Author's response to reviews

Title: Drug Utilization Evaluation of Cefepime in the First Affiliated Hospital of Bengbu Medical College: A Retrospective and Prospective Analysis

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Author's response to reviews: see over
Dear Dr. Harris,

I was very glad to receive your letter. Thank you very much for your patience and the requirement of some final clarifications on the ethical approval and consent sought for our work. I would like to provide this cover letter to give a point-by-point response to the concerns raised.

Reviewer: Editors

1. Many thanks for clarifying that you did not obtain consent for the prospective arm of your study. Could you clarify if the Department of Health waivered the need for this?

This study (No. 09C170), entitled “Establishment the model of clinical pharmacy via application of drug use evaluation for antibiotics” was approved by the Department of Health of Anhui Province in China and the Ethics Committee of The First Affiliated Hospital of Bengbu Medical College in 2009. The research of “Drug Use Evaluation of Cefepime in the First Affiliated Hospital of Bengbu Medical College: A Retrospective and Prospective Analysis” is the part of DUE study for antibiotics. Various research methods are used in DUE studies. Such as, prospective, concurrent or retrospective DUE studies. A prospective DUE study is to evaluate patients’
planned drug therapies before the medication is administered, while a retrospective DUE study is to review drug therapies after the patients’ have completed courses of therapies.

The study was approved by the Department of Health of Anhui Province in China, and the DUE criteria for cefepime and the DUE procedure were approved by the Drug and Therapeutics Committee (DTC) of the hospital. So the prospective arm of my study is just one of research methods, repeated approval is not required.

2. Many thanks also for clarifying that specific ethical; approval was not sought due to the permission of the Department of Health. Could you clarify if this department has the authority to act as an ethical committee?

This project is the research approved by the administrative department of health. The principal aim of DUE research is to facilitate rational use of drugs, which implies the prescription of a well documented drug in an optimal dose on the right indication, with correct information and at an affordable price.

In China, the Department of Health is the government organization in charge of health, with the supervision and management of hospitals. The authority for approval of scientific research project can be directly implemented in the hospitals. This study (No. 09C170), entitled “Establishment the model of clinical pharmacy via application of drug use evaluation for antibiotics” was approved by the Department of Health of Anhui Province in China and the Ethics Committee of The First Affiliated Hospital of Bengbu Medical College, and patient consent was not required because of the observational nature of this study.

The revised section was marked in blue in the manuscript and the certification document of the authority to approval by the the Department of Health of Anhui Province in China and the Ethics Committee of The First Affiliated Hospital of
Bengbu Medical College were submitted together.

The above documents have been submitted in electronic version to *BMC Infectious Diseases*. If you have any questions or queries, please write to me by the email given below. I am looking forward to acknowledge the receipt of this article by email.

Thank you very much.

Yours sincerely,
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