Author's response to reviews

Title: Epidemiology of bloodstream infections in patients with acute myeloid leukemia undergoing levofloxacin prophylaxis

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Author's response to reviews: see over
Dear Editor,

thank You for considering a revised version of our paper entitled “Epidemiology of bloodstream infections in patients with acute myeloid leukemia undergoing levofloxacin prophylaxis”.

We uploaded the revised manuscript, with changes highlighted in yellow and underlined in black.

Please find hereafter a synthesis of our corrections to the reviewers’ comments, with details of page and line numbers.

1) This is a retrospective study but from the text it is unclear if this is based on data from standard patient care or a clinical trial.
   The Ethics Committee approval was unnecessary due to the retrospective nature of the study and was waived with the approval of the Hospital Medical Direction for patients given prophylaxis with levofloxacin before 2006. Beginning in 2006, consecutive adult patients with AML were prospectively included in the multicenter AML 02/06 (EudraCT number 2006-003817-429) study by our center, belonging to the Northern Italy Leukaemia Group (NILG) and approved by the Ethical Committee. (Page 4, line 3-8)

2) Who made the decision to treat the patients using this prophylaxis and if this was standard care in your hospital?
   Before 2006, i.e. before the multicenter AML 02/06 multicenter trial, patients were given levofloxacin prophylaxis according to an internal protocol. (Page 4 Line 5, 13-14)

3) Why the ethics committee needed to approve the study (and whether patients
provided informed consent). The protocol and the consent form of the multicenter study were approved by the Ethics Committee, AML 02/06 study and each patient provided the informed consent to receive chemotherapy, antinfective and nutritional therapy. As stated above, for patients treated before 2006, the Ethical Committee approval was waived due to the retrospective nature of the study. (Page 4, line 3-4, 11-12)

4) If this was based on trial data we would be grateful for inclusion of the relevant Trial Registration Number (TRN) and references to any other manuscripts based on this data. The EudraCT number is 2006-003817-429. The full results have not yet been published (Page 4, line 7).

We hope that the requested changes are appreciated by the Editor and by the Reviewers.

Best regards

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