
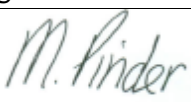




STANDARD OPERATING PROCEDURE FOR:

SOP for Distribution and blinding of LLIN for the AvecNet Main Trial (AvecNet specific)

SOP Details:

Version: 1.0 Eng The French Version is definitive	Date operational:	28/05/2014
Author(s): Alphonse Ouedraogo Title: Dr	<i>Signature</i>	<i>Date</i>
		11/05/2014
Reviewed by: Sagnon Nfale. Title: Dr	<i>Signature</i>	<i>Date</i>
		11/05/2014
Approved by: Margaret Pinder Title: Dr	<i>Signature</i>	<i>Date</i>
		11/05/2014
Date to be reviewed:	June 2015	
Current review changes: Non-applicable, new SOP		
Location:	Original hard copy with: Sagnon Nfale / Study File (Lydia Dabré) Hard copies with: Alphonse Ouedraogo / Electronic version: Steve Lindsay / Margaret Pinder / Study File	
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Review History:

First Operational:	June 2014			
Reviewed:				
Updated yes/no:				

1. DEFINITIONS AND ABBREVIATIONS

AvecNet	AvecNet is a consortium of African and European researchers committed to ensuring the sustainability of malaria vector control in Africa and is an EU funded project lead by Prof Hilary Ranson, Liverpool School Tropical Medicine
AvecNet Trial	AvecNet is the short name for the trial "To assess whether addition of pyriproxyfen, an insect juvenile hormone mimic, to long-lasting insecticidal mosquito nets provides additional protection against clinical malaria over current best practice. Protocol for a two-armed cluster randomized wedge-shaped trial in Burkina Faso", which is funded by AvecNet as part of WP6
CNRFP	Centre Nationale de Recherches et Formation sur le Paludisme, Burkina Faso
CSPS	The Banfora CNRFP Centre
LLIN	Long-lasting Insecticidal bed Net
PPF-LLIN	Long-lasting Insecticidal bed Net with pyriproxyfen in addition to permethrin
SOP	Standard Operating Procedure

2. BACKGROUND

Reductions in malaria are currently being recorded in many countries in sub-Saharan Africa¹ largely due a massive scale-up of long-lasting insecticidal nets (LLINs) and indoor residual spray campaigns^{2,3}. Future success, however, is threatened by the development of insecticide resistance in the vectors and currently bed nets can only be treated with pyrethroids⁴. To increase the effectiveness of LLINs, alternative types of bednets are being developed where another active ingredient is added to the pyrethroid. The AvecNet trial investigates the effectiveness of pyriproxyfen added to permethrin on LLIN⁵. Pyriproxyfen is an insect juvenile hormone mimic, recommended for vector control by the World Health Organization since it is effective at extremely low concentrations and is safe to people, and there is no cross resistance with other classes of insecticide used for vector control⁶. The primary objective of the AvecNet trial is to assess whether PPF-LLINs provide added protection against clinical malaria in children compared with LLIN over two malaria transmission seasons of follow up.

A cluster-randomized controlled trial design will be used since: (1) LLINs are a community-level intervention, and (2) the village cluster is a suitable unit for randomization. The study design is a step-wedge in which the standard intervention is provided throughout the trial area and then gradually replaced by the test intervention. At the beginning of the main transmission season, LLIN (Olyset), manufactured by Sumitomo Chemical Company, will be distributed across all the village clusters. These LLINs are WHO recommended and meet WHO specifications⁷ with 2% w/w permethrin incorporated into polyethylene fibres giving adequate release of permethrin for about five years. Then, every four weeks from June to September 2014, the LLIN (Olyset) nets will be removed in five randomly pre-selected village-clusters and replaced by PPF-LLIN (Olyset-Duo), from the same manufacturer. At the end of 2014 half the clusters will have LLIN nets and half PPF-LLINs. From June to September 2015 additional clusters will receive PPF-LLIN selected in the same manner as for 2014 until all clusters have PPF-LLINs. It is important that within the study area there are few, if any, villages that are not enrolled in the study in order to ensure the PPF-LLINs have maximum impact on larval populations, avoiding the spill-over of mosquitoes from villages without these nets.

In cluster-randomised controlled trials it is particularly important to minimize imbalance for factors likely to be correlated with the outcome. Observer bias will be reduced where feasible. Both types of nets will be of a similar shape and colour. Field workers conducting the monthly net and travel surveys, nurses following adverse events and entomology technicians conducting light trap catches and related investigations will be blinded to the net type. The trial is thus partially blinded.

The current SOP details the methods for blinding, numbering and donation of the nets.

3. SCOPE

This SOP involves the Principle Entomologist / CNRFP AvecNet Coordinator and the Field supervisor in charge of net distribution and the field staff in charge of net donation. The field staff effecting the donation should not play other roles in the trial. This SOP is effective for all net donations for the Main AvecNet Trial

4. RESPONSIBILITIES

The Principle Entomologist, Dr Sagnon Nfale, is responsible for overall management and facilitation of this SOP. The field supervisor is responsible for the application of this SOP in the field. The field staff are responsible for carrying out this SOP at village level.

5. HEALTH & SAFETY

- 5.1 Heavy lifting techniques are required when moving the bales of nets.
- 5.2 Disposable gloves should be worn when handling the nets

6. PROCEDURES

- 6.1 Both types of bednets used in this study are stored locked at room temperature in Banfora under the responsibility of the Principle Entomologist.
- 6.2 At the start of the study all consenting households will receive 1.1 LLIN (Olyset) for every two people in the household. In June, July, August, September 2014 and 2015 the LLIN (Olyset) will be removed from five randomly, pre-selected clusters and will be replaced with PPF-LLIN (Olyset-Duo).

Donation of LLIN (Olyset) - May 2014

- 6.3 A Household Net Distribution List Round 1 (Annexe 1) will be prepared in advance for each village from the July 2013 DSS data with household number, the name of the household head, number of members in the household, the calculated number of nets to be donated, and the range of unique net identity numbers for the household. This list will have blank fields to complete the "lot number" of the net, the date and time of donation, the name of the recipient, or in case of children, the name of the parent/carer, the unique net identity number and if a previous net was surrendered. These lists will be provided to the Field Supervisor before distribution starts.
- 6.4 The number of bales required for each of the villages will be calculated and signed out of the stock rooms by the driver under the supervision of the representative of the Principle Entomologist.
- 6.5 The bales will be delivered by lorry to the Health Facility associated with each village. The officer in charge of the Health Facility signs for the reception of the bales. These records are checked during the field supervisor's weekly visit.
- 6.5 The net bales are then signed out of the Health Facility and the required numbers are transported to individual villages where they will be held in a suitable central place, under the responsibility of a named village leader. The driver of the "delivery van", or motorbike rider, will keep record of the delivery. These records are checked by the field supervisor's weekly visit.
- 6.6 In a central place in the village, field staff effecting the donation will prepare the nets for each household as follows:
 - i. cut open the bags the net is delivered in and place on a table,
 - ii. locate the manufacturers label,

- iii. carefully cover the trademark of the net type with a thick black permanent marker,
 - iv. add the unique net identity number (Annexe 2)
 - v. Complete the Household Net Distribution List Round 1 with the "lot number" of the net and the unique net identity number.
- 6.7 The nets are then given to the household providing the adult responsible for each sleeping place gives witnessed written informed consent to join the trial (Annexe 3).
- 6.8 All nets currently in position will be taken down and the donated net will be hung.
- 6.9 The field staff will then complete the Household Net Distribution List Round 1 for the date and time of donation and the name of the recipient, or in case of children, the name of the parent/carer and if a previous net was surrendered.
- 6.10 During these procedures it will be made clear that net recipients will be able to leave the study at any time but their original net will not be returned.
- 6.11 To encourage net use, in addition to hanging the nets, the recipients will be taught on net use following the Burkinabe Government Roll Back Malaria information, education and communication package. In addition the manufacturer's packaging, which has pictorial and written instructions for care and use of the nets, will be left with the users.
- 6.12 All nets taken down will be removed from the village. Those in excellent condition will be donated to the Burkinabe National Malaria Control Programme for distribution to unprotected communities outside the study area. Used nets in less than excellent condition will be destroyed by a WHO approved method⁷.
- 6.13 The completed Household Net Distribution List Round 1, consent forms and signed will be taken to the Banfora CNRFP Centre.

Donation of PPF-LLIN (Olyset-Duo) – June, July, August, September 2014 and 2015

- 6.14 The exchange donation of PPF-LLIN (Olyset-Duo) cannot start until the donation of LLIN (Olyset) is completed and all remaining nets in the Health Facilities have been returned to Banfora, signed by the field supervisor and verified by the Principle Entomologist.
- 6.15 Once 6.13 is completed, the distribution PPF-LLIN (Olyset-Duo) will follow the same procedures as for the LLIN (Olyset), but only five clusters will receive these each month.
- 6.16 A separate Household Net Distribution List Round 2 will be prepared with the same fields as the Household Net Distribution List Round 1 but with the addition that the month and year of donation will be added. The list for each month of donation will be kept in a separate A4 envelope with the date of donation clearly written on the outside.

7. MATERIALS

The nets are all white "Extra Family" rectangular (180cm W x 190cm L x 150cm H).
 Waterproof black markers, medium -50
 Waterproof black markers, fine - 50
 Scissors, 5
 Disposable gloves, large and medium
 Pens

References

1. O'Meara WP, Mangeni JN, Steketee R, Greenwood B. Changes in the burden of malaria in sub-Saharan Africa. *Lancet Infect Dis.* 2010; **10**: 545-55.

2. WHO. World Malaria Report 2011. Geneva: World Health Organization; 2011.
3. Lengeler C. Insecticide-treated bed nets and curtains for preventing malaria. The Cochrane Database of Systematic Reviews. 2004; (2): CD000363 pub2. DOI: 10.1002/146.
4. Pluess B, Tanser FC, Lengeler C, Sharp BL. Indoor residual spraying for preventing malaria. Cochrane Database Syst Rev. 2010; **4**: CD006657.
5. Ranson H, N'Guessan R, Lines J, Moiroux N, Nkuni Z, Corbel V. Pyrethroid resistance in African anopheline mosquitoes: what are the implications for malaria control? Trends Parasitol. 2011; **27**: 91-8.
6. http://www.who.int/whopes/Long_lasting_insecticidal_nets_Aug09.pdf
7. WHO recommendations on the sound management of old long-lasting insecticidal nets March 2014

Annexe 1. Household Net Distribution List Round 1

Annexe 2. Net label before and after numbering (shows unique net identity number)

Annexe 3. Witnessed written informed consent

Annexe 1 Household Net Distribution List Round 1

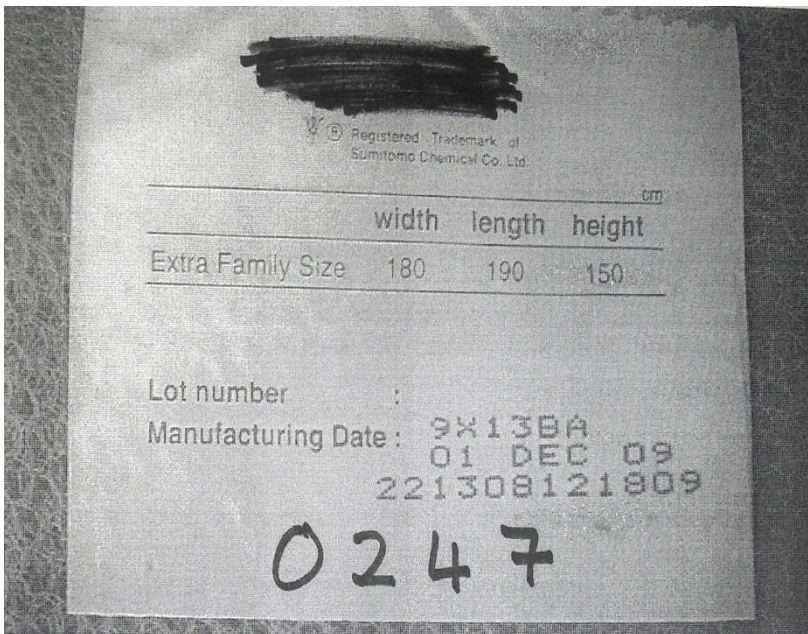
LLIN donation June 2014

Ménage_ id	Centre de Santé	uni vill	Village	Chef de ménage	nbre lits	total ménage	nbre mosq	Nom de résident(e)	sex e	âge	DONATION				
											Nom	lot LLIN	nbre LLIN	Date	Heure
1600101	Tiefora	1	Natiera	Kinda Issaka	4	7	0	Kinda Issaka	1	27					
	Tiefora	1	Natiera					Belem Lizanata	2	25					
	Tiefora	1	Natiera					Ki Mamoudou	1	25					
	Tiefora	1	Natiera					Kindo Alimata	2	44					
1600201	Tiefora	1	Natiera	Da Maimouna	1	3	1	Da Maimouna	2	52					
	Tiefora	1	Natiera					Da Manma	2	31					
1600301	Tiefora	1	Natiera	Konate Abdoulaye	2	3	0	Konate Abdoulaye	1	50					
1600401	Tiefora	1	Natiera	Ly Boureima	4	5	0	Ly Boureima	1	43					
	Tiefora	1	Natiera					Daro Aicha	2	37					
1600601	Tiefora	1	Natiera	Belem Idrissa	5	11	0	Belem Idrissa	1	58					
	Tiefora	1	Natiera					Kindo Kalidiata	2	43					
	Tiefora	1	Natiera					Belem Kalidiata	2	28					
	Tiefora	1	Natiera					Belem Sayouba	1	22					
	Tiefora	1	Natiera					Kindo Hairoune	2	18					
1600701	Tiefora	1	Natiera	Ouedraogo Rasmane	5	12	0	Ouedraogo Rasmane	1	46					
	Tiefora	1	Natiera					Karambiri Zoenabo	2	40					
	Tiefora	1	Natiera					Ouedraogo Omar	1	35					
	Tiefora	1	Natiera					Mande Safoura	2	31					
	Tiefora	1	Natiera					Sawadogo Mariam	2	22					

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Page 1

Annexe 2 Net label before and after numbering (shows unique net identity number)



**FORMULAIRE D'INFORMATION ET DE CONSENTEMENT DU PARTICIPANT POUR TOUS
LES PARTICIPANTS A L'ETUDE AvecNet**

Version 1.0 - 18 Septembre 2013

Evaluation de l'impact de l'addition de la pyriproxifène, un mimétique d'une hormone de l'insecte jeune, aux moustiquaires insecticides à longue durée d'action: Quelle protection additionnelle à celle que confère les bonnes pratiques actuelles contre les épisodes cliniques de paludisme. Un essai clinique randomisé en grappe à schéma « cunéiforme» à deux bras au Burkina Faso.

Responsables scientifiques et personnel médical en charge de l'essai

Dr Tiono Alfred, Dr Sagnon N'Fale, Dr Margaret Pinder et Professeur Steve Lindsay.

Type du document:

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Basé sur:

Protocole, v1.0, daté 18 –Septembre- 2013

ID Participant _____

Introduction:

Vous êtes invité à prendre part à un essai Clinique. Avant toute décision, il serait important que vous compreniez pourquoi la recherche est conduite. Permettez moi de vous expliquer ce qu'il en est ainsi que les implications y afférentes. Prenez votre temps pour écouter attentivement et posez des questions si vous voulez des clarifications ou si vous n'avez pas compris.

But: Pour tester l'efficacité d'une nouvelle moustiquaire imprégnée d'insecticide à longue durée (MOUSTIQUAIRE OLYSET DUO) à réduire le taux de paludisme chez les enfants au Burkina Faso, nous vous invitons à participer à cet essai clinique.

Que se passera t-il? Si vous acceptez de participer, nous vous demanderons de vous conformer à ce qui suit :

1. Nous donnerons une nouvelle moustiquaire imprégnée d'insecticide en échange de celle que vous possédez déjà. Le cas échéant, la nouvelle moustiquaire vous sera donnée. On vous demandera de l'utiliser aussi longtemps que possible.
2. Quelques semaines plus tard, nous vous rendrons visite pour vous demander votre avis sur la moustiquaire et votre accord pour l'examiner.
3. Plus tard, nous vous donnerons une autre moustiquaire en retour de celle qui vous a été précédemment remise. Alors, nous vous remettrons deux moustiquaires, l'une imprégnée avec un seul type d'insecticide et l'autre avec deux types d'insecticides.
4. Nous pensons que les deux types de moustiquaires peuvent être utilisés sans problème mais pour vérifier cela on vous posera des questions sur votre état de santé à la fin de la saison pluvieuse. Si vous avez des inquiétudes par rapport à la moustiquaire ou si vous ne vous sentez pas bien, veuillez contactez le Dr Sagnon N'Falé Tél: 70 23 91 09 ou le Dr Alfred B. Tiono Tél: 70 28 57 26.

Durée: Vous participerez pendant 27 mois à cette recherche.

Risques: Il existe plusieurs informations qui prouvent que les insecticides utilisés sur les moustiquaires sont uniquement nocifs aux moustiques et aux insectes. Cependant, on vous demandera si vous avez déjà eu un problème lié à l'utilisation des moustiquaires.

Bénéfices: Vous recevrez gratuitement des moustiquaires pour votre participation et vous les garderez à la fin de l'étude. Les résultats de l'étude pourront nous aider à mieux lutter contre le paludisme.

Confidentialité: Toute information fournie sera gardée secret. Cette information est généralement collectée sous différentes formes (papier ou électronique) sans votre nom ou tout autre détail qui pourrait vous identifier. Cependant dans certains cas, votre nom ou d'autres informations spécifiques (ex. : date de naissance) sont requises pour s'assurer de l'exactitude des informations reportées sur le formulaire. Vos informations personnelles seront gardées confidentielles ; elles seront uniquement divulguées aux personnes autorisées. Ces personnes sont tenues par le secret professionnel et peuvent être composées de celles qui conduisent et suivent cette étude (équipe de l'étude, moniteurs, le sponsor ou les entités gouvernementales et les comités d'éthique/comité de revue institutionnel). Les résultats sont anonymes et peuvent être remis à ces entités pour la vérification de l'exactitude des données et des résultats de l'étude. Cette information pourrait être sous forme électronique alors la signature de ce formulaire signifie que vous êtes d'accord avec ce qui est dit. Dans la mesure du possible les informations seront divulguées de manière anonyme afin de garder la confidentialité.

Paiement: Aucun paiement ne sera reçu pour votre participation à cette étude.

Approbation institutionnelle: Cette étude a été approuvée par le comité d'éthique pour la recherche en santé (CERS) du Burkina et le comité institutionnel de bioéthique (CIB) du CNRFP.

Si vous avez des questions sur vos droits en tant que participant, veuillez contacter le président du CERS Tel. : 50 32 41 76 et/ou la présidente du CIB/CNRFP Tel. : 70 24 06 84.

FORMULAIRE DE CONSENTEMENT ECLAIRE

Je soussigné (e),(nom) accepte participer à l'essai clinique dénommé : AvecNet.

J'ai eu l'occasion de poser des questions concernant cet essai et de recevoir des réponses entièrement satisfaisantes. Pour toute question éventuelle je pourrais contacter le Dr Sagnon N'Falé Tél.: 70 23 91 09 ou le Dr Alfred B. Tiono, Tel. : 70 28 57 26.

J'ai également compris que je suis libre de retirer mon consentement à tout moment sans aucun préjudice ou perte de mes bénéfices.

Signature et date de l'adulte.....

Adresse
.....
.....

Nom du témoin,

Signature..... Date.....

Nom de l'investigateur.....

Signature..... Date.....

Empreinte si incapable de signer
