Dix-neuvième Journée Scientifique

Nineteenth Scientific Day

12 juin 2009 - 12th June 2009

Résumés des communications

Abstracts of the presentations

epicentre
ÉPIDÉMIOLOGIE • EPIDEMIOLOGY

MEDECINS SANS FRONTIERES

Paris le 12 juin 2009

Chers collègues et amis,

Tout en conservant l'objectif premier de présenter les travaux de l'année écoulée, la journée scientifique de cette année apporte son lot de différences.

Tout d'abord nous avons souhaité renforcer les moments d'expression et de débats afin que des regards critiques soient posés sur les enjeux de la recherche dans nos contextes classiques d'intervention. En fin de matinée tout d'abord, à propos de la recherche clinique, puis lors de la session sur le choléra.

Puis en fin de journée, nous avons introduit une session de « late-breakers », ces présentations de dernière minute reflétant des travaux tout récemment menés dans le cadre notamment des programmes d'urgence.

Enfin nous souhaitons la bienvenue à la Drugs for Neglected Diseases initiative (DNDi) qui prend un peu d'espace dans le hall d'entrée, manière d'accueillir conjointement les résultats de l'étude de longue haleine menée par Epicentre sur un nouveau mode de traitement de la maladie du sommeil.

Dans la première session nous présentons le bilan de plusieurs années de programme au Malawi et avec l'analyse du devenir des patients perdus de vue. La question de la toxicité du traitement antirétroviral est abordée à travers une analyse multicentrique. Nous présentons également les premiers éléments de pharmacocinétique lors de l'administration conjointe du traitement antituberculeux et de la névirapine.

Les résultats de ces travaux confirment que si la décentralisation de la prise en charge des patients est une voie possible elle doit s'accompagner d'un renforcement de communication avec le patient couplée à des outils de suivi adaptés. Cela constitue des éléments d'orientation à l'heure où MSF s'interroge à nouveau sur sa stratégie de programmes et de soins de traitements des malades séropositifs. Les moyens de prise en charge médicale évoluent, les stratégies vont prendre de nouveaux tournants et les acteurs de terrain, pour construire leurs programmes et leurs messages, ne feront pas l'économie de la recherche.

Dans l'expression d'une politique médicale, le choix des traitements est un élément important. Pour contribuer à des solutions thérapeutiques nouvelles, Epicentre a ainsi mené plusieurs essais cliniques dont nous présentons les résultats cette année. Sur le traitement du paludisme avec la comparaison de l'efficacité et de la tolérance de la quinine et de la combinaison artemether-luméfantrine chez la femme enceinte, projet soutenu par l'ensemble des 19 sections de MSF, ou encore avec la participation à une étude multicentrique de comparaison de l'efficacité et de la tolérance de cette même combinaison artemether-luméfantrine avec la dihydroartémisinine-pipéraquine chez l'enfant. Ces deux essais ont été menés à Mbarara en Ouganda où Epicentre est implanté depuis 10 ans au sein du centre hospitalo-universitaire. Dans le cas de la trypanosomiase africaine les résultats d'un long essai, mené en Afrique avec le soutien des sections belge et hollandaise de MSF et de la DNDi, ont mis en évidence l'efficacité et la tolérance de la combinaison nifurtimox-eflornithine. L'OMS a d'ailleurs très récemment introduit cette combinaison dans la liste des médicaments essentiels ce qui est un aboutissement majeur et exemplaire pour ce type d'activité. Mais ces résultats auront été le

fruit d'efforts organisationnels et financiers importants, de questionnements éthiques qui interrogent MSF et Epicentre dans leur rôle. Ces questions, entre autres, seront examinées dans la table ronde qui clôturera la matinée.

La première session de l'après-midi reviendra sur une maladie ancienne et toujours d'actualité : le choléra. Cette année 2008-2009 aura vu Epicentre intervenir en Guinée-Bissau, au Zimbabwe et en Zambie. L'investigation en Guinée-Bissau rappelle l'importance des fondamentaux de l'investigation dans la planification des réponses opérationnelles. Au Zimbabwe, MSF exprimera un point de vue critique sur son action et celle des autres acteurs dans un contexte d'une rare ampleur. La prise en charge rapide et efficace d'un nombre élevé de cas dans des environnements aux structures souvent désorganisées est limitée par des contraintes opérationnelles pour lesquelles la recherche peut aider à définir l'apport des différentes stratégies, notamment préventives. La place d'outils tels que le test de diagnostic rapide et le vaccin doit être précisée. Ce sera un axe de discussion de la table ronde qui suivra.

La dernière session met en lumière la diversité des questions et des contextes d'études d'Epicentre. Elle discute également l'apport des travaux menés pour éclairer les décisions.

Nous avons ainsi investigué une épidémie de rougeole au Cameroun survenue dans une région pourtant couverte par des campagnes de vaccination antérieures. Les résultats permettent de discuter l'efficacité de telles actions de masse et d'adapter les réponses futures.

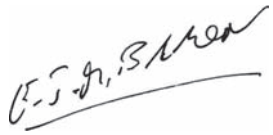
Au Niger, nous avons documenté l'étiologie des tableaux infectieux sévères chez des enfants sévèrement malnutris ainsi que la sensibilité des différents germes retrouvés aux antibiotiques couramment utilisés.

Puis seront présentés les résultats d'enquêtes menées pour le compte de trois sections de MSF en République Démocratique du Congo mettant en évidence les violences subies par la population civile. Les questions de pertinence, de réalisation et de limites d'interprétation de ce type d'enquêtes sont discutées autour des résultats du travail mené dans la bande de Gaza.

Et puis cette journée est l'occasion de présenter et de mettre en avant des collaborations sans lesquelles Epicentre ne pourrait accomplir tous ces travaux. Des équipes de terrain de MSF aux instituts internationalement renommés, nous les remercions de leur apport et de leurs critiques constructives.

Un espace de débat est prévu à l'issue de chaque session. Une traduction simultanée français/anglais sera assurée en permanence.

Nous comptons sur votre participation active au cours des discussions et vous souhaitons une Journée Scientifique agréable et enrichissante.



Emmanuel Baron
Directeur Général, Epicentre

Paris, 12 June 2009

Dear friends and colleagues,

While retaining our original objective of presenting work from the past year, this year's Scientific Day will offer a number of differences.

First, we wanted to have more time for expression and debate, to encourage a critical look at research issues in our classic intervention contexts. With this in mind, there will be one round table discussion at the end of the morning session, on clinical research, and another at the session on cholera.

Next, we've added a "late breaker" session at the end of the day for last minute presentations on very recent work, conducted mainly within the framework of emergency programs.

Finally, we welcome the Drugs for Neglected Diseases initiative (DNDi), which will have space in the entrance hall, so that together we can greet the results of Epicentre's long-awaited study on a new method for treating sleeping sickness.

The first session includes a summary of several years of the Malawi program and an analysis of outcomes for patients who were lost to follow-up. The issue of antiretroviral toxicity is addressed in a multicentric analysis. Also presented are the pharmacokinetic parameters during co-administration of anti-TB drugs and nevirapine. The results of these studies confirm that while a decentralized patient care approach is possible, it must be accompanied by better patient communication coupled with suitable monitoring tools. This offers some guideposts at a time when MSF is questioning, once again, its program and treatment strategies for HIV-positive patients. Medical management methods are evolving, strategies will be taking new turns, and people in the field will be looking to research when constructing their programs and their messages.

When elucidating a medical policy, the choice of treatments is an important element. To contribute to new therapeutic solutions, Epicentre has conducted several clinical trials whose results we will present this year. On malaria treatment, one study compares the efficacy and tolerability of quinine to that of artemether-lumefantrine in pregnant women, a project supported by all nineteen MSF sections. In another, we participated in a multicenter study comparing the safety, efficacy, and tolerability of that same artemether-lumefantrine combination with that of dihydroartemisinin-piperaquine in children. These two trials were carried out in Mbarara, Uganda, where Epicentre has been working for ten years at the university hospital center. For human African trypanosomiasis, a lengthy study conducted in Africa with support from MSF Belgium, MSF Holland, and the DNDi, has demonstrated the efficacy and tolerability of nifurtimox-eflornithine combination therapy. Moreover, the WHO recently added this combination to its list of essential medicines, a major and exemplary outcome for this type of activity. But these results were only possible through significant organization and financial effort, and raised ethical questions about the role of MSF and Epicentre. These questions, and others, will be examined at the round table concluding the morning session.

The first afternoon session will return to a very old, yet still newsworthy, disease – cholera. The year 2008-2009 will have seen Epicentre intervene in Guinea-Bissau, Zimbabwe and Zambia. The investigation in Guinea-Bissau reminds us of the importance of investigation fundamentals in planning operational responses. In Zimbabwe, MSF will present a critical view of its own actions and those of other actors in a context of unusual scope. The rapid and effective treatment of large numbers of cases in environments where structures are often disorganized is limited by operational constraints; research can help detail the benefits of various strategies, particularly preventive ones. The role of tools like the rapid diagnostic test and the vaccine needs to be clarified. This will be one focus of the round table that follows.

The final session showcases the wide variety of Epicentre issues and study contexts, and discusses the contribution of studies aimed at informing decisions. For example, the investigation of a measles epidemic in a part of Cameroon previously covered by vaccination campaigns has enabled us to discuss the efficacy of such large-scale actions and to adapt future responses.

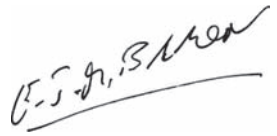
In Niger, we documented the etiology of severe infections in severely malnourished children, as well as the sensitivity of the different microorganisms that were found to the antibiotics currently in use.

The results of studies conducted on behalf of three MSF sections in the Democratic Republic of the Congo highlighting the violence suffered by the civilian population will also be presented. The relevance and limits of interpretation of this type of study will be discussed using the results of work done in the Gaza strip.

The conference is also an opportunity to introduce and highlight the collaborations without which none of this work would be possible. From MSF field teams to internationally renowned institutions, we would like to thank everyone for their contributions and their constructive criticism.

There will be time for discussion at the end of each session. A simultaneous French-English interpretation will be available throughout the day.

We look forward to your participation in the discussions and sincerely hope you will enjoy this Scientific Day.



Emmanuel Baron
General Director, Epicentre

Journée Scientifique Épicentre/Médecins Sans Frontières - Vendredi 12 juin 2009

8h45 Accueil et café
9h30 Introduction générale

9h45 Session 1
SIDA
Modérateur : Dr. Gilles Raguin, ESTHER, France

- Devenir des patients avant et sous traitement antirétroviral qui ne sont plus suivis par le programme VIH/SIDA à Chiradzulu, Malawi. *Megan McGuire*
- Impact de la disponibilité des traitements antirétroviraux sur l'accès aux soins et les perdus de vue, Chiradzulu, Malawi. *Elisabeth Szumilin*
- Analyse multicentrique de la toxicité à 3 ans des traitements antirétroviraux dans les programmes VIH/SIDA de MSF. *Mar Pujades*
- Pharmacocinétique de la névirapine administrée à pleine dose d'emblée chez des patients co-infectés TB-VIH sous rifampicine: sous-étude de l'essai CARINEMO - ANRS 12146 à Maputo, Mozambique. *Maryline Bonnet*

10h45 Pause café

11h15 Session 2
Recherche clinique
Modérateur : Muriel Vray, Institut Pasteur, France

- Efficacité et innocuité de la quinine vs. artéméther/luméfantrine dans le traitement du paludisme non-compliqué pendant la grossesse, Mbarara, Ouganda. *Patrice Piola*
- Innocuité, efficacité et tolérance à la dihydroartémisinine-pipéraquine pour le traitement du paludisme non compliqué chez des enfants africains : un essai randomisé ouvert de non-infériorité et de phase III dans 5 pays africains. *Carolyn Nabasumba*
- Un nouveau traitement pour la maladie du sommeil au deuxième stade : résultats finaux de l'essai multicentrique de non-infériorité de l'association nifurtimox-eflornithine. *Gerardo Priotto*

12h15 Table ronde
Défis de la mise en œuvre des études cliniques dans les projets de MSF.

Introduction : extrait du film « Dans le service de la maladie du sommeil, Banda, République Démocratique du Congo. MSF/DNDi »

Participants :
- Dr. Manica Balasegaram, Drug for Neglected Diseases Initiative, DNDi, Suisse
- Pr. Frederick B. Nozmo Mukiibi, Mbarara University of Science and Technology, MUST, Ouganda
- Dr. Jean-Hervé Bradol, Médecins Sans Frontières/CRASH, France

13h00 Déjeuner - Buffet sur place

14h15 Session 3
Choléra
Modérateur : Dr. David Olson, Médecins Sans Frontières, USA

- Epidémie de choléra en Guinée-Bissau : importance du contexte spatial. *Francisco Luquero*
- Evaluation du Cholera : une responsabilité éthique. *Jean-Clément Cabrol*
- Evaluation d'un test rapide de diagnostic du choléra en conditions de terrain pendant une épidémie. *Anne-Laure Page*

15h00 Pause café

15h15 Table ronde
Stratégies opérationnelles et place de la recherche dans les épidémies de choléra.

Introduction: mise à jour sur l'introduction des vaccins dans la lutte contre le choléra. *Rebecca Freeman Grais*

Participants :
- Dr. Dominique Legros, Organisation Mondiale de la Santé (OMS) Suisse
- Dr. David Noguera, Médecins Sans Frontières, Espagne
- Dr. Anna Lena Lopez, International Vaccine Institute, Corée du Sud

16h15 Session 4
Présentations Late breaker
Modérateur: Francesco Checchi, Organisation Mondiale de la Santé (OMS) Suisse

17h30 Pot de clôture à MSF France, 8 rue St Sabin 75011 Paris

Epicentre/Médecins Sans Frontières Scientific Day - Friday, June 12th 2009

8.45 Welcome and coffee
9.30 General introduction

9.45 Session 1
AIDS
Chairman: Dr. Gilles Raguin, ESTHER, France

- Outcomes of ART and pre-ART patients defaulting from care in the HIV/AIDS program of Chiradzulu, Malawi. *Megan McGuire*
- Impact of scaling up on access to care and program retention, Chiradzulu, Malawi. *Elisabeth Szumilin*
- Three-year reported severe ARV toxicity in MSF HIV/AIDS programs: a multicentric analysis. *Mar Pujades*
- Pharmacokinetic parameters of nevirapine when initiated without a 2-week leading dose in tuberculosis-HIV co-infected patients receiving rifampicin: substudy of the CARINEMO - ANRS 12146 Trial in Maputo, Mozambique. *Maryline Bonnet*

10.45 Coffee break

11.15 Session 2
Clinical Research
Chairman: Muriel Vray, Institut Pasteur, France

- Efficacy and safety of quinine vs. artemether/lumefantrine in uncomplicated malaria during pregnancy, Mbarara, Uganda. *Patrice Piola*
- Safety, efficacy and tolerability of dihydroartemisinin-piperaquine for the treatment of uncomplicated malaria in African children: a randomized open-label, phase III, non-inferiority trial in 5 African countries. *Carolyn Nabasumba*
- A new treatment for second-stage sleeping sickness: final results of the multicenter, non-inferiority trial of nifurtimox-eflornithine combination therapy. *Gerardo Priotto*

12.15 Round table
Challenges in conducting trials in MSF settings.

Introduction: extract of the film "In the sleeping sickness ward - Banda, Democratic Republic of the Congo -MSF/DNDi"

Participants:
- Dr. Manica Balasegaram, Drug for Neglected Diseases Initiative (DNDi) Switzerland
- Pr. Frederick B. Nozmo Mukiibi, Mbarara University of Science and Technology (MUST) Uganda
- Dr. Jean-Hervé Bradol, Médecins Sans Frontières/CRASH, France

13.00 Buffet lunch on site

14.15 Session 3
Cholera
Chairman: Dr. David Olson, Médecins Sans Frontières, MSF, USA

- Cholera epidemic in Guinea Bissau: the importance of “place.” *Francisco Luquero*
- Cholera evaluation: an ethical responsibility. *Jean-Clément Cabrol*
- Evaluation of a rapid diagnostic test for cholera in field conditions during an outbreak. *Anne-Laure Page*

15.00 Coffee break

15.15 Round table
Operational response and the role of research in cholera epidemics.

Introduction: update on integrating cholera vaccines into control efforts. *Rebecca Freeman Grais*

Participants:
- Dr. Dominique Legros, World Health Organization, WHO, Switzerland
- Dr. David Noguera, Médecins Sans Frontières, Spain
- Dr. Anna Lena Lopez, International Vaccine Institute, South Korea

16.15 Session 4
Late breaker presentations
Chairman: Francesco Checchi, World Health Organization (WHO) Switzerland

17.30 Farewell drink at MSF France, 8 rue St Sabin 75011 Paris

First Session

AIDS

Outcomes of ART and pre-ART patients defaulting from care in the HIV/AIDS program of Chiradzulu, Malawi

M. McGuire[1], T. Munyenyembe[1], S. Althomsons[1], N. Bouithy[1], M. Paih[1], J. Mpunga[2], A. Said[1], E. Szumilin[3], A. Heinzelmann[3], M. Pujades-Rodríguez[4]

[1] Médecins Sans Frontières, Malawi; [2] Ministry of Health, Malawi; [3] Médecins Sans Frontières, France; [4] Epicentre, France

Background
Describing treatment outcomes of patients defaulting from care and investigating contributing factors are important to improve quality of care and to correct mortality estimates.

Methods
We traced ART-initiated and pre-ART patients living within the health catchment area of Chiradzulu and defaulting from care between July 2004 and September 2007. Defaulting was defined as missing a scheduled appointment for >1 month. Up to 3 home visits were attempted. Family members or neighbors reported deaths and moves. Patients found were interviewed to determine reasons for defaulting.

Results
1,637 patients with contact information were traced. Of the 656 patients on ART, 30% were followed in the hospital. Median last recorded CD4 count was 145 [IQR 85-222; n=40] cells/mm^3. 37% died, 13% moved, 18% were alive and 31% were not found. Main reasons for defaulting given by the 190 patients interviewed were poor treatment/information by medical staff (33%), improved health (19%), stigma (19%) and ARV toxicity (9%). Of the 981 pre-ART patients, 20% were followed in the hospital. 35% died, 7% moved, 26% were alive and 29% were not found. 56% of deaths occurred within 3 months of the last visit. Stigma (39%), poor treatment/information by medical staff (26%), improved health (23%) and high transportation costs (17%) were the main reasons for defaulting reported by the 54 patients interviewed. 59% of all patients found returned into care after the survey.

Discussion
In Chiradzulu, 36% of defaulters had died and many did so shortly after care discontinuation, suggesting that deaths were HIV-related. Main reasons for defaulting were dissatisfaction with care or behavior of medical personnel and stigma. Programmatic efforts usually focus on scaling up ART, but the regular evaluation of services provided is essential to ensure the long-term effectiveness of therapy.

Impact of scaling up on access to care and programme retention, Chiradzulu, Malawi

E. Szumilin[1], L. Pinoges[2], E. Poulet[2], M. McGuire[3], M. Pujades Rodriguez[2]

[1] MSF Paris; [2] Epicentre; [3] MSF Malawi

Background

With over 950,000 HIV-infected individuals and an estimated 90,000 AIDS-related deaths per year, Malawi has one of the largest HIV-related burdens. Médecins Sans Frontières began free antiretroviral treatment (ART) delivery in the Chiradzulu District in 2001 and decentralisation of patient care started in 2003. The scaling-up strategy implemented included decentralisation of care delivery to health centres, MSF mobile teams, HIV training and supervision of nurses and counsellors, increase of drug supply, laboratory equipment and logistic support. The means implemented required great increase in yearly budgets.

We aimed to describe effects of scaling up and care decentralisation on care access and early programme attrition.

Methods

We analysed monitoring data to describe time trends in patient clinico-immunological characteristics at enrolment and ART initiation; and 1-year outcomes in adults who received decentralised or centralised care exclusively. Calendar periods considered were: 2000-2002, 2003-2004, 2005-2006, 2007-2008.

Results

By the end of 2002, 941 adults had enrolled in the program and 236 had initiated ART. By the end of 2008, 21 334 patients visited the clinics and 13 802 had started ART. At programme inclusion and at ART initiation, the proportion of patients with advanced clinical disease decreased over time and was lower in decentralised patients: 60% & 71% respectively in 2003-04; and 30% & 57% in 2007-08. The overall percentage of patients with available CD4 measurements at ART initiation increased from 54% in 2003-04 to 88% in 2007-08. Patients receiving decentralised care were less immuno-suppressed than those in centralised care: 191 vs. 145 cell/mm^3 at enrolment, 179 vs. 156 at ART initiation, (median). No changes in median BMI were observed over time. Fifty percent of patients started ART within 1 month of eligibility diagnosis. At 1 year of ART, 80% of decentralised and 70% of centralised patients remained on therapy. Delays in ART start and outcomes remained unchanged over time.

Discussion

Our analysis suggests that the scaling-up through decentralisation has been successful in Chiradzulu despite of the large amount of patients seeking care. Acceptability of care provision at centres closer to home was good. This strategy has required important investments in human & financial resources and training.

Three-year reported severe antiretroviral toxicity in MSF HIV/AIDS programs: a multicentric analysis

M. Pujades-Rodríguez[1], D. O'Brien[2], S. Balkan[2], P. Humblet[2]

[1] Epicentre, France; [2] MSF AIDS Working Group

Background
Evaluations of the tolerability of recommended antiretroviral (ARV) regimens in resource-limited countries are scarce but essential to inform patient management and to optimize therapeutic first-line strategies.

Methods
We used routine monitoring patient data from MSF programs collecting drug toxicity information with the FUCHIA software (Epicentre, Paris). All ARV-naïve adults (>15 years) started on antiretroviral therapy (ART) 3 years before the date of the analysis were included. Kaplan-Meier methods were used to estimate probabilities of first reported severe ARV-toxicity episodes (toxicity leading to a change in the ART regimen). Robust multiple logistic regression with clustering by cohort was used to identify predictors of toxicity.

Results
A total of 15,357 patients treated in 19 HIV/AIDS programs contributed 31,975 person-years to the analysis. At ART start median age was 35 years and median CD4 nadir 94 cells/mm^3 (33-167). 93% of all patients received stavudine-based therapy.
Severe toxicity was recorded in 2,111 (14%) patients after a median of 13 months of ART. Overall toxicity rate was 6.7/100 person-years (95%CI 6.3-6.9) but rates varied across sites from 1 to 24/100 person-years. 5% of patients had peripheral neuropathy, 4% lipodystrophy and 2% cutaneous toxicity. Toxicity was more frequently reported in urban clinics (OR=1.68, 95%CI 1.09-2.56) and in Asians (4.91, 95%CI 3.17-7.61) and increased with time since ART start (trend p-value 0.0006) and lower CD4 nadir levels (trend p-value 0.008). Older patients and those who switched to second-line therapy (1.74 (1.12-2.70)) had also significantly increased risk of toxicity.

Discussion
In MSF-supported projects 14% of patients changed therapy due to toxicity but rates varied across sites. Patients with severe toxicity were at increased risk of later switching to second-line therapy. Use of well tolerated ARV regimens and early management of ARV-related toxicity are essential to maintain patient adherence to treatment and to maximise the duration of ART.

Pharmacokinetic parameters of Nevirapine (NVP) when initiated without 2-weeks leading dose in tuberculosis (TB)-HIV co-infected patients receiving Rifampicin (RMP): substudy of the CARINEMO- ANRS 12146 Trial in Maputo (Mozambique)

M. Bonnet[1], N.B. Bhatt[2], I.V. Jani[2], A. Slawuski[3], C. Silva[1], C. Rouzioux[4], A. Calmy[5], A. Barrail-Tran[6], V. Furlan[6], A.M. Taburet[6] and the ANRS 12146 study group

[1] Epicentre, France; [2] National Institute of Health, Mozambique; [3] Médecins Sans Frontière, Switzerland; [4] Hospital Necker, France; [5] Access Campaign for Essential Medicine, Médecins Sans Frontière, and Geneva University Hospital, Switzerland; [6] Hospital Bicêtre, France

Background

In HIV high prevalence and poor resource countries, TB is the leading opportunistic infection and NVP-lamivudine-stavudine the main antiretroviral therapy (ART). Risk of sub-therapeutic NVP concentration and increased toxicity prevents co-administration with RMP. Skipping NVP leading dose in patients under RMP could avoid sub-therapeutic concentration and treatment failure.

In a randomised open-label trial comparing efficacy and safety of NVP (400 mg without leading dose) versus EFV (600 mg) -based ART initiated 4 weeks after starting TB regimen, we evaluated the NVP pharmacocinetic (pk) in the first 20 patients during co-administration and after completion of RMP-based therapy.

Methods

Blood samples were collected before and 0.5, 1, 1.5, 2, 4, 6, 8, 10 and 12 hours after NVP intake. NVP was assayed in plasma by a validated HPLC assay and pk parameters calculated with a model independent method. NVP trough concentrations (Ctrough) were measured 2 weeks (W2) after initiating ART. Data are means ± standard deviation (SD). Twelve weeks (W12) plasma HIV-RNA and toxicity are presented.

Results

Eleven male and nine female patients (mean weight 52.2kg) were enrolled. Baseline median CD4+ and HIV-RNA were 99 cells/mm^3 and 5.5 $\log_{10}$ copies/mL, respectively. Four patients did not complete the 2nd pk: 2 shifted to EFV due to hepatitis, 1 withdrew consent and 1 had psychosis. NVP Ctrough at W2 (n=19*) were 5.83±2.29mg/L.
NVP pk parameters (n=16):

	No RMP	RMP	Ratio [90%CI]	*p*
C_{min} mg/L	5.74 ±1.83	4.86 ±1.77	1.14 [0.99-1.31]	0.06
C_{max} mg/L	7.77 ±2.24	6.86 ±1.81	1.13 [0.99-1.28]	0.11
AUC_{12} h.mg/L	80.03 ±24.05	70.05 ±20.96	1.20 [1.02-1.42]	0.09

At W12 (n=19*), mean HIV-RNA reduction was 3.5±0.5 $\log_{10}$ with 17 (89.5%) patients reaching <400 copies/mL. There was no severe rash.
**1 patient withdrew consent*

Conclusion

Starting NVP full dosing in RMP recipient patients lead to therapeutic (3mg/L) NVP concentrations and potent plasma HIV-RNA decline. These encouraging results need to be confirmed with the results of the ongoing phase 3 trial.

Second Session

Clinical Research

Efficacy and safety of Quinine vs. Artemether-Lumefantrine in uncomplicated malaria during pregnancy, Mbarara, Uganda

P. Piola[1], C. Nabasumba[2], E. Turyakira[2], M. Dhorda[2], C. Fogg[3], G. Snounou[4], E. Ashley[5], K. I. Barnes[6], R. McGready[7], F. Nosten[7], P.J. Guérin[1]

[1] Epicentre, France; [2] Epicentre, Uganda; [3] Drug Safety Research Unit, United Kingdom; [4] INSERM UMR S945, France; [5] Imperial College NHS Trust, United Kingdom; [6] Cape Town University, South Africa; [7] Shoklo Malaria Research Unit, Thailand

Background
Malaria during pregnancy is associated with maternal and fetal morbidity and mortality. Quinine was the only recommended drug until 2006, when WHO recommended ACTs during the 2nd or 3rd trimesters. However, data on the efficacy and safety of ACTs during pregnancy in Africa are scarce.

Objectives
This study examined the efficacy and safety of the use of artemether-lumefantrine (AL) compared to oral quinine (SQ7) IN treating uncomplicated falciparum malaria during the 2nd and 3rd trimesters of pregnancy in Mbarara, Uganda.

Methods
An open label, randomized, prospective, non-inferiority trial was conducted in which 304 pregnant women were followed weekly until delivery (alpha 5%, power 80% to detect a -5% margin). The cure rate at day 42 (primary outcome) and at delivery were confirmed by PCR genotyping. Adverse events, pregnancy outcome and newborn growth and development at 1 year of age were assessed.

Results
Overall 304 women (152 in each arm of the trial) were enrolled. In the Per Protocol (PP) analysis AL efficacy was high: 99.2% (95.7-99.) at D42 and 98.1% (93.3-99.8) at delivery. SQ7 efficacy was 97.4 (92.1-99.3) at D42 and 95.7 [88.7-98.6) at delivery. In the PP analysis AL efficacy was not inferior to SQ7 at D42 (+1.8% difference with 95% CI lower limit at -0.9%), and at delivery (+2.4% difference with 95% CI lower limit at -1.7%). The trends and significance in the Intention to Treat Analysis were similar. There were no serious adverse events related to the experimental treatment. Intolerable side effects were significantly higher with SQ7, resulting in 4 cases of interrupted treatment in this arm (none with AL). Birth outcomes were similar in both treatment arms.

Discussion and conclusion
The high efficacy and better toleration of a 3 day regimen of AL compared to SQ7 adds further reassuring information to current data regarding malaria in pregnancy treated with artemisinin derivatives. The lumefantrine pharmacokinetic data are currently being analyzed and will be important as we fully interpret these results. More information on the safety of ACTs in the first trimester is needed urgently.

Safety, efficacy and tolerability of Dihydroartemisinin-Piperaquine for the treatment of uncomplicated malaria in African children: a randomized open-label, phase III, non-inferiority trial in 5 African countries

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Background

Artemisinin combination therapies (ACTs) are presently the best option for treating non-complicated malaria; the only fixed dose ACT, manufactured according to internationally recognised good manufacturing practices (GMP) being artemether-lumefantrine (AL).
Registration number: ISRCTN 16263443 (http://www.controlled-trials.com).

Methods

This study tested the non-inferiority of dihydroartemisinin-piperaquine (DHA-PQP), produced according to GMP, versus AL in children 6–59 months old with non-complicated *P. falciparum* malaria in five African countries (Burkina Faso, Kenya, Mozambique, Uganda and Zambia). Patients were randomised (2:1) to receive either DHA-PQP or AL. Non-inferiority was assessed using a margin of -5% for the lower limit of the one-sided 97.5% confidence interval on the treatment difference (DHA-PQP vs. AL) of the polymerase chain reaction (PCR) corrected day 28 cure rate. Efficacy analysis was both intention-to-treat (ITT) and per-protocol (PP).

Findings

Of the 1553 children randomised, 1039 received DHA-PQP and 514 AL. The PCR-corrected day 28 cure rate was 90.4% (ITT) and 95.7% (PP) in the DHA-PQP group, and 90.0% (ITT) and 95.7% (PP) in the AL group. The lower limits of the 97.5% CI of the difference between the two treatments were -2.80% and -2.24%, in the ITT and PP populations, respectively. The risk of recurrent infection at day 28 was significantly lower in the DHA-PQP (ITT: 12.3%; PP 7.1%) than in the AL (ITT: 23.3%; PP 18.6%) group.

Conclusions

Dihydroartemisinin-piperaquine is as efficacious as AL in treating uncomplicated malaria in African children and shows a comparable safety profile. Importantly, it has a superior efficacy in preventing new infections.

A new treatment for *Trypanosoma brucei gambiense* second-stage sleeping sickness: final results of the multicenter non-inferiority trial of Nifurtimox-Eflornithine combination therapy

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Background
Human African trypanosomiasis (sleeping sickness) is a fatal disease occurring in isolated, poor, war-torn areas. Current therapies for second-stage patients are toxic and ineffective (melarsoprol) or impracticable in field conditions (eflornithine). We evaluated the efficacy and safety of a nifurtimox-eflornithine combination (NECT) regimen in comparison to the standard treatment with eflornithine.

Methods
A multicentre randomised, open-label, active control, phase III non-inferiority trial was conducted at four treatment centres in endemic foci of Congo and the Democratic Republic of Congo. Adult patients were randomly assigned to receive intravenous eflornithine 400 mg/kg/day, every 6 hours for 14 days (E); or intravenous eflornithine 400 mg/kg/day, every 12 hours for 7 days + oral nifurtimox 15 mg/kg/day, every 8 hours for 10 days (NECT). Safety assessments included clinical adverse events, haematology, and biochemical monitoring of hepatic and renal functions. Patients were followed up for 18 months. Outcomes were cure rates and adverse events attributable to treatment.

Results
Between 2003 and 2006, 287 patients were enrolled. Cure rates (*per protocol* analysis) were E=91.7% (122/133) and NECT=97.7% (129/132). Drug reactions were frequent. Severe reactions occurred among 28.7% of E-group patients and 14.0% of NECT patients (p=0.002), resulting in nine and one treatment suspensions, respectively. Three patients died in the E group and one in the NECT group.

Conclusion
The efficacy of NECT is not inferior to standard eflornithine. Further, it presents safety advantages. Other advantages include simplicity of administration, lighter logistics (four times less volume of infusion fluids and related materials, shorter hospitalization), lower cost, and potential protection against the emergence of resistant parasites. This therapeutic alternative could improve the results of sleeping sickness programmes while reducing costs.

Challenges in conducting trials in MSF settings

Introduction: extract of the film "In the sleeping sickness ward - Banda, Democratic Republic of the Congo -MSF/DNDi"

Participants:

- Dr. Manica Balasegaram, Drug for Neglected Diseases Initiative (DNDi) Switzerland
- Pr. Frederick B. Nozmo Mukiibi, Mbarara University of Science and Technology (MUST) Uganda
- Dr. Jean-Hervé Bradol, Médecins Sans Frontières/ CRASH, France

Third Session

Cholera

Cholera epidemic in Guinea-Bissau: the importance of place

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Background
As resources are usually limited when responding to cholera outbreaks, knowledge about where to orient interventions is crucial. Here, we describe the cholera epidemic affecting Guinea-Bissau in 2008 focusing on place in order to guide prevention and control activities. We also conducted a cluster analysis to obtain more detailed information in the most affected area of the capital (Barrio Bandim) with the same aim.

Methods
Data collected included age, sex, place of residence, treatment center, and outcome using the WHO clinical case definition. Attack rates (AR) were adjusted by age and sex using a Poisson regression model. For the cluster analysis, we randomly selected 140 houses from the 2,202 structures identified by satellite photo (Google Earth™). Field teams actively searched for cases in the selected houses and in the four closet houses (defined by field teams). We calculated K-functions for households with and without cases, and the difference was used to detect clustering (R© Statistical Software).

Results
A total of 9,394 cases and 73 deaths were reported in the capital, corresponding to an AR of 2.3% and a CFR 0.78%. Barrio Bandim was the most affected area with an AR of 3.9%. From the 140 randomly selected structures in Bandim, we were able to assess 136 (including the four closest) households, a total of 616 were included in the analysis). We found at least one case in 140 households (22.7%; 95CI: 19.5-26.2%). Houses with cases were more clustered than houses without cases ($p<0.001$). In the most affected areas of Barrio Bandim, we estimate 35% of houses had at least one case and in the least affected only 1.0%.

Discussion
Our analysis allowed for the identification of the high risk areas within the capital. The cluster analysis identified two areas within Barrio Bandim at highest risk: a market and an intersection where runoff accumulates waste. Although water, sanitation and hygiene conditions must be improved to avoid further outbreaks, these improvements take time and investment. Preparedness plans should be developed considering the high risk areas identified here.

Cholera evaluation: an ethical responsibility

J-C. Cabrol, Médecins Sans Frontières, International Office, Switzerland

MSF has intervened in the last two major cholera outbreaks affecting a whole country (Angola 2006 and Zimbabwe 2009). These interventions can be considered massive with the involvement of several sections, an important number of personal and subsequent budgets. In these two outbreaks MSF took more than 50% of the cases in charge alone or in collaboration with the MoH. A retrospective evaluation has been done in Angola, one is planned in Zimbabwe unfortunately again retrospective, both with Epicentre.

The purpose of the evaluation in Zimbabwe is to analyze the different strategies, emergency preparedness and timely response with a specific focus on rural settings. The lessons learnt from Angola together with Zimbabwe can help MSF to continue to improve its cholera responses. These evaluations are not only an exercise to look at the positive and negative points and to be accountable, but they are also critical reviews to give recommendations, to propose improvements, to challenge MSF. Our main challenge is our ability to learn from previous experiences, to adapt our strategies with the technical progress, to innovate and to advocate for better investment in the response to cholera outbreaks and prevention. We can considerer the innovation, the strategic adaptation to the context and population as a medical responsibility, an ethical obligation from an organization so implicated in cholera outbreaks.

Evaluation of a rapid diagnostic test for cholera in field conditions during an outbreak

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Background
Early cholera outbreak detection and confirmation is crucial for rapid implementation of appropriate interventions. However, laboratories for culture confirmation are generally difficult to reach from regions where outbreaks often occur. A rapid diagnostic test designed for field conditions would greatly facilitate the early detection of cholera outbreaks.

Methodology
We evaluated the performance of the dipstick immunochromatographic assay Crystal VC (Span Diagnostics Ltd, Surat, India) in field conditions during a cholera epidemic in the city of Lubumbashi in the Democratic Republic of Congo. Suspected cholera patients, according to the WHO case definition during an epidemic, were enrolled in the study after written consent. Stool specimens were collected: (i) to perform the test on site by a laboratory technician trained to use the test and by clinicians with no specific training and only access to test instructions (ii) to perform culture, considered as the gold standard to estimate the test performance, from specimen sent in Cary Blair medium and on filter paper to Institut Pasteur, Paris, France.

Results
The test showed a sensitivity of 92.2% (95% CI 86.8%- 95.9%) and a specificity of 70.6% (95% CI 60.7%-79.2%) when used by a laboratory technician. The specificity was lower when the test was performed by clinicians with no specific training (60.4%, 95% CI 50.2%-70.0%). The test was found to be easy to use and well adapted to field conditions.

Conclusions
The good sensitivity of the test, together with its ease of use, suggest that this test can be used for the early detection of outbreaks in conditions where biological confirmation could delay intervention. However, due to its low specificity, several positive tests from several patients should be obtained before launching an intervention. The low specificity of the test also means that it is inappropriate for individual diagnosis.

Round table

Operational response and the role of research in cholera epidemics

Introduction: update on integrating cholera vaccines into control efforts. *Rebecca Freeman Grais*

Participants:

- Dr. Dominique Legros, World Health Organization, WHO, Switzerland
- Dr. David Noguera, Médecins Sans Frontières, Spain
- Dr. Anna Lena Lopez, International Vaccine Institute, South Korea

Fourth Session

Late breaker presentations

A long-lasting measles epidemic in Maroua, Cameroon 2008-2009: the need to rethink vaccination strategies

F.J. Luquero[1,2], D.A.T Cummings[1], H. Pham[1], P.E. Ngaundji[3], M. Nimpa Mengouo[4], C. Ndong Ngoe[3], C. Galinier[5], R.F. Grais[1]

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Background
Despite a safe, effective and inexpensive vaccine, national childhood immunization program coverage for measles remains insufficient in many African countries and recurrent epidemics occur. In early 2008, the measles surveillance system in Cameroon, consisting of weekly morbidity and mortality reports compiled by the Ministry of Health, identified an increased number of measles cases in the northern city of Maroua (population 245,000). Despite reinforcement of routine vaccination activities in 2008 and two vaccination interventions conducted in October 2008 and January 2009 in response to the epidemic, cases continued to be reported. In order to investigate the causes of this epidemic, we performed a vaccination coverage survey and a case control study to determine vaccine effectiveness.

Methods
We performed a stratified household-based survey using cluster-based sampling to determine measles vaccination coverage. After informed oral consent, the present female head of household, with the aide of a local events calendar, provided the measles vaccination history for all children 9 months to 15 years under her care. For the case control study, cases were obtained from health center registries. Controls were selected among respondents to the vaccination coverage survey.

Results
Both studies were conducted between April 11-17, 2009. A total of 3025 children were included in the vaccination coverage survey. Overall, 32% (95%CI: 20.2-43.6) confirmed measles vaccination by card and 89.7% (95%CI: 86.6-92.9) orally. Considering both card and oral history, 73% (95%CI:68.9-77.3) of children aged 9 months to 5 years and 77% (95%CI: 73.2-81.6) of children 5 to 15 years were vaccinated through the routine system. After the vaccination campaign in January 2009, approximately 7% of all children remained non-vaccinated, 25% had received one dose, 46% two doses and 21% three doses. The overall vaccine effectiveness was above 90%. The main reasons for non-vaccination were lack of information and refusals both in routine and epidemic response vaccination activities.

Discussion
These results confirm that insufficient vaccination coverage was the main determinant of this epidemic. Although the different interventions provided a second and sometimes third opportunity for children to be vaccination, future strategies need to be revised to ensure that interventions reach those children never vaccinated previously.

Infections in severe acute malnourished children: results of a descriptive study

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Background

Few data exist on the ecology of infections in severely malnourished children in Sub-Saharan Africa. As a result, both diagnosis and treatment are probabilistic and empirical. Here, we describe infections found in severe acute malnourished children admitted to the MSF-France inpatient program in Maradi, Niger.

Methods

Inclusion criteria were: 1) age 6 months to 5 years; 2) newly admitted to the inpatient nutrition center; 3) severe acute malnutrition and one or several associated complications; 4) no antibiotic therapy in the previous 7 days; and 5) consent of the mother/caregiver. The desired sample size was 1000 over a one year period. Clinical examinations and biological sampling were performed at admission and during the follow up. Laboratory examinations included bacterial culture (blood, urine, CFS), rapid tests for viral agents, parasitological exams, hematology and biochemistry.

Results

Due to early interruption of the study, only 311 children were enrolled in the study from November 2007 to July 2008. The sex ratio M/F was 1.2 and median age was 13 months. A total of 29 deaths occurred with the principle cause as septicaemia (n=11). Principle clinical diagnoses at admission were diarrhea (38.3%, n=119), respiratory infection (20.6%, n=64) and malaria (14.8%, n=46). Overall, at least one microbiologically confirmed infection was found in 70.1% children (n=218/311). A total of 24.9% (n=75/301) children had a positive blood culture; *Staphylococcus aureus* (n=18) and non typhoid salmonellae (n=14) were the most frequently isolated. A total of 14.7% (n=43/292) had a confirmed P. *falciparum* malaria infection and 26.3% (n=79/300) had a urinary tract infection. Among patients with diarrhea, 20.3% (n=36/177) had at least one bacterial infection (18 *Salmonella* spp., 20 *Shigella* spp.), 13.4% (n=23/171) had rotavirus and/or adenovirus infection, 4.6% (n=8/172) had parasites, and fungal infection with *Candida* in 6.2% (n=11/177). Non typhoid salmonellae and shigellae were resistant to amoxicillin and co-trimoxazole and sensitive to ceftriaxone. *Staphylococcus* aureus was sensitive to oxacillin (n=16/17).

Discussion

The results of this study highlight the importance of further studies on the ecology of infectious diseases in severely malnourished children to ensure appropriate treatment. Diagnostic tools should be integrated into case management of highly vulnerable children suffering of severe acute malnutrition and therapeutic guidelines should be revised accordingly.

What do we expect from a survey in a post-conflict context. An example: Gaza, March 2009

A. Ronsse[1], B. Pedalino[1]

[1] Epicentre, France

Background

Post conflict surveys are usually conducted to 1) provide information not otherwise available on the context in terms of crisis assessment, identification of health related problems; 2) monitor the impact of operations; 3) build evidences for advocacy and documentation. In March 2009, the latter triggered a survey in Gaza following the conflict.

Methods

In our example, 48 days after the conflict a cross sectional household based survey was conducted in 2 out of five Governorates in Gaza strip covering an 801605 population. Data were collected on demography, family perceived needs, casualties and deaths, as well as tetanus vaccination coverage, acute and chronic diseases.

Results

A total of 786 families (6613 individuals) were included. Results could be obtained on: demographic data, immediate and most urgent needs, casualties related to violence, case management, tetanus vaccination coverage, chronic and acute diseases, deaths and main cause of deaths.

Discussion

Although results could be obtained in the Gaza survey, a number of questions on the quality of data collected remains pending. Several factors may have introduced possible bias in the survey: 1) too many objectives, 2) the survey was conducted some time after the conflict, 3) the accuracy of the collected information as only the head of the family was interviewed and may have given his/her own interpretation of, for instance the needs. Other examples of similar surveys, i.e. Irak, Sudan, Chad, DRC show the importance of these type of surveys although they have to be considered only one of element needed to describe the context together with the observation of the field team, the medical data and data coming from other sources.

Impact of war on 3 civilian populations in North Kivu, Democratic Republic of Congo

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Background

After a period of relative calm, in late August 2008, fighting between governmental and rebel forces recommenced in multiple sites across the province of North Kivu in the Democratic Republic of Congo. Eight months after the renewed combat, surveys were conducted to document the impact of the fighting on the civilian population.

Methods

Using the same questionnaire, three surveys were conducted at sitesin which MSF currently runs programmes: Kabizo/Bambou (MSFF), Masisi (OCB) and Kitchanga/Mweso (OCA). The sites are located less than 150 km from one another. Systematic sampling was employed for the survey in Kabizo/Bambou. In Masisi and Kitchanga/Mweso a two-stage cluster sampling method was used. Families were asked about displacement, deaths in their families, violence against persons or belongings (theft), possession of essential non-food items and access to agricultural land.

Results

At each site, at least one third of the population had been displaced at least once since the beginning of the recall period, with the most commonly reported cause for displacement being direct attack on the village or person. The crude mortality rate ranged from 0.2/10 000/day (95% CI: 0.2 – 0.4) in Kabizo/Bambou to 0.7/10 000/day (95% CI: 0.6 – 0.9) in Kitchanga/Mweso. The under-5 mortality rate ranged from 0.7/10 000/day (95% CI: 0.4 - 1.5) in Kabizo/Bambou to 1.5/10 000/day (95% CI: 1.1-2.1) in Kitchanga/Mweso. The most commonly reported cause of death in both in Kabizo (4/15; 26%) and Masisi (31/67, 46%) were medical causes, while in Kitchanga/Mweso it was violence (45/94, 48%). A total of 92, 916 and 909 episodes of violence were reported in Kabizo/Bambou, Masisi and Kitchanga/Mweso respectively with forced labour being the most reported type in Masisi (383/916: 41.8%) and in Kitchanga/Mweso (465/909: 51.2). Over 50% of families in all sites reported theft of property during the recall period. Approximately 36% reported regular access to agricultural land in Kabizo/Bambou, 38% in Masisi and 20% in Kitchanga/Mweso..

Discussions

These surveys re-emphasise both the depth and duration of the impact of war on the civilian populations in North Kivu and the variation over small geographic areas. Our results show the importance of good recording and evaluation, both initial and ongoing, to ensure appropriate humanitarian aid to the population.

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