursery. Most women would choose the second alternative, each time. Which means that the random population samples are already compromised by mothers seemingly choosing their own welfare and that of their babies by choosing an ERC.

This information sheet is already biased toward having the research subjects choose one option over the other, the ERC. The perspective on ERC presented in this information sheet glosses over the fact that women in developed countries are dying from the consequences of preventable cesareans. Some of the risks women are facing now in this era of absurdly high cesarean rates include venous thromboembolism, uterine rupture, adult respiratory distress syndrome, pulmonary edema, myocardial infarction, severe postpartum hemorrhage requiring hysterectomy, and assisted ventilation. The death rate among women with these severe maternal injuries is 158 times that of the entire sample according to the September 27, 2005 CMAJ study *Severe Maternal Morbidity in Canada, 1991–2001* which looked at the hospital records of 2,548,824 women who gave birth in Canadian hospitals between 1991 and 2000.

The information sheet also states:

There have been no good studies that have compared the safety for women and their babies of planned VBAC with a planned elective repeat caesarean birth. Both planned vaginal birth and planned elective repeat caesarean section are available in clinical practice.

If the medical establishment continues to deny the evidence from 20 years of studies that VBAC is safer in most cases than ERC, the results of your randomised research will not shed new light. ICAN suggests that the randomised aspect of the research be removed and the research focus on the many aspects of VBAC that remain un-researched such as midwives as caregivers or water labour and water birth.

## 2) What is the Study:

The information sheet, in the 'what is the study' section, reads:

Randomised controlled trials are the best way to compare alternative forms of care, and are recognised as the 'gold standard'. Why is this? Because the randomisation guarantees that the groups being compared are chosen by chance, and so are similar in all ways except for the treatment being compared. In this study, planned VBAC is compared with planned elective repeat caesarean.

ICAN is concerned here that women are asked to choose between a VBAC or an ERC, with the goal being obtaining random population samples, which means healthy women with healthy babies could be undergoing unnecessary major abdominal surgery with all the risks entailed. This is not a gold standard of care. On the other hand, the randomisation could have women choosing VBAC who do not really care one way or the other how they give birth. The difference is that to achieve a VBAC it often requires a supreme effort, hours of labour with or without an epidural plus pushing. An ERC requires no significant effort until it is time to get out of the hospital bed to go on with one's life to discover the monumental task that is surgical recovery while caring for a newborn.

The randomised aspect of the research is indeed a very troubling aspect. While this is necessary to perform a good research, there are millions of ERCs and VBACs taking place everyday that offer great data. What will happen when the results are confirmed, yet again, that VBAC is safer? The women randomised for a cesarean can never undo the damage they received by undergoing multiple cesareans. The research is clear on that.

Because of the emotional and physical commitment required to achieve a VBAC, the results of the randomised study will be compromised showing lower VBAC achievement rates and higher ERC rates. Furthermore, VBAC outcomes will be poorer because women willing to be randomised for a VBAC will likely accept any medical intervention, such as oxytocin inductions and epidurals, without regard for the consequences thus unnecessarily increasing the level of danger of VBAC. This happened in the breech cesarean research trials (Hannah) which caused a breech cesarean policy in all north american hospitals and it is now being re-investigated because the randomisation aspect compromised the data.

## 3) What is involved for me if I participate in this study?

The information sheet, in the 'what is involved' section, reads:

**Planned VBAC:** If you are randomised to this group or choose this group, you will be reassessed when labour starts to confirm a vaginal birth is still appropriate. Your care during labour will follow standard guidelines. If a complication arises and your doctor feels that a caesarean section is necessary for you or your baby, this will be performed.

**Planned elective repeat caesarean:** If you are randomised to this group or choose this group, you will be booked for a caesarean birth between 38 and 40 weeks of pregnancy. If you go into labour before this scheduled time a caesarean section will be performed.

ICAN is concerned also that women choosing a cesarean are not reassessed to confirm if a cesarean birth is appropriate. Healthy women with healthy babies could therefore be given major abdominal surgery unnecessarily. Randomizing placebo vs. a drug being tested for studies may be necessary, but randomizing normal birth vs. major surgery cannot be justified with all the possible long term physical and emotional consequences involved. Birth is too important and life-altering an event to leave the method to chance while removing the element of mother's choice in the process.

**Birth After Caesarean Study  
Patient Information Sheet**

<b>Principal Investigator</b>	<b>Local Principal Investigator</b>	<b>Local Study Coordinating Centre</b>
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**Thank you for taking the time to read this information sheet.**

We would like to invite you to take part in a study for women who gave birth by caesarean in their last pregnancy. The study is comparing women who have a planned vaginal birth after caesarean (VBAC) with women who have a planned elective repeat caesarean section.

**BACKGROUND**

For someone like yourself, who has had a previous caesarean section you will need to make a decision about how you will plan to birth. The choice is for either a planned vaginal birth or planned elective repeat caesarean. In making your decision you will have the opportunity to discuss the choices with your partner, family and health care professionals, including an obstetrician.

For any woman giving birth, there is a risk that problems may develop. In this information sheet, we use a small risk to mean that the problem may happen for between 1 in 20 to 1 in 50 women or babies. A very small risk would mean the problem may happen for between 1 in 150 to 1 in 250 women or babies. There are benefits and risks associated with both planned VBAC and planned elective repeat caesarean.

**For women having a planned VBAC**, there is a very small risk of the uterus tearing leading to serious problems for the mother such as major bleeding or needing a hysterectomy. For the baby there is a small risk of them being unwell at birth and a very small risk of the baby dying. The chances of all these complications are less with a caesarean birth.

**For women having a planned elective repeat caesarean birth**, there is a small risk of needing a blood transfusion, having a temperature after birth needing treatment with antibiotics, and a very small risk of hysterectomy. The chances of a vaginal birth after a caesarean section may be reduced. For the baby there is a small risk that they may need to spend a short time in the nursery due to breathing problems.

The chances of all these complications are less with a vaginal birth.

There have been no good studies that have compared the safety for women and their babies of planned VBAC with a planned elective repeat caesarean birth. Both planned vaginal birth and planned elective repeat caesarean section are available in clinical practice.



### **WHAT IS THE STUDY?**

Because there is minimal reliable evidence to recommend either a planned vaginal birth or a planned elective repeat caesarean, many health professionals in Australia and New Zealand are taking part in this study to help provide better information about the safety for women and their infants of these two forms of care.

Randomised controlled trials are the best way to compare alternative forms of care, and are recognised as the 'gold standard'. Why is this? Because the randomisation guarantees that the groups being compared are chosen by chance, and so are similar in all ways except for the treatment being compared. In this study, planned VBAC is compared with planned elective repeat caesarean.

Randomisation means that neither you nor your doctor choose the method of birth, but that this is chosen at random or by chance. Women who are randomised will have an equal (50%) chance of being in the vaginal birth group, or in the planned caesarean group. The process of randomisation to choose your treatment in a study is very important to help answer the question, in this case which mode of birth is safer for you and your baby.

If you are willing to be randomised to either a planned VBAC or planned elective repeat caesarean section, your mode of birth will be determined by 'randomisation'.

If you are willing to be in the study but would prefer to choose your planned mode of birth you can do so.

Whichever treatment group you are randomised to or choose, you will receive standard care according to your treating doctor. The Mater Mothers' Hospital follows the recommendations of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) in regard to Caesarean Section (CS) and Vaginal Birth after Caesarean Section (VBAC). You will be provided with two pamphlets on CS and VBAC from RANZCOG, which should be used in consultation with your obstetrician, to help you understand more fully about both CS and VBAC. If you do not understand any of the information in this or any other information sheets provided please ask either your obstetrician, midwife or the research team to clarify any details you are unsure about.

### **WHAT IS INVOLVED FOR ME IF I PARTICIPATE IN THIS STUDY?**

To be able to take part in the study, you must have reached 37 weeks of pregnancy and have had a caesarean in your last pregnancy. Your baby needs to be of average size, and there should be no problems that might increase the possibility of difficulties with a labour and vaginal birth. If you agree to be take part in the study you will be asked to complete a questionnaire relating to your health, how you are feeling, and your preferences for birth.

**Planned VBAC:** If you are randomised to this group or choose this group, you will be reassessed when labour starts to confirm a vaginal birth is still appropriate. Your care during labour will follow standard guidelines. If a complication arises and your doctor feels that a caesarean section is necessary for you or your baby, this will be performed.

**Planned elective repeat caesarean:** If you are randomised to this group or choose this group, you will be booked for a caesarean birth between 38 and 40 weeks of pregnancy. If you go into labour before this scheduled time a caesarean section will be performed.

**Follow-up in the study:** If you enter the study, the progress of you and your baby will be followed whilst in hospital.

**4 months after birth:** For the success of the study, we will need details of you and your baby's progress after discharge from hospital. Four months after birth you will be sent a questionnaire in the post from the coordinating centre in Adelaide asking you to complete some questions about you and your child's health. These include how you are feeling, your satisfaction with your pregnancy care, how feeding your baby is going, whether you have experienced any pain, incontinence, or other problems and how your child is progressing.

**Longer term follow-up:** The coordinating centre in Adelaide will also contact you to find out about you and your baby's health when he or she is 18-24 months old. In order for the coordinating centre in Adelaide to contact you for the follow up your details such as your full name, address and phone number will need to be sent to the coordinating centre in Adelaide.

The study is due to be completed in the year 2009 and if you are interested in receiving details of the results of the trial the coordinating centre in Adelaide will forward these to you.

### **WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THE STUDY?**

If you decide not to take part in the Birth after Caesarean Study, the options for your care will include planning for a vaginal birth or planning for a Caesarean section. You and your doctor will decide on the method of delivery that is to be planned.

Also, if you agree to participate in the trial you have the right to change your mind and withdraw from the trial at any time without prejudice to you or your baby's treatment.. You and your doctor will then decide on the method of delivery that is to be planned. However, if possible we would still like to invite you to be involved in the follow up part of the study including the answering of the questionnaires.

**Should you have any concerns after reading this information please do not hesitate to ask for further clarification from your midwife or doctor or the Principal Trial Investigator: Dr Paul Devenish-Meares.** You may contact the Mater Research Secretariat on 3840 1585 should you have any complaints about the conduct of the research, or wish to raise concerns. The Research Secretariat may contact the Patient Representative or Hospital Ethicist at its discretion.