Author's response to reviews

Title: Mutiple-antigen ELISA for melioidosis - A novel approach to the improved serodiagnosis of melioidosis

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Author's response to reviews: see over
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Philippa Harris
Senior Executive Editor
BMC Infectious Diseases

Dear Dr. Harris,

Response to the request for clarification of ethics approval status for the current study

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Research article title: Multiple-antigen ELISA for melioidosis - A novel approach to the improved serodiagnosis of melioidosis
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This is in reference to the email from Nathaniel Nazareno dated 16th November 2012 requesting for clarification of ethical approval to use the sera samples presented in our submitted manuscript.

As mentioned in our earlier communication, all the human sera samples used in the current study were archived samples previously stored at multiple hospitals across Malaysia between 1985 and 2005. The samples originated from patients presenting with fever and general malaise at outpatient clinics who were later confirmed as melioidosis culture-positive. These diseased sera as well as control sera from healthy individuals were samples kept in storage and no longer required by the hospitals/institutes. These samples were not collected from the individuals concerned as part of a research programme, hence, no consent was required at the time of sample collection as this was part of standard patient care. Since no names of individuals were made available to us when the samples were provided, we were unable to obtain the consent from these individuals when the current study was initiated ten months ago.

This study was also initiated at a time when the university’s Guidelines for Ethical Review of Research Conducted on Human Samples had yet to be endorsed. These guidelines were only endorsed on 28 June 2012 and any reference to research on archived samples is not immediately evident in the document (enclosed for your reference). My co-authors and I strongly believe that the findings of the current study have no bearing on the individuals who provided the blood samples as diagnosis of melioidosis was confirmed using the gold standard of bacterial culture. Furthermore, the aim of our study was to identify more sensitive diagnostic antigens for improved diagnosis and management of melioidosis is potentially beneficial to countries where the disease is endemic, including Malaysia and will contribute to minimise socio-economic loss associated with morbidity and mortality of this disease.

I hope this explanation is satisfactory and the editorial board will proceed with the peer review process for this manuscript.

Yours sincerely

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