



BULLETIN

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OVERALL TOTAL: 957
TOTAL FOR THIS MONTH: 58

We have reached a new monthly high! Keep up the great work!

Second Interim Analysis

Congratulations on recruiting more than 900 women to the trial, making us ready to move on to the second interim analysis. If you have not yet sent all your overdue data booklets please do so immediately – we need all cases complete and clean before performing the analysis. Also, please resolve and



return any queries that are outstanding as soon as possible! We greatly appreciate your cooperation and look forward to receiving the data booklets and queries.

Recruitment Excellence!

This month we are recognizing centres with their **first** recruit – Congratulations to:

- Dr Gazala Khan and Mrs Natalia Quadros, Khoula Hospital, *Muscat*, OMAN



Quote of the Month

If you care at all, you'll get some results. If you care enough, you'll get incredible results.

~ Jim Rohn

**Recruitment
(planned enrolment of 1460)
as of May 31, 2007**

Annual Goal	Dec	Jan -	Jan -	Jul -	Jan -	Mar	Apr	May	Grand Total
	2004	Dec 2005	Jun 2006	Dec 2006	Feb 2007	2007	2007	2007	

COUNTRY	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
AUSTRALIA	54		67	47	57	18	8	3	16	216
CHILE	53		50	44	33	15	8	10	7	167
CANADA	156	1	34	34	34	16	9	13	10	151
THE NETHERLANDS	12		35	32	17	13	5	5		107
ARGENTINA	47		11	5	12	7	4	5	7	51
ISRAEL	68		17	14	16	2	1			50
IRELAND	19		11	1	20	2	1			35
JORDAN	14		16	10	2		2	1		31
SPAIN	10		3	9	5	1	2	2	4	26
DENMARK	17					3	7	7	7	24
UK	23			7	7		1	2	3	20
ESTONIA	5			5	10	1		1	2	19
USA	35		7	2	4	4	1			18
GERMANY	9		5	4	4			3		16
EGYPT	20		5	8	2	1				16
POLAND	5			3					1	4
PORTUGAL	7			3						3
OMAN	10								1	1
HUNGARY	7			1						1
BRAZIL	12			1						1
Total	583	1	261	230	223	83	49	52	58	957

CENTRES BY COUNTRY

(Shaded area is prior to start-up)

AUSTRALIA

Centre	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Box Hill, Box Hill	5		27	15	16	6	1		5	70
Royal Prince Alfred, Sydney	9		9	11	11	1	3	1	4	40
Ipswich Hospital, Ipswich	5			9	14	6	2		3	34
St George, Sydney	6		8	4	5	3	1	1	3	25
Toowoomba Base Hospital, Toowoomba	3		18	3	3					24
Royal Women's, Carlton	11		4	2	3		1	1		11
Royal North Shore Hospital, St Leonards	10			3	4	1			1	9
Townsville Hospital, Townsville	5		1		1	1				3

CHILE

Centre	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Padre Hurtado, Santiago	17		31	21	14	6	2	2	2	78
Clinico San Borja, Santiago	19		8	13	10	4	5	4	2	46
Universidad Catolica, Santiago	7		11	10	7			2		30
Hospital Parroquial San Bernardo, San Bernardo	5				2	5	1	1	3	12
Hospital Clinico Universidad de Chile J.J. Aguirre, Santiago	5							1		1

CANADA

Centre	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Children's & Women's Health Centre of BC, Vancouver	18	1	18	5	6	2				32
Mount Sinai, Toronto	16			5	7	2	6	2	1	23
IWK Health Centre, Halifax	11			1	5	2	1	4	2	15
Sunnybrook Health Sciences Centre, Toronto	10		4	1	1	2		2		10
Royal Alexandra, Edmonton	10		2	4	2	1		1		10
Lion's Gate, Vancouver	4		2	4	4					10
St Michael's, Toronto	7			2	4	2				8
Ottawa Hospital General Campus, Ottawa	10			1	1	4	1			7
Regina Health Region, Regina	8		3	3		1				7
Royal Columbian, New Westminster	7		2	3	1				1	7
St Paul's, Vancouver	4		2	4						6
St Joseph's Health Centre, London	14							2	3	5
Trillium Health Centre, Mississauga	10							2	3	5
Calgary Health Region - Foothills Hospital, Calgary	25				3		1			4
North Bay General, North Bay	2		1	1						2

THE NETHERLANDS

Centre	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Atrium Medical Center, Heerlen	5		19	6	5	6	3	3		42
Academisch Ziekenhuis, Maastricht	3		12	16	7	5	1	1		42
Sint Lucas Andreas Ziekenhuis, Amsterdam	4		4	10	5	2	1	1		23

ARGENTINA

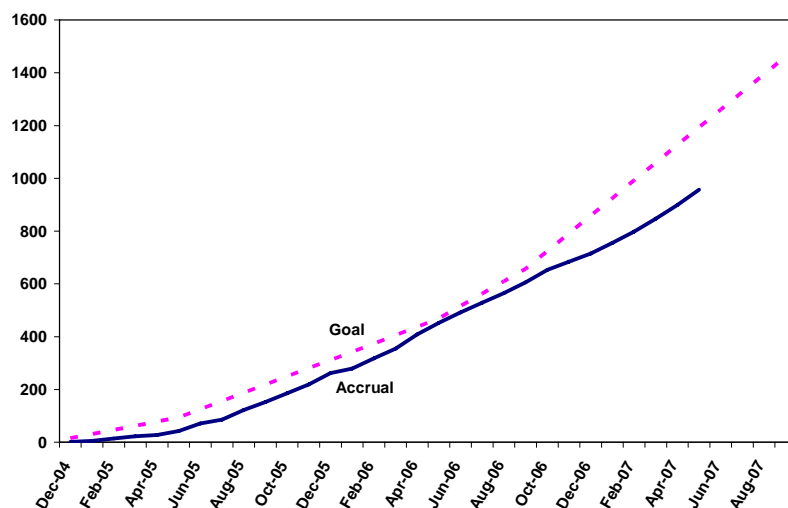
Centre	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Hospital Posadas, Buenos Aires	10		9	2	4	1		3	2	21

	Annual Goal	Dec 2004	Jan - Dec 2005	Jan - Jun 2006	Jul - Dec 2006	Jan - Feb 2007	Mar 2007	Apr 2007	May 2007	Grand Total
Ramon Carrillo, Santiago del Estero	16				6	1	2		3	12
Hospital Avellaneda, Tucuman	10		2	3				1	1	7
Hospital Alvarez, Buenos Aires	4					4	1		1	6
Hospital Penna, Bahia Blanca	7				2	1	1	1		5
ISRAEL										
Meir Hospital, Kfar Saba	14		7	6	15	2	1			31
Edith Wolfson, Holon	9		7							7
Soroka, Beer Sheva	30			6	1					7
Ma'ayney Hayeshua Medical Center, Bnai Brak	15		3	2						5
IRELAND										
Coombe Women's, Dublin	19		11	1	20	2	1			35
JORDAN										
Islamic, Amman	14		16	10	2		2	1		31
SPAIN										
University of Barcelona Hospital Clinic, Barcelona	10		3	9	5	1	2	2	4	26
DENMARK										
Aarhus University, Aarhus	12					3	6	5	4	18
Gentofte University Hospital, Hellerup	5						1	2	3	6
UK										
Bradford Royal Infirmary, Bradford	14			7	4			2		13
Royal Blackburn Hospital, Blackburn	9				3		1		3	7
ESTONIA										
Tartu University Clinics, Tartu	5			5	10	1		1	2	19
USA										
University of Iowa, Iowa City	4		4	2	3	1	1			11
University of South Carolina, Columbia	6		3			1				4
Maricopa, Phoenix	10				1	1				2
New York University School of Medicine, New York	15					1				1
EGYPT										
Assiut University Hospital, Assiut	20		5	8	2	1				16
GERMANY										
Charite Universitatsklinikum, Berlin	9		5	4	4			3		16
POLAND										
Medical University of Gdansk, Gdansk	5			3					1	4
PORTUGAL										
Distrital de Faro, Faro	7			3						3
OMAN										
Khoula Hospital, Muscat	10								1	1
HUNGARY										
University of Debrecen, Debrecen	7			1						1
BRAZIL										
ISCMPA-Maternidade Mario Totta, Porto Alegre	12			1						1

Centres awaiting first patient: [COUNTRY: Hospital, City (annual goal)] [month/year start-up package sent]

AUSTRALIA: West Gippsland Healthcare Group, *Warragul* (2) [03/05]; **POLAND:** Polish Mother's Memorial, *Lodz* (9) [03/05]; **ARGENTINA:** Hospital Durand, *Buenos Aires* (5) [03/07]; **THE NETHERLANDS:** TNO Prevention and Health, *Leiden* (4) [11/05]; **OMAN:** Khoula Hospital, *Muscat* (10) [11/06]; **UK:** Nottingham City, *Nottingham* (15) [04/07]

EECV2 Recruitment Graph



Special Recognition to centres who have met their Annual Recruitment Goal recently:



- Dr Duncan Farquharson and Ms Sarah Hudson, Royal Columbian, *New Westminster*, CANADA
- Dr Greg K Davis and Ms Lynne Roberts, St George Hospital, *Sydney*, AUSTRALIA
- Dr John R Neil and Ms Joanne Baumgartner, Box Hill, *Box Hill*, AUSTRALIA
- Dr Mario SF Palermo and Dr Dolores Montes Varela, Hospital Posadas, *Buenos Aires*, ARGENTINA
- Dr Cristian Kottmann, Hospital Parroquial San Bernardo, *San Bernardo*, CHILE
- Dr Birgitte Østberg and Dr Janne Foss Berlac, Gentofte University Hospital, *Hellerup*, DENMARK

Recruitment Ideas



Check out our recruitment insert in this month's newsletter with all the ideas shared at our various meetings including our more recent visits to Australia and our Canadian Teleconferences. We hope you will find these tips useful in maintaining or initiating enthusiasm for the trial at your centre. Please let us know if you have any more ideas to share with us!

We're almost at 1000!!!



Who will recruit our 1000th woman to the EECV2 Trial? We will send a certificate to acknowledge their contribution to the centre that achieves this important milestone!

Recruitment Tips

This insert will provide you with all the recruitment ideas that have been shared at our collaborators' meetings and teleconferences with your EECV2 colleagues around the world. We hope these help new centres just joining in getting their first recruit, as well as helping to maintain the momentum at our seasoned centres that have been with us from the beginning! If you have more recruitment tips to share that are not included here, please let us know at eecv2@sw.ca.

Tips from our International Collaborators' Meeting in Toronto, April 2005

Getting your first recruit...and your second, and your seventy-sixth (!):

- Create a research office with a focus on ECV
- Present the trial to all relevant departments to increase knowledge and interest in the trial, such as: the department of obstetrics, ultrasound, family practice, midwifery, etc.
- Promote the study to everyone, at all times, on every occasion
- Educate physicians and patients about the ECV procedure and benefits of taking part in the trial
- Share information about the EECV2 trial with other practitioners that provide care to pregnant women
- Reassure care providers that they will continue to provide obstetric care during the course of the trial - for example, talk to primary care midwives about referring breech babies between 33-35 weeks instead of 36+ weeks – let them know that home delivery is still possible if the baby is cephalic (that is the women will stay under their care)
- Share information about the trial with your colleagues in the ultrasound department and get them on board with the study. Your colleagues in the ultrasound department can keep a list of patients with breech position from 30 weeks on, and their obstetricians to contact
- Display EECV2 Posters everywhere, for example in the outpatient area, obstetric ward, waiting rooms, delivery room, admission room, perinatal ultrasonography centre, patient washrooms in ultrasound area
- Be patient – it may take time for interest in the study to build
- Be aware of the learning curve – for both yourself and others involved
- Discuss fine tuning your recruitment approaches with those involved
- Make a separate appointment for the woman to meet with the trial investigators for specific information, informed consent and randomisation
- Word of mouth – get everyone talking about the study (informal hall-way conversations are a good start!)
- Build a great supportive team
- If possible, recommend a standard ultrasound at 34 weeks for all patients
- Have patient information brochures available in every room
- Enlist support from general practitioners and obstetricians so that they can talk to their patients with breech pregnancies about the trial and give them a patient information brochure, before they are approached by study staff.



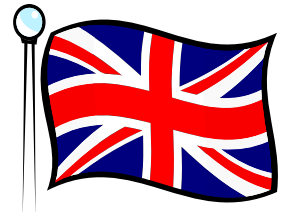
- Create awareness of the trial through a public relations campaign and providing promotional materials



- Post a list of all on-going obstetrical studies at your centre in the out-patient clinics, with the EECV2 Trial included
- Remind everyone *regularly* about the study
- Encourage staff training in ECV and simulator practice, if available
- Provide date wheels with inclusion and exclusion criteria, tape measures and brochures to practitioners
- Believe in the study!

Tips from our London Collaborators' Meeting, November 2005

- Identify who refers suspected breech presentations (i.e. GPs, medical staff, antenatal clinic staff, community midwives, antenatal wards, ultrasound department) and get the trial information out to them
- Provide Inclusion/Exclusion criteria and timeframes to all prenatal care providers
- Use promotional materials e.g., place posters in all out-patient rooms and in the ultrasound department
- Introduce yourself as the EECV2 trial coordinator or investigator to all the care providers and make yourself known
- Speak about trial at any available opportunity.
- Determine where women with confirmed breech presentations are referred and at what gestational age
- Send out flyers to all practitioners
- Present the trial to community midwives
- Speak to the Ultrasonographers



Tips from our South American Collaborators' Meeting, April 2006

- Include primary care centres in your referral network - if primary care midwives are informed about the study, they can be an excellent source of referrals
- Make referrals easy - i.e. keep specific clinical hours where primary care midwives or physicians can phone in to make an appointment with the EECV2 clinicians
- To keep the trial on the fore of everyone's mind - remind doctors, nurses and midwives about the study at shift changes; share the results of referrals with your team
- Update your team with progress of the trial
- Provide opportunities for feedback at monthly meetings & training sessions
- When approaching women about the study, apart from the patient information sheet, talk to women on a personal level and include partners or close relatives in the discussion
- Consider creating an out-patient clinic or a special area within an existing clinic for the EECV2 Trial so that women recruited into the study can continue their ECV related care in a special office created for the trial



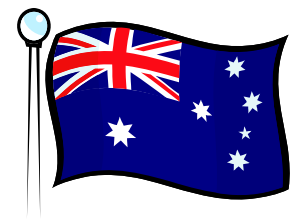
- Organize fun and interesting ways to remind colleagues about the EECV2 protocol; for example one collaborator described quizzing the medical and obstetrical residents about the EECV2 protocol, and giving out date wheels, tape measure or pens, for correctly answering questions



- Post EECV2 posters everywhere possible: for example, to interest patients, posters can be placed in outpatient clinics, obstetrics wards, waiting rooms and the admissions area; for fellow practitioners, posters can be placed in the delivery rooms, meeting rooms and the ultrasound area
- Approach all women with a single breech presentation after 30 weeks gestation to do an initial screening for the trial, and provide them with a brochure. Then follow-up with them again at 34 weeks

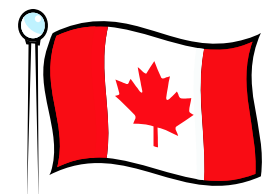
Tips from our Australian Visits and Local Meetings, March-April, 2007

- Change the routine 36 week obstetrical visit to 34 weeks
- Have a dedicated mobile phone line for the trial coordinator
- Develop a personal relationship with your colleagues in the ultrasound department so you have the opportunity to squeeze in women recruited to the trial
- Use posters around the hospital as a reminder for your colleagues that the study is ongoing
- Provide small recognition and incentives to your colleagues for referring patients. One centre uses a “lolly jar” where small chocolates or treats are kept and are given to individuals who refer patients as a token of appreciation
- Make recruiting fun - foster a competitive atmosphere with the chocolates or treats by tracking how many each person has received
- Try regional mail outs to family physicians and midwives
- Perhaps use the local paper as a way to promote the trial directly to women
- If there are too many general practitioners in your area to talk to individually, identify the ones with the most patients or who are most likely to refer their patients and speak to them about the trial
- Another idea, if there are many general practitioners to reach, is to present the trial at their meeting and regularly update them on the progress of the trial and their contribution to recruitment
- Include a line for the referral to the trial in the ultrasound report to let care providers know that the woman could be eligible for the trial
- Develop a breech clinic where all women with breech pregnancies are counseled regarding their options, including the trial, and what to expect in general



Tips from our Canadian Teleconferences, April 2007

- Try signs on the inside of washroom doors to remind colleagues of the study
- Put up recruitment numbers for the study overall and for your centre in a place where everyone involved with the trial can see them. In addition, you can have a monthly unveiling of the numbers where you serve coffee



and treats to increase interest and team-building in the trial

- Approach all family doctors in the area – in some centres they have asked the head of family medicine to approve a letter that will be sent to all general practitioners inviting them to refer their patients for possible participation in the study
- Once a woman has been referred to the coordinator, try explaining a little bit of the history of ECV and the recent research that has been conducted around safety as some women may not have heard of the procedure before
- Present the trial at rounds and departmental meetings so that everyone can be informed and you make yourself visible and available. Then make yourself visible around the unit and ultrasound department to serve as a reminder to your colleagues about the trial
- Emphasize that there is nothing to lose in terms of the safety of the procedure, but doing the procedure earlier may improve the success rate
- Do a mail out to all family doctors in the area including a one-page summary of the trial. It may also be helpful to send some promotional items such as gestational wheels and tape measures
- Include updates around the trial and recruitment in the departmental newsletter
- Enhance community outreach to midwives and family doctors by presenting the trial at their meetings or doing mail-outs



- Bring a cup of tea or coffee or a little treat to the Obstetrician performing the ECV
- Use the EECV2 website (www.utoronto.ca/miru/eev2) as a tool during the recruitment conversation with patients. You can also give them a study brochure with the website address so they can have a look at home as well
- Have a “lunch and learn” with everyone who could be involved with the trial at your centre including fellows, residents, the ultrasound department, the booking clerk etc. to go over eligibility, inclusion/exclusion criteria and any potential barriers to recruitment with solutions. By bringing everyone together for discussion it will serve as a team-building experience and create buy-in for the trial

Tried and True Tips for Building Enthusiasm from the Coordinating Centre

- Include food at information sessions for the trial (donuts, muffins, pizza lunches, etc)
- Consider hosting recognition sessions for Study Staff
- Consider using ECV promotional items as incentives for Study Staff
- Provide regular updates on a bulletin board (perhaps in Labour & Delivery), showing study progress
- Healthy competition between centres can be a strong motivator
- The constant presence and availability of the EECV2 coordinator and investigator will be important - work to build and maintain a spirit of teamwork
- Enthusiasm is contagious – spread the excitement of the EECV2 trial

