- Bolan Medical Complex Hospital, Pakistan, PI Tasneem Ashraf
- Bugando Medical Centre,
- Tanzania, PI Anthony Massinde Dschang District Hospital, Cameroon, PI Kenfack Bruno
- Federal Government Services Hospital Unit III, Pakistan, PI Naila Israr
- Federal Medical Centre Birnin-Kebbi. Nigeria, PI Yusuf Tanko Sununu
- Federal Medical Centre Makurdi. Nigeria, PI Andrea Jogo
- Jos University Teaching Hospital. Nigeria, PI Josiah Mutihir
- Kassala New Hospital (Al Saudi), Sudan, PI Abdalla Ali Mohammed
- Lady Reading Hospital,
- Pakistan, PI Sadagat Jabeen Lagos Island Maternity Hospital,
- Nigeria, PI Aigbe Ohihoin Muhimbili National Hospital, Tanzania. PI Hussein Kidanto
- Nyanya General Hospital, Nigeria, PI Ola Okike
- Obafemi Awolowo UTH.
- Nigeria, PI Babalola Adeyemi Regional Hospital Fier,
- Albania, PI Besnik Brahimaj ❖ Regional Hospital Limbe,
- Cameroon, PI Robert Tchounzou Seventh Day Adventist Hospital,
- Nigeria, PI Peter Opreh
- Shalamar Hospital,
- Pakistan, PI Lubna Riaz Dar
- St Francis Hospital Buluba. Uganda, PI Elizabeth Nionzima
- ❖ St Theresa's Catholic Hospital, Cameroon, PI Mutsu Venantius
- Sunderland Royal Hospital,
- UK. PI Kim Hinshaw
- University of Maiduguri Teaching Hospital, Nigeria, PI Audu Idrisa Yaounde Gynaeco-Obstetric Hospital,
- Cameroon. PI Pascal Foumane

Pakistan, PI Hbiba Sharaf Ali

Ziauddin University Kemari Campus,



Kassala New Hospital (Al Saudi), Sudan, PI Abdalla Ali Mohammed This team passed the 50 cases station and is heading towards the nundredth! PPH is a nightmare for every doctor in a low resource country; we have to do so much with so little. We are delighted to nave had no PPH cases since our ast randomisation on October 14th, after 534 deliveries. This is an unusual event that might nave gone unnoticed before we

The trial team here have decided to make use of an android application for communication during randomisation to minimise errors. Najla Dakeen (top right) was first to use WhatsApp to communicate with the PI by sending entry and outcome forms while he was abroad. Iman (front left) randomised the 9000th case to the trial.





Jos University Teaching Hospital, Nigeria, PI Josiah Mutihir





Nyanya General Hospital, Nigeria, Pl Ola Okike







ederal Medical Centre Birnin-Kebbi, Nigeria, PI Yusuf Tanko Sununu

Regional Hospital Limbe Cameroon, PI Robert Tchounzou The WOMAN trial is still going smoothly in Limbe, thanks to the team, above from left to right: Fofe Kenne (assistant nurse), Ann Itoe (midwife), Tchounzou Robert (PI), Eboude (state registered nurse), Simo Wambo

(obstetrician and gynaecologist), Mbome Kristy (assistant nurse). Not

appearing in this picture is Keka Dorothy whom we want to commend

particularly for her huge commitment and contribution to this trial.



Regional Hospital Fier, Albania, PI Besnik Brahimaj

Trial Coordinating Centre, Clinical Trials Unit, LSHTM, Room 180, Keppel Street, London WC1E 7HT, UK Tel: +44(0)20 7299 4684, Fax: +44(0)20 7299 4663, Email: thewomantrial@Lshtm.ac.uk www.womantrial.Lshtm.ac.uk

NEWSLETTER



APPROACHING 10,000 PATIENTS

Dear Collaborators,

As the end of 2013 approaches, it is a time for reflection on our achievements and planning our future. We have been working together for some time with a clear purpose. Our purpose is to find better ways to improve the health and well being of mothers who suffer from postpartum haemorrhage. This is something you all do on a daily basis. However, we need to acquire new knowledge to improve the care, and the best way to do it is through properly conducted research such as the WOMAN trial. You have all been involved in making this trial a success and, therefore, each and every one of you is a role model to all health care professionals worldwide - be proud of your work!

The WOMAN trial collaborators globally are visionary, principled, enthusiastic and expert researchers. This team is made of thousands of doctors, nurses, midwives, pharmacists and administrators, all working without remuneration, who understand the power of building knowledge by working together. By the time you receive this newsletter we will have recruited 10,000 women to the trial. This is a landmark achievement for which we should all congratulate ourselves!

Year 2013 has seen recruitment jump from 5,500 to 10,000. WE NOW HAVE A BIGGER TARGET. The Trial Steering Committee has agreed that the sample size of the trial should be increased from 15,000 to 20,000. As you know, the primary outcome is a composite end point of mortality and hysterectomy. Having monitored the hysterectomy data, we believe that the trial needs to have adequate power to look at the effect of tranexamic acid on mortality alone. This increased sample size will give us the power to do so. We will write to each Principal Investigator in the new year to provide more information.



Year 2013 was also very special as we were able to meet with collaborators in several countries, including Sudan, Ethiopia, Nigeria and Pakistan. This has allowed us to build personal links with a wonderful diversity of amazingly generous people. We look forward to building stronger relationships in the coming year.

On behalf of the Trial Coordinating Centre, we thank you for being part of this global effort. Haleema and Jan



Mother & Child Hospital Akure, Nigeria

Nigeria was the first country

to join the trial.

The 39 participating sites have

now collectively recruited over

4,000 patients - THANK YOU!

PI Adesina Akintan with the trial team







Yosamu Nsubuga & Christine

Christine Biryabarema (also the Uganda National Coordinator) says: All members of the department who are not in the study

are very enthusiastic to help identify study participants. We now know the burden of PPH and the outcomes in our hospital. The women have been willing to participate in the study; only two have declined since we started recruiting. The study team here has shown a lot of enthusiasm.





Temeke Municipal Hospital, Tanzania, from left PI Muzdalifat Salim Abeid, Magreth Zacharia, Khadijah,

Collaborating in the WOMAN trial is a great pleasure. Like everyone else, we wish to see PPH removed from the list of maternal death causes. I would like to mention Sister Magreth Zacharia for her continuous effort in maintaining good records and her commitment in following up patients.



Wad Medani Teaching Hospital of Obstetrics and Gynaecology, Sudan, PI Somia Khalfalla Abdelrahiem Ahmed

Thanks to the WOMAN trial team for giving us the opportunity to share in this very important research that has a great role in reducing maternal mortality and morbidity. This research will have a great impact in women's health. Last year 29 mothers died with PPH, which is the biggest cause of death in our hospital. We are hoping to reduce this number by sharing in this research. The WOMAN trial team are amazing in their organisation and dedication. We are hoping to learn a lot from them and we wish to satisfy them with our participation.





Livinastone General Hospital, Zambia, Pl Isaiah Hansinao

Kena Kabuta: I am happy to be part of the WOMAN trial at Livingstone General Hospital. Research for a new drug or a new treatment is an exciting and hard task at all times. At the moment our number of randomised patients per month is reduced. We are trying to review our way of estimation of the blood loss in every case of PPH, especially for the referred

Martha Chiqova: Sub-Saharan Africa, like many developing countries, has marked numbers of women who die from PPH or its complications. This leaves families, especially children, vulnerable to abuse, HIV or malnutrition and leads to child headed families. By participating in the WOMAN trial and finding new and improved methods of preventing and managing PPH, we not only improve the wellbeing of the women, but also improve the welfare of children, families and subsequently of communities. I believe, therefore, that the effect of the WOMAN trial will not only be felt locally but will have a global impact. Henceforth, it is a venture worth investing time and resources into.

Loveness Chikumbi: I am collaborating in the WOMAN trial because if the results turn out to be positive, it will give me satisfaction to see a patient with PPH recover and be discharged after all the interventions. I am happy to be part of the team.





Garissa Provincial Hospital, Kenya, PI Vincent Oyiengo



University of Calabar Teaching Hospital, Nigeria, PI Saturday Job Etuk

About 25% of maternal death in our environment is as a result of obstetric haemorrhage with PPH taking the lead. Many attempts have been made to find a solution to this carnage but some of them cannot be useful in rural areas where most of these women die. The WOMAN trial is making the effort to search for a solution that can be useful everywhere. Therefore, we all should support this dream.

In our centre, the trial has succeeded in stimulating the interest of all staff involved in obstetric practice regarding the impact of PPH on the lives of our women. Every staff member now believes that there should be a solution. I strongly believe that every obstetric unit should get involved, so that in the end we will all share in the joy of saving the lives of our mothers, wives and sisters.

Of special mention in our centre is **Ubong Akpan** who has made an immeasurable contribution to this project. The trial has now become part of his life. He randomises any time any day and would feel very bad if he missed a case. We strongly appreciate his effort.



Chittagong Medical College Hospital, Bangladesh





PI Rokeya Begum & Farzan



Ayinur & Zeenat



Kenyatta National Hospital, Kenya, with PI Zahida Qureshi, who is also the Kenva National Coordinator

This photo is showing the KNH labour ward staff during a sensitization meeting to prepare for the next phase of refresher training and recruitment.



bn Sina Medical College Hospital, Bangladesh, PI Nazlima Nargis



AIC Kijabe Hospital, Kenyam PI Alfred Osoti

Of special mention is our group of medical officer interns. They are the ones on the floor and in first contact with every mother who develops PPH. Without their support and prowess we would not have been able to recruit the patients that we have.

Gadarif Obstetric & Gynaecology Hospital,

Sudan, PI Huaida Mardi Mohammed Ahmed

The Gadarif WOMAN trial team is so proud to be

part of the study and to contribute to reducing

Looking forward to a successful trial!

maternal mortality.

Every patient counts



Dhaka Medical College Hospital, Banaladesh. PI Ferdousi Islam

Women are now being recruited into the trial in 18 countries across the world!



Olujide Okunade and Olusade Adetayo from the Nigeria National **Coordinating Centre**



Church of Uganda Kisiizi Hospital, Sandra Namuganga, Rita Atim Kitsamba, Betty Nassolo and PI Francis Banya Ogwang We are privileged to be part of the worldwide WOMAN trial team. We are indebted to the coordinating team in London for their encouraging messages which have kept us going.



El Obeid Teaching Hospital, Sudan, Pl Khidir Awadalla Since we joined the WOMAN trial we have felt that we are part of a very great team, friends we have not met, but they are the most respectable and disciplined people we ever knew!



Regional Hospital Elbasan, Albania, PI Armida Tola

We are all thrilled to be part of this trial. PPH is one of the most critical issues in obstetrics and we are very proud to contribute to this trial and eager to continue the collaboration.

Rity Mather & Buby Hospital ENTRANCE

Moi Teaching & Referral Hospital, Kenya, PI Hillary Mabeya (second from left)

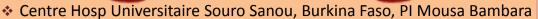


The WOMAN trial has seen some important achievements in the last year in Albania. Patient recruitment rate has increased and the Albanian sites have now randomised more than 250 patients. New sites have joined this year and others are in progress for approval from the National Ethics Committee.

Obstetric Gynaecology University Hospital K Gliozheni

Another big development is the WOMAN ETAPlaT study (Effect of Tranexamic Acid on PLAtelet function and Thrombin generation in a sample of participants in the WOMAN trial), which has been approved by LSHTM and the National Ethics Committee and has recently started recruitment at University Hospital of Obstetric Gynaecology Koço Gliozheni. The aim is to provide evidence about the haemostatic effect and antithrombotic effect of TXA in women with clinical diagnosis of PPH, through evaluating the platelet function and thrombin generation. These findings could have major implications in obstetrics and for surgical patients.

I invite all colleagues to participate in the WOMAN trial as soon as possible and to recruit all eligible patients and thus contribute to a better treatment of PPH and its serious complications.



- City Hospital Nottingham, UK, PI Jim Thornton
- Coast Provincial General Hospital, Kenya, Pl Musimbi Soita
- * Federal Medical Centre Abeokuta, Nigeria, Pl Moses Alao
- * Federal Medical Centre Katsina, Nigeria, PI Ibrahim Habib
- * Federal Medical Centre Lokoja, Nigeria, PI Onile Temitope
- ❖ Holy Family Hospital, Obs & Gyn Unit 1, Pakistan, PI Rizwana Chaudhri
- * Holy Family Hospital, Gyn & Obs Unit 2, Pakistan, PI Fehmida Shaheen
- Irrua Specialist Teaching Hospital, Nigeria, PI Felix Okogbo
- * Khartoum North Teaching Hospital, Sudan, PI Wisal Nabag
- Lagos State University Teaching Hospital, Nigeria, PI Oluwarotimi Akinola
- Liverpool Women's Hospital, UK, PI Zarko Alfirevic
- Maitama District Hospital, Nigeria, PI Frank Alu
- Moi Teaching and Referral Hospital, Kenya, PI Hillary Mabeya
- ❖ Nepal Medical College Teaching Hospital, Nepal, PI Pramila Pradhan
- Omdurman Maternity Hospital, Sudan, PI Taha Umbeli
- * Royal Victoria Infirmary Newcastle, UK, PI Paul Ayuk
- University of Abuja Teaching Hospital, Nigeria, PI Olatunde Onafowokan



Nepal Medical College Teaching Hospital, PI Pramila Pradhan (right) and matron

Every patient counts



PI and the Pakistan National Coordinator Rizwana Chaudhri







Federal Medical Centre Lokoja, Nigeria, PI Onile Temitope



Rophina Msengeti has been the key investigator of the trial at our site. It is due to her hard work and dedication to the trial that we have been able to randomise nearly 200 women over a year. For the trial to succeed at any site it is important to have midwives who are dedicated and focused on the research benefits to health, and not individual benefits from the trial.

The WOMAN trial team from Coast Province General Hospital, Kenya, Pl Musimbi Soita

Omdurman Maternity Hospital, Sudan, PI Taha Umbeli

Omdurman is a specialist maternity hospital with 35–37,000 deliveries per year. A high number of complicated cases are delivered in this hospital with a high rate of PPH. In Sudan, the maternal mortality rate last year was 189 per 100,000 live births; 30.9% due to obstetric haemorrhage and out of those 76% PPH.



We acknowledge the WOMAN trial to have positive impact on maternal mortality and morbidity from PPH, not only on treatment, but we are also looking for a method for prevention. We expect to be part of another trial for efficacy of TXA for the treatment and prevention of PPH.

Since we were included in this trial we have randomised more than 120 women; however we face a number of challenges. High turnover of co-investigators and secretariat necessitates the training of newcomers and the need to change the database password. In spite of the challenges, we are doing well with WOMAN trial.



Maitama District Hospital, Nigeria, PI Frank Alu



Training session at Federal Medical Centre Abeokuta, Nigeria,



Irrua Specialist Teaching Hospital, Nigeria, PI Felix Okogbo



Training session at University of Abuja Teaching Hospital, Nigeria, PI Olatunde Onafowokan



Khartoum North Teaching Hospital, Sudan, PI Wisal Nabag
Our team have randomised over a hundred patients and here I want to thank the following people for their great efforts: Sister Mai Omer Yousif, Nurse Amna, Midwife Amal. All disciplines in KNTH know about the worldwide WOMAN trial.



Abdulfetah Abdosh, the Ethiopia National Coordinator on the left, Ian Roberts in the middle and Wisal Nabag on the right.

We shared the KNTH experience in the WOMAN trial session at FIGO in Addis Ababa, October 2013.

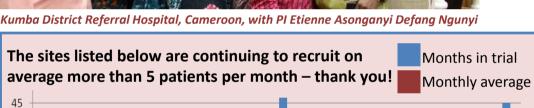


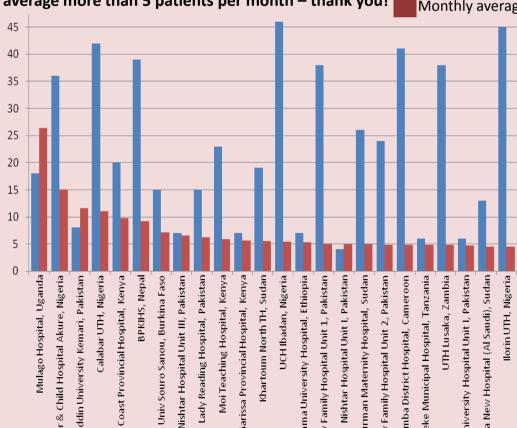
Team from University of Ilorin Teaching Hospital, Nigeria, with PI Abiodun Peter Aboyeji

BP Koirala Institute of Health Sciences, Nepal, with PI Mohan Regmi in the middle



Zambia National Coordinator and PI Bellington Vwalika, Willies Silwimba and Mwanahamuntu, from University Teaching Hospital, Lusaka







Collaborators were rewarded for their efforts. One such reward received here by Audu Idrisa, **University of Maiduguri** Teaching Hospital.



Haleema in her recent visit to Nigeria, with Tosin Lawal from the Nigeria Coordinating Centre



Nike Bello from the WOMAN team at UCH Ibadan, Nigeria

Nigeria Collaborators Meeting November 2013 Our wonderful Nigerian teams have collectively recruited over 4,000 patients. A celebratory meeting was held in Lagos on 26 November. Photos will also soon be posted on the website under the Nigeria page.











COLLABORATORS MEETINGS IN PAKISTAN AUGUST 2013 Meetings were held in Islamabad, Karachi and Lahore. The photos here also include site visits and source data verification meetings.

10% 9 . 9 . 9 . 9 . 16



