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Name of Journal: *World Journal of Hepatology*

ESPS Manuscript NO: 23472

Manuscript Type: MINIREVIEWS

Shui Qiu,

Science Editor, Editorial Office

Baishideng Publishing Group Inc

Dr Dr Qiu,

Re: ESPS Ms NO: 23472 : Antiviral therapy for chronic hepatitis C: has anything changed for pregnant and lactating women?

Further to your message dated December, 28th 2015, I am hereby resubmitting the above-mentioned review for publication in *World Journal of Hepatology*.

A requested, the manuscript has been revised and edited by a professional author's editor who is a member of the European Association of Science Editors, and whose first language is English

The Language Certificate has been downloaded in the text.

We have addressed the points raised by the reviewers (see item-by-item response) and have revised the text accordingly (see highlighting). The linguistic editing is too extensive to highlight. Attached is a tracked copy for your convenience.

The text has been checked and the references are correctly and properly cited.

In addition to the item-by-item reply to the reviewers, appended are the required documents signed by the Authors.

Looking forward to hearing from you,

Yours sincerely,

Dr Anna Maria Spera
University of Naples Federico II

Signature: Anna Maria Spera Date: 2/02/16 (February 9th 2016)

Reply to reviewer 00502973

In the current manuscript, the author reviewed the available knowledge of the effects of current anti-HCV drugs on pregnancy and breastfeeding, and their potential application in these female patients. This is interesting. However, some concerns should be addressed before its acceptance. 1. The English was not meet the standard of publication, and should be polished carefully.

Authors' reply. The English has been revised and edited by an experienced professional author's editor whose first language is English, and who is a longstanding member of the European Council of Science Editors.

2. In this manuscript, the author presented the search strategy and selection criteria, thus the search and selection results should be presented either.

Authors' reply. As suggested also by another reviewer we have deleted the section devoted to search strategy and selection criteria in order to conform the paper to a review format as opposed to a meta analysis (page 5, line 26).

3. Page 10, the last paragraph: "Dasabuvir reaches T-max after 4-5 from oral administration." 4-5 hours or days?

Authors' reply. We meant "hours", and have changed the text accordingly (page 14, line 4)

4. There was a Discussion section after the Search strategy and Selection criteria section. However, the author presented the 2nd Discussion section at the bottom. There should not be 2 discussion sections in a single manuscript.

Authors' reply. We now end the paper with a Conclusion section (page 14, line 18)

Reply to reviewer00036624

The paper addresses a very inimportant issue and is well writen. Some typos shluld be amended in page 9 and 10: "inhibs" and homologate the name of the drug Paritaprevir that appears with some original variants. Another tyopo regards Viekira that appears as Vierkira in one occasion

Authors' reply. Thank you for your kind comments. We have corrected all the typos throughout the text, and now consistently use the same names for the drugs mentioned. (Page 12 lines 32, 33; page 13 lines 1, 9 and 24; page 14, line 4).

Reply to reviewer00070845

The main reason to treat a pregnant female with chronic HCV is to prevent vertical transmission. This actually is quite uncommon and specifics and references should be included in the Introduction to clarify the purpose of the review.

Authors' reply. We take the reviewer's point and have added the following passage to the Introduction. (page 4, lines 8 to 14 and 30 to 32; page 5, lines 1 to 3; page 6 lines 5 to 8)

We have also added the following References

4. **Kanninen T.T.**, Dieterich D., Ascitti S. HCV vertical transmission in pregnancy: New horizons in the era of DAAs. *Hepatology*. 2015 Aug 3. [doi: 10.1002/hep.28032]. Epub ahead of print
5. Viral Hepatitis in pregnancy. *ACOG Practice Bulletin*. 2007; 110: 941 – 955.
6. **Jhaveri R.** Diagnosis and management of hepatitis C virus-infected children. *Pediatric Infect Dis J*. 2011 Nov; 30(11):983-5.
7. **Dunkelberg JC**, Berkley EM, Thiel KW, Leslie KK. Hepatitis B and C in pregnancy: a review and recommendations for care. *J Perinatol* 2014 Dec; 34(12) 882-91.
8. **Tosone G.**, Maraolo A.E., Mascolo S., Palmiero G., Tambaro O., Orlando R. Vertical hepatitis C virus transmission: Main questions and answers. *World J Hepatol* 2014 August 27; 6(8): 538-548 ISSN 1948-5182 (online).

There is a Search Strategy and Selection sections (equivalent of a methods section) as if this is a meta analysis but it is a comprehensive review. I would organize the paper like a review paper.

Authors' reply. We have deleted the Search Strategy and Selection sections, so that the manuscript is now in a "Review" format (page 5, line 26).

In the section on interferon and ribavirin on page 5, I would point out that pegylated interferon has a low SVR rate (<30%) without ribavirin. Since ribavirin is not an option, it really is not either.

Authors' reply. Thank you for raising this point. We now report the different rate of SVR for Peg-IFN alone and for Peg-IFN plus ribavirin, also in relation to the different responses to HCV genotypes (see page 7, lines 18 to 25).

In the discussion of sofosbuvir, I would discuss genotype 2 since the current regimen is sofosbuvir and ribavirin, and ribavirin should not be used. This would be a difficult to treat genotype in pregnancy until another drug is approved that is pan genotypic and specific for genotype 2

Authors' reply. Point taken. However, recently the Italian authorities have approved a Ribavirin free regimen for the treatment of genotype 2 infection. We have included this information in the revised version of the manuscript. (see page 15, lines 15 to 20).

We also added the following reference

49. Agenzia Italiana del Farmaco - AIFA Unità Coordinamento Segreterie Organismi Collegiali • Esiti Ufficio Ricerca e Sperimentazioni Cliniche CTS 11, 12 e 13 novembre 2015 C) Legge 648/96: richieste di inserimento, punti 9 e 10; Pubblicazione come da POS AIFA n. 273 Rev. 0 - "Pubblicazione OdG ed esiti

relativi alla CTS e CPR” Available from
http://www.agenziafarmaco.gov.it/sites/default/files/esiti_SPER_CTS_nov2015.pdf