

15% and 28% of these patients had severe hepatotoxicity at 4 and 24 weeks, respectively. Serum levels of all enzymes increased significantly ( $p < 0.05$ ) with increased treatment duration. Univariate analysis revealed that the risk factor of developing severe hepatotoxicity was significantly ( $p < 0.05$ ) greater in patients  $< 30$  years, males, low BMI, low monthly income earners and patient on AZT+3TC +NVP regimen. While multivariate analysis at  $p < 0.09$  showed that age  $< 30$  years, Low BMI, low monthly income, or the use of AZT +3TC +NVP regimen were independent risk factors.

**Conclusion** Low BMI,  $< 30$  years, low monthly income and the use of AZT+3TC+NVP regimen were identifiable risk factors for the development of severe hepatotoxicity. As such, these factors should be considered as important for strategy by clinicians to prevent hepatotoxicity.

**PO 8194** OPTIMISED INFORMED CONSENT FOR PARTICIPANTS IN A RANDOMISED CONTROLLED TRIAL IN RURAL UGANDA: A COMPARATIVE PROSPECTIVE COHORT STUDY

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**Background** Poor participant understanding of research information can be a problem in community interventional studies in rural African women where levels of illiteracy, dependency and compliance are high. We assessed the impact of alternative consent models on participants' understanding of the clinical trial information and its contribution to the informed consent process in rural Uganda.

**Methods** This was a prospective comparative cohort, nested within a pilot study of community distribution of alcohol-based hand rub to prevent neonatal sepsis (BabyGel). As part of the informed consent process, information about the trial was presented using one of three consent methods: standard researcher-read information; a 'slide show' using illustrated text on a flip chart; and a video showing the patient information sheet (PIS) being read as if by a newsreader in either English or the local language. In addition, all women received a written PIS in their preferred language. Each information method was used for 1 week of recruitment. Two days after recruitment, women's understanding of the clinical trial was evaluated.

**Results** A total of 30 pregnant women from 13 villages in Mbale participated in this study. Majority 90% (27/30) were assessed for recall of trial information within planned 48 hours. The slide-show was the most popular, with a mean score not less than 4.2 highest [mean (sd) range: 4.8 (0.6) [4–5]] by women who had been recruited using any of the three models. The slide show was preferred by 63% of the women (19/30), compared with 17% (5/30) and 20% (6/30) who preferred the standard and video show message, respectively. Reasons given included the benefits of having pictures to aid understanding, and the logical progression of the information.

**Conclusion** Our results suggest that a slide-show message is an effective and popular alternative way of presenting trial

information to women in rural Uganda, many of whom had little or no literacy.

**PO 8208** CYTOKINE PROFILES IN SUDANESE CHILDREN PRESENTED WITH SEVERE MALARIA, UNCOMPLICATED MALARIA COMPARED TO HEALTHY COMMUNITY CONTROLS ACCORDING TO WHO CRITERIA

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**Background** Immune system response to *Plasmodium falciparum* (*P. falciparum*) malaria infection outlines the disease course and outcome. This is attributed to variable production of cytokines that either promote (pro-inflammatory) or curtail (anti-inflammatory) the inflammatory process. Elucidating underlying immunological disease interactions may direct development of effective treatment and provide better understanding of the disease process.

**Methods** A case control study was conducted in Mohamed Elamin Paediatrics Hospital (March- August 2016) in Omdurman in central Sudan, an area that is characterised by unstable malaria transmission. The study aims to investigate the role/interaction of cytokine profiles of gamma interferon (IFN- $\gamma$ ) and Interleukin-10 (IL-10) in children infected with *P. falciparum* malaria. Enzyme-linked immunosorbent assay was used to measure the concentrations of cytokines, IFN- $\gamma$  and IL-10, in serum from Sudanese children. Thirty-five children with complicated *P. falciparum* malaria were enrolled to the study; well-matched 35 uncomplicated *P. falciparum* malaria and another 35 healthy children were controls. Informed written consent was obtained from the parents or guardian. Complete blood count, blood urea and random blood glucose were measured by using standard laboratory procedures.

**Results** The concentrations of IFN- $\gamma$  and IL-10 levels were significantly higher in children with severe malaria compared to uncomplicated malaria and healthy control. There was a strong positive correlation observed between IL-10 and IFN- $\gamma$  ( $r = 0.688$   $p = < 0.001$ , as well as a strong positive correlation detected between IFN- $\gamma$  and urea levels ( $r = 0.73$ ;  $p = 0.010$ ). There was moderate correlation between IL-10 and urea ( $r = 0.386$ ;  $p = < 0.001$ ). While negative moderate correlation was observed between IL-10 and haemoglobin levels ( $r = -0.316$ ;  $p = 0.003$ ), no correlation was detected between IFN- $\gamma$  and haemoglobin levels. All patients were discharged home in good condition.

**Conclusion** These results indicate both IFN- $\gamma$  and IL-10 are involved in shaping the course and outcome of the severe malaria in children.

**PO 8239** BASELINE ASSESSMENT OF LYMPHATIC FILARIASIS IN 18 COMMUNITIES IN WESTERN GHANA BEFORE THE IMPLEMENTATION OF TWICE-YEARLY TREATMENT

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**Background** Lymphatic filariasis (LF) is a neglected tropical disease targeted for elimination as a public health problem by