

Noticias *NEWS* Nouvelles

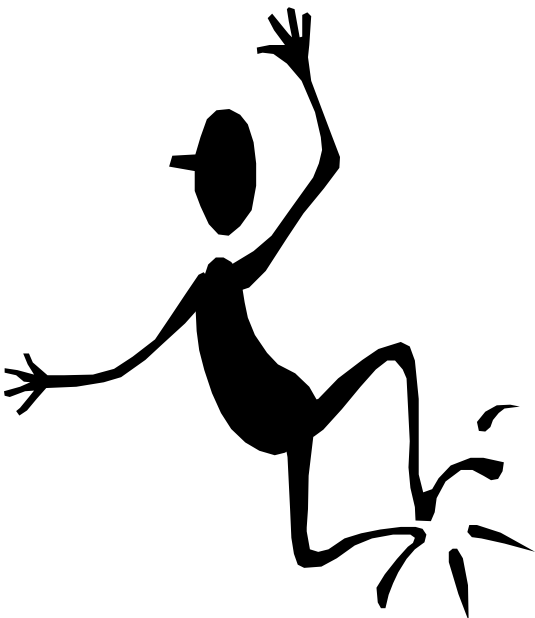
**Volume 5 Issue 3
1999**

March 31,

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at The Centre for Research in Women's Health

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**Total recruited in March: 68
Overall Total: 1275**



**A BIG THANK YOU TO
EVERYONE FOR HELPING
US PREPARE FOR THE
INTERIM ANALYSIS – WE
ARE ALMOST THERE.....**

OUR SINCERE APOLOGIES FOR
HASSLING SOME OF YOU. WE, LIKE
YOU, WANT THE TERM BREECH
TRIAL DATA TO BE AS COMPLETE
AND ACCURATE AS POSSIBLE



Although we all must remain blinded to the results of the interim analysis (except the Data Monitoring Committee), we think it is reasonable to look at, as a group, the overall baseline data for those included in the interim analysis. We hope to include this information in a newsletter soon.

Mugs this month:

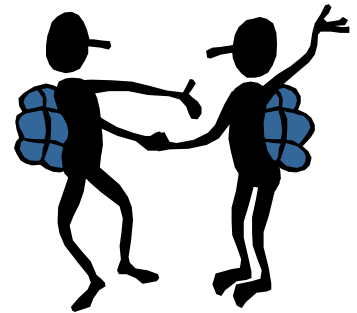
(for centres reaching or passing their annual goal)



Jinnah PMC, Karachi, PAKISTAN (#8); Makassed Islamic, Jerusalem, ISRAEL (#3); Caroline Chisholm, Liverpool, AUSTRALIA (#3); Princess Badeea, Irbid, JORDAN (#2); Civil, Karachi, PAKISTAN (#2); Materno Infantil, Goiânia, BRAZIL (#2); Pilgrim, Boston, UK; University of New Mexico, Albuquerque, USA; Boston City, Boston, USA; Islamic, Amman, JORDAN; IOMC-Polizu, Bucharest, ROMANIA.

CORD BLOOD

We would like to apologize to you for not making it clearer in our study protocol that cord gases for base deficit should be obtained on all study babies (if you provide pH and HCO₃ we can calculate the base deficit here). We also need to apologize for not bringing this to your attention earlier. We understand that for many of you this is not your usual practice. However, because a high base deficit is a neonatal outcome of the Term Breech Trial, it is important that cord blood be taken for as many babies as possible in the study. You may find it helps to prepare heparinized syringes in advance so that they are ready in the labour and delivery rooms when a Term Breech Trial mum delivers.



GENITAL HAEMATOMA

Genital haematoma in the *Neonatal Form* should only be ticked ‘yes’ if the haematoma is ‘significant’, that is, it is of some concern to the physician.

CLARIFICATIONS AND DATA QUERIES

At the Data Centre, we have had some learning to do regarding what needs to be queried and what doesn't need to be queried in the Term Breech Trial. Also, as is often the case in research, some of the questions in our data collection forms are not quite as perfect as we would like them to be. Please forgive us if some of our queries have seemed irrelevant or simply a bit stupid. Up until now, we have erred on the side of being overly cautious. The preparations for the interim analysis have allowed us to review our data checking procedures and, in future, the queries will be more efficient and hopefully also more relevant. The process that we have in place for data checking is a multi-step procedure. Initially we send back to you for clarification, any inconsistencies or unusual responses that are identified with the logic and range check programs. However, after data are clarified and at times corrected and re-entered into the database, the revised data are then assessed again to ensure there are no other inconsistencies or additional unusual responses. We only declare a case ‘finalised’ when this final check reveals all the data to be OK. This means, unfortunately, that occasionally, you may receive different queries for the same case, at different times (hopefully not too often). **We DO appreciate your patience and good will!!!**



Recruitment

Recruiting centres
as of March 31, 1999

Annual Goal	Jan- Dec	Jan- Jun	Jul- Dec	Jan	Feb	Mar		Total
	97	98	98	99	99	99		

(shaded area is prior to recruitment)

CANADA	163	63	51	26	9	8	2		159
PAKISTAN	29	13	54	54	10	10	12		153
UK	140	43	32	29	6	7	3		120
ARGENTINA	43	13	26	46	7	3	6		101
INDIA	45	14	18	37	7	3	3		82
BRAZIL	34	1	19	42	11	4	1		78
ISRAEL	96	15	21	25	5	4	8		78
AUSTRALIA	51	14	36	21		1	3		75
JORDAN	42	1	10	34	8	7	8		68
SOUTH AFRICA	41	12	28	23	2				65
CHILE	46	7	3	37	5	3	6		61
USA	114	16	11	22	2	2	3		56
ZIMBABWE	39		1	23	4	5			33
FINLAND	13	15	4	3		1			23
POLAND	22	1	6	6		5	1		19
YUGOSLAVIA	15	5	10	1			1		17
EGYPT	12		4	8	2	2	1		17
ROMANIA	9			2	1	4	8		15
SWITZERLAND	9	3	6	5					14
PORTUGAL	7			11		1			12
THE NETHERLANDS	5			8		2	2		12
MEXICO	12		3	5					8
GERMANY	7	1		5	1				7
NEW ZEALAND	5			1					1
DENMARK No longer recruiting									1
Total	999	237	343	474	80	72	68		1275

CANADA									
Riverside, Ottawa	6	19	10	6	1				36
Guelph General	4	8	1	3	2		1		15
St Joseph's, London	11	7	3		1	1	1		13
Sunnybrook & Women's Coll, Toronto	8	6	2	1		1			10
St Boniface, Winnipeg	10	4	3		2	1			10
Misericordia, Edmonton	9		6	2					8
St Joseph's, Hamilton	8		2	3	2	1			8
Grey Nuns', Edmonton	9		6		1				7
Foothills, Calgary	12		2	4					6
BC Women's, Vancouver	19	1	4						5
Kingston General	6		2	3					5
Scarborough Centenary	7	3	1						4
Regina General	9	1	3						4
Royal Victoria, Barrie	4	1	2						3
York County, Newmarket	5			2		1			3
Ottawa General	7	1		1					2
CUSE (Site Fleurimont), Sherbrooke	8					2			2
Montfort, Ottawa	6		1						1
Royal Alexandra, Edmonton	11			1					1
Brantford General	4					1			1
Centre(s) no longer recruiting									15

PAKISTAN									
Jinnah PMC, Karachi	14	6	46	42	5	7	7		113
Civil, Karachi	11			12	5	3	5		25
Liaquat National, Karachi	4		6						6
Centre(s) no longer recruiting									9

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as of March 31, 1999**

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	97	98	98	99	99	99		

(shaded area is prior to recruitment)

UK								
Treliske, Truro	11	5	4	12	2	4		27
Bradford Royal Infirmary	11	7	5	2				14
Arrowe Park, Wirral	11	6	6	2				14
Liverpool Women's	14	7	3	2	2			14
Leeds General Infirmary	11	7	3	2		1	1	14
Ormskirk General	3		2	4	1			7
Peterborough Maternity Unit	9	3	2	1			1	7
Friarage, Northallerton	4	3	2					5
Pilgrim, Boston	5		1	1	1	1	1	5
St John's, Chelmsford	10		3					3
Royal United, Bath	9			2				2
North Staffordshire, Stoke on Trent	15			1		1		2
Lewisham	7	1						1
St James's University, Leeds	12	1						1
Northern General, Sheffield	8		1					1
Centre(s) no longer recruiting								3

ARGENTINA								
LC Lagomaggiore, Mendoza	19		18	40	4	2	1	65
Maternidad "Martin", Rosario	11	7	7	2	1		1	18
Ramos Mejia, Buenos Aires	3		1	4		1	2	8
Prof A Posadas, Buenos Aires	10				2		2	4
Centre(s) no longer recruiting								6

INDIA								
Nowrosjee Wadia, Mumbai	13	12	8	12	1	1	1	35
Christian Medical College, Vellore	14	2	10	14	3	2	2	33
LTMCM & LTMGH, Mumbai	18			11	3			14

BRAZIL								
Jundiaí, São Paulo	6		8	15	6	3	1	33
ISCOMPA, Porto Alegre	13		1	17	3			21
Hosp das Clinicas da UFPE, Recife	10		7	4	1			12
Materno Infantil, Goiânia	5	1	3	6	1	1		12

ISRAEL								
Ma'ayney Hayeshua, Bene Beraq	10	8	7	3			1	19
Edith Wolfson, Holon	9		1	7	4	3	1	16
Makassed Islamic, Jerusalem	5		9	4		1	3	17
Meir, Kfar Saba	14	5		1			1	7
Poriya, Tiberias	5	2	2	2				6
Bnai-Zion, Haifa	10			5			1	6
Soroka, Beer Sheba	25		2	1	1			4
Chaim Sheba, Tel Hashomer	18			2			1	3

AUSTRALIA								
Caroline Chisholm Centre, Liverpool	7		10	10			1	21
Mornington Peninsula, Frankston	5	9	3	4				16
Logan, Meadowbrook	8		10				1	11
King George V, Sydney	12	2	1	5		1	1	10
St George, Sydney	7	2	4	2				8
Gosford	7		3					3
Mona Vale	2		3					3
Women's & Children's, Adelaide	3	1	1					2
Centre(s) no longer recruiting								1

JORDAN								
Princess Badeea, Irbid	24	1	7	26	7	4	3	48
Islamic, Amman	18		3	8	1	3	5	20

SOUTH AFRICA								
Medunsa	25		23	21				44
Coronation, Johannesburg	16	12	5	2	2			21

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as of March 31, 1999**

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(shaded area is prior to recruitment)

CHILE								
Sótero del Río, Puente Alto	37			34	4	3	5	46
Universidad Catolica, Santiago	9	7	3	3	1		1	15
USA								
Univ Utah, Salt Lake City	6	5	2	3				10
Univ New Mexico, Albuquerque	10	6	1	2			1	10
St John's Mercy, St Louis	16	4	3					7
Boston Medical Center	5		1	2	1		1	5
Baylor College of Medicine, Houston	12		1	2		1		4
Univ Iowa, Iowa City	4		3					3
Univ Michigan, Ann Arbor	8			3				3
Maricopa, Phoenix	8			3			1	4
Oregon Health Sci Univ, Portland	6			2				2
Hutzel, Detroit	16			2				2
Univ Mississippi, Jackson	9			1	1			2
Univ Maryland, Baltimore	4	1				1		2
Texas Tech Univ, Lubbock	6			1				1
Harbor, Baltimore	4			1				1
ZIMBABWE								
Harare Maternity	39		1	23	4	5		33
FINLAND								
Central University, Helsinki	13	15	4	3		1		23
POLAND								
NRI of Mother & Child, Warsaw	6		4	2		1	1	8
University of Gdansk	5	1	2	1		1		5
Polish Mothers Memorial, Lodz	11			3		3		6
YUGOSLAVIA								
Novi Sad	15	5	10	1			1	17
EGYPT								
Assiut University	12		4	8	2	2	1	17
ROMANIA								
IOMC-Polizu, Bucharest	9			2	1	4	8	15
SWITZERLAND								
Hôpitaux Universitaires, Geneva	7	3	4	4				11
Regionalspital, Biel	2		2	1				3
PORTUGAL								
Distrital, Faro	7			11		1		12
THE NETHERLANDS								
Atrium, Heerlen	5			8		2	2	12
MEXICO								
Dr M G Gonzalez, Mexico DF	12		3	5				8
GERMANY								
Ludwig Maximilians, Munich	4			5	1			6
University, Bonn	3	1						1
NEW ZEALAND								
Queen Mary Maternity, Dunedin	5			1				1
DENMARK								
No Longer Recruiting								1

March 31, 1999, centres awaiting first patient: Centre, city, COUNTRY, (annual goal) [month/year start-up package sent]

Slaska Akademia Medyczna, Bytom, POLAND (4) [3/99]; Hadassah Ein Karem, Jerusalem, ISRAEL (10) [2/99]; Sunderland Royal, Sunderland, UK (10) [1/99]; Diana Princess of Wales, Grimsby, UK (6) [1/99]; Jefferson Medical College, Philadelphia, USA (6) [9/98]; Countess of Chester, Chester, UK (10) [7/98]; Hosp Parroquial de San Bernardo, Santiago, CHILE (9) [6/98]; Royal University, Saskatoon, CANADA (11) [4/98]; Instituto Materno Infantil de Pernambuco (IMIP), Recife, BRAZIL (15) [3/98].