

OVER 5,000 WOMEN RANDOMISED

ALREADY ONE OF THE LARGEST RANDOMISED CONTROL TRIALS FOR THE TREATMENT OF POSTPARTUM HAEMORRHAGE

What a historic year it has been for the WOMAN trial. At the end of 2012 we have more than doubled recruitment and we are well on track to deliver this landmark trial by December 2014. Recruitment now stands at 5,500. If we continue adding new hospitals at the current rate, we will deliver the trial on time. Please remember to promote the trial everywhere you go. Many of our teams have been working on this trial for some time now and we know it is difficult to keep up momentum as we hit the middle stage. We now need maximum effort from all to get up the steepest part of the recruitment curve.

You can congratulate yourselves on being part of one of the largest randomised control treatment trials ever to be done in PPH. **This trial belongs to the collaborators and your continued dedication and input is required to see it through.** We cannot forget why we are working on this trial and that each woman recruited so far has had a life threatening condition, and too many have died or have had a hysterectomy. **The quest to find better ways of treating them must continue.**

Haleema and Ian on behalf of your Trial Coordinating Team



From left to right:
Hamza, Abdalla, Ihsan, Awadia,
Fatma & Abdelazeem
(Amira not present)

PI Abdalla Ali Mohammed in front

WOMAN TRIAL at Kassala New Hospital (Al Saudi)

Sudan is one of eleven countries that are responsible for 65% of global maternal deaths. I saw the WOMAN trial as an opportunity to join an international collaboration for assessment of a drug that could contribute to a global reduction of maternal morbidity and mortality from PPH. Also, this is our first time to join such randomized controlled study of international calibre.

Kassala New Hospital team is ready to start and is composed of obstetricians and an anaesthetist; all are front liners in fighting PPH: Awadia Khojali, obstetrician – Head of Department of Obstetrics & Gynaecology and co-investigator; Hamza Mohamed Ali, Obstetrician, Hospital Director (the youngest member of the team) – second on call for emergency; Abdelazeem Abdalla, Obstetrician with good research experience; Ihsan Ziada, Anaesthetist, always present in PPH cases; Fatma Hamid, Obstetrician, Deputy Director of the hospital; Amira Okoud, Obstetrician – second on call for emergency.

ACHIEVEMENTS – Thank you!

Since the last newsletter the following new milestones have been achieved by our hard working teams:

100 PATIENTS

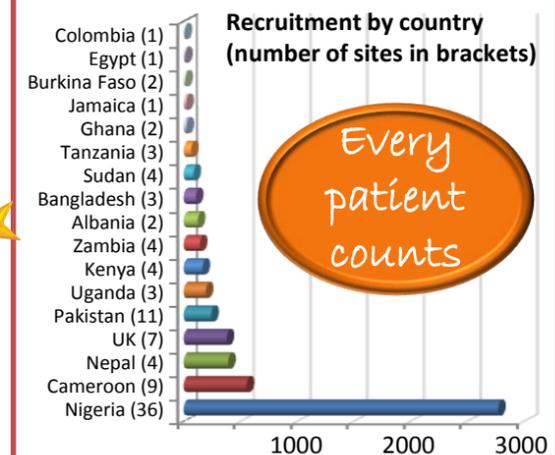
- ❖ Mulago Hospital, Uganda, PI Christine Biryabarema
- ❖ Kumba District Referral Hospital, Cameroon, PI Etienne Asonganyi
- ❖ University Teaching Hospital Lusaka, Zambia, PI Bellinton Vwalika
- ❖ Lagos University Teaching Hospital, Nigeria, PI Omololu Adegbola
- ❖ Hopital Laquintinie de Douala, Cameroon, PI Tschela Tchana
- ❖ Delta State University Teaching Hospital, Nigeria, PI Lawrence Omo-Aghoja
- ❖ Federal Medical Centre Owo, Nigeria, PI Olufemi Akinsanya
- ❖ Federal Medical Centre Gusau, Nigeria, PI Kamil Shoretire

250 PATIENTS

- ❖ BP Koirala Institute of Health Sciences, Nepal, PI Mohan Regmi
- ❖ Mother & Child Hospital Akure, Nigeria, PI Adesina Akintan
- ❖ University of Calabar Teaching Hospital, Nigeria, PI Saturday Job Etuk

50 PATIENTS

- ❖ Liverpool Women's Hospital, UK, PI Zarko Alfirevic
- ❖ Coast Provincial General Hospital, Kenya, PI Musimbi Soita
- ❖ Holy Family Hospital, Obs & Gyn Unit 1, Pakistan, PI Rizwana Chaudhri
- ❖ Maitama District Hospital, Nigeria, PI Frank Alu
- ❖ Queen's Medical Centre Nottingham, UK, PI Jim Thornton
- ❖ Ladoke Akintola University of Technology Teaching Hospital Osogbo, Nigeria, PI Adetunji Adeniji
- ❖ Moi Teaching and Referral Hospital, Kenya, PI Hillary Mabeya
- ❖ The Royal Victoria Infirmary Newcastle, UK, PI Paul Ayuk
- ❖ Lagos State University Teaching Hospital Nigeria, PI Oluwarotimi Akinola



El-Obeid Teaching Hospital team collaborating in the WOMAN trial

We decided to join the WOMAN trial immediately following Prof Elsheikh's presentation in the last conference of the Sudanese OB/GYN Society in February 2012. It was a convincing invitation for the audience.

Reduction of maternal mortality and morbidity, through any intervention, is one of our biggest dreams. Our team members in El-Obeid Teaching Hospital are highly motivated and this will ensure that all eligible patients will be randomized.

The first patient in Sudan was recruited in September 2011. The four active sites have now randomized a total of 86 patients.



Team at Khartoum North Teaching Hospital with PI Wisal Nabag

Also Prof Elsheikh, National Coordinator

Wisal Nabag says: We were inspired to join the WOMAN trial collaboration because the trial was planning to address the most common cause of maternal mortality which is one of the leading causes of mortality in Sudan.

The most important accomplishment in our hospital so far is that we have established a team of doctors, nurses, midwives and administrators who can work together to decrease maternal mortality, whatsoever the cause.

I would advise new collaborators not to miss the trial, which really needs a team working together. Each member should know exactly his or her responsibility, and to succeed the trial needs dedication and commitment.

Trial teams in PAKISTAN

Shumaila Wasim, Shamsunnisa Sadia and PI Faresa Waqar, Pakistan Railways Hospital



The trial team at Patel Hospital with PI Samina Saleem Dojki

EGYPT



The trial team at Mataria Hospital with PI Hussein Khamis

Mataria Teaching Hospital participated in the CRASH-1 trial (corticosteroids in head injury) and the CRASH-2 trial (tranexamic acid in traumatic hemorrhage). That experience of meticulous research work inspired our Obstetrics & Gynaecology Department to join the WOMAN trial.

We have a busy labour ward with many cases of PPH, some of which come with late referral. Bleeding is still a leading cause of maternal mortality in Egypt. Joining a randomized multi-center trial, per se, is an important accomplishment for us. We need to learn more about research work including study design, randomization, patient consent, accurate documentation and clear communication. The WOMAN trial gives us this opportunity.

We'd like to assure new collaborators that little effort and time is needed to fulfill the study requirements. Challenges – if any – can be overcome by teamwork.
Hussein Khamis, National Coordinator

BURKINA FASO

In Burkina Faso at the moment, three hospitals are trained while two have just started recruiting patients. Next, it will be better to target peripheral hospitals where PPH is more common than in national hospitals.

At the moment, haemorrhage represents 22% among the causes of maternal mortality in Burkina Faso. Therefore, in reducing this rate, I am convinced that the WOMAN trial will help to save the lives of many Burkinabé women and hence help the country to reach the fifth Millennium Development Goal 'Reduction of Maternal Mortality' by 2015.

Pictures from the first site training in Burkina – PI Roamba Pabakba and his team in CHR Dédougou



CAMEROON



I received information about the WOMAN trial and immediately resolved to join because anything that can save women's lives is of the utmost importance to me. Who in Cameroon can ignore that among factors involved in case fatality of PPH, the lack of blood products represents the first... my motivation and enthusiasm to pursue this trial is greater again!

Since I joined in 2010, the greatest achievement is the reduction of PPH incidence in my service, for the staff here pay more attention to this complication and are more interested in understanding PPH.

One of the most important obstacles is the fact that the trial is dependent on the PI and in the absence of the PI the trial simply stops. I strongly invite every colleague to come and join this exciting trial but do make sure you have a strong team where each member considers him/herself a PI!

Cameroon aims to be top recruiter or, better, top researcher!
Robert Tchounzou, National Coordinator

The team of Kumba District Hospital enjoying a meal out to celebrate their 100 patient milestone in a local restaurant. PI Etienne Asonganyi tells us, "the nurses treated themselves with a local specialty called 'Poulet DG', which translated means Chicken for CEOs."



WOMAN TRIAL at University Teaching Hospital Lusaka

Eugine Kaunda writes: I was inspired to join the WOMAN trial because I saw it as a golden opportunity to be part of the 'gold standard' of research – a double blinded multicenter randomised controlled trial. The trial's most important accomplishment at our hospital is the 100 mark of women randomised. To new collaborators, don't be left behind! Be part of this trial.

Hammond Kapapa, Registered Midwife, wrote: I was inspired to join the WOMAN trial because I was impressed that there could be an alternative to mothers bleeding after childbirth. If this study can make a difference between life and death for a new mother then I am proud to be part of it.

Some of the UTH team members from left to right: Hammond Kapapa, Rhoda Amafumba, Eugene Kaunda, Peter Musongole, Chishimba Kalandanya, Christine Ntambo. (PI and National Coordinator Bellington Vwalika not in the photo)



Trial teams in ZAMBIA
4 sites have recruited a total of 143 patients since November 2010

WOMAN TRIAL at Livingstone General Hospital, by Isaiah Hansingo, Principal Investigator

When we were given an opportunity to collaborate in the WOMAN trial, we acknowledged that it would be a privilege to be associated with a major medical advance if the treatment with tranexamic acid is found to improve outcomes for women with PPH. Our hospital would greatly benefit from such treatment as it would contribute towards significant reduction in the local and national maternal mortality ratio (MMR).

Livingstone General Hospital (LGH) recruited its first participant in June 2012 and we have recruited 12 women so far – slightly less than anticipated (delivery rate about 1,600 per year). In order to recruit more women in the coming year, we have posted notices for all nursing and clinical staff to notify the team when they attend to a PPH patient if none of the team members are on duty. We also intend to sensitize and re-sensitize new and old members of staff respectively. However, the trial has generated interest and enthusiasm in the management of PPH among the team members and others.

We would like to encourage other health facilities worldwide, especially in developing countries, to come on board and participate in this important international clinical trial.



Left to right: Loveness, Kena, Isaiah (PI), Lishomwa, Florence, Martha, Peter, Bopili

Trial teams in the UK



Team from the Royal Victoria Infirmary, Newcastle, with PI Paul Ayuk



Eugene Oteng-Ntim & team at St Thomas' Hospital, London



St Mary's Hospital, Manchester
PI Clare Tower on the left

Seven hospitals in the UK have recruited 380 patients since February 2011



Sunderland Royal Hospital team with PI Kim Hinshawe on the right

Remember to submit entry forms within 24 hours!

ETHIOPIA



In our day-to-day life we experience severe and unforgettable pain due to maternal deaths related to bleeding after birth. To be involved in research, like the WOMAN trial, which may find a solution to reduce postpartum bleeding related problems, will be a blessing and a rewarding activity.

The problem of PPH is very relevant to Ethiopia where maternal mortality and morbidity is high. Hence, I believe Ethiopia can contribute to the WOMAN trial by recruiting eligible women who may also benefit from the trial. If the trial results are positive, Ethiopia will be one of the countries to use the drug for treatment of PPH.

The challenges of getting approvals from the regulatory authorities were not easy to overcome. But when legal experts and responsible individuals in the authorities realized the importance of the trial, the process became easy and fast. **I would like to appreciate His Excellency Dr Tewodros Adhanom, Minister of Federal Ministry of Health, Yeyulu Deneke, Director General of FMHACA, and all individuals involved for their relentless efforts in realizing the approval of the WOMAN trial to be carried out in Ethiopia.**
Abdulfetah Abdulkadir Abdosh, National Coordinator

National Meeting in KENYA

In KENYA we held a 2-day National Meeting for team members of six sites

Three are recruiting, one is ready to start recruitment and two other sites have shown commitment to joining the trial. The most interesting part of the training were the discussions and role plays on consent taking – a major concern for all sites, and it is now hoped that future recruitment will be much higher.

The new sites learned a lot from those already recruiting and all sites hoped to have started discussions with at least two more sites by the end of the year as possible future sites.

A plan was made to make a presentation at the next Kenya Obstetrics and Gynaecology conference scheduled to be held in Eldoret on 13–15 February 2013, and we hope this will attract more interested teams to join in.



The visit by the TCC team has invigorated the local teams and we are looking forward to more hospitals joining the trial. By contributing to the success of this landmark trial we hope we can make a difference in the management of PPH and global maternal mortality rates.

Zahida Qureshi, National Coordinator



The trial team at Federal Medical Centre Katsina

Any inquiry into any treatment modality of PPH is a motivating task for most obstetricians. That is why we joined this pragmatic trial, like most other centers.

In our centre at the Federal Medical Centre Katsina the trial has brought to us various achievements both socially and otherwise. It has strengthened our unity as the group consists of doctors, nurses, midwives, pharmacists and record officers. It has created an avenue where we all sit and discuss the challenges we face. It has also indirectly helped us in auditing the outcomes of our patients with PPH, especially with regard to death and obstetric hysterectomy.

The trial has so far been a success in our centre. The simple reason for this is that every member of the team is being carried along. We hold regular meetings where we discuss various challenges and share our experiences. Duties are also apportioned to members such that addressing challenges becomes easier. Towards the end of last year we had a get-together where we invited other staff members of the hospital to celebrate our success.

For the new collaborators, having regular sessions bringing all team members together is of utmost importance to the success of the trial.

Ibrahim Habib, PI

NIGERIA

The first patient of the WOMAN trial was randomised in Nigeria in March 2010. Now, 36 hospitals have recruited a total of 2,800 patients.

UGANDA

WOMAN TRIAL at Mulago Hospital

How recruitment has moved on

Mulago site started recruiting patients in the last week of July 2012. The team is composed of three doctors and four midwives. The doctors are: Christine Biryabarema, PI and national coordinator, Nsubuga, Obstetrician and Gynecologist, and Dinah Amongin,



The trial team at Mulago Hospital, Uganda, with PI Christine Biryabarema

a final year postgraduate student pursuing a Master of Medicine in Obstetrics and Gynaecology at Makerere University, College of Medicine. The midwives are Dorothy Mugabi, Rebecca Nakawooya Lwasa, Joselyn Ayikoru and Regina Akello. The team was picked on the basis of showing keen interest in conducting the study. All the doctors had participated in many of the previous research projects in Mulago Hospital/Makerere. Two of the nurses had participated in other studies.

The team was oriented to the study and then spent time acquainting themselves with the various forms. We produced dummy forms we all had to practice filling before we could fill the actual forms. The TCC also provided training through Skype. All the team members were assigned duties. The nurses agreed between themselves that all three shifts had a WOMAN trial team nurse.

The first cases were randomized under the supervision of a doctor. The process was discussed after randomization and any mistakes corrected there and then. The midwives were doing most of the randomization because they were in the labour ward most of the time. They filled the entry form and part of the outcome form. Completion of the outcome form was carried out by the doctors. The PI took the responsibility of uploading the completed forms into the database.

What were the challenges?

At the start we missed some patients. We informed the other midwives and doctors on a regular basis including constant reminders about the study drug and the importance of the study. Once the trial was well known, a team member would be contacted as soon as there was a PPH. The contact details of the study team are readily available in the delivery room.

Blood loss is not always estimated accurately and most often it is underestimated. We discussed with other staff members on how we should estimate blood loss. The kidney dishes used to scoop blood after delivery contain 500mls. We agreed if that dish is full then the mother qualifies to have a diagnosis of PPH. We still have a challenge of measuring the blood loss at caesarian section. Mostly this is underestimated.

Mulago hospital handles up to 90 deliveries each day. The team of nurses has been very vigilant in surveilling the labour ward to make sure they miss as few eligible women as possible.

Every patient counts

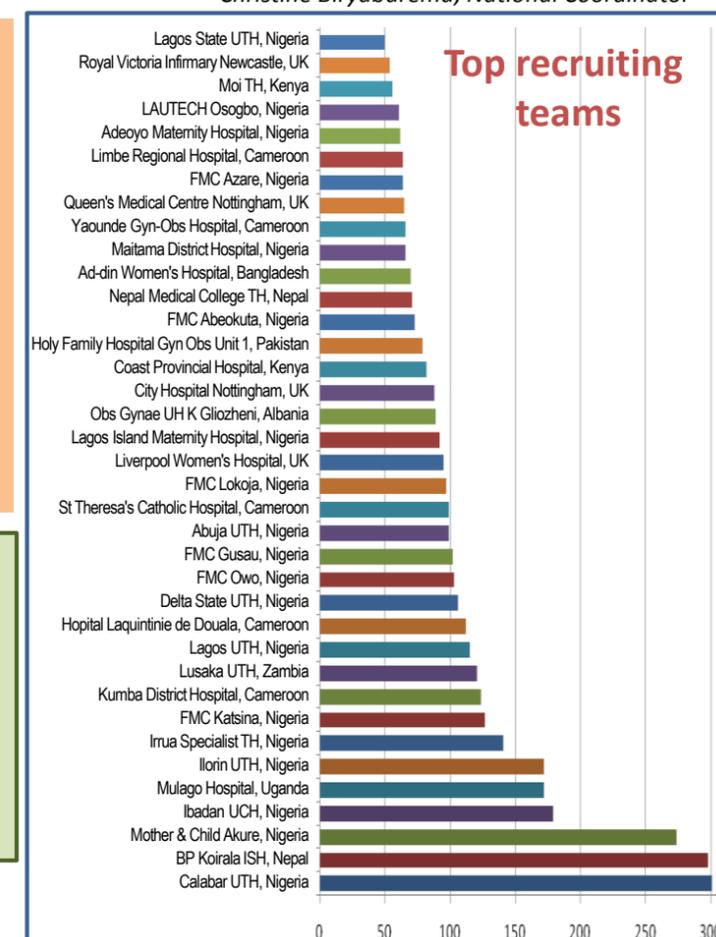
Christine Biryabarema, National Coordinator



A National Meeting of collaborators was held in Uganda in February 2012.

The first patient in Uganda was recruited in July 2012 and already the three participating sites have jointly randomised 200 patients.

A great big THANK YOU to the team at Mulago Hospital, leading the way by recruiting on average 29 patients per month!



NIGERIA (more overpage)

The WOMAN trial in Mother & Child Hospital, Akure

I learned about the trial through the Nigeria National Co-ordinator Bukola Fawole. I was excited about the prospect of finding another drug that might further assist us in the fight against primary PPH.

At our hospital the morbidity and mortality pattern prior to the commencement of the trial showed that pry-PPH is the most common problem. The trial has further increased the our awareness.

The trial has been hugely successful in the hospital. This is due to 1) the high level of awareness of the trial among the hospital staff; 2) the support of the hospital management; 3) regular updates for the trial team.

My advice to new investigators is to have people with passion in the team, to organize regular training and updates for team members. The PI should at every point share the success achieved with members of his team and carry them along. *Adesina Akintan, PI*



WOMAN TRIAL at Federal Medical Centre Owo

My centre was enrolled at the inception of this trial in Nigeria in March 2010 at University College Hospital Ibadan. The motivation to be part of it was to make the trial a success, since my country was counted worthy to provide an answer to a bothering clinical condition in which women in my country contribute 10% of global statistics.

In my centre over 100 women have been recruited and the nurses contributing to the success of the trial.

The success achieved so far has been due to the motivation of the registrars in the department by constantly reminding them of the trial by phone calls, monitoring and evaluation of the drug packs, ensuring compliance with the rules of the trial and promptly sending the data forms to the TCC before they pile up.

My advice to new collaborators is that the effective supervision of the project should not be delegated; with time your trusted registrar could become weary.

Olufemi Akinsanya, Principal Investigator



WOMAN trial collaboration: the University of Calabar Teaching Hospital (UCTH) experience

In our experience about 25% of maternal death is as a result of obstetric haemorrhage with PPH being the main factor. It has been our concern to find ways of curbing this carnage in our environment and therefore work towards the attainment of the Millennium Development Goal (MDG) 5.

The coming of this trial to our hospital has become a source of enlightenment, an 'eye opener' to all staff regarding the impact of PPH on the lives of our mothers. Every staff member in maternity now watches out for PPH and raises alarm in an attempt to find solution to it. Before now, we were preaching the gospel of reduction of maternal mortality through prevention and treatment of PPH but we never got to this level. This is a big gain to us irrespective of what the benefit of tranexamic acid will turn out to be at the end of the project.

I would want to appeal that every hospital keys into this project for the sake of our mothers, our sisters and our daughters. The project may be time consuming but the end result may likely bring a lasting joy to our obstetric world. I strongly invite those who are watching to please join us, and those who are already there to continue to forge ahead. *S J Etuk, PI*



WOMAN TRIAL at University of Ilorin Teaching Hospital

It is great to see how successful the WOMAN trial project has been since it started. The need to reduce the scourge of PPH informed our decision to be part of research that may bring about reduction in maternal mortality. Taking part in the trial has improved our knowledge and understanding of the protocols and collaborations involved in multicenter randomised control trials.

We believe strongly that the success of the WOMAN trial so far in this hospital is due to great team efforts displayed by the TCC, the PI, the randomisers and other team members. It is very important to note that the success of a new collaborator joining the trial would be dependent on emphasis on the following: 1) understanding what the trial is about; 2) team work; 3) TCC's timely supervision. Therefore, it is important that everybody in the new collaboration should be carried along in order to achieve the desired success. *Abiodun Peter Aboyeji, PI*



WOMAN TRIAL at University College Hospital Ibadan

I was inspired to join the WOMAN trial because of the simplicity the result of the trial would offer to an enormous problem of PPH, which could be made immensely simpler by the use of tranexamic acid.

The most important accomplishment of this trial in my hospital so far is the WOMAN-ETAC study. I am grateful for the privilege of being part of a great team not only trying out tranexamic acid to reduce mortality and morbidity from PPH, but also to have information on its mechanism of action in doing this.

The most important reason why I think we are able to contribute what we have to the trial is team work. We have a large team at UCH and every member has shown great commitment to the trial. For those just joining the trial, the advice is to pick a good team and involve everybody who participates in the care of women in labour. *Adeyemi Afolabi, PI*



THE WOMAN TRIAL at Delta State University Teaching Hospital

Principal Investigator Lawrence Omo-Aghoja writes about his and the team's efforts to get the trial going at Delta State UTH.

"For some years I have been involved in research, documentation, service delivery and advocacy in issues of maternal health and safe motherhood. I have been part of national and global initiatives at documenting the status of maternal health and factors that challenge safe motherhood.

Therefore, it is clear to me that if the twin effort of the safe motherhood initiative and millennium development goal targeted at maternal mortality reduction is to be achieved, then all initiatives at tackling PPH must be supported and keyed into. It was for these reasons that I readily embraced being part of this trial, when the concept of the WOMAN trial was first introduced to me by Dr Fawole, the Nigeria National Coordinator."

TCC representatives first carried out a training session and the hospital then satisfied all ethical clearances. The PI says:

"As a first step I presented the trial to the hospital management team who were quite glad with the tenets of the trial; in particular that our hospital had been given the privilege of being one of the trial sites in this global initiative. We extracted a commitment from the hospital management that the members of the trial team will be kept together in the hospital for as long as the trial lasted. At the departmental level we presented the trial and recruited our team members based on those who volunteered. The department approved that the trial details be incorporated into the antenatal clinic health talk and Mrs. Jackson has taken the lead in doing this. We think most sincerely that to have made ownership of the trial to cut across all – the management, the staff and the patients alike has been one of the key reasons for the success of the trial in our center so far, amongst other factors."

The response to PPH at Delta State UTH has dramatically changed since the start of the trial.

"Interestingly the response in the use of other strategies of dealing with PPH has been well streamlined such that most times at the earliest bleed staff are usually very proactive with the use of other measures which may result in the patients not meeting the criteria that defines PPH and therefore not eligible for recruitment. Even though this seems to affect our recruitment rate, we believe strongly that this repositioning of our response and proactive approach to management of PPH since the commencement of the trial has been one of the significant accomplishments of this study in our hospital."

At the outset the members of the trial team were sensitized to respond to calls in cases of PPH alert. Dr Omo-Aghoja writes:

"We displayed the phone numbers of team members conspicuously in labor ward and purchased a GSM phone handset domiciled in labor ward for ease of contact. We have periodic evaluation and monitoring of our activities and training and retraining of our members from time to time. This has significantly helped the success of the trial. Indeed, one of the training sessions involved in the process of consent taking was coordinated by the TCC and was quite fulfilling. The challenges

we had with the consenting process were effectively addressed after this center-specific training by teleconference."

There have been some political and technical problems in Nigeria which have affected all of our trial sites.

"The trial has not been without challenges and leading amongst these is the incessant shutdown of hospitals for industrial dispute. And when the hospital eventually re-opens it takes a while for patients' inflow to build up. This often affects our recruitment rate and may hamper our ability to contribute the 300 patients we had projected. We are, however, hopeful to reach this target. The other challenge we have had to contend with is the epileptic and often poor nature of our internet access; this has been one of the key factors delaying sending the data. The attrition of our team members either from transfer of nurses or our resident doctors exiting the training program causes concern from time to time. To replace residents, we have periodic recruitment and training of new members."

"Clearly, for any new collaborator joining the trial group, the steps listed below may be part of the recipe for a successful trial. Foremost is the passion of the PI for maternal health issues; putting in place a great team of staff who voluntarily offer their time and energy for the trial; an effective antenatal clinic counseling and education team; and making all feel ownership of the project, in particular getting the management team to understand the tenets of the trial and buying into it. Other strategies that would be helpful are periodic monitoring and evaluation of the trial team, as well as training and retraining."