OPEN PEER REVIEW

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Peer Review

International Journal of Infection
Article DOI: https://doi.org/10.5812/iji.114751
Published in: International Journal of Infection: 9(1) ; e114751

Peer Review Report for "The Importance of Antiretroviral Pharmacovigilance"

Author(s): Khontile Nobuhle Kunene, Shyh Poh Teo

Review Timeline:

Submit Date:	21 Mar 2021
Revised Date:	5 Sep 2021
Accepted Date:	10 Oct 2021

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE : Reviewer — 15 May 2021

Dear AE
1) The article should be summarized if possible.
2) The items are commented in the attachment.
Best regards

REFEREE : Reviewer — 23 May 2021

Dear AE
This letter addresses the important issue of monitoring the use of new drugs and evaluating their benefits over the risks associated with their use. However, the author's main concern about the use of dolutegravir is "neural tube defects" in children born to pregnant women taking this drug. A similar letter was published by

Rebecca Zash et al., entitled "Neural-Tube Defects with Dolutegravir Treatment from the Time of Conception" in the N Engl J Med Journal. Following initial reports and mentioned concerns, a cohort study was conducted in Brazil, and a report entitled "Dolutegravir and pregnancy outcomes in women on antiretroviral therapy in Brazil: a retrospective national cohort study" was published in The Lancet. It has not been confirmed a significant relationship between the use of this drug and the mentioned complication. Monitoring long-term side effects of medications is generally necessary, but this study seems to address this concern about dolutegravir, at least for now.
Best regards.

REFEREE : Reviewer

24 Aug 2021

Dear AE
There were some corrections mentioned in the attached file.

Actually, pharmacovigilance is considered spontaneous reporting of all Adverse Drug Reactions (ADR) during post-market surveillance; therefore, your title is not very interesting.
My suggestion is "the importance of ARVs pharmacovigilance" or something like that.
Best regards

REFEREE : Associate Editor

4 Sep 2021

Dear EIC
Please ask the author to correct the following comments.
Reviewer 1:
There were some corrections mentioned in the attached file.
Actually, pharmacovigilance is considered spontaneous reporting of all Adverse Drug Reactions (ADR) during post-market surveillance; therefore, your title is not very interesting.
My suggestion is "the importance of ARVs pharmacovigilance" or something like that.

Reviewer 2:

1) The article should be summarized if possible.
2) The items are commented in the attachment.

Reviewer 3:

This letter addresses the important issue of monitoring the use of new drugs and evaluating their benefits over the risks associated with their use. However, the author's main concern about the use of dolutegravir is "neural tube defects" in children born to pregnant women taking this drug. A similar letter was published by Rebecca Zash et al., entitled "Neural-Tube Defects with Dolutegravir Treatment from

the Time of Conception" in the N Engl J Med Journal. Following initial reports and mentioned concerns, a cohort study was conducted in Brazil, and a report entitled "Dolutegravir and pregnancy outcomes in women on antiretroviral therapy in Brazil: a retrospective national cohort study" was published in The Lancet. It has not been confirmed a significant relationship between the use of this drug and the mentioned complication. Monitoring long-term side effects of medications is generally necessary, but this study seems to address this concern about dolutegravir, at least for now.
best regards

Hamidreza Kouhpayeh : EIC

4 Sep 2021

Dear author,
Please revise the manuscript based on the following comments.
Reviewer 1:
There were some corrections mentioned in the attached file.
Actually, pharmacovigilance is considered spontaneous reporting of all Adverse Drug Reactions (ADR) during post-market surveillance; therefore, your title is not very interesting.
My suggestion is "the importance of ARVs pharmacovigilance" or something like that.

Reviewer 2:

1) The article should be summarized if possible.
2) The items are commented in the attachment.

Reviewer 3:

This letter addresses the important issue of monitoring the use of new drugs and evaluating their benefits over the risks associated with their use. However, the author's main concern about the use of dolutegravir is "neural tube defects" in children born to pregnant women taking this drug. A similar letter was published by Rebecca Zash et al., entitled "Neural-Tube Defects with Dolutegravir Treatment from the Time of Conception" in the N Engl J Med Journal. Following initial reports and mentioned concerns, a cohort study was conducted in Brazil, and a report entitled "Dolutegravir and pregnancy outcomes in women on antiretroviral therapy in Brazil: a retrospective national cohort study" was published in The Lancet. It has not been confirmed a significant relationship between the use of this drug and the mentioned complication. Monitoring long-term side effects of medications is generally necessary, but this study seems to address this concern about dolutegravir, at least for now.
Best regards.

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Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear Editors and Reviewers,

Thank you for your feedback. The responses to the Reviewer comments are as follows (in BLUE font). The changes made to the manuscript are highlighted.

Associate Editor 1:
Dear author,
Reviewer 1:
There were some corrections which mentioned in attached file.

Thank you. I have made the corrections to the manuscript.

Actually pharmacovigilance is considered as spontaneously reporting all Adverse Drug Reactions (ADR) during post-market surveillance, therefore your title is not very intresting.
My sugesstion is "the importance of ARVs pharmacovigilance" or something like that.

We have changed the title to 'The importance of antiretroviral pharmacovigilance'.

Reviewer 2:

1) The article should be summarized if possible.

The following summary was added before the Conclusion section:

In summary, the high HIV prevalence in Eswatini necessitates treatment of a significant number of people with ARV. The adoption of dolutegravir as first line treatment for HIV for such a large number of people highlighted pharmacovigilance as an important component of drug safety monitoring.

2) The items are commented in the attachment.

Thank you. I have made the corrections to the manuscript.

Reviewer 3:

This letter addresses the important issue of monitoring the use of new drugs and evaluating their benefits over the risks associated with their use. However, the author's main concern about the use of dolutegravir is "neural tube defects" in children born to pregnant women taking this drug. A similar letter was published by Rebecca Zash et al., Entitled "Neural-Tube Defects with Dolutegravir Treatment from the Time of Conception" in N Engl J Med Journal. Following initial reports and mentioned concerns, a cohort study was conducted in Brazil, and a report entitled "Dolutegravir and pregnancy outcomes in women on antiretroviral therapy in Brazil: a retrospective national cohort study" was published in The Lancet. It has not been confirmed a significant relationship between the use of this drug and the mentioned complication. Monitoring long-term side effects of medications is generally necessary, but this study seems to address this concern about dolutegravir, at least for now.

Thank you for sharing the paper. The following sentence was added:

Subsequently, a retrospective national cohort study from Brazil of 1427 women did not identify any association between dolutegravir and neural tube defects.[5]

The following reference was added:

Pereira GF, Kim A, Jalil EM, Fonseca FF, Shepherd BE, Veloso VG, et al. Dolutegravir and pregnancy outcomes in women on antiretroviral therapy in Brazil: a retrospective national cohort study. Lancet HIV 2021;8(1):E33-41.

All other subsequent references have been renumbered accordingly.

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Revision (1)

REFEREE : Reviewer — 26 Sep 2021

Dear AE
Thanks for the corrections that have been made.
Best regards

REFEREE : Reviewer — 4 Oct 2021

Dear AEd
Apart from some spelling and grammatical mistakes, it's OK for publication.
Best regards.

Hamidreza Kouhpayeh : Associate Editor — 10 Oct 2021

Dear EIC
This article has been accepted into the International Journal of Infection and will be published in future issues.
Best Regards

Hamidreza Kouhpayeh : EIC — 10 Oct 2021

Dear author
Your article has been accepted into the International Journal of Infection and will be published in future issues.
Best regards
EIC