

Sent: 11-10-2015 23:42

RE: RTS,S and non-specific effects of vaccination ?

Dear SAGE – Since SAGE is going to discuss the RTS,S malaria vaccine at its upcoming meeting it is appropriate that we inform SAGE that we submitted two letters to Lancet after the publication of the main RTS,S trial (attached). A combined version of the two letters will appear shortly.

The key points are that the RTS,S groups had higher than expected mortality and that this trend has increased with longer follow-up. Strangely for a disease-specific vaccine there is a trend (non-significant) that the case fatality in severe malaria is higher for RTS,S recipients than for controls.

Previous discussions on post-licensure monitoring has mainly focused on the excess of meningitis cases. If randomized trials to measure the impact on all-cause mortality are not demanded there should be monitoring of all-cause deaths and of the case fatality in malaria infection.

Best regards

Christine S Benn and Peter Aaby