Reviewer's report

Title: Determinants of access to experimental antiretroviral drugs in an Italian cohort of patients with HIV: a multilevel analysis

Version: 1 Date: 1 September 2011

Reviewer: Michael Horberg

Reviewer's report:

Authors: Enrico Girardi, Paola Scognamiglio, Claudio Angeletti, Andrea Gori, Dora Buonfrate, Massimo Arlotti, Giovanni Mazzarello, Antonella Castagna, Massimo Andreaoni, Antonella d'Arminio Monforte, Andrea Antinori, Giuseppe Ippolito and I.Co.Na Foundation Study

Title: Determinants of access to experimental antiretroviral drugs in an Italian cohort of patients with HIV: a multilevel analysis

Journal: BMC Health Services Research

Reviewer: Dr Michael Horberg, Kaiser Permanente (michael.horberg@kp.org)

This study is an exploration of the factors that are associated with placing patients on “experimental” ARV prior to regulatory approval. The topic is interesting and of importance to HIV clinicians and health service leaders. However, there are some clarifications needed prior to approval:

1. Abstract: The cohort name implies all patients are ARV naïve, but this is not the case. That needs clarification. The results section would benefit from some actual results (odds/hazard ratios, etc.).

2. Throughout there are multiple spelling and grammar errors.

3. Methods: page 5, “defined as any initiation of any antiretroviral drug”—does this mean single drug changes also? Page 6: “EAP on that drug in Italy, we assumed”—this assumption could be wrong and needs to be discussed in the limitations.

4. Discussion: Page 10: last sentence is unclear. Page 12, Line 7: “somehow” should be “somewhat”. The discussion section would also be strengthened if the authors discussed which results surprised them (i.e. they didn’t expect), which they found consistent with prior thought, and how the results will be used in Italy and their care system.

5. Tables: As formatted, they are difficult to read.

To directly address the questions of the editors:

1. Is the question posed by the authors well defined?—Yes.

2. Are the methods appropriate and well described?—Yes.

3. Are the data sound?—Appear so, within the confines of the cohort.

4. Does the manuscript adhere to the relevant standards for reporting and data
deposition? –Yes.
5. Are the discussion and conclusions well balanced and adequately supported by the data?—Yes. But note comments above
6. Are limitations of the work clearly stated?—Note the comments above.
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?—Yes
8. Do the title and abstract accurately convey what has been found?—Yes, but noting comments above.
9. Is the writing acceptable?—Yes, but needs some editorial assistance.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'