Track 8: Parasitic Infections **Venue: KEMRI Conference Hall**

5.001

Rodent parasites isolated from KEMRI animal house

David Muriu, Timothy Kamau, Joseph Mwatha, Kimani Gachuhi

CBRD, KEMRI.

Background: In the course of our work in Schistosomiasis Laboratory, we came across two rodent parasites in mice acquired from the Kemri animal house facilities: Syphacia species and Rodentolepis nana. Syphacia are rat and mouse pinworms of the family Oyxuridae. Syphacia are common in wild and pet animals including laboratory animals. Syphacia species have a direct lifecycle of 11-25 days. Infection is through ingestion of food or water contaminated with embryonated eggs which go to the caecum/colon. Rodentolepis nana is the dwarf tapeworm which infects mice. Transmission can be by an indirect mode with cockroaches, grain beetles, or fleas as intermediate hosts. R. nana can also be transmitted by direct ingestion of hexacanth ova or by autoinfection in which the entire life cycle occurs in the host's small intestine. Life cycle takes 14 to 16 days. Humans are susceptible to infections with R. nana. It's important to keep experimental laboratory animals free of these parasites as they may influence the outcome of the various studies being undertaken.

Objectives: (1) To identify eggs and larvae seen in the gut contents of both experimental (2) breeding mice is this an objective (3)Control of the parasites by use of anti-helminthics this features nowhere in the results.

Methodology: 20 mice were sacrificed after being anaesthetized with Sagatal. Individual livers and guts of each mouse were kept separately and digested with trypsin, incubated at 37oC, taken through sieves (710, 410, 212, 125, 106, and 45 um), spun and pellet examined under the compound microscope.

Results: 11/20 samples had Syphacia species ova and 4/19 had ova of Rodentolepis nana.

Conclusion/ recommendations: All rats and mice in the Animal House should be treated with anti-helminthics: The drug for Syphacia species is Fenbendazole whereas the one for is R. nana is Niclosamide. Cockroaches should be eliminated. The source of the parasites should be identified so as to prevent re-infection. Could we add abit on the importance for human infections.

5.002

Factors influencing compliance with mass treatment for Lymphatic Filariasis Elimination in Kenya: quantitative and qualitative results

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Background: Lymphatic filariasis (LF), which is a potentially eradicable neglected tropical disease is caused by filarial worms and transmitted by mosquitoes and is ranked as the second largest cause of disability in the world. In controlling it, programme managers are required to implement their programme using the principal of directly-observed treatment. In Kenya, MDA based on diethylcarbamazine and albendazole, using community-directed treatment (ComDT).

Objective: To identify factors that influence compliance with mass treatment, a retrospective cross-sectional study was conducted in Kwale and Malindi districts after 2008 MDA.

Methodology: In Kwale, Tsimba location was selected for high and Gadini for low compliance, in Malindi, Goshi location represented high and Gongoni low compliance. Using systematic

random sampling, a total of nine villages were selected from the four locations. Quantitative data was collected from a total of 965 randomly selected household heads. For qualitative data, eighty opinion leaders, eighty LF patients with clinical signs were purposively selected and interviewed. Sixteen FGDs were conducted with single-sex adult and youth male and female groups.

Results: Religion was associated with compliance; while about one half (49.1%) from high compared to 34.3% from low compliance villages were Christians, 40.6% from low compared to 29% from high compliance villages were Muslims. The level of income influenced compliance; 27% from low compared to 12.2% from high compliance areas had a main occupation indicative of higher income and 95% from low compared to 78% from high compliance areas owned land, also an indicator of high income. Correct knowledge of cause of swollen limbs was more prevalent, (37%) in high compared to 25.8% in low compliance areas and so was correct knowledge of cause of swollen genitals (26.8% in high compared to 14% in low). Risk perception was higher in high compliance areas although not statistically significant (52% compared to 45%). Access to MDA information which seemed to have been better in high compared to low compliance areas was another contributing factor. Disease burden also influenced compliance; patients from high compliance areas had a higher mean number of years with chronic disease (15.2 compared to 9.7).

Conclusions/recommendations: Alternative methods of drug distribution in high income areas and among the Muslim communities need to be considered. To improve knowledge of etiology of LF, there is need to invest more in health education in both high and low income households. Adequate MDA information should be made accessible to all the communities targeted for treatment.

5.003

Specific Humoral Responses To Schistosoma Mansoni Crude Antigens In Primary School Children Before And After Treatment In Makueni District, Kenya.

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Background: Schistosomiasis mansoni is a tropical disease caused by a trematode in the Genus *Schistosoma* and is prevalent in Kenya among other tropical and sub-tropical countries of the world.. In Kenya the problem is believed to affect over 3 million people. Although there is treatment for the disease, reinfection after treatment is rapid.

Objective: To determine and compare levels of humoral responses to *S. mansoni* crude antigens in school going children infected with *S. mansoni* before and after single and double treatment.

Methodology: 3 stools per child were collected at 0 weeks, 2 weeks and 20 weeks after treatment from 96 pupils of Kikwasuni Primary school and screened for *S. mansoni* by Kato-Katz technique, all the children were treated at 0 weeks and 2 weeks after 50% of the children were given a second treatment with a single dose of Praziquantel 40mg/kg body weight. Also serum for antibody responses was collected at 0 weeks, 2 weeks and 20 weeks. Antibody responses to crude worm and egg antigens were determined by ELISA.

Results: The pre-treatment mean egg per gram of faeces was 230.3 ± 43.5 ($n = 86$) comprising of 256.3 ± 67.9 ($n = 40$) for males and 200.3 ± 51.9 ($n = 46$) for females. Two weeks after treatment with a single dose of Praziquantel 40mg/kg body weight, the infection intensities reduced from mean eggs per gram of 230.3 ± 43.5 to 9.4 ± 2.8 for males and 185.8 ± 47.8 to 21.3 ± 8.8 for females ($t = 5.163$, $p < 0.001$, $df = 85$). Two weeks after treatment, there were increased specific humoral responses (anti-SEA and SWA IgG1, IgG4, IgM, IgA, IgE) except anti-SEA IgG4 in blood of Praziquantel treated children ($p<0.001$). All the specific antibody responses remained high (maintained) 20 weeks after treatment though not at the same level as it were 2 weeks after treatment ($p<0.001$).There were no significant differences in specific humoral responses between the single and double treated children.

Conclusion: Treatment enhances immune responses to schistosomes which may be protective and delay reinfection. However, in this study second treatment 2 weeks following the initial treatment did not boost humoral immune responses.

5.004

Factors influencing Malaria treatment seeking behavior among caregivers of children under five years in Mwea Irrigation scheme.

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Background: Malaria remains a major challenge worldwide with most Malaria illnesses and deaths caused by Plasmodium *falciparum* parasite. About 300-500 m clinical cases are reported each year, 90% in Sub Saharan Africa. The burden of Malaria is greatest among children under five and pregnant women. In 2000, there were about 116 million malaria episodes in children under five years of age, In Kenya, an estimated 8.2 million cases are reported every year. Malaria kills about 26,000 children less than 5 years of age annually. Malaria in Mwea has been reported at a prevalence of 24% based on a parasitological survey among children.

General objective: To determine factors that influence Malaria treatment seeking behavior among caregivers of children under five years in Mwea irrigation scheme.

Methodology: The study was a descriptive cross-sectional that incorporated both qualitative and quantitative methods in data collection. Three locations were purposively selected for the study. Four villages from each location were selected randomly. Quantitative data was collected from a total of 370 randomly selected household heads. Four FGDs were conducted with mothers of children under five.

Results: Majority of caregivers (71.1%) sought treatment from health facilities compared to 28.9% who sought treatment from other sources. However, only 39% sought for treatment promptly. Majority perceived malaria as a major problem in the area (97.2%). 94.2% had adequate knowledge of the causes, and 87.3% believed fever was a dangerous sign in children. Of those who sought treatment from health facilities, 74% had finished primary schooling. Reduced cost and improved attitude of care providers encouraged care seeking from the health facilities.

Conclusion: Continued health promotion activities at community level. Continued sustainable funding of the health care system.

5.005

Distinct pathogenic states in severe malaria reflect parasite rosetting and PfEMP1 expression patterns

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Background: PfEMP1 is a family of surface antigens on *Plasmodium falciparum* infected erythrocytes that are involved in immune evasion and thought to play a role in malaria pathogenesis. Parasites from children with severe malaria preferentially express a minor sub-group of PfEMP1 genes called "cys2".

Objective: To explore the role of cys2 PfEMP1 in pathogenesis

Methodology: we measured in clinical parasite isolates, PfEMP1 expression together with two disease-associated and PfEMP1-mediated cytoadhesion phenotypes, "rosetting" and "clumping". These were assessed in relation to two major life-threatening manifestations of severe malaria, impaired consciousness and respiratory distress.

Results: Using regression analysis we show that the rosetting phenotype is specifically associated with respiratory distress, while cys2 *var* gene expression is specifically associated with impaired consciousness.

Conclusion: The results suggest that specific disease manifestations may result from different underlying parasite immune evasion strategies.

5.006

Malaria Microscopy: Enhancing Proficiency for Clinical and Research Settings

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Background: Microscopy remains the 'reference' method for malaria diagnosis in clinical and research settings yet diagnostic errors such as false positive and negative, species misclassification and parasite quantitation have diminished its reliability as a diagnostic tool. Since accuracy is dependent on skills of microscopists; higher levels of diagnostic accuracy can only be attained through quality training, standardized procedures, objective competency/proficiency bench marks, and robust quality systems.

Objectives: Major objective is to improve proficiency of malaria microscopists in clinical and research settings though training; and sustain attained proficiency levels through periodic assessments.

Methodology: Proficiency enhancement is by way of 10 day microscopy workshops. Components include morphological characteristics of parasites, species differentiation, parasite counting and standardization of operating procedures. Assessment of training endpoints is through pre and post tests. Continuous proficiency assessment is done by sending between 5 – 20 validated blood films at quarterly intervals to participating sites and read independently by site microscopists and results compared with validated results. Sites also send 5 blood films each for cross-checking. Proficiency indicators are sensitivity, specificity, species identification and parasite counting.

Results: Average proficiency of 215 clinical participants trained since October 2007 improved from 51% - 83% in sensitivity, 75% - 85% specificity, 38% - 81% species identification and 46% - 82% in parasite counting. Of the 133 research participants trained, sensitivity improved from 67% - 86%, specificity 82% - 91%, species identification 57% - 83% and parasite counting 66% - 86%. In eight rounds of proficiency assessments, sensitivity was between 88% - 100%, specificity ~ 100%, species identification 65% - 98% and parasite counting 54% - 91%.

Conclusion: Microscopy diagnostic errors remain a challenge to most clinical and research settings. Competency-based training, objective evaluation of training outcomes and continuous proficiency assessments are valuable tools for proficiency improvement.

5.007

PHASE II TRIAL ON THE USE OF DEXTRAN OR STARCH FOR SUPPORTIVE THERAPY IN KENYAN CHILDREN WITH SEVERE MALARIA

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Background: Previous studies done in Kilifi and a previous meta-analysis have shown a consistent survival benefit in children with severe malaria receiving human albumin solution (HAS) compared to other resuscitation fluids. HAS is expensive and not readily available in Africa. This study explores whether other colloids could be used instead of HAS.

Objective: To examine the safety and efficacy of the fluid resuscitation in children with severe malaria and shock using two synthetic colloids, Dextran 70 and hydroxyethyl starch to inform future trial design.

Methodology: An open-label randomised controlled, phase II safety and efficacy trial conducted at the High Dependency Unit, Kilifi District Hospital, Kenya. Participants were

children aged >6months with severe falciparum malaria and acidosis (base deficit >8 mmol/). Emcrolled children received 20 - 40mls/kg boluses of 6% Dextran 70 and 6% hydroxyl ethyl starch (HES 130/0.4). Primary endpoint: resolution of shock over 8 hours. Secondary endpoints include resolution of acidosis, in-hospital mortality, adverse events (allergic reactions, pulmonary oedema, neurological sequelae).

Results: A total of 79 children were enrolled: 39 received Dextran and 40 received HES. No significant difference was observed in Dextran and HES groups for shock resolution at 8 hours: 23/37 (62%) and 25/39 (64%) respectively (p=0.99). Acidosis resolution and respiratory distress was marginally superior in HES group: 3/39 (8%) remained acidotic at 8 hours versus 10/37 (27%) in Dextran arm (p=0.05). There were 4 deaths (5%), two per arm; including 3 deaths in the coma subgroup (3/39, 8%). No other new adverse event was reported.

Conclusions: Correction of shock by volume expansion with either Dextran or HES in children with severe malaria acidosis is safe with low mortality, including the highest risk cases admitted in coma. Both solutions present an attractive and practical option for consideration in future volume resuscitation trials in severe malaria.

5.008

Post treatment changes in cytokine and chemokine production associated with *Schistosoma haematobium*-Induced Urinary Tract Morbidity

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Abstract

Bladder and kidney disease, which affects about 25-30% of subjects infected with *Schistosoma haematobium*, is mediated by T cell dependent granulomatous response to schistosome eggs. The current study examines: 1) whether enhanced IL-10:TNF-α ratio is associated with infection and lack of bladder wall morbidity and whether this translates to diminished praziquantel efficacy; 2) whether active infection is required to sustain a strong egg-antigen-specific IL-10 responses; 3) whether identification of certain chemokines and cytokines in the urine are associated with the presence of urinary schistosomiasis and ultrasound associated morbidity; 4) and does the release of these inflammatory molecules provide insight into the local pathogenesis of disease? Bladder morbidity coincides with early acquisition of infection in children. Specifically, tumor necrosis factor alpha (TNF-α) is decisive pro-inflammatory mediator essential for granuloma formation. Urinary schistosomiasis often infects the majority of children in endemic communities. In humans' immune regulation without disease is characterized by a strong Th2-cell response, low levels of Th1 cells, and CD4+ T cells that express high levels of interleukin-10 (IL-10), which might indicate strong regulatory T (T_{reg})-cell activity. The dominant host immune response with chronic schistosome infection is to antigens released by viable ova trapped in tissues. Some of the persisting infections may represent re-infections or recently acquired infections at the time of treatment since praziquantel does not effectively kill immature worms. It is not appropriate to directly biopsy inflammatory lesions in the bladder-wall; however, urinary schistosomiasis provides an unique opportunity to measure the inflammatory responses in the bladder wall. Chemokines play pivotal roles in the recruitment of inflammatory cells into multiple tissues including the bladder wall and kidney. Previous studies have measured serum or urine cytokine levels and suggest an imbalance of the T cell-mediated immune response.

5.009

Sustained decline in prevalence of lymphatic filariasis in spite of missed rounds of mass drug administration

Sammy M. Njenga[1], Charles S. Mwandawiro[1], C. Njeri Wamae[1,2], Dunstan A. Mukoko[3], Anisa A. Omar[3], Masaaki Shimada[1,4], Moses J. Bockarie[5], David H. Molyneux[5]

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5 *Centre for Neglected Tropical Diseases (CNTD), Liverpool School of Tropical Medicine, Liverpool, UK*

Background: Mass drug administration (MDA) of antifilarial drugs is the principal strategy recommended for global elimination of lymphatic filariasis (LF) as a public health problem by the World Health Organisation (WHO). Kenya launched a National Programme for Elimination of Lymphatic Filariasis (NPELF) in Kilifi District in Coast Province, in 2002.
Objective: This long term longitudinal study was conducted to examine the impact of 4 rounds of MDA given to 8 study communities over 8-year period, on LF infection.
Methodology: The study was conducted in an LF-endemic focus along River Sabaki in Malindi District. The first round of MDA was administered in April 2002. Parasitological surveys were conducted to assess the impact of MDA on LF infection. The most recent post-MDA survey was conducted in April/May 2009. *Wuchereria bancrofti* microfilariae and filarial antigenaemia were determined using the counting chamber method and immunochromatographic (ICT) test, respectively.
Results: The study especially paid attention to the fact that annual MDA was not administered for several years and focus on the effect this may have for the progress of control programmes. The overall prevalence of microfilariae declined significantly from 20.9% in 2002 to 0.9% in 2009. Similarly, the prevalence of filarial antigenemia declined from 34.6 % in 2002 to 10.8% in 2009. All the examined children born since the start of the programme were negative for filarial antigen.
Conclusions/Recommendations: This study suggests that two consecutive rounds of MDA with diethylcarbamazine plus albendazole given yearly, with high treatment coverage, have the potential to significantly reduce the prevalence of microfilariae (and circulating filarial antigen). Subsequent rounds of MDA appear necessary to sustain the effects of the first two rounds. An evaluation of the role of vector control, assumed to complement MDA during LF elimination activities, is recommended.

5.010

Sustained decline in prevalence of lymphatic filariasis in spite of missed rounds of mass drug administration

Sammy M. Njenga[1], Charles S. Mwandawiro[1], C. Njeri Wamae[1,2], Dunstan A. Mukoko[3], Anisa A. Omar[3], Masaaki Shimada[1,4], Moses J. Bockarie[5], David H. Molyneux[5]

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5.011

Concentration *of leishmania donovani* amastigotes in bone marrow aspirates for diagnosis of visceral leishmaniasis.

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CCR-Kemri

Background: Visceral *leishmanisis* in Kenya (VL) or Kala-azar is a disease caused by intracellular . protozoan parasite of the *Leishmania donovani* complex. Routine diagnosis of this
disease in laboratories is by the detection of antibodies against *leishmania* in the suspect's blood and then confirmed microscopically by demostration of *Leishmania amastigotes* (LD) on smears made directly from splenic or bone marrow aspirates. The presence of *leishmania promastigotes* in cultures is thought to be even better that microscopy results. In this study, two method of demonstrating amastigotes on smears made from bone marrow aspirates were compared. In the first (old) method, thin bone-marrow smears were made on microscope slides before bone marrow material cloted in the syringe while in the second method (concentration), the smears were made after the bone-marrow material was left to clot and all the fluid (serum) removed from the clot. Two sets of cultures were done on each sample using the two different methods of sample preparation.

Results: A total of 164 bone marrow aspirates were done on 81 patients who were on the Sitamaquin study at the Centre for Clinical Research. Out of 164 bone marrow aspirates, 18 direct bone marrow smears were positive for leishmania donovano (LD) while all the 22 cultures were positive for leishmania promastigotes. All the 22 smears made from clotted bone marrow aspirates and the corresponding cultures were positive. Therefore, the old method gave a sensitivity of 84.615% and a specificity of 100 % . The improved diagnostic method (clot method), gave 100% sensitivity and specificity, the same as the cultures.

Conclusions & Recommendations: The microscopy of thin smears from bone marrow gave 18 % false negative results that could have made these patients declared cured were it not for the clotted bone marrow smears and the cultures.The microscopy on bone marrow thin smears for the detection of *leishmania donovani* (LD) is difficult due to the presence of too many macrocytic immature leukocytes, erythrocytes and granules which make difficult to make a good smear. It was very easy to identify promastigotes in cultures made from the bone marrow clots instead of the un-clotted bone marrow aspirates. In order to get good reliable and reproducible results; both thin and clotted smears should be made from each and every sample. Cultures should be set using bone marrow clot instead of direct from un-clotted aspirate.

Track 8: Parasitic Infections **Venue: KEMRI Administration Block (Reception Area)**

5.012

Schistosomiasis and soil transmitted helminths in informal settlements around Kisumu City

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Background: Access to health interventions continues to be a major challeng for a large proportion of underserved urban populations in Kenya where parasitic diseases are endemic. The community-directed intervention (CDI) strategy of health care delivery has worked very well and shown a lot of promise in several rural settings throughout Africa, but has not been tested in urban settings.

Objective: The goal of ongoing activities is to test the feasibility of equipping communities living in informal urban settlements in Kisumu City with strategies that will enable them to effectively take charge in control of schistosomiasis and soil transmitted helminth (STH) infections that are widespread debilitating but preventable parasitic diseases, using the CDI strategy. Partners in the study include the Ministry of Education, Municipal Council of Kisumu, local administration and Ministry of Health. This poster addresses phase I of the study, which provides a framework for the CDI entry strategy.

Methods: We collected data on schistosomiasis and STHs from 1,308 primary school children using the stool-based Kato-Katz technique, and identified water sources & healthcare facilities in informal settlements around Kisumu.

Results: Up to 34 % of children were infected with either *Schistosoma mansoni*, hookworm, *Ascaris lumbricoides* or *Trichuris trichiura*, 21% were infected with *S. mansoni,* whereas 16.2 % were infected with one or more other STH.

Conclusion: At 21% *S. mansoni* prevalence, this urban community falls under WHO's Moderate-Risk community category, with a recommendation of treating all school-age children (enrolled and not enrolled) once every two years, and also adults considered to be at risk.

Track 9: R&D **Venue: KEMRI Administration Block (Reception Area)**

7.001

Title: Establishing a national nutraceuticals and phytomedicines development pipeline: Process optimization of a herbal based low sodium table salt.

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Background: Development of a natural products innovation system provides the much needed impetus for the successful integration of traditional medicine into the national health system. The World Health Organization (WHO) estimates that 80% of the world's

population relies on these "alternative" plant-based medicines as their primary medical intervention. Impediments to the integration of traditional medicine with conventional practice include the unavailability of safety, quality and efficacy data and value added herbal products. Papyrus reed ash has been used traditionally as a salt substitute in Western Kenya. Early studies carried out at KEMRI indicated that Potassium salt substitution derived from local papyrus reed has a favourable K/Na ratio that is suitable for use to regulate high blood pressure in hypertensive patients when used in place of table salt.

Objective: The general objective was to establish a national development pipeline for the development of a nutraceutical from natural products.

Methodology: The plant material was collected from two study sites in Rift Valley then cleaned, chopped, dried and ashed at KIRDI. Extraction was done using the laboratory scale method at KEMRI and an optimized method for industrial scale at KIRDI. The industrial method was developed and optimized based on the laboratory scale method.

Results: The ash percentage yield for the two samples was between 23 and 29 %. The herbal salt yield for the laboratory scale processing was about 10 % for both samples but 13 and 22 % using the optimized extraction procedure for the Nakuru (KTM-4) and Naivasha (KTM-3) samples, respectively. On further purification of the pilot scale herbal salt, pure herbal salt was obtained. Preliminary results show the K/Na ratios to be 4.48 for KTM-3 and 18.02 for KTM-4. Elemental analysis results indicate the presence of both essential and non-essential elements. Heavy metal contamination was also found to be within the WHO provisional tolerable weekly intake (PTWI) values /Acceptable Daily Intake.

Conclusion: The preliminary data indicate this product will not only be favourable for persons with mild hypertension but can also be a source of other essential trace elements such as chromium, Zinc and manganese among others.

7.002

Drugs for Neglected Diseases Initiative – Overview

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Background

Drugs for Neglected Diseases I*nitiative* (DNDi), is a collaborative, patients' needs-driven, not-for-profit drug Research and Development (R&D) organization that is currently developing new treatments against human African trypanosomiasis (HAT), visceral leishmaniasis, Chagas disease and malaria. DNDi was established in 2003 by Institut Pasteur and Médecins Sans Frontières along with four publicly-funded research organizations in neglected disease-endemic countries – including the Kenya Medical Research Institute (KEMRI). Working in partnership with industry and academia, DNDi has built the largest ever R&D portfolio for the kinetoplastid diseases and currently has 6 clinical and 4 pre-clinical projects.

Objectives: The primary objectives are to (1) Deliver 6-8 new treatments by 2014 for leishmaniasis, sleeping sickness, chagas disease and malaria. (2) To establish a robust R&D portfolio. The secondary objectives: - (1) To strengthen existing capacity in disease-endemic countries. (2) To raise awareness and advocate for increased public responsibility.

Methodology: Underscoring the need for public leadership and involvement in neglected diseases, DNDi drew Founding Partners primarily from the public sector in neglected disease-endemic countries: the Foundation Oswaldo Cruz /Farmanguinhos in Brazil, the Indian Council for Medical Research, KEMRI, the Ministry of Health in Malaysia, Médecins Sans Frontières, the Institut Pasteur, and TDR as special observer. DNDi has a small team of permanent staff in Geneva, 4 regional support

offices in Kenya, India, Brazil, and Malaysia; an office in North America, and 2 regional project support offices in the Democratic Republic of the Congo and Japan.
Results: DNDi successfully delivered its first product in 2007, a fixed-dose antimalarial ASAQ, ASMQ in 2008 and Nifurtimox-Eflornithine Combination Treatment (NECT) for HAT, in 2009. This year, DNDi will deliver new treatments for VL in both South Asia, with the completion of the VL Combo-07 trial, and in East Africa with the completion of the LEAP 0104 trial. DNDi is currently carrying out a significant amount of its clinical research supported by its coordination and data management team in KEMRI working in tandem with local partners, including Leishmaniasis East Africa Platform.
Conclusion: Seven years since DNDi was founded, significant progress has been made in delivering quality, affordable and adapted treatments for neglected diseases. Strong partnerships have been set up.

7.003

Kenya vision 2030 and the national innovation system: challenges and opportunities in Biomedical Research

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Background: Although the link between poverty and health has been long documented, national policy on health in national development continues to be solely informed from the social services point of view. Consequently, this unbalanced view has led to the sidelining of biomedical R&D in the national health system, with Kenya and the region remaining a net importer of foreign technologies or health interventions. Whereas public health objectives may be met in the short term, this is often unsustainable as the achievements are made at the cost of undermining the local capacity for innovation and wealth creation through value addition, job creation, and the attraction of foreign direct investments (FDI) among others.
Objective: Biomedical R & D in Kenya faces several significant challenges from both within and without in the development and commercialization of R&D including the lack of venture capital, poor market structures and limited demand for local IP in the regional pharmaceutical sector, among others. This paper discusses the various initiatives, opportunities and strategies available to biomedical research institutions in order to play their expected role in the achievement of *Kenya Vision 2030.*
Methodology: The paper focuses on the business side of science not the R&D; with the biotechnology sector's prevailing business models *vis a vis* a literature review of salient national/regional factors serving to inform the discussion and KEMRI's strategy development as one of the leading biomedical R & D institution in Kenya and the region.
Recommendations: The science-business gap between the scientific community and the industry, financial institutions and policy makers may be the greatest impediment towards participating in the global knowledge economy. The promotion of innovation systems thinking in the national health system, STI and industrialization policies and *modus operandi* is therefore critical for KEMRI's effective contribution towards *Kenya Vision 2030.*

7.004

Leishmaniais East Africa Platform (LEAP): Strengthening Clinical Research Capacity in Africa

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Background: The Leishmaniasis East Africa Platform (LEAP), is a regional clinical research network collaborating to study new treatments for African patients suffering from visceral leishmaniasis (VL). Founded in 2003 in Khartoum, Sudan, LEAP incorporates partners from across the spectrum of clinical research, and disease control organizations, which are working in leishmaniasis-endemic countries in East Africa. Currently composed of more than 50 members from 4 countries, LEAP serves to strengthen clinical research capacity, which is lacking due to the remoteness and geographical spread of the patients, most of whom are in the most impoverished or rural regions of Africa.

Objective: (1) To evaluate, validate, and register improved options that address regional needs for VL. (2) To provide capacity strengthening for drug evaluation and clinical studies in the region.

Methodology: As part of its role, LEAP brings its members together at biannual meetings. In addition, physical upgrading of facilities directly related to clinical trials is taking place within disease endemic regions. Such capacity strengthening includes the building and renovation of hospital wards, clinics, and health posts; renovation and re-equipping of clinical laboratories; and training of health service personnel with particular emphasis on building expertise in clinical trial methodology, Good Clinical Practice, Good Clinical Laboratory Practice and Ethics.

Results: LEAP has successfully completed Paramomycin multi-centre clinical trial. The results of this trial will be discussed in detail in another presentation. AmBisome clinical trial for Africa as well as rapid diagnostic tests evaluations are currently on going. Strengthening of clinical trial capacity in Ethiopia, Kenya, Sudan and Uganda is ongoing in terms of personnel, communication and infrastructure.

Conclusion: Solid gains have been made by LEAP in the last 7 years. Clinical trials capacity has been strengthened. LEAP is a success story of a regional partnership.

7.005

A Multicentre Comparative Trial Of Efficacy and Safety Of Sodium Stibogluconate (SSG), Paromomycin (PM) and The Combination of SSG And PM as First-Line Treatment For Visceral Leishmaniasis In East Africa - LEAP 0104.

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Background: Visceral leishmaniasis (VL) or Kala-azar is the most severe form of leishmaniasis. It is estimated that 500,000 new cases world wide of VL are diagnosed annually. 90% of VL cases occur in developing countries: India (especially Bihar), Bangladesh, Nepal, North Eastern Brazil and Sudan. For the past 100 years, antimony has been the first line of treatment for VL cases despite considerable toxicity and the requirement for 4 weeks hospitalization. Resistance to antimony coupled with emergence of HIV associated with VL is on the increase. New and improved treatment options are urgently needed to replace or complement the few currently available drugs. The wide variety of epidemiological situations and clinical presentations of this disease further warrant a series of treatment options instead of one single treatment or control strategy for the affected populations.

A phase III multicentre, prospective, open label, parallel group, comparative trial was set up to determine the efficacy and safety of sodium stibogluconate (SSG) 20mg/kg/day given for 30 days, Paromomycin (PM) 15mg/kg/day for 21 days, and a combination of SSG and PM, 20mg/kg/day, 15mg/kg/day respectively, given for 17days in the treatment of patients suffering from VL in Ethiopia, Kenya, Sudan and Uganda.

Objectives: (1) Registration of PM as new treatment for VL in East Africa (Sudan, Ethiopia, Kenya & Uganda) (2) Evaluation of shorter course (17 days) combination of PM+SSG as alternative treatment for VL

Methods: Patients who had clinical symptoms and a confirmed parasitological diagnosis of VL by splenic aspirate, lymph nodes aspirate or bone marrow aspirate and who fulfilled the inclusion/exclusion criteria and had a signed informed consent were enrolled.

Patients received either SSG alone given intramuscularly or Intravenously IM/IV (according to usual hospital practice) for 30 days or paromomycin alone given IM for 21 days or a combination of SSG and PM given for 17 days, for the treatment of VL. The primary endpoint was cure rate at 6 months post treatment. Secondary endpoints were cure rate at end of treatment (Day 31 for SSG, Day 22 for PM, Day 18 for PM + SSG) and at three months post treatment.

Results: In the Intention to Treat (ITT) population 328/359 (91.4%) of patients in the Combination arm and 337/359, (93.9%) of patients in the SSG arm had parasite clearance at 6 months after End of Treatment (EOT). The difference in efficacy between arms was 2.5% (95% CI: -1.3% to 6.3%, p = 0.198). Treatment Emergent Adverse Events (TEAE) occurred in similar proportion of patients in the two arms: 207/381 (54%) of patients in the Combination arm and 237/386 (61%) of patients in the SSG arm had ≥1 TEAE. There was no overall difference in the TEAE adjusted rate ratio was 1.01 (95% CI: 0.88 to 1.17, p = 0.851). In each arm, approximately 3% of patients had SAEs (13 in the Combination and 10 in the SSG arm) that were considered drug-related, but these resolved by the end of the trial.

Conclusions: The difference in efficacy between PM and SSG was between 3.6% and 15.7%. The combination appeared to be as efficacious and safe as the standard treatment with SSG with no differences seen between sites and countries. The combination is cheaper and of shorter duration, thereby offering a potential advantage for health care providers and patients. Registration and recommendation of the combination is now ongoing in Sudan, Ethiopia, Kenya and Uganda. The WHO expert committee on the control of Leishmaniasis has recommended combination treatment as the preferred treatment regimen for VL in East Africa

7.006

Good Clinical Practice and Data Management of Clinical Trials for Neglected Tropical Diseases: Experiences and Possibilities

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Background: Drugs for Neglected Diseases initiative (DNDi) and Leishmaniasis East Africa Platform (LEAP) have been conducting randomised controlled trials on the treatment of Visceral Leishmaniasis (VL) since 2004. The central Data Centre is responsible for creation and maintenance of data management and statistical analysis systems that meet good clinical practice (GCP) standards, for reporting to national, regional and international regulatory organisations. The supported trials are primarily phase II and III.
Objective: To highlight our experience as a data management unit and to present aspirations for future improvements and skills sharing.
Methods: Presentation is made of data flow through the data management system, from retrieval on-site to database lock. At each stage, measures taken to ensure data quality and validity are reported according to standard operating procedures (SOPs). Possibilities for automation of each part of the data management process and the use of Open-Clinica, an open-source database software resource, are illustrated.
Results: *OpenClinica* has several advantages including generation of an audit trail of data changes and continual development by an international user community willing to share their technical expertise. The semi-automated *Query Management and adverse event coding systems* have substantially reduced operating time compared to previous manual procedures.
Conclusion: The DNDi/LEAP Data Centre is now an established data management group, with the technical skills and resources to manage large clinical trial databases according to GCP requirements. The next steps are to set up pharmacovigilance studies and to pilot electronic data capture possibilities with the aim of improved automation of data management systems. We are also keen and open to collaborative activities with other organizations within KEMRI as well as those in the region so as to share our skills and expertise.

7.007
The importance of Lot to Lot testing in good clinical laboratory practice and research

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Background: Laboratory reagents and control materials are exposed to many variables due to conditions in transportation and storage environments in different laboratory settings. The validation of new reagent kits with old reagent kits is performed to ensure that, in spite of varying environmental conditions, there are no significant differences in the results obtained when different lot numbers of reagents are used.
Study results are impacted greatly by several factors including specimen collection, testing personnel, equipment status and to a great extent, the quality of reagents used in the running of assays. Misleading results can be obtained if the quality of the reagents used is not monitored.
Methodology: New lots of reagents should be validated by running them in parallel with the old lot numbers and the results obtained should be within the defined acceptability ranges. A lot to lot result sheet is filled with the appropriate information including but not limited to: Date of assay, Testing Technologist initials, Lot to lot sample type, Kit/assay or reagent name and manufacturer, Old lot/batch number and expiry date, New lot/batch number and expiry date, Old lot/batch results and new lot/batch results, Results interpretation (Criteria for acceptance and space to indicate if the results obtained on

the new lots were acceptable) and any corrective action taken. Results should be reviewed and confirmed that there is agreement between the results for the two lots. Results are entered in the worksheet and conclusions made. Lots checks are done in cases where the same lot is in use.

Conclusions/Recommendations: Laboratories must document that samples are tested in parallel with each current lot and new lot before the new lot is put in use. Relevant documentation must be filled at all times and kept for audit purposes and for monitoring of the test kits performance over time.

7.008

Evaluation of Demographic Data Collection via Handheld Computers in Western Kenya

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Background: Previously, the Demographic Surveillance System (DSS) used a scannable forms-based data management system. The expanded vital statistics and demographic data system is voluminous and complex, utilizing 25 forms collected from 205,000 people three times yearly. Large reference books with details of households and individuals are printed for field use. Forms with errors were returned to the field for correction. This system required substantial time and personnel to manage, had numerous errors, and was subject to backlogs and scanner breakdowns.

Methods: A data collection system was developed for handheld computers (PDAs) aimed at improving data quality at the collection point, and reducing costs. System benefits included: reduced paper purchasing, printing, and storage needs; reduced data processing time and personnel, reduced field trips for error correction, saving gas and vehicle maintenance. The electronic forms mimicked paper forms to simplify training needs. We replaced the reference books with PDA-based queriable databases. We created data and form usage checks.

Results: The PDA system eliminated human errors by more than 90%, data errors by 80%, and data management staff costs by 78%. Collecting consistent field data eliminated the need for data checking clerks. The time lag between data collection and reporting reduced from six weeks to less than 1 week.

Conclusion: The PDA system improves data quality while reducing costs and time requirements. The system requires programming skills and the initial cost of PDA purchase, but eliminates the needs for expensive scannable forms software and high-speed scanners. The system, in use for its third round, operates smoothly.

7.009

A Study on Effect of Education on Biosafety Techniques in NUITM-KEMRI Laboratory

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Background: The principle of biosafety is that laboratory workers are not infected and that there should be no contamination of the surroundings (WHO Laboratory biosafety manual, 3rd Edition 2004). The Institute of Tropical Medicine, Nagasaki University (NUITM) in collaboration with Kenya Medical Research Institute (KEMRI) installed the biosafety level 2 and 3 laboratory (P2 and P3 lab) at the Center for Microbiology Research in 2007 and a variety of pathogens including *Vibrio cholerae* and *Mycobacterium tuberculosis* as well as viral pathogens such as West Nile and Yellow fever virus have been handled.

Objective: The aim of this study was to evaluate the quality of biosafety measures at level 2 and 3 (P2 and P3) laboratories as enforced by the laboratory workers and researchers and to document the challenges faced in the process.
Methodology: We have, since 2007 conducted annual biosafety seminars to introduce the concept, followed by short term practical training in P3 which included manual biosafety handling of biological substances and monthly biosafety meetings. Furthermore, we evaluated the process and included post-seminar results and pre- and post- practical training results. The monitoring on biosafety practices was evaluated by questionnaire and supervision.
Results: It was observed that biosafety practices among the laboratory users greatly improved after the seminar and the practical training. Training on biosafety techniques and monthly biosafety meetings enhanced and improved sensitivity of users in the laboratories.
Conclusions/recommendations: Sustainability of the practical implementation remains a challenge.
Refresher training to the laboratory workers on the aspect of biosafety should be carried out periodically.

7.010
Digitized mobile data management by means of smart phones, bar coding and PDS's in the CGHR schistosomiasis research program
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Background: Digitized Data Collection is becoming a popular if not necessary means of Information Consolidation from the point of collection. Many research programs within the country and our research centers are exploring ways of incorporating the use of such means.
Objective: We wish strengthen data management and sharing among stakeholders using smart phones.
Methods: Schistosomiasis Data and Field teams are using PDA's and just recently introduced are the smart phones. The PDA's have presented the capability of both Form based data entry with pre-selection capability (Drop Down boxes & options) as well as the ability to integrate other accessories to itself like GPS Receiving units For Geo-Coding and mapping information, this can be included in the forms being entered within it. Smart phones are now being integrated to the very operations of Schistosomiasis Field / Data operations. This has seen the entry of the Android Based Mobile devices that are open source and allow a vast array of software and development aspect to be integrated. These include but are not restricted to barcode reading, Picture ID and Relational databases and field forms. Bar coding is also being integrated with lab operations to go hand in hand with data collection operations.
Results and Conclusions: these efforts are aimed at an integrated system to allow for a more thorough and efficient data management system that is eventually consolidated through a live streaming online data based web server within the Program in conjunction with the ICT department

7.011

Challenges of Laboratory Accreditation for Clinical and Research Purposes

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Background: Laboratory accreditation is a development in clinical laboratory world to provide third-party certification of competency in performing a specific test or type of tests. Accreditation is a formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do. However, laboratories seeking accreditation do encounter challenges that are either specific to an individual laboratory and need to be addressed solely by the laboratory, or require the collaboration between the laboratory and the manufacturer of the in vitro medical diagnostic devices/reagents.

Objective: To identify the challenges of laboratory accreditation process and provide possible solutions to the challenges/issues of laboratory accreditation.

Methodology: Review of laboratory accreditation processes was done at the Clinical Research Center Laboratory at KEMRI/Walter Reed Project Laboratory between the years 2009-2010. This involved review of all processes that are followed in getting accreditation.

Results: From the analysis, the following were some of the challenges identified: Choice of accrediting body/process; Levels of Staff development and qualification; Establishment and implementation of Standard Operating Procedures; Harmonization of manuals; Validation/Verification of laboratory procedures/equipment; Definition and determination of reference values/ranges; Equipment maintenance schedules; Proficiency Testing processes; Budgetary allocation issues; State of Physical facility and Logistics /Co-ordination of processes.

Conclusions / Recommendation: Effective management of laboratory accreditation challenges allows a laboratory to produce high quality and reliable data, create a unified standard of acceptance, enhance self confidence, and enjoy benefits of recognition of competence. Overcoming the challenges with total commitment to quality enhances capabilities of research laboratories moving forward to meeting its aspiration of vision 2030 of being world class.

7.012

Preventing clinical trial co-enrollment through biometric participant identification: the experience of 3 HIV prevention trials in Nyanza Province

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Background: Participant co-enrollment in simultaneous biomedical intervention trials can be unsafe and scientifically problematic, but is difficult to prevent. Three HIV prevention trials in Nyanza Province undertook a novel collaboration, using identical biometric methods for participant identification and periodic intra-study database merging, to prevent and/or identify co-enrollment by participants.

Methods: All studies implemented identical hardware, software, and methodologies for fingerprinting to identify study participants at each study visit. Study-specific biometric

identifier databases for participants were developed; these did not include other identifying information and did not store fingerprint images directly (to protect confidentiality). Databases from each site were merged at regular intervals to determine if participants had been screened and/or enrolled in one study before participating in another. All activities were IRB-approved from all relevant authorities for each study.

Results: Following initial challenges in standardizing fingerprint capture methodology across sites and optimizing accuracy of database merging procedures, the team was able to successfully determine retrospectively that 2 out of 4891 participants had been screened for more than one study. 1 out of 1488 participants was found to be enrolled in two studies simultaneously, and the study teams are working together with one another, their protocol teams, and the affected participants/couples to resolve this situation.

Conclusion: Biometric participant identification using fingerprinting offers great potential for prevention of co-enrollment in intervention trials with overlapping recruitment areas and study eligibility criteria. Care must be taken to ensure consistency of procedures across sites/studies and to validate if database merging and querying for co-participation is effective and timely in order to prospectively prevent participants from enrolling in multiple studies. Issues of participant autonomy, safety, scientific validity, confidentiality and research ethics must be carefully managed when implementing such novel collaborations between studies.

7.013

Fingerprinting in the KEMRI/CDC Health & Demographic Surveillance System (HDSS), Western Kenya, 2010

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Background: The western Kenya KEMRI/CDC HDSS faces challenges in the re-identification of individuals resident in the HDSS due to similar names, imprecise identifiers such as age, and high mobility within the area. These challenges have resulted in double enumerations and failed linkages between household and clinical data. We implemented a fingerprinting system for individual identification. We sought to evaluate public acceptability of fingerprinting as a mode of individual identification.

Methodology: We implemented a fingerprint identification system using Graiule fingerprint SDK as a platform. We used the Secugen Hamster Plus fingerprint reader and accompanying system to capture fingerprints of the HDSS and the non-HDSS participants at the households in the HDSS. Children less than1 year of age were enrolled by referencing them to the parents or guardians. We assessed acceptability by seeking consent before enrolling the individuals.

RESULTS: From July 2010 through December 2010, we targeted a total of 326,741 individuals; 115,074(35%) individuals of the target could not be reached due to migration, death or were unknown to the individuals leaving in the compound, 33,538(10%) individuals required a revisit, 8,842(3%) individuals refused to be consent, 165,287(51%) individuals consented and their fingerprints were attempted to be taken of which 155,108 (94%) individuals were successfully enrolled. During enrollment, a 2% sample of individuals successfully enrolled was revisited to re-identify the individuals. We found that 68% of the individuals were successfully re-identified. The challenges encountered included difficulty in capturing clear fingerprints of children less than 5 years of age and adults over 60 years of age.

Conclusion: Although our data are preliminary, the fingerprint system appears to be acceptable and largely reliable. Fingerprinting will likely improve the re-identification of individuals in the HDSS, thus potentially facilitating more accurate and efficient linkages between health facility and household surveillance data. Such linkages can be used for important public health analyses and design of interventions.

7.014

Challenges of conducting clinical trials in low-resource settings: A phase III RCT in Western Kenya

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Background: The past decade has witnessed the introduction of life-saving interventions into developing countries. The early clinical trials for these interventions were conducted in the developed world, however, rigorous phase II and III trials must be conducted in developing countries where the affected populations are. We sought to evaluate the challenges of conducting clinical trials in resource-poor settings, by evaluating challenges encountered during a rotavirus vaccine trial.

Methodology: From July 2007 to October 2009, we conducted a randomized, placebo controlled, double blinded study of the safety, immunogenicity and efficacy of an oral rotavirus vaccine with 1308 infants 4-12 weeks old,consented and enrolled, given study vaccine (RotaTeq^{TM}) or placebo according to 6,10,14 weeks (EPI) schedule and followed up for 12-20 months. Challenges were identified and recorded from periodic meeting minutes and solutions implemented, as necessary.

Results: The observed challenges included: 1) Limited pool of staff with research experience; 2) a study community that was research naïve; 3) community skepticism and expectations before, during and after the study; 4) delayed participant appearance for scheduled visits; 5) participant loss to follow up; 6) Lack of appropriate peripheral clinics to aid planned enrollment. We managed these challenges, respectively through: 1) Adequate initial and sustained study staff training on the protocol, research ethics, good clinical practice and data quality assurance program; 2,3) community education through practical demonstrations at 'Barazas' 4) providing diaries to caregivers of participants to remind about next visit dates, supplemented with periodic reminders by study staff; 5) phone calls to reach missing participants; 6) renovation of facilities, including required equipments and supplies. The study successfully enrolled the targeted number of children; clinical monitors did not find excess errors and protocol deviations beyond what is expected for studies in developed countries.

Conclusion: Our experience revealed that clinical trials can run successfully in resource-limited settings, through proper planning, understanding of the study site/area, adequate staff training on research ethics and good clinical practice and the protocol, proper and continuous community engagement, and established efficient communication structures within the study and to the community.

7.015

Electronic Data Capture for randomised controlled trials and pharmacovigilance in resource limited settings: a pilot study proposal

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Background: Historically, data collection for clinical trials is a very manual process involving use of pen and paper which is slow and labour intensive. Electronic data capture (EDC) is not a new concept, yet it has taken long to be adopted. It encompasses several types of technology depending on who is using it; from electronic replacement for paper case report forms (CRF's) to interactive voice response (IVR) systems meaning that patients can report information over the phone to electronic diaries or patient reported outcomes using personal digital assistants (PDA's).

Objective: To demonstrate potential advantages of using EDC in resource limited settings for clinical trials and pharmacovigilance studies and identify solutions to potential challenges in implementing it through a pilot study.

Methods : Pilot studies will be undertaken in two Visceral Leishmaniasis clinical trial sites, in relatively remote locations of Kenya and North Sudan. We aim to design EDC systems using open-source software such as *OpenClinica* and *Epicollect* and train local staff to use them. We will also evaluate technical challenges and solutions to implementation and maintenance, for example, data security, extent of technical support required and availability of internet connectivity.

Results: We hope to measure the reduction in time and cost, to achieving key milestones such as production of a data cleaning audit trail and analysis reports, with minimal time spent on data entry and validation without a reduction in data quality.

Conclusions: With full implementation, EDC will significantly shorten the time taken to have clean data ready for analysis as well as being cost effective in the long run and hence the time taken to inform treatment decisions and policies. Study sites will also feel more ownership through involvement in data collection and capture process. It is important that the whole process assures continuity, integrity, accuracy and at the same time increase confidence in the final results that come out of the process.