

## Format for ANSWERING REVIEWERS

March 25, 2015



Dear Editor,

Enclosed please find the edited manuscript in Word format. (ESPS Manuscript No 16846 final revision.docx)

Title: Urgent Need to Change Clinical Practices Around Postpartum Contraception

Author: Crystal Goldsmith, Anita Nelson

Name of Journal: World Journal of Obstetrics and Gynecology

ESPS Manuscript NO: 16846

The manuscript has been edited and these edits underlined according to the suggestions of reviewers:

- 1) A running title has been added
- 2) The Contribution statement has been edited.
- 3) The Conflict of Interest statement has been added.
- 4) The phone and fax number for the corresponding author has been added.
- 5) References have been removed from the abstract.
- 6) The keywords have been separated by semicolons.
- 7) The core tip has been added. While we would be willing to record a core tip, arranging audio/visual assistance will take a significant amount of time and we do not want to delay the publication of this editorial.

To the editorial board and reviewers:

Thank you so much for your constructive comments. Please see our responses below.

Reviewer 00730309

No requested edits.

Reviewer 00742297

No requested edits.

Reviewer 00742373

1) Suggest no references in the abstract.

The abstract has been revised to remove references.

2) Page 2 “traditionally, the only contraception offered in the immediate postpartum period has been tubal ligation” seems arguable. Suggest to change.

We have revised the text on Page 2, last paragraph, to say “Traditionally, the only contraception offered in the immediate postpartum period has been tubal ligation or progestin only pills.” Certainly this is changing as more and more clinicians see the value and safety in immediate postpartum IUDs, implants and DMPA

3) Give the whole name the first time for all abbreviations. For example, DMPA.

Depot Medroxyprogesterone Acetate has been spelled out in the text on Page 3, last paragraph.

4) The effectiveness (of postplacental IUDs) was discussed in the paper, but we didn't see the discussion of loss of IUD placed after delivery of placenta. In addition, the discussion of the complications are limited. It will be very significant to find a report from a prospective study on IUD placed immediate after delivery.

On page 4, in the second paragraph, I have specifically addressed the risks of infection, perforation and side effects of pain and bleeding, indicating that there are no differences in incidence whether the IUD is placed immediately postplacental or in a delayed fashion. No study of postplacental IUD has had perforation, infection or side effects as a primary outcome. Therefore, the reported data to date is sparse. I have specifically changed the text to say “These studies consistently show there is no increased risk of infection with immediate postplacental placement, though women diagnosed with chorioamnionitis, chlamydia or gonorrhea in pregnancy without evidence of a negative test of cure, or ruptured membranes for more than 24 hours are not candidates for immediate postplacental IUD due to infection risk.<sup>23,34,37</sup> No increase in perforation rates have been reported when compared to interval insertion at 6-8 weeks postdelivery.<sup>37</sup> Postpartum pain and bleeding also do not differ when comparing women receiving immediate postplacental IUDs and women receiving no contraceptive method.<sup>34</sup>”

The subsequent paragraph (page 4, paragraph 3) addresses the issue of expulsion and we attempted to further highlight the higher expulsion rates in the text, as this is the disadvantage to immediate postplacental placement. There have been a few prospective studies to focus on expulsion and these are cited in the text, The expulsion rates vary tremendously, and seem to vary by delivery type. The text now reads “The risk of expulsion with postplacental IUD insertion is higher than seen with interval insertion at 6-8 weeks postdelivery. The reported expulsion rate varies significantly in the literature, ranging from to 0.3% to 24%.<sup>30,32-39</sup> This increased risk of expulsion appears to depend on mode of delivery and interval between placental delivery and IUD placement. Studies of IUDs placed immediately after a vaginal delivery show expulsion rates of 20-24%.<sup>31,34,36</sup> When the IUD is placed at the time of a cesarean section, expulsion rates

are typically lower (0.3%-5%) and similar to those seen with interval placement at 6 weeks postpartum.<sup>29,34,36,40</sup> Additionally, placement that occurs greater than 10 minutes after delivery of the placenta is associated with higher rates of expulsion than placement less than 10 minutes after placental delivery.<sup>31,41,42</sup> These findings appear consistent across multiple types of IUDs, indicating that the question of which IUD to place should be made based on patient preference and IUD availability. While the risk of expulsion may be higher with immediate postplacental IUD insertion, this risk must be weighed against the patient's risk of not returning for interval insertion. For many women with minimal access to care the expulsion risk is worth taking. While specialized training is needed to place IUDs in the immediate postpartum setting, short didactic sessions with residents have demonstrated excellent outcomes.<sup>43</sup>

Reviewer 00742046

1) It is uncommon to see the abstract containing cited references.

References have been removed from the abstract.

2) The main contraception method in this article seemed to focus on the long acting reversible contraception method. Please clarify it, because levonorgestrel releasing intrauterine system might be one of the best examples. If the authors would like to introduce this device, please focus on it.

In the text, we refer to Long Acting Reversible Contraceptives. However, we did not clearly define that LARC methods include the contraceptive hormonal implant and all intrauterine devices (IUD). This has been clarified in the abstract. As such, this paper references literature on the contraceptive implant and intrauterine devices. The vast majority of prospective literature regarding immediate postpartum placement of IUDs has been focused on copper containing IUDs and the LNG IUD. We could locate only one clinical trial that directly compared different types of IUDs placed in the immediate postpartum period (the Gyne T and the Gyne T Postpartum which included a fundal suture). Therefore, we cannot and do not make any recommendation for one type of IUD over another, but instead advocate regarding the timing of placement. Rather, a decision about which type of IUD to insert should be made based on patient preference and availability. This has been stated more clearly in the text. The abstract now contains the text “As reliance on permanent contraception has diminished, timely access to highly effective contraceptive methods, namely long acting reversible contraceptives (LARC) - which includes the contraceptive hormonal implant and intrauterine device (IUD) - has become even more important.” Additionally, on page 4 in the second paragraph we now reference all the IUDs studied to date in the context of immediate postplacental placement. Immediate postplacental IUD placement has been researched in multiple settings internationally and with multiple types of IUDs, including Lippes Loops, Delta T, Delta Loop, Gyne T, CuT380A and LNG IUD

3) The argument for postpartum contraception might be what is the best “time.” Immediate after delivery, 2 weeks or later or complete resolution of the uterus (4-6 weeks postpartum). The author might be needed to discuss it.

Timing of postpartum IUDs has essentially be divided into immediate postplacental (<10 minutes after delivery of

the placenta), early postpartum (10 minutes to 48 hours) after placental delivery and delayed (6 weeks) .While there is some debate about the advantages and disadvantages of placing IUDs earlier (2 weeks postpartum) or later (8+ weeks postpartum) in the postpartum period, we feel this controversy is outside the scope of this paper, as any insertion that requires an additional patient visit, be it at 2 weeks or 6 weeks postpartum, serves as an additional barrier to access. We have added information comparing immediate postplacental and early postpartum placement, specifically highlighting the differences in expulsion rates on page 4, third paragraph. “This increased risk of expulsion appears to depend on mode of delivery and interval between placental delivery and IUD placement. Studies of IUDs placed immediately after a vaginal delivery show expulsion rates of 20-24%.<sup>31,34,36</sup> When the IUD is placed at the time of a cesarean section, expulsion rates are typically lower (0.3%-5%) and similar to those seen with interval placement at 6 weeks postpartum.<sup>29,34,36,40</sup> Additionally, placement that occurs greater than 10 minutes after delivery of the placenta is associated with higher rates of expulsion than placement less than 10 minutes after placental delivery.<sup>31,41,42”</sup>

4) What other types of intrauterine device might be an alternative choice? Why do the authors prefer LNG-IUS?

Again, the vast majority of prospective literature regarding immediate postpartum placement of IUDs has been focused on copper containing IUDs and the LNG IUD, which is why these two devices are discussed more extensively than others. There is a dearth of data comparing different IUDs placed in the immediate postpartum setting. While we discuss the copper IUD and the LNG IUD because of the more extensive data available, we cannot and do not make any recommendation for one type of IUD over another. Rather, a decision about which type of IUD to insert should be made based on patient preference and availability. The other IUDs that have been studied are now listed on on page 4 in the second paragraph. “Immediate postplacental IUD placement has been researched in multiple settings internationally and with multiple types of IUDs, including Lippes Loops, Delta T, Delta Loop, Gyne T, CuT380A and LNG IUD.” In the subsequent paragraph, we specifically state, in reference to expulsion rates, “These findings appear consistent across multiple types of IUDs, indicating that the question of which IUD to place should be made based on patient preference and IUD availability.”

Reviewer 00742368

1) Minor typo and grammar changes:

“to eradicate systemic barriers blocking access to methods during hospital stay” has been changed to “to eradicate systemic barriers blocking access to contraceptive methods during hospital stay” in the abstract.

Semi colon has been added after postpartum contraception in the “key words” on page 2.

“hat” has been changed to “that” on page 2.

“range from 6040% depending on population” has been changed to “range from 6-40% depending on the population studied, and are particularly high among adolescents.<sup>10-12”</sup> on page 2, second to the last paragraph.

“increases risk for unintended pregnancy for several reasons” now reads “increases the risk for unintended pregnancy for several reasons” in the last paragraph on page 2.

Move the parenthesis to after insurance status – this has been corrected on page 3, first sentence.

On page 3, first paragraph “This disconnect most affects women of lower socioeconomic status and women who lost insurance coverage” now reads “This disconnect mostly affects women of lower socioeconomic status and women who lost insurance coverage.”

Define abbreviation for ENT. This was meant to abbreviate etonogestrel, which we now spell out throughout the text.

On page 4, second paragraph “The placement of intrauterine devices in the immediate postpartum period

(within 10 minutes of placental expulsion) has been shown to be safe by many metrics” now reads “The placement of intrauterine devices in the immediate postpartum period (within 10 minutes of placental expulsion) has been shown to be safe by many respects.”

“More impressive is data” has been changed to “More impressive is the data” on page 5, first paragraph.

A missing period has been corrected on Page 5, second paragraph.

“Hospital with emergency services” has been edited to read “hospital without emergency services” on page 6, first paragraph.

Page 6 first paragraph has been edited from “her provider discuss contraception” to “her provider discussed contraception”

“reduces the changes” has been changed to “reduces the chances” on Page 6, first paragraph.

On Page 6, in the last paragraph, “and in the actual” has been changed to “and the actual.”

On page 7, the last paragraph now reads “Contraceptive implants require only that the provider undergo a brief 2-3 hour training course for certification.”

On page 7, in the last paragraph in the sentence “As referenced above, surveys demonstrate there is still a lack of knowledge among providers and there staff regarding LARC” - there was changed to their.

On page 8, in the conclusion, “outdate practices” now read “outdated practices.”

2) Han et al found that every dollar spent to provide immediate postpartum etonorgestrel implants to adolescents save \$6.50 – please review. Only \$6.50?

Han et al indeed reports that the state insurance plan (Medicaid) would save \$6.50 USD for every \$1 spent on immediate postpartum implants. This is consistent with prior findings that the general provision of contraception free of charge saves the government \$4-8 dollars for dollar spent.

Thank you sincerely for you thoughtful comments and consideration.

Crystal Goldsmith

Thank you so much for your constructive comments.

Sincerely yours,



Anita L Nelson, MD

Department of Obstetrics and Gynecology

David Geffen School of Medicine at Harbor-UCLA

1457 3<sup>rd</sup> Street

Manhattan Beach, CA 90266

Phone: 310-937-7226

Fax: 310-937-1416