In this unique issue of our newsletter, we have highlighted the significant contribution of Africa to the WOMAN trial. Africa bears the biggest burden of maternal mortality and helping to find solutions is a moral obligation.

African countries have contributed nearly 70% of the patients randomised to date. What an achievement! We have 13,500 patients in the trial and need to get to 20,000 and are well on track to achieving this by March 2016. We need to engage all hospitals across Africa where maternal mortality still happens, so please ensure all of your colleagues know about the trial and encourage them to take part.

Some of you have been working on the trial from the start and the next phase will be the hardest. We understand this and together we need to find ways to keep the teams engaged and motivated.

Many of you have shared with us the benefits of taking part. Below are some of the positive aspects you have identified and which I want to repeat.

You want:

- ☐ To find an intervention to address the leading cause of maternal mortality and, given the challenges facing its health systems, Sub-Saharan Africa will probably benefit the most from this simple intervention:
- ☐ To contribute to the reduction of a major public health problem;
- ☐ To find an extra weapon in the fight against fatality associated with this obstetric complication;
- ☐ The opportunity to be associated with the progress of modern medicine;
- ☐ To be part of largest ever intervention study for PPH;
- ☐ The opportunity for your staff to:
 - o learn the science and practice of clinical research;
 - o gain confidence and experience in conducting international pragmatic trials;
 - learn the administrative aspects of research, keeping essential documentation and providing adequate information to patients and relatives;
 - o make improvements in clinical care of patients e.g. highlighting the importance of intervening in the early hours postnatal to save lives;
 - o improve skills in the prevention, detection and early management of postpartum haemorrhage.

To say thank you for all the hard work seems insufficient - this is also your trial and it is only with superb collaboration from all that the trial is such a success!

In the next 18 months we need to include another 6,500 women into the trial. We are still looking for new collaborators. Please do spread the word among your colleagues in other hospitals and other countries.



WOMAN TRIAL IN AFRICA



THANK YOU TO OUR STAR PERFORMERS

Over 500 patients



Mother & Child Hospital in Akure Nigeria joined the trial in January 2011 and have since recruited about 700 patients, at the rate of around 15 patients per month. The team is led by Adesina Akintan.



The team at Mulago Hospital in Uganda started recruiting patients in August 2012 and now have almost 800 patients. Pl Christine Biryabarema is also the Uganda National Coordinator.

Over 200 patients



University of Calabar Teaching Hospital, Nigeria, joined the trial in July 2010 and is fast approaching the milestone of 500 patients. The PI is Saturday Job Etuk



Bellington Vwalika is the PI for

University Teaching Hospital Lusaka and the National Coordinator for Zambia. The team has been in the trial since November 2010.



The team at University College Hospital Ibadan, Nigeria, under the leadership of Oladapo Olayemi, were the first to recruit a patient into the WOMAN trial, in March 2010.



Khartoum North Teaching Hospital, Sudan, with the PI Wisal Nabag started patient randomisation in June 2012.



trial in August 2010, with Etienne Asonganyi as the Pl.



University of Ilorin Teaching Hospital, Nigeria, was one of the first wave of Nigerian hospitals to join the trial in April 2010. The PI is Abiodun Peter Aboveii.



SUDAN

For every woman who dies following PPH, there are thirty women who suffer a maternal morbidity and another ten who experience 'near miss mortality'. Any intervention that reduces blood loss following delivery will greatly reduce maternal mortality especially in low and middle income countries. The positive results of tranexamic acid use in traumatic bleeding (CRASH-2 trial), general surgery and gynaecological practice are encouraging and results of its use in PPH may augment our armaments for PPH management.

The WOMAN trial is pertinent to our situation and practice in Sudan. The first case in the Sudan was recruited in September 2011 and now nine hospitals are actively recruiting, with almost 600 women included in the trial. The presentation of the trial protocol in our last conference of the Obstetrical and Gynaecological Society of the Sudan (OGSS) resulted in great awareness and enthusiasm from our fellow Obstetricians to participate in the trial.

Professor Mohamed Ahmed ElSheikh FRCOG, National Co-ordinator, Sudan



Gadarif Obs & Gynae Hospital team, led by PI Huaida Ahmed



Kassala New Hospital (Al Saudi); part of the team: Abdelazeem, Abdalla Ali Mohammed (PI), Awadia, Ihsan, Fatima, Hamza.

Our concern to reduce maternal mortality in Sudan and the initiative of LSHTM to investigate a drug that could reduce PPH, inspired us to join this collaboration. The trial brought PPH to top agenda of our clinical meetings. We have enjoyed the team work with fantastic people from the TCC team and we strongly recommend colleagues to join this collaboration and not to miss this opportunity.

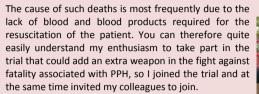


Soba University Hospital team; Top photo: Tagwa Hamad, Siddig Adam, Hala Yaseen, Issam; Bottom: Sahar Amin, PI Hala Abdullahi, Amira Alamir, Moemen Mohamed

It has been a marvellous experience to join such a well organised trial. The response and advice from the trial team are fantastic. We hope the results will be very informative and helpful to women worldwide.

CAMEROON

The hypothesis of the WOMAN trial is that the use of TXA within 24 hours of the development of PPH may reduce mortality, as well as the rate of hysterectomies and blood transfusions. When LSHTM invited my hospital to take part, I reviewed the number of maternal mortalities at Hôpital Regional de Limbe over the last five years. The review showed that out of 34 reported deaths, 11 (32.5%) were due to PPH. PPH complicates 2.9% of the deliveries at our hospitals, and worse still, 8% of the patients with this obstetric complication die.



Participation in this study of such high standard will permit better management of PPH cases and has allowed my team to initiate clinical trials and therefore gradually rectify shortcomings in the care of patients.



Regional Hospital Limbe, PI Robert Tchounzou & team



Kumba District Hospital, PI Etienne Asonganyi & team

With more than 13,000 patients randomised, Cameroon can still contribute heavily to its success. So dear colleague, dear friend, join us! You will work without pay, but just think of the dying woman that will beg you to save her life. If proven effective, you can give her one gram of tranexamic acid in the years to come.

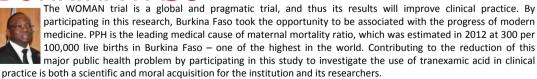
Robert Tchounzou, Cameroon National Coordinator



More team members from Kumba



BURKINA FASO



From 2012 to 2014, Burkina Faso has recruited a total of 143 participants for the WOMAN trial. A key constraint for the trial in Burkina Faso is the system of payment after service used by the trial sponsor. As a developing country, hospitals in Burkina Faso have limited ICT resources; the costs are very high and the service is not available to all. On the other hand, recruitment can be more successful through regular field supervision and evaluation of recruitment sites by a local PI to whom resources are allocated.

For all new collaborators, the primary motivation to join this trial must be purely for scientific reasons. The establishment and conduct of the trial at sites in Burkina Faso has allowed the local staff to enhance their science and practice of clinical research. It has also helped to gain experience in conducting pragmatic trials internationally.

TANZANIA





Temeke Municipal Hospital team, led by PI Muzdalifat Salim
We are honoured to be part of the WOMAN trial, which is indeed a trial
of great importance to our women. We hope to get the solution for
PPH from it.

ETHIOPIA

I was inspired to be involved in the WOMAN trial because it might be an appropriate intervention study to address the leading cause of maternal mortality. We have randomised almost 200 patients from two hospitals in Ethiopia. Another three hospitals are about to join. To be part of the largest trial in PPH ever conducted is a major accomplishment for Ethiopia.

My advice to new sites and countries is that for a successful result the Pl and National Coordinator WOMAN trial needs great commitment, devotion and close follow-up, with Abdulfetah Abdulkadir Abdosh the spirit of team work. Keep the whole staff of your hospital, departments and management informed about the importance and relevance of the trial.

The moment you start randomising patients, remember you are contributing your time, knowledge and skill for the benefit of improving the quality of women's health. I would like to thank all the members of teams in Ethiopia for our great achievement. This would not be possible without your commitment and devotion driven by your desire to reduce maternal mortality and morbidity.

Abdulfetah Abdulkadir Abdosh, National Coordinator, Ethiopia



St Paul's Hospital team.



Jimma UTH team with PI Hailemariam Segni



Omdurman Maternity Hospital, PI Taha Umbeli

In Sudan the maternal mortality rate is 172/100,000 LB last year 2013, 28.0% due to obstetric haemorrhage; PPH is 81.1%. We hope the WOMAN trial to have a positive impact on maternal mortality and morbidity from PPH, not only on treatment, but we are also hoping to look at prevention. Since we were included in the trial we have randomised 190 women.

EVERY

PATIENT

COUNTS

to PPH.



MORE SUDAN



Khartoum North Teaching Hospital team, led by Wisal Nabag

We were inspired to join the trial as it was planning to address the most common cause of maternal mortality, PPH, which is a great burden for caregivers and a painful realization for the family and the society. We have learnt while conducting the trial that working as a team is key to success. Not only in the trial, but in every activity we learn from each other.

Our most important accomplishment is that we have established a trained team of doctors, nurses, midwives and administrators who are working together to decrease maternal mortality and morbidity from PPH. I would advise new collaborators not to miss the trial which really needs the team working together and each member should know exactly his or her responsibility. The trial needs dedication and commitment in order to succeed.



Wad Medani Teaching Hospital team led by PI Somia Abdelrahiem

ZAMBIA





Kafue District Hospital team, from left: Malungo Catherine, Mwansa Ketty Lubeya (PI), Nyangu and Imakando; Fredrick, Lubeya, Shamilimo, Agness

The biggest motivation was to be part of the team accelerating attainment of the Millennium Development Goals to reduce maternal mortality by 2015. If we all get involved, we shall win!



Livingstone General Hospital team: Standing from left Kena Kabuta, Loveness Chikumbi, Florence Kashweka, Lishomwa Katolo, Bopili Noojiri. In front Sylvia Kaunda, Isaiah Hansingo (PI)

FVFRY PATIENT COUNTS

UTH Lusaka team: PI and National Coordinator Bellington Vwalika, Willies Silwimba and Mulimbi **Mwanahamunt**

As a hospital, we support any measures that would contribute towards reduction of PPH deaths. Therefore, we willingly decided to collaborate in the WOMAN trial in order to be part of the big worldwide family that would contribute towards provision of the evidence for the effectiveness (or otherwise) of TXA in the management of PPH. In the past year, we virtually have had no deaths due PPH at our hospital. This could be attributed to the staff being vigilant as they look out for patients to recruit for the trial, resulting in early recognition and treatment of PPH. However, this has negatively affected our recruitment rate. This is good for our patients, but 'bad' for the study in terms of achieving the required sample size.

Elmek Nimir University Hospital team; Sami Hummeda, Sami Tagelsir, Moawia Elsayed, Nafisa Tagelsir, Samia Elhaj, a midwife and medical officer who are very active members of the trial team. PI Saeed Abdelrahman Abdelgabar (bottom right).



The main goal for joining the trial is to provide good quality services for mothers and to help in reducing maternal mortality due to PPH. While conducting the trial we learn many things, such as reinforcing team work and discovering that anyone can have a role in the trial.

-10-

KENYA



Team training at Kenvatta National Hospital. with PI and **National Coordinator** Zahida Qureshi

FVFRY PATIENT COUNTS



Nakuru Provincial General Hospital team, PI Otara Amos The Rift Valley Provincial General Hospital is located in Nakuru town, the headquarters of Nakuru county. The hospital is a regional referral facility offering various specialist services. The maternity unit handles on average 700 deliveries per month, besides other obstetric referrals from the surrounding facilities. The hospital elected to participate in the WOMAN trial since PPH has been recognised as a major cause of maternal mortality and morbidity in the facility. It is hoped that participating in the WOMAN trial will be a major boost in the efforts to discover a solution to this problem. A team comprising specialist doctors, medical officers and nurse midwives has randomised over 50 patients to date. Most members have learnt about clinical trials through reading the study protocols. This has also given the labour ward team more information on PPH via directed CMEs. This is a worthy exercise and I would recommend it to any facility. Let us all ioin hands to make childbirth safe.



Mwingi District Hospital team, PI Bonface Musila

Coast Province General Hospital Kenya team, PI Musimbi Soita

Our participation in the trial has improved our skills in the prevention, detection and early management of PPH, one of the major causes of maternal mortality in our unit. It is due to the commitment and hard work, especially from Rophina, that our unit has been able to identify and randomise more than 200 women into the trial.





Garissa Provincial General Hospital team from right: Eveline Ngokonyo, Penina Waigi, Fatuma Issa, Aden Hambe. The PI Vincent Oviengo (back right) says: "The hospital administration is very happy to have the trial in Garissa!"

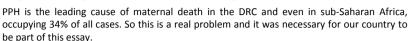


IAC Kijabe team, PI Evelyn Ndinda

DEMOCRATIC REPUBLIC OF CONGO

The DRC is a vast country of 2,345,000 km2 in area and has more than 70 million people, of which 60% are women. The country faces serious problems in the area of maternal and child health with a high rate of maternal death. Note that the postpartum haemorrhage presents in 25% of deliveries.

Also note that the Congolese people's culture makes women tend to have many children; we know women who are in their 15th pregnancy and maternity is very frequent. There are hospitals that carry out between 100-400 deliveries per month.





Hope Medical Centre team with PI and National **Coordinator for DRC Mateus Sahani**

The WOMAN trial began in the DRC in April 2014 after a year-long administrative process that had already demoralised some principal investigators. But after its start-up investigators resumed courage. The trial had no barrier in hospitals and saw the collaboration of the authorities and the participating families and their respective mothers. Eleven hospitals have already joined the trial and eight have begun recruiting patients. The remaining three are to start soon and two others have recently sent their documents to join the trial.

My advice to new collaborators is to stay in touch with other collaborators. Follow the trial protocol and master the investigator's brochure. Mateus Kambale Sahani. National Coordinator DRC Centre Médical HOPE



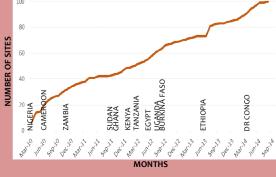


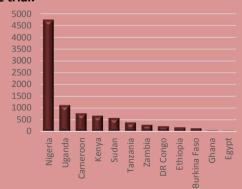


CSR Carmel team. PI Kato Faida woman

Virunga General Hospital team led by PI Phanny Kambere Simisi

When did the sites and countries in Africa join the trial?











University College Hospital Ibadan, Pl Oladapo Olavemi

MORE **NIGERIA**



Adeovo Maternity Hospital team led by PI Akintunde Kehinde Avinde



University of Ilorin Teaching Hospital, Pl Abiodun Peter Aboyei



Team from Lagos University Teaching Hospital with PI Omolulu Adegbola





UGANDA



Team from Mubende Regional Referral Hospital, from left: PI Patrick Komagum, Nayiga Annet, Kyazike Magaret, Nakirigya Nulu, Kalyesubula Esther, Kyazike **Ruth & Isabirve Rebecca**

I was inspired to join the WOMAN trial by the fact that the hospital was facing a challenge to reduce maternal mortality of which PPH contributed about 50% due to the hospital's referral status. I have learnt that documentation and consultation is very important in patient management and that the relatives should always be updated in whatever management we render. Our accomplishment is that the trial has built teamwork and enlightened the staff of alternative remedies of PPH management. Let's embrace the WOMAN trial as PPH affects everyone and the trial is designed so simply that it is easily carried out as long as you adhere to the protocol.



Church of Uganda Kisiizi Hospital team: Sandra Namuganga, PI Francis Banva and Ritah Atim



Mulago Hospital team: Ruth Bulime, Pl and National Coordinator Christine Birvabarema. Christine Namulwasira, Joselyn Ayikoru and Yosamu Nsubuga



Angal St Luke Hospital team: Acayo Irene, Iciru Anastasia and PI Grace Meregurwa



Entebbe General Hospital team, front from left: Ndagire Betty, Nalunkuuma Jackline, Mpanga Robert, Namazzi Rose and PI Aviko Ben, Back from left: Nassuuna Sylvia, Acen Janet and Nyanzi **Mathias Mugabi**

The plight of many women worldwide, especially in Africa, who die from preventable conditions like PPH inspired us to join this research. We have learnt that there is hope in stopping PPH with TXA. My advice to any new collaborators is not to hesitate to ioin this noble research.



The team from St Francis Hospital, Buluba, PI Elizabeth Nionzima

What inspired me to join the trial is that I felt the need to save mothers at this critical time of their life. I realise many mothers die, not because there is lack of what to use or not knowing what to do, but due to lack of commitment to do something. Being part of this international study is motivating in itself. I have learnt to be committed to my work but also to be more observant. The trial has taught me that simple procedures can actually save lives and also the importance of the first six hours of the postnatal period in saving mothers and their babies.

The trial's most important achievement is building team work for a common cause. All the midwives and doctors have taken keen interest in the study and can now identify a mother with PPH easily. We have also appreciated the need for taking vital information. I would say to new collaborators that the study is enjoyable, but you also learn a lot in the area of patient management. It exposes you to international researchers and other colleagues.

NIGERIA

The WOMAN trial addresses a major public health problem that is of mutual concern to all countries in sub-Saharan Africa. Any intervention that will effectively treat PPH will prevent almost a quarter of all maternal deaths in Africa. If TXA is proven to be effective, sub-Saharan Africa will perhaps be the greatest beneficiary from this simple In the photo the Provost of College of Medicine University of Ibadan, Those were the considerations that motivated me into members, with Haleema Shakur. joining the trial in Nigeria – and I believe I speak for most African collaborators. It is for those same volume, integrity and quality reasons that all hands must remain on deck to ensure that the trial is conducted to the best standards of data contributed so far, so that we have good quality data that will assure valid results. This is a responsibility we must bear in is a clear pointer to the depth mind. The trial is going well in Nigeria with about 50 sites spread across the length and breadth of the of efforts and commitment

been the enthusiasm with which colleagues continue to accept the trial. We are particularly delighted to share with you some other benefits of the WOMAN trial in Nigeria. of your resourcefulness. The WOMAN trial has contributed in no small measure to the evolution of progressive policies and I strongly believe we won't rest coordination within our ethics committee at the national level, as well as the clinical trial unit of our on our oars until this alldrug regulatory agency. We have witnessed a gradual transition to seamless coordination which important clinical question is translates to valuable support for the WOMAN trial and other trials in Nigeria. This must be one of the answered. lasting legacies of WOMAN in our country. We encourage other countries and sites to join the trial. Jide Okunade, Nigeria Beyond conducting the trial, collaborators have so much to learn from the guidance from the Coordinating Centre coordinating team at LSHTM. Welcome aboard! Bukola Fawole, Nigeria National Coordinator



intervention, given the challenges facing health systems. Prof O O Akinyinka, with some of the Nigeria Coordinating Centre team

The output, premised by country. It is always reassuring to note that the morale among collaborators remains high. Such has of the African collaborators. It is a marvellously true show







Jos University TH team, led by Josiah Mutihir











Fatimah Habeeb from Lagos UTH and Suleiman Umar from Ahmadu Bello UTH visiting the TCC in London, with Eni Balogun.









Olatunde Onafowokan





EVERY PATIENT COUNTS



led by PI Adeniyi Fasanu...











with PI Babalola Adevemi



