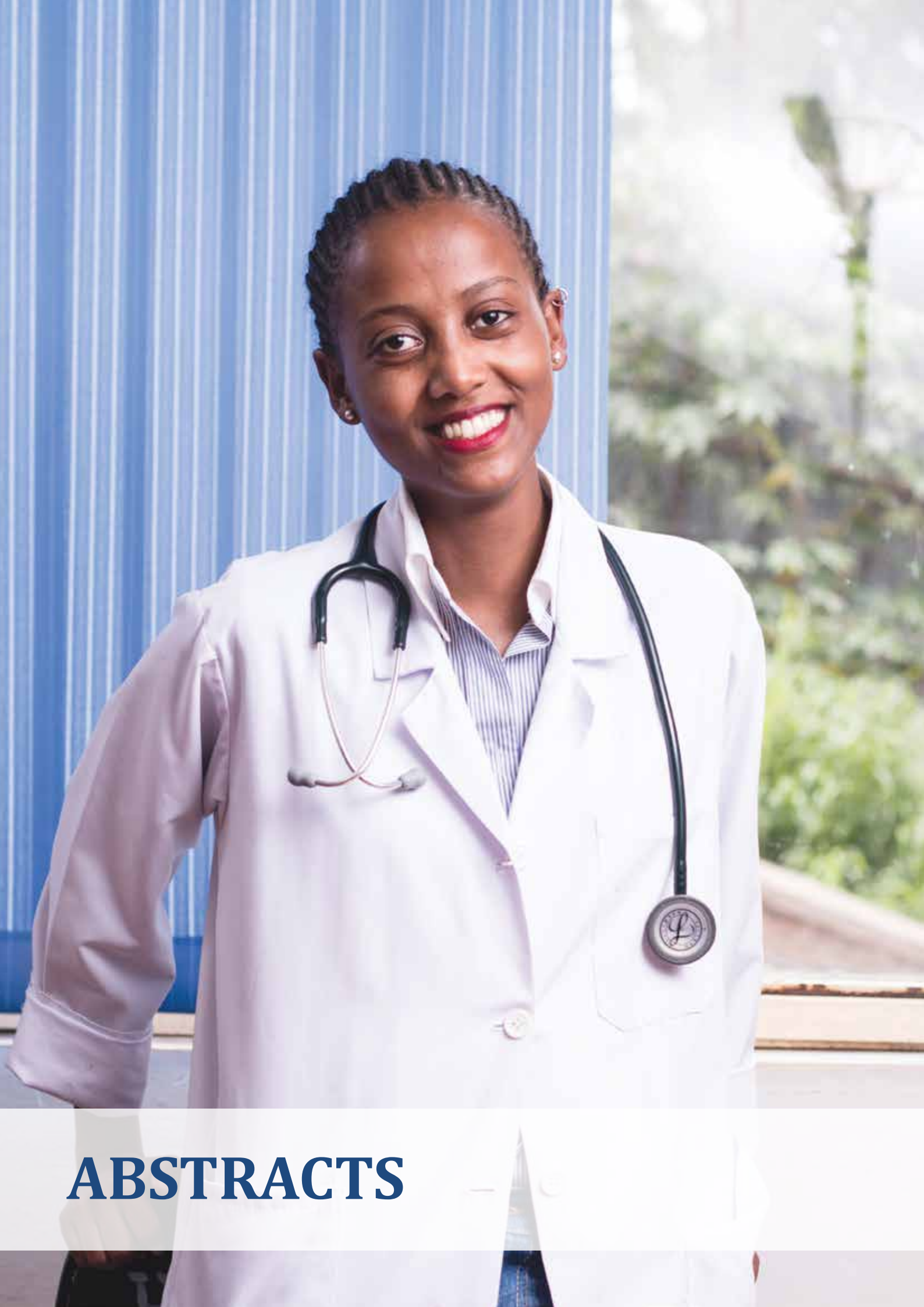

ABSTRACTS

THE CHALLENGES OF MANAGING PATIENTS WITH KALA-AZAR IN SUDAN

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Visceral leishmaniasis (kala-azar) is an increasingly recognized major health problem and it is unique in Sudan. Control measures, that include case-detection, treatment with antimonial drugs and vector control, have been disappointing. Recent epidemics have been responsible for displacement of large populations, high morbidity and mortality. Practicing physicians face major problems: kala-azar endemic areas are geographically remote with inadequate health facilities. Transport from the endemic areas to central hospitals is difficult, costly and impossible during the rainy season. Moreover, civil unrest and social instability limit access to the available health services. Accurate data on the burden of kala-azar does not exist in many kala-azar foci as large proportions of kala-azar cases are not recorded. Non-governmental organizations (NGOs) are using their own protocols for diagnosis and treatment. Sodium stibogluconate (SSG) alone or in combination, although still efficient, they are not free from toxicity. Alternative drugs are numerous yet none registered in Sudan. Post kala-azar dermal leishmaniasis (PKDL) ensues in 60% of treated kala-azar. The cost of supportive treatment and treatment of concurrent diseases like AIDS and TB is always beyond the financial capabilities of the patients.

In conclusion, remote harsh endemic areas, poverty, civil unrest, toxic drugs, emerging resistance to conventional antimonials and concurrent infectious diseases remain the main challenges of managing patients with kala-azar in the Sudan.

PAROMOMYCIN/SODIUM STIBOGLUCONATE COMBINATIONS, SAFETY AND POSSIBLE EFFICACY FOR TREATMENT OF POST KALA-AZAR DERMAL LEISHMANIASIS CASE SERIES

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Post kala-azar dermal leishmaniasis (PKDL) is a recognized dermatologic complication of successfully treated visceral leishmaniasis (VL). PKDL lesions are suspected to be important reservoirs for VL transmission in Sudan. Prolonged treatment schedules, feeling of general well-being and the social stigmata of PKDL prevent most patients seeking treatment. The mainstay of treatment is cardiotoxic sodium stibogluconate (SSG) for 60-120 days. Recently, liposomal amphotericin B (Ambisome®) and immunochemotherapy gave promising results. Ambisome® is expensive and difficult to prepare under field conditions. Paromomycin/SSG combination has been shown to be safe, efficacious and can save time in VL treatment. This report aims to prove that Paromomycin/SSG combination can cure and reduce PKDL treatment duration.

Nineteen cases of patients with PKDL lesions of ≥ 6 months duration who were diagnosed by clinical signs, histopathological/immunohistochemical and PCR. Patients' mean age was 14.9 ±5.9 years. Nine patients (9/19; 47.4%) among whom (3/19; 15.8%) patients failed previous SSG treatment of 2-3 months duration responded completely to 40 days of Paromomycin (single)/SSG (single) combination daily doses while (5/19; 26.3%) responded to 30 days of the Paromomycin (single)/SSG (single) combination. One patient (1/19; 5.26%) relapsed following the 30 days combination regimen.

A second group of ten patients (10/19; 52.6%) with (2/19; 10.52%) patients who failed previous SSG treatment, responded to 15-20 days of Paromomycin (double)/SSG (single) daily doses.
In conclusion, Paromomycin/SSG combinations are time-saving, safe and efficacious for PKDL treatments.

SECONDARY PROPHYLAXIS OF VISCERAL LEISHMANIASIS RELAPSES IN HIV CO-INFECTED PATIENTS USING PENTAMIDINE AS A PROPHYLACTIC AGENT: A PROSPECTIVE COHORT STUDY (NCT01360762)

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The relapse rate of visceral leishmaniasis (VL) among HIV coinfected patients in the first year of treatment reaches 60%. This is despite being on antiretroviral treatment (ART). Established risk factors for VL relapse include previous episodes of VL, low CD4 count and advanced HIV clinical stage. No single study has evaluated the value of secondary prophylaxis in VL-HIV coinfection in L donovani endemic regions. Such strategies should be safe, effective and feasible to implement in low-income settings. Since pentamidine (PM) is not used for VL treatment in many countries, it has been proposed for secondary prophylaxis in regions with anthroponotic transmission.

To share preliminary findings of an ongoing clinical trial on use of pentamidine as a secondary prophylaxis for VL in HIV positive patients

The effectiveness, safety and feasibility of PM infusion (4 mg/kg; monthly infusion for at least one year) in VL-HIV co-infected adults were evaluated in a prospective cohort study in Northern Ethiopia. ART is systematically provided. Three groups of patients were recruited: 1) Current primary VL: active VL during the study period and with risk factors for future VL relapse (CD4 count< 200 cells, WHO stage IV HIV disease; 2) Current VL relapse: presenting with VL relapse during the study period; 3) Past VL: a history of VL but presenting with risk factors for VL during the study period. Exclusion criteria include pre-existing renal dysfunction or diabetes mellitus, pregnancy and lactation.

A total of 161 patients were screened at the two clinical trial sites, and 74 patients were recruited from Nov 2011 to Sept 2013. The main reasons of screening failure were high CD4 count and too far away residency from the study sites. So far seventeen (23%) patients have relapsed, seven died (including two after VL relapse) and four were lost to follow up. The other causes of death were to renal failure and infections such as meningitis, pneumonia and sepsis. One patient was made to discontinue PM due to (reversible) hyperglycemia.

This is the first large-scale prophylaxis study in VL-HIV coinfection that is assessing the effectiveness, safety and feasibility of the intervention. The study is still ongoing and the final results of the clinical trial will be available by the end of this year.

A SCREEN AND TREAT STRATEGY TARGETING VISCERAL LEISHMANIASIS IN HIV INFECTED INDIVIDUALS IN ENDEMIC EAST-AFRICAN COUNTRIES: THE WAY FORWARD?

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In the wake of the HIV epidemic, visceral leishmaniasis (VL) has been re-emerging, particularly in North-Ethiopia where up to 40% of patients with VL are co-infected with HIV. Management of VL in HIV co-infection is complicated by increased drug toxicity, and high mortality and treatment failure rates, despite initiation of antiretroviral treatment. Tackling L donovani infection before disease onset would thus be a logical approach. A screen and treat approach targeting latent or the early stage of infection has successfully been implemented in other HIV-associated opportunistic infections. While conceptually attractive in the context of VL-HIV, the basic understanding and evidence underpinning such an approach is currently lacking. As a first step, studies will have to be conducted to quantify the risk of VL in different risk groups and across CD4 cell count levels. This study aims to develop and test a "screen and treat" strategy for VL in HIV-infected individuals.

We propose to conduct a multi-centre prospective cohort study in a VL endemic region in North-Ethiopia, where large numbers of HIV-infected patients are enrolled in HIV care. A pilot study will be started in Metema before the end of 2014. As residents of this region with high VL-endemicity, these HIV patients are exposed to L donovani infection and are in regular medical follow-up. Patients will be monitored for leishmania infection and VL for a period of up to three years with three-monthly clinical and laboratory evaluation. In addition, the immunoprofile of the different types/stages of leishmania infection and the associated risk profiles will be determined.

Based on this information, we aim to develop and evaluate prognostic clinical tools, integrating host, HIV and Leishmania infection markers, to detect individuals at high risk of VL. Ultimately, this could lead to a "screen and treat" strategy for VL in HIV-infected individuals living in VL-endemic areas.

IMPACT OF THE USE OF A RAPID DIAGNOSTIC TEST FOR VISCERAL LEISHMANIASIS ON CLINICAL PRACTICE IN ETHIOPIA: A RETROSPECTIVE STUDY

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Clinical diagnosis of visceral leishmaniasis (VL) is inaccurate with the probability of disease being 40-60% with clinical case definition, and should be supported by a standardized diagnostic algorithm. Guidelines recommend the use of rK39 rapid diagnostic test as a first step followed by a second test (DAT or tissue aspiration) if negative. A properly screened patient fulfilling the clinical case definition and positive with rK39 will have a positive predictive value above 85%. We assessed the routine practice applied in diagnosing VL at a research center in a teaching hospital in Ethiopia. Retrospective record analysis was done for all patients who had rK39 rapid diagnostic test at Leishmaniasis Research and Treatment Center (LRTC) of University of Gondar (UoG) Hospital, Northwest Ethiopia between June 2012 and June 2013.

From a total of 928 patients tested 308 (33.2%) were rK39 positive. Tissue aspiration was done for the 237 (77.2%) rK39 positive patients and parasitological confirmation was made in 165 of the patients showing positive predictive value of rK39 to be 69.6%. If the 71 rK39-positive patients that had not undergone tissue aspiration would all be considered to be VL cases, the PPV would increase to 77%. Only 126 (20.3%) of the 620 patients with a negative rK39 test underwent tissue aspiration.

The VL diagnostic algorithm appeared to be applied in a reverse manner: a negative test was most of the time not followed by a second test. Unlike the previous evidences the PPV was found to be low, maximum of 77%. While further studies are required to know why the guidelines are not followed, implementation of quality control for leishmania RDT and trainings may help improve the practices in VL diagnosis.

SIMPLIFIED MOLECULAR DETECTION OF LEISHMANIA PARASITES IN VARIOUS CLINICAL SAMPLES FROM PATIENTS WITH LEISHMANIASIS

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Molecular methods to detect Leishmania parasites are considered specific and sensitive; but despite this, the tests are at present not ideal for field diagnosis as they employ equipment that is not practical in field conditions moreover often expensive. In the present study isothermal, nucleic acid sequence based amplification (NASBA) was coupled to a single step detection technique oligochromatography (OC) to simplify and reduce time for the diagnosis of leishmaniasis.

Blood was collected 30 from Sudanese visceral leishmaniasis patients, confirmed by microscopy; and 50 healthy individuals (endemic controls) were included. For cutaneous leishmaniasis, skin biopsies were collected from Brazil (n=43), Suriname (n=27) and control skin biopsy samples (n=5). NASBA assay in this study targeted a 170-bp region in the 18S rRNA, and was performed using the NuclisenseBasicKit™ on Boom-extracted DNA. Amplicons were detected using an oligochromatographic dipstick at 55°C for 5min. Test accuracy was determined in a 2X2 table and level of test agreement with microscopy was determined by the Kappa (K) values with 95% confidence intervals using Epi-info version 6.

Ethical clearance for sample collection in Sudan was approved by the Faculty of Medicine, University of Khartoum and from the National Ethical Committee at the Federal Ministry of Health Sudan; in Suriname by the Medical Ethical Committee of the Academic Medical Centre, Amsterdam, The Netherlands (MEC 03/228); in Brazil, the Brazilian National Review Board of the Ministry of Health (Commissão Nacional de ÉticaemPesquisaParecer no. 1142/2005). Written informed consent was obtained from study cases before clinical samples for research purpose were collected.

Diagnostic sensitivity of NASBA-OC was 93.3% (95% CI: 76.5%-98.8%) and specificity was 100% (95% CI: 91.1%-100%) on blood samples, while sensitivity and specificity on skin biopsy samples was 98.6% (95% CI: 91.2%-99.9%) and 100% (95% CI: 46.3%-100%), respectively.

This NASBA-OC is more sensitive than previously documented PCR tests, and thus offers hope for diagnosis of leishmaniasis especially in Sudan, where generally parasitaemia is reported to be low. The NASBA-OC format brings implementation of molecular diagnosis of leishmaniasis in resource poor countries one step closer by eliminating the need of a thermocycler and use of ethidium-stained agarose gel while reducing the test-time.

THE PHARMACOKINETICS OF SINGLE INTRAMUSCULAR DOSE OF PAROMOMYCIN SULFATE, SODIUM STIBOGLUCONATE AND THEIR COMBINATION IN HEALTHY VOLUNTEERS

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Pharmacokinetic properties of drugs used for treatment of visceral leishmaniasis (VL) are implicated in the variation in their efficacy. Although Sodium stibogluconate (SSG) is still in use in East Africa with acceptable efficacy and safety, there is a growing interest to combine it with paromomycin (PM) to bring down its cost and improve its efficacy and safety. Available information on the pharmacokinetics of PM and SSG is limited, this study was conducted to characterize the pharmacokinetics of PM, SSG and their combination in healthy Sudanese participants and to investigate the pharmacokinetics of drug- drug interaction.

Following informed consent, 18 healthy males were enrolled in this study. Of these 8 participants received SSG 20 mg/kg IM, 5 participants received Pm 15 mg/kg IM and 5 participants PM 15 mg/kg plus SSG 20 mg/kg. Plasma was collected at 0.25, 0.5, 1, 2, 4, 6, 8, 12 and 24 hours after administration of PM, SSG and the combination of both drugs. Urine samples were collected during 0 to 2, 2 to 4, 4 to 6, 6 to 8, 8 to 12, and 12 to 24 hours of the injections. The analysis of plasma and urine samples for PM detection and quantification was performed with a high-performance liquid chromatographic (HPLC) whereas detection and quantification of Sb was performed in a graphite furnace atomic absorption spectrometer. Pharmacokinetic parameters were analyzed using the pharmacokinetic program Kinetica 4.4.

Peak PM concentrations were achieved within 2 hours and it was undetectable beyond 8 hours in both participants who received PM alone and PM/SSG combination. SSG was detected after 24 hour in both in participants administered SSG alone and PM/SSG combination. The mean concentrations of urinary PM at 2-4 and 4-6 hours were higher in the participants administered PM/SSG combination ($p<0.05$). Generally, most of the administered dose was excreted in the urine of volunteers within 24 hours suggesting that absorption was complete. PM half-life 2.58 (hr), C max 19.5 (µg/ml), T max 2 (hr), AUC total 78.8 ((hr)*(µg/ml)), Clearance 12.5 (mg/kg*hr/(µg/ml)), and volume of distribution 47.11 (mg/kg/(µg/ml)), when given alone. PM when given in combination with SSG showed half- life 1.85 (hr), C max 18.09 (µg/ml), T max 1.25 (hr), AUC total 70.64 ((hr)*(µg/ml)), Clearance 12.76 (mg/kg*hr/(µg/ml)), and volume of distribution 33.41 (mg/kg/(µg/ml)).

SSG half-life 3.07 (hr), C max was 48.3 (µg/ml), T max 1.75 (hr), AUC tot 240.97 ((hr)*(µg/ml), clearance 5.52 (mg/kg*hr/(µg/ml)), and volume of distribution 23.18 (mg/kg/(µg/ml)), when given alone; it showed half-life 2.81(hr), C max 40.56 (µg/ml), T max 1.81 (hr), AUC tot 197.74 ((hr)*(µg/ml), clearance 6.05 (mg/kg*hr/(µg/ml)), and volume of distribution 24.19 (mg/kg/(µg/ml) when given in combination with PM.

Variation in the efficacy of drugs in the treatment of leishmaniasis is frequently due to differences in drug sensitivity of leishmania species, the immune status of the patient, or the pharmacokinetic properties of the drug (Simon; et al., 2006).

The pharmacokinetic parameters for paromomycin in healthy volunteers in this study generally are in agreement with results obtained in previous studies (Kanyok, 1997). However, the pharmacokinetics of aminosidine was not affected significantly when it was administered with sodium stibogluconate in healthy volunteers.

Similarly there was no significant difference between mean plasma drug concentrations of Paromomycin (15 mg/kg) alone and (paromomycin 15 mg/kg +Sodium stibogluconate 20 mg/kg), and no significant difference between sodium stibogluconate 20 mg/kg alone and (sodium stibogluconate 20 mg/kg + Paromomycin 15 mg/kg) in healthy volunteers.

Generally, although not significant; aminosidine seems to decrease the concentration of sodium stibogluconate, this in contrast with results obtained by Belloli and colleagues (1995), who reported that serum concentrations of antimony was increased when it was administered with aminosidine in dogs, but antimony did not significantly modify the kinetics of paromomycin.

EVALUATION OF COMPLEMENT ACTIVATION RELATED PSEUDO ALLERGY (CARPA) AMONG SUDANESE VISCERAL LEISHMANIASIS PATIENTS TREATED WITH HIGH SINGLE DOSE LIPOSOMAL AMPHOTERICIN B (AMBISOME®)

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Despite the fact that Liposomal Amphotericin B (Ambisome®) is in common use to treat many protozoal and fungal diseases, it was only recently studied to be used in single high dose for treatment of visceral leishmaniasis (VL). Although it has been documented that complement activation related pseudo allergy (CARPA) due to Ambisome® occurs in animals, its safety when given in high single dose was not studied in humans. Therefore, this study aimed at evaluation of CARPA among Sudanese patients with VL treated with high single dose of Ambisome®.

A longitudinal study was conducted at the Field Stations, Institutes of Endemic Diseases and University of Khartoum as part of a ClinicalTrials.gov.NCT00832208 to develop Ambisome® at a single high dose treatment for VL. All patients with parasitological confirmed VL who gave written consent to participate were enrolled and allocated to receive Ambisome® either 10mg/kg single dose at day 1 or standard treatment (3mg/kg at day 1,2,3,4,7,14 and 21). Blood samples were obtained immediately before treatment, day 3, 7 and 14 following Ambisome® and used for C3a, C5a and sC5b-9 measurement using Human ELISA kits. Quantitative PCR was performed serially to look for parasite load and pattern of clearance. Clinical data were collected to assess CARPA. Epi Info 7 was used for data processing and analysis.

Thirty-six (n=36) patients participated in this study. Nineteen patients treated with high single dose (G1) and 17 patients treated with standard dose of Ambisome® infusion (G2).The mean age was 10 ± 4.1 years and 11 ± 6 years respectively. None of the patients developed CARPA. Before treatment the levels of MAC, C5a and C3a were high ($p=0.0001$) and comparable in either group ($p>0.05$). At day 3 the mean levels of MAC, C5a and C3a were low in G1 and G2 compared to baseline ($p=0.01$, 0.6, 0.1), ($p=0.02$, 0.1, 0.7) respectively. This could be due to waning of the inflammatory response due to reduction of the parasite load (G1 $p=0.04$, G2 $p=0.0001$). At day 7 MAC mean level was significantly low in G2 ($p=0.02$) and also tended to decrease in G1 ($p=0.1$). C5a mean level tended to increase in both groups but not significant (G1, $p=0.1$ & G2, $p=0.5$). This could be attributed to liposomes since the parasite load is low at this stage. Also Parasite load showed significant reduction among G2 ($p=0.0001$) as well as G1 ($p=0.0001$). The parasite load showed direct relationship with the levels of the complement components till day 7.

Visceral leishmaniasis manifests with high levels of MAC, C3a and C5a as a result of the inflammatory process. Ambisome® given in high single dose of 10 mg/kg correlates positively with activation of MAC, C5a and C3a but not sufficient to induce CARPA. Its use at such a dose is safe for patients with VL.

ALTERNATIVE APPROACHES FOR ANTI-LEISHMANIA VACCINE DEVELOPMENT: IN SILICO PREDICTION OF IMMUNOGENIC T CELL EPITOPES OF LEISHMANIA DONOVANI GP63 PROTEIN AS VACCINE CANDIDATES.

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Visceral leishmaniasis (VL) is a major parasitic childhood disease in sub-Saharan Africa. Expensive and toxic anti-leishmanial drugs are current control methods. Safe, effective and cheap vaccines are potentially powerful strategies to control VL. Traditional vaccine development techniques have failed to deliver an effective vaccine. The prospects for vaccine development may benefit from immunoinformatic tools. This paper describes an in silico prediction method for immunogenic Leishmania donovani-GP63 T cell epitopes as VL candidate vaccines.

Using the EpiMatrix algorithm, the amino acid sequence of L. donovani donovani GP63 protein (GenBank accession: ACT31401) was screened for putative T cell epitopes that would bind to the most common HLA class II alleles among at-risk populations. Nine epitopes were initially identified using the EpiMatrix. Based on cluster score, number of EpiMatrix hits, hydrophobicity, and number of EpiBars, four peptides (P1-P4) were selected for synthesis.

In a proof of concept study, consenting healthy, leishmanin skin test (LST) reactive and non-reactive volunteers' blood was stimulated and IFN-γ, IL-4, and IL-10 were measured. IFN-γ and IL-4 levels were similar in both groups. However, mean IL-10 levels were significantly reduced in LST reactive individuals. To evaluate the potential cross-reactivity with the human genome (HG), the human gut microbiome (HM) and common human pathogens (HP), the sequences of the evaluated peptides were screened using JanusMatrix. One of the peptides (P1), which increased IL-10 in the LST reactive volunteers, showed high cross-reactivity with HG, suggesting that P1might induce a regulatory immune response in humans.

Immunoinformatic tools provide a promising alternative approach for anti-parasite vaccine development. Data obtained can be used in the development of epitope-based Leishmania vaccine.

IMMUNOCHEMOTHERAPY OF POST KALA AZAR DERMAL LEISHMANIASIS: SUDANESE EXPERIENCE

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Post-Kala-Azar dermal leishmaniasis (PKDL), a dermatosis that follows apparently successful treatment of Visceral Leishmaniasis (VL) caused by Leishmania donovani. It is believed to be immunologically mediated. The skin lesions are viewed as reservoirs for leishmania parasites. Therefore treatment could help in the control of VL. The available treatment options are far from satisfactory as they are either expensive (liposomal amphotericin B) or toxic (antimonials), or resistant parasites have either emerged or are imminent with monotherapy.

Sodium stibogluconate (SSG) combined with first generation candidate vaccine (Alum-precipitated autoclaved L major plus BCG) for leishmaniasis was tried in 2 studies; and in combination with second generation candidate vaccine (LeishF2 plus MPL-SE) for leishmaniasis in one study. The Treatment was evaluated by the clinical outcome, safety and the immune responses.

Interestingly, the first option was found to be safe, strongly immunogenic and efficacious and studies leading to phase III are underway. In contrast, latter option was found to be safe and immunogenic but not promising in terms of efficacy.

Immunochemotherapy is a novel option whereby a low-dose or short course of an effective drug is given with one injection of a vaccine or immunomodulator to rapidly induce the effector immune response. This is instead of relying on chemotherapy alone to reduce the parasite burden, and waiting for the effector immune response to develop which may take longer time, to control the parasites.

LEISHMANIASIS IN UGANDA: HISTORICAL ACCOUNT AND A REVIEW OF THE LITERATURE

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Visceral leishmaniasis (VL) or kala azar is a disease caused by protozoan parasites and occurs worldwide. Eastern Africa forms the second largest focus of VL after Asia (India, Bangaladesh and Nepal). But the disease is more neglected in Uganda compared to its Eastern African neighbors. In this paper we give a historical account and review available literature on visceral leishmaniasis in Uganda to raise more awareness about the disease in the country and worldwide. Information was collected from Amudat hospital records, MEDLINE, records of Ministry of Health (Uganda), reports from non-governmental organizations, dissertations and personal communication.

Reports on VL in Uganda first appeared in the 1950's, followed by almost four decades of silence. Earlier records on VL in Amudat hospital are also incomplete. This is indicative of neglect for VL for long. From early 2000, reports, mainly on the disease management and risk factors, started to appear. Management of VL has mainly been by non-governmental organizations including MSF, Swiss. Currently DND*i* is funding management of VL and clinical trials on drugs in Amudat hospital through LEAP. New foci of VL were identified recently in Moroto and Kotido districts, about 100 and 250 km North of Amudat hospital respectively.

The history of VL in Uganda is incomplete because there is a gap of nearly 40 years when reports on the disease is missing. Visceral leishmaniasis is apparently more widespread in north-eastern Uganda than originally thought. Disease management is well established in Amudat hospital and is currently funded mainly by DND*i* through LEAP. However its sustainability and wider coverage remains a challenge. Strengthening the capacity of local institutions to; conduct research and surveillance combined with effective management should mitigate VL in Uganda.

NUTRITION AND LEISHMANIASIS CONTROL IN SUDAN, CURRENT CHALLENGES AND FUTURE STRATEGIES: A GUIDE FOR THE FORMULATION OF REGIONAL POLICY

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Nutritional risk factors determining development of Leishmaniasis are not totally understood. The influence of nutrition on the outcome of Leishmania infection needs to be assessed by comparing the quantitative body composition measurements and nutrients consumption with susceptibility, severity and treatment of leishmaniasis. This includes research focused on interactions between nutrition and the chronic infection of leishmaniasis.

Results from these assessments will inform the design of intervention strategies to reduce childhood morbidity and mortality and possible provide insight on how to improve drugs, efficacy, availability and absorption.

All global research done in nutrition and leishmaniasis (1969-2014), was evaluated and reviewed, gaps identified and (short and long term) strategic plans formulated according to international needs in health planning and resources available in the African context. Stakeholder meetings along with PRA were also done.

Apart from diagnostics, prevention and control strategies for leishmanaisis, no formal complete quantitative work for the evaluation of nutritional factors had been carried out. A 6 year strategy was developed for the evaluation and adoption of control nutrition strategy and policy in all preventive, agnostic and curative settings. This strategy is intended for use as guidance for the formulation of nutrition policy in LEAP participating countries

A clear research strategy must be adopted. A wide spectrum of studies ranging from development of strategies to be implemented at field sites and scaling up of new policy interventions is planned. Suggested areas for study include research on detection of nutritional biomarkers for disease susceptibility, severity and response for treatment
This will open a new attractive corner for research important for the achievement of MDGs

THE ECONOMIC IMPACT OF VISCERAL LEISHMANIASIS IN BARINGO, KENYA

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Visceral Leishmaniasis (VL) is a deadly parasitic disease transmitted by the bite of a female sandfly. According to the World Health Organization, VL is ranked as the third most important parasitic disease after malaria and lymphatic filariasis in terms of disease burden (Desjeux 2004; WHO 2009). The main objective of the study was to examine the economic impact of VL on households (HHs) in Baringo County, Kenya.

A random sample of 84 out of 108 VL patients was calculated using the Creative Research Online sample calculator. Questionnaires were used to collect data from 30 HHs and analyzed using descriptive methods.

A single VL episode costs Kshs. 31,200 (USD.390, at exchange rate of 80) which is triple the average monthly income for the affected HHs or 1.6 times their annual per capita income. These costs are beyond the reach of majority poor HHs, 70% living in the first two poorest quintiles, and they are forced to employ a combination of coping strategies. In most cases, patients could still not meet the cost of treatment even after exhausting available coping strategies. Comparisons of cost lines indicate that short-term direct costs outweigh short-term indirect costs. We concluded that the economic burden of caring for VL patients and the subsequent stripping and compromise of coping mechanisms can institute a vicious cycle of poverty in a household and may undermine sustainable development of disease endemic communities

We recommended that VL disease control programmes need to adopt novel mechanisms to fast track VL patients' diagnosis and treatment so as not to compromise livelihood and food security of their HHs. The support systems are necessary if the communities have to sustain good health, welfare and development in order to achieve the economic and health aspirations enshrined in the Vision 2030.

INNOVATIVE APPROACHES TO CLINICAL DATA MANAGEMENT IN RESOURCE LIMITED SETTINGS USING OPEN SOURCE TECHNOLOGIES

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Clinical Data Management of clinical trials for Neglected Tropical Diseases in endemic countries can be difficult due to limited resources and expertise. There is a need to develop improved systems for data management which are efficient and affordable without violating the principles of Good Clinical Practice. Open source tools offer good alternatives when compared to proprietary systems but challenges in validation still abound.

We have developed an offline version of Open Clinica, making it possible to collect data in areas with limited internet infrastructure, together with an in-house system for query management which is a crucial component in data management. Both have been possible as a result of our experience in managing large multi-centre clinical trials in Africa on Neglected Tropical Diseases such as Visceral Leishmaniasis, with sites located in very remote areas.

We demonstrate that innovative approaches to clinical data management are possible and that open source tools with good functionality are available and can be further developed to assure production of high quality and reliable data. It is also important to share knowledge on best practices, such as on systems validation and source code development, for better management of data from clinical trials in resource limited settings

BENEFITS ACCRUING FROM COLLABORATIVE RESEARCH AND DEVELOPMENT PROGRAM ON LEISHMANIA IN UNIVERSITY OF GONDAR

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The burden and challenges of neglected tropical diseases is especially noticeable in hospitals close to endemic sites. University of Gondar (UoG) hospital in north-west Ethiopia is the only referral hospital close to the main visceral leishmaniasis (VL) endemic focus in the country. VL is one of the most severe and fatal neglected diseases. The management of VL has been a significant problem not only for the hospital but also for the country at large and the neighboring countries where the disease occurs.

The ten years research and development collaboration with Drugs for Neglected Diseases initiative (DND*i*) and Leishmaniasis East African Platform (LEAP) was described. The records of both clinical and administrative activities were used.

The University Hospital is one of the clinical trial sites for VL in the LEAP consortium of four East African countries (Ethiopia, Sudan, Kenya and Uganda). It hosts a research and treatment center that conducts clinical trials aimed at improving the management of VL patients. The research outputs have provided scientific evidence that has helped to improve international guidelines (WHO guidelines and that of the LEAP countries). One of the studies conducted recently evaluated a short (17 day) regimen combination therapy of sodium stibogluconate plus paramomycin. Annually, more than 700 patients are screened while close to 350 VL patients get treatment. Site staffs have developed skills in clinical research and good clinical practices. The outputs and the research setting developed have attracted additional collaborators that helped strengthen the consortium thus attracting bigger research grants such as FP7.

The north-to-south research and development collaboration has helped for skill transfer, sharing of experiences, resource mobilization and conduct of GCP compliant trials in resource limited setting that brought changes on several guidelines. The experience from this collaborative platform can be adopted for other similarly challenging diseases of public health importance.

CHALLENGES IN ETHICAL REVIEW IN KENYA

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The Kenya National Bioethics committee is set up by an act of parliament. It is responsible for policy issues, preparing various guidelines, arbitration, international collaboration and accreditation of all the ethics committees in the country. There are many new institutions established which are involved in research. To reduce the burden on the few previously established ethics committees we have allowed some institutions to establish their own ethics committees which have to be accredited by the National Bioethics committee. This paper will cover challenges at different levels.

Information about the functioning of the various ethics committees and the challenges faced were gathered during conversations with chairs of various ethics committees at different informal meetings. Also independent Observations were made by the National Bioethics Committee during visits to various institutions before accreditation process was established. Challenges faced after accreditation process were identified during deliberations of NBC meetings.

It was noted that there were major challenges in the review process, in monitoring, dissemination of results and communication, material transfer agreements, study extension, collaborative research, clinical trials and the role of Pharmacy and Poisons Board.

There are gaps between ethical review process ideals and reality. Establishment of new committees has come with its own challenges. There is a need for harmonization of ethical review process, streamlining of proposal review, strengthening of the monitoring process and empowering local researchers in collaborative research projects with international institutions.

INTEGRATION, COLLABORATION OR JOINT REVIEW: WHICH WAY TO SPEED UP RESEARCH ETHICS REVIEW IN EASTERN AFRICA

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National Commission for Science, Technology and Innovation, Kenya

Progress of Research ethics review in Africa has been slow for various reasons. It has in the last few years been reinvigorated by the growing research enterprise. African countries, all with a vibrant young population have seen the number of universities grow. This has led to more research activities and the accompanying need for review. Research ethics establishments in the eastern Africa region are mainly traditional. Established in large hospitals, they are usually medical ethics establishments.

The paper looks at research ethics review in four countries in eastern Africa: Kenya, Uganda, Tanzania and Ethiopia. It explores the differences and similarities in organization and focus. We looked at the documents that are available, describing the processes and compared them to make observations and conclusions that may assist in deciding whether to integrate or collaborate in other ways.

Results will explain the governance structures adopted in the four countries and highlight the areas of similarity and those that are different. The most relevant ones for discussions on integration will be picked out.

The paper will present the current position in the countries and contribute to the current discussions regarding closer collaboration among ethics review committees.

INSTITUTIONAL REVIEW BOARDS AND CLINICAL RESEARCH IN EAST AFRICA: CHALLENGES, OPPORTUNITIES AND PROPOSED SOLUTIONS

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Ethics in clinical research focuses largely on identifying and implementing the acceptable conditions for exposure of some individuals to risks and burdens for the benefit of society at large. The Ethics Committee stands as the bridge between the researcher and the Ethical Guidelines. IRBs are an important link between subject protection program and their function defines ethical credentials of clinical research.

A review of documents, African publications and future strategies in bioethics was conducted. Key interviews were conducted using a semi structured questionnaire.

Regional requirements differ from the international guidelines. IRBs face numerous challenges, in establishment, composition, and implementation. Some of these challenges are due to conflict of guidelines, some inherent to guidelines, and other reasons. There is need to study the problems of IRBs in depth to assess their needs.

There is urgent need for oversight of IRB functions and the regulators need to have a division which will have oversight over IRB functions, monitoring them regularly, auditing them sometimes, and help to protect human subjects. There should be national or regional ethics forums which will work with the IRBs so that subjects are protected better and clinical research gains ground.

Some organization at regional level takes the lead in setting up a Forum of ECs. The Forum can lay down the requirements for training of IRB members, and also create a core team of trainers to actually deliver the training modules, and other needed responsibilities:

The formation of local forum and regional ethics committees can be considered as a viable solution. This will also speed up the EC review process, and bring about the much needed fertile landscape for the growth of clinical research in Africa.

MONITORING IMPLEMENTATION OF A PHARMACOVIGILANCE PLAN FOR A NEGLECTED TROPICAL DISEASE IN EAST AFRICA

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Pharmacovigilance is key to identifying rare adverse events. Neglected diseases like leishmaniasis currently use toxic drugs. To improve data quality, monitoring is necessary but the standard clinical trial monitoring is stringent and far less adapted for monitoring Pharmacovigilance in resource limited settings.

DNDi introduced a Pharmacovigilance plan for Sodium Stibogluconate and Paromoycin (SSG/PM) in Eastern Africa following successful completion of Phase III clinical trials in Sudan, Ethiopia, Kenya and Uganda. The objective of the plan was to monitor efficacy and safety of the combination treatment in the immediate post approval period. The plan was approved by Regulatory Authorities and Ethical Committees accordingly and a monitoring plan was developed to improve data quality. Health staff were trained on Pharmacovigilance data collection, reporting of SUSARs and treatment failure. Routine monitoring visits were undertaken 3 monthly to assess consent forms, CRF completion, adverse events reporting and confirmation of treatment failures.

A total of 3,112 patients were recruited across 11 PV sentinel sites and data entry has been completed. Overall, data quality was good, the PV plan was adhered to, AEs and SAEs and treatment failures were reported. Common queries noted in some of the Case Report Forms were related to consenting, incomplete data, patient IDs and SAE follow up. Three Periodic Safety Update reports have been reviewed by the PV Plan Steering Committee. Monitoring was not intense.

Despite challenges of treating Neglected Tropical Diseases in remote rural facilities in Sub Sahara Africa, good PV data has been obtained and forwarded to Regulatory Authorities. The Pharmacovigilance data quality was enhanced through training and monitoring of sites.

FACTORS INFLUENCING COMPLIANCE WITH MASS DRUG ADMINISTRATION FOR LYMPHATIC FILARIASIS ELIMINATION IN KENYA

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The main strategy adopted for Lymphatic Filariasis (LF) elimination globally is 4 to 6 rounds of mass drug administration (MDA) annually. At least 65% of the total population (100% of the eligible population) should be treated in each round for LF elimination to occur. In Kenya after 3 MDA rounds using diethylcarbamazine citrate (DEC) and albendazole, data showed declining compliance (proportion of eligible population who receive and swallow the drugs) levels (85%-62.8%). A retrospective cross-sectional study based on 2008 MDA was conducted between January and September 2009 in Kwale and Malindi Districts to determine the factors influencing compliance with MDA.

In each district, one location with high and one with low compliance levels was selected. Through systematic sampling, nine villages were selected from the four locations and quantitative data collected from 965 systematically sampled household heads. Qualitative data were generated from 80 opinion leaders, 80 LF patients with clinical signs and 15 community drug distributors (CDDs) all purposively selected and interviewed. Sixteen focus group discussions (FGDs) were also conducted with single-sex adult and youth male and female groups.

Several socio-economic factors including; religion, primary occupation, ownership of property, knowledge of LF signs and cause, risk perception ($P<0.001$) and disease stage ($P<0.05$) influenced compliance with MDA. Personal opinions and experiences also influenced compliance with MDA; house-to-house method of drug distribution, lack of perceived need to take the drugs, CDD not visiting to issue drugs and being absent. A dislike for modern medicine and experience of side effects ($P< 0.001$) also influenced compliance. Social support, alcohol and substance use were not associated with compliance with MDA ($P>0.05$). Additionally, knowledge about MDA was not associated with compliance with MDA ($P>0.05$) but frequency of receiving information on MDA influenced compliance ($P< 0.001$). Factors that positively influenced the CDDs motivation were: higher education levels, trust and familiarity with community members, feeling of recognition and desire to help their communities. Negative factors included: inadequate training, drug supplies, community sensitization and lack of supervision.

There is need to have different strategies to reach specific religious groupings and those in casual employment. Community sensitization on treatment, drugs used and their potential side effects and that the health personnel are on standby for management is necessary for confidence building. Factors that motivate CDDs are those that enhance their capacities to perform their duties and endear respect in the communities where they serve.

EVALUATING DRUG DELIVERY STRATEGIES TO PRE-PRIMARY SCHOOL AGE CHILDREN FOR TREATMENT OF SOIL-TRANSMITTED HELMINTHIASIS AND SCHISTOSOMIASIS INFECTIONS IN MALINDI DISTRICT, COASTAL KENYA

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The Government of Kenya through the National School-based deworming program treats children in Early Childhood Development (ECD) Centres. However, the Program does not consider the ECD Center teachers as eligible for training to conduct deworming of the ECD Centre children. The Program therefore requires that ECD children whose centers are not within (standalone) the Primary Schools be taken to the nearby primary schools to receive treatment from the trained primary school teachers. This type of ECD centre children therefore have to travel an average of 5km or more to receive treatment. This may have negative implications in terms of accessing the nearest school and majority of the ECD Centre children are likely to miss the treatment. This study therefore aimed at developing and implementing an alternative drug delivery method in order to help maximize treatment coverage for this vulnerable age group.

The study adopted a comparative cross-sectional study design. We conducted 64 Key Informant Interviews with Community Health Extension Workers (16), Primary School Health teachers (12), Early Childhood Development Centre (ECD) Teachers (18) and Community Opinion leaders (18). Purposive sampling technique was used to identify participants and the sample was based on saturation model. Health teachers and CHEWs were trained to treat children in primary schools and standalone ECDs respectively. The data was collected by trained and experienced KEMRI staff, transcribed, coded and analysed using ATLAS.ti version 6.

In our preliminary findings, many participants displayed a strong preference for ECD centre treatment highlighting that the young children should not be subjected to walking long distances for treatment. Abdominal pain was a major side effect among consumers of Praziquantel, while those who took albendazole only, reported no reaction. ECD teachers were widely used during treatment with children being the main mobilization strategy.

ECD teachers have the capacity to treat children and all they need is training. To maximize treatment coverage, pre-school children should be treated at their centers and other mobilization techniques should be employed to enhance community participation.

BEHAVIOUR CHANGE IS REQUIRED FOR ELIMINATION OF ACTIVE TRACHOMA IN NAROK COUNTY, KENYA

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Trachoma, a leading infectious cause of blindness found in areas with poor hygiene is controlled by implementation of AFE: Antibiotic treatment, Facial cleanliness and Environmental improvements. Active trachoma is monitored by the prevalence of trachomatous follicles (TF) in children 1-9 years old (the reservoir). Surveys are conducted after every 3 to 5 years and mass drug administration MDA conducted if TF prevalence is ≥ 5%. A baseline survey was conducted in Narok in 2004 followed by impact assessment surveys in 2010 and 2014. Trachoma remains endemic in Southern Narok despite uninterrupted MDA since 2008. A qualitative study was conducted to investigate this.

The study was conducted in two segments in Narok South where prevalence survey results had confirmed a prevalence of TF >20%. Qualitative data was collected through 12 Focus Group Discussions (FGDs) and 12 Key Informants Interviews (KIIs) so as to assess Knowledge, Attitude and Practices of community members on trachoma transmission and control. The group members and opinion leaders were purposively selected. Data was analyzed manually by study themes.

Majority of the community members complied with MDA and were willing to continue in subsequent rounds. Non-compliance was due to lack of awareness and fear of side effects. Majority of FGD participants were aware that keeping domestic animals away from human dwellings helps reduce transmission, but this was impossible as the animals needed protection from raiders, wild animals and harsh weather conditions. Children washed their faces every morning but shared water, basins and towels and toilets were unacceptable due to socio-cultural reasons therefore bushes were preferred. Majority of the informants stated that community members dispose faeces of young children in bushes and that flies are regarded as blessings, sign of rain and future richness.

Health education is needed for behaviour change and improved compliance with MDAs among the communities living in endemic areas.

PREDICTORS OF NON-COMPLIANCE WITH MASS DRUG ADMINISTRATION FOR SCHISTOSOMIASIS CONTROL IN WESTERN KENYA-THE SCORE PROJECT

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Mass drug administration (MDA) is being used to control schistosomiasis, lymphatic filariasis and other neglected tropical diseases of public health significance. However, achieving optimal community participation during implementation remains challenging. When a critical proportion of the population fails to participate in MDA, a potential reservoir for the parasite is left untreated, opening the opportunity for resurgence of the infection and reducing the probability of successful transmission control. This study was designed to identify predictors of non-compliance with MDA in western Kenya in villages with ≥25% prevalence of schistosomiasis in order to develop more effective health educational and delivery strategies.

We used a population based unmatched case-control study design nested within a cross sectional household survey employing a structured questionnaire administered to 550 heads of households. Both univariate and multivariate analyses were used to identify the independent predictors of non-compliance.

Two hundred and forty respondents (44.9%) reported being non-compliant. By univariate analysis, non-compliance was significantly associated with the household head not asking the community health workers (CHWs) questions about the program, crude odds ratio (COR) 10.3, 95% CI [6.61-15.93], not having heard about the program COR 2.4 [1.6-3.6], and low schistosomiasis risk perception COR 3.1 [1.89-5.03]. In a logistic regression model, the odds of being non-compliant significantly increased amongst household heads who perceived their CHW not to be doing good work during the MDA exercise; adjusted odds ratio (AOR) 4.9, 95% CI [1.82-13.74], heads of households who lacked knowledge about schistosomiasis control methods AOR 7.5 95% CI [3.3-16.8], and those who did not know how the CHW was selected AOR 2.5 95% CI [1.3-5.0]..

In order to improve compliance with MDAs, effective strategies should be identified to ensure CHWs are well-trained and supervised to ensure quality service provision. Health education is also necessary to increase the knowledge levels of the disease in the community

A QUALITATIVE DESCRIPTION OF COMMUNITY PARTICIPATION IN WATER AND SANITATION ACTIVITIES IN THE CONTROL OF BILHARZIA IN NYALENDA B, AN INFORMAL SETTLEMENT IN KISUMU CITY, WESTERN KENYA

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Community participation is central to the success of primary health care. However, over 30 years since the Alma Ata declaration, absence of universal community participation remains a main obstacle to achieving the millennium development goal of combating diseases. This study investigated community participation in water and sanitation activities towards Bilharzia control in Nyalenda B, an informal settlement in Kisumu City

Eight key informant interviews (KIIs) and eight focus group discussions (FGDs) were conducted. In addition, data on NGOs dealing with water and sanitation activities in Kisumu was collected from the local NGO registration Board. Qualitative data was organized into themes and concepts and analyzed using Atlas.ti.

Most participants felt that project implementers did not involve them in key levels of project implementation leading to unsustainable projects and unacceptance from the community. Community structures identified that could be used as avenues of engaging the community in improving water and sanitation situation included use of organized groups such as youth, gender-based, farmers and HIV support groups, and merry-go rounds. Factors mentioned that hindered community participation included negative attitude from community members, poor monitoring and evaluation strategies, limited disclosure of project details, and over-dependence from the community. Poor drainage systems, low latrine coverage, broken pipes and leakage of the sewerage systems were the leading factors associated with poor water and sanitation conditions.

Effective community participation in water and sanitation activities requires a multi-pronged paradigm that incorporates change of attitude from the community, information sharing and consultation, improved monitoring and evaluation, transparency and accountability. All levels of community leadership and engagement need to be considered before planning and executing a development project in the community for acceptance and sustainability.

BURDEN OF CYSTIC ECHINOCOCCUS IN SELECTED PASTORAL AND AGROPASTORAL DISTRICTS OF UGANDA

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Echinococcosis is one of the neglected infections found throughout the developing world. While a prevalence of 66.3% of echinococcosis was reported in dogs in Karamoja, studies on prevalence of echinococcosis in human among communities living in Agro-pastoral and Pastoral areas of Uganda are scanty.

A cross sectional study was done in selected agro-pastoral districts of Uganda to determine the knowledge gap and attitude of the community about echinococcosis and to establish its prevalence.

2,903 participants were interviewed in selected pastoral and agro-pastoral districts in Eastern, Northeastern, Central and Western regions. 80% had not heard about echinococcosis and 85% did not know mode of transmission or treatment. 3% believed it was acquired through eating raw meat or unboiled milk. Only 23% the health workers were aware about the disease in all the selected districts.

3601 participants (1107 males; 2494 females) were screened. Fifty eight cases of suspected cystic Echinococcosis lesions were identified in all the regions. 17 and 41 were in the male and female subjects respectively. Northeastern region had the highest cases (n=25) compared to other regions (Central n=15; Western n=10; Eastern n=8).

Liver had 37 lesions with 30 cases in the right lobe. The kidney had 11 lesions; spleen 6; omentum 6 and one lesion in the lung. Other diseases included; fibroids, polycystic kidney disease, Kalazar, hapatomas and ovarian cyst.

Most of the respondents in Pastoral and Agro –Pastoral communities of Uganda are not aware of echinococcosis. The cases of echinococcosis were found in all the study regions with North Eastern having the highest prevalence. Other diseases were also detected in the survey. There is need to sensitize the communities about the disease and establish intervention centers in the affected areas.

CYSTIC ECHINOCOCCOSIS IN EASTERN AFRICA -A PUBLIC HEALTH PROBLEM-

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Cystic Echinococcosis (CE) is a neglected, debilitating, zoonotic disease, caused by the larval stage of the tapeworm Echinococcus granulosus. CE has a worldwide distribution and is more frequent in livestock rearing areas. CE is endemic in pastoral nomadic communities in Eastern Africa with Northern Turkana in Kenya, having one of the highest infection rates in humans in the world. CE is a public health problem. Its importance and socio-economic impact is fairly underrated due to lack of reliable prevalence data in the region and information on the relationship between the parasite, domestic animals, wildlife and humans. Data on CE in East Africa are scanty. More data are available from Kenya, especially from Turkana, where a hydatid disease control programme has been running since 1983.

The objectives of the presentation are to introduce CE, create awareness of the disease, linking it to other diseases, coexisting in the same areas such as visceral leishmaniasis and possible common approaches for prevention and control.

HOST PREFERENCE ANALYSIS OF PHLEBOTOMUS (LARROUSSIUS) ORIENTALIS (DIPTERA: PSYCHODIDAE) USING CYTOCHROME B PCR AND REVERSE LINE BLOTTING IN THE VISCERAL LEISHMANIASIS ENDEMIC AREA OF TAHTAY ADIYABO DISTRICT, NORTHERN ETHIOPIA

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Knowledge of the host preferences of phlebotomine sandflies under natural conditions is an important factor for understanding the epidemiology and for developing efficient control strategies for visceral leishmaniasis. However, in Ethiopia and other parts of East Africa there are large remaining gaps in identifying the feeding habits of Phlebotomus orientalis, the vector of Leishmania donovani. The aim of the study was to determine the host preference patterns of P. orientalis from Tahtay Adiyabo district, Northern Ethiopia.

For blood meal analysis, sandflies were collected from three villages (i.e., Ademeyti, Lemlem and Mentebteb) of Tahtay Adiyabo district using CDC light traps and sticky traps. DNA was individually extracted from blood fed sandflies and PCR amplified for vertebrate-specific cytochrome (cyt) b region, followed by reverse-line blot (RLB) analysis.

Out of 180 P. orientalis tested for the source of blood meals by cyt b PCR and RLB, the blood meals of 135 were successfully identified. P. orientalis mainly fed on cattle followed by human, goat, sheep and camel. Mixed blood feeding was also identified in ten female P. orientalis.

Results obtained from bloodmeal analysis using cyt b PCR-RLB revealed that P. orientalis is mostly an opportunistic in its host preference with higher level of zoophilic feeding behavior. The epidemiological significance of these domestic animals as blood sources for P. orientalis and possible reservoir hosts of L. donovani should be thoroughly investigated for better understanding the transmission dynamics of visceral leishmaniasis in northern Ethiopia.

Members of Staff - DND*i* Africa Office, Nairobi

Back Row: Simon bolo, Seth Okeyo, Michael Ochienge, Renee Olende, Josephine Kesusu, Raymond Omollo, Robert Kipmutai, Moses Waweru

Front Row: John Ambasa, Brian Muthida, Truphosa Omollo, Rhoda owiti, Peninah Menza, Punam Amratia, Godfrey nyakaya, Joy Malongo, Nicholas Bonyo, Monique Wasunna