Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Nicolas P, Maia MF, Bassat Q, et al. Safety of oral ivermectin during pregnancy: a systematic review and meta-analysis. *Lancet Glob Health* 2020; 8: e92–100.
Protocol deviations

In the protocol, the main outcomes described as maternal morbidity attributable to the drug include: abortions, pre-term births, stillbirths, low birth weight, congenital anomalies, neonatal death, infant survival up 2 years of age, hospital admissions in the first two years of life, and developmental milestones in the first two years of life. Because of the limited evidence available for such a broad number of variables with different severity, pregnancy outcomes have been sub grouped as severe adverse events and adverse events following FDA definition for a more accurate analysis based on severity.

Therefore, in this review abortion, stillbirth, congenital malformations, and neonatal death are considered SAE; non-severe maternal morbidity, pre-term births, and low birth weight are classified as AE.

Infant survival, hospital admissions and developmental milestones in the first two years of life have been dismissed in order to address the analysis to pregnancy outcomes that can be measured during pregnancy or in a short time after delivery.

Risk of bias assessment for observational studies is not described in the protocol; during the development of the review the Newcastle-Ottawa scale (NOS) was used to assess the risk of bias of observational studies found. However, for the one RCT found, the Cochrane tool for risk of bias assessment was used as described in the protocol.

Finally, the McMaster quality assessment scale of harms tool was included in registered protocol to evaluate the quality of adverse pregnancy outcomes, however this tool was not used due to the low number of severe adverse events found in the review.
Supplementary Table 1: Reproductive toxicity studies submitted by Merck as part of the New Drug Application of ivermectin

| Species     | Timing               | Daily dose     | Cumulative dose       | Adverse maternal effect   | Adverse pregnancy outcome |
|-------------|----------------------|----------------|-----------------------|---------------------------|---------------------------|
| **Mice**    | Gestation days 6-15  | 0, 0.1 mg/kg/day | 0-1 mg/kg in 10 days | Not found                 | Not found                 |
|             |                      | 0.2 mg/kg/day   | 2mg/kg in 10 days     | Tremors and convulsions   | Not found                 |
|             |                      | 0.4 mg/kg/day   | 4mg/kg in 10 days     | + Some maternal deaths    | Teratogenicity Cleft palate |
|             |                      | 0.8 mg/kg/day   | 8 mg/kg in 10 days    | As above                  | + exencephaly             |
|             |                      | 1.6 mg/kg/day   | 16 mg/kg in 10 days   |                           |                           |
| **Rats**    | Gestation days 6-17  | 0 mg/kg/day     | -                     | Not found                 | Not found                 |
|             |                      | 2.5 mg/kg/day*  | 30 mg/kg in 12 days   | Not found                 | Incomplete ossification   |
|             |                      | 5 mg/kg/day     | 60 mg/kg in 12 days   | Not found                 | bone ossification         |
|             |                      | 10 mg/kg/day    | 120 mg/kg in 12 days  | Some maternal deaths      | + cleft palate and wavy ribs |
| **Rabbits** | Gestation days 6-18  | 0 mg/kg/day     | -                     | Not found                 | Not found                 |
|             |                      | 1.5 mg/kg/day   | 19.5 mg/kg in 13 days | Not found                 | Cleft palate Clubbed forepaws |
|             |                      | 3 mg/kg/day     | 39 mg/kg in 13 days   | Not found                 | Cleft palate Clubbed forepaws |
|             |                      | 6 mg/kg/day     | 78 mg/kg in 13 days   | Body weight loss          | + abortions and stillbirths |
| **Primates**|                      |                |                       |                           |                           |
|             |                      |                |                       |                           |                           |
|             |                      |                |                       |                           |                           |
|             |                      |                |                       |                           |                           |
|             |                      |                |                       |                           |                           |
|             |                      |                |                       |                           |                           |

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Supplementary Table 2: Search Strategy

**MEDLINE (PubMed)**

| #1 | (ivermectin OR mectizan OR stromectol) |
|----------------|--------------------------------------|
| #2 | #1 AND (pregnan* OR gestation)        |
| #3 | #2; Filters: Humans                  |
| #4 | #3; Filters: Clinical Trial          |
| #5 | #3 AND abortion                      |
| #6 | #5 OR stillbirth                     |
| #7 | #3 AND (malformation OR congenital anomaly) |
| #8 | #3 AND (low birth weight OR prematurity OR death) |
| #9 | #3 AND adverse events                |

**Toxnet**

| #1 | (ivermectin OR mectizan OR stromectol) |
|----------------|--------------------------------------|
| #2 | #1 AND pregnan*                       |
| #3 | #2 AND human                          |
| #4 | #2 AND stillbirth                     |
| #5 | #2 AND malformation                   |
| #6 | #2 AND congenital malformation        |

**Scopus**

| #1 | (ivermectin OR mectizan OR stromectol) |
|----------------|--------------------------------------|
| #2 | #1 AND pregnan*                       |
| #3 | #2 Filters: Human, Clinical Trials    |
| #4 | #3 AND stillbirth                     |
| #5 | #3 AND malformation                   |
| #6 | #3 AND congenital malformation        |
| Reference                                      | Comment                                                                                           |
|------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Abengunde et al. 2016 [1]                      | Does not include pregnant women.                                                                  |
| Alout et al. 2014 [2]                          | Study is based on field entomological assessments.                                                |
| Ashraf et al. 2016 [3]                         | In vitro study.                                                                                    |
| Bialek et al. 1999 [4]                         | Provides general information about the negative effect of ivermectin in pregnancy based on preclinical evidence. |
| Biritwum et al. 1997 [5]                       | Does not include pregnant women.                                                                  |
| Blackburn et al. 2006 [6]                      | Does not include pregnant women.                                                                  |
| Brieger et al. 2002 [7]                        | Does not include pregnant women.                                                                  |
| Cartel et al. 1992 [8]                         | Does not include pregnant women.                                                                  |
| Chippaux et al. 1995 [9]                       | Evaluates different methods of pregnancy screening during ivermectin MDA.                         |
| Cook et al. 1995 [10]                          | Review that provides general information about adverse effects of chemotherapeutic agents used in tropical medicine. |
| Cupp et al. 2004 [11]                          | Assesses the effects of long-term community level treatment with ivermectin (Mectizan) on adult Onchocerca volvulus. |
| Da Silva et al. 1997 [12]                      | Review that provides information of clinical pharmacology of anthelmintic drugs.                  |
| Dupouy-Camet et al. 2003 [13]                  | Provides information about ivermectin use in tropical medicine and the general safety for pregnant women is discussed. |
| Einsiedel et al. 2008 [14]                     | Does not include pregnant women.                                                                  |
| Fawcett et al. 2003 [15]                       | Provides information about ivermectin use in scabies and concludes that ivermectin safety in pregnant women has to be established. |
| Guderian et al. 1997 [16]                      | Describes spontaneous abortions in areas of ivermectin MDA without direct treatment of pregnant women. |
| Hengge et al. 2006 [17]                        | Provides general information of scabies.                                                           |
| Henriquez-Camacho et al. 2016 [18]             | Does not include pregnant women.                                                                  |
| Executive Committee of Guideline for the Diagnosis of scabies in Japan et al. 2008 [19] | Guidelines that indicate that ivermectin safety is not established for pregnant women.             |
| Johnston et al. 2005 [20]                      | Does not include pregnant women.                                                                  |
| Kearns et al. 2015 [21]                        | Does not include pregnant women.                                                                  |
| Kearns et al. 2017 [22]                        | Does not include pregnant women.                                                                  |
| Krolewiecki et al. 2013 [23]                   | Review that indicates that ivermectin is contraindicated in pregnant women.                       |
| Lawrence et al. 2005 [24]                      | Does not include pregnant women.                                                                  |
| Reference                        | Details                                                                 |
|---------------------------------|-------------------------------------------------------------------------|
| Masud et al. 2009 [25]          | Does not include pregnant women.                                        |
| Osei-Atweneboana et al. 2007 [26]| Does not include pregnant women.                                        |
| Osei-Atweneboana et al. 2011 [27]| Commentary/review.                                                     |
| Ottesen et al. 2008 [28]        | Evaluates the impact of the global programme to eliminate lymphatic filariasis. Mentions the contraindication of ivermectin during pregnancy. |
| Pacque et al. 1989 [29]         | Does not include pregnant women.                                        |
| Potsman et al. 1998 [30]        | Case report about a pregnant traveller that ingested ivermectin and other drugs and had an elective abortion. |
| Richard-Lenoble et al. 2003 [31]| Provides general information about anti-parasitic treatments in pregnant women. |
| Richard-Lenoble et al. 2003 [32]| Provides general information about ivermectin and filariasis, and mentioned that ivermectin is contraindicated in pregnant women. |
| Rosenblatt et al. 1992 [33]     | Provides anti-parasitic agents information.                             |
| Rosenblatt et al. 1999 [34]     | Provides anti-parasitic agents information.                             |
| Sheele et al. 2013 [35]         | Does not include pregnant women.                                        |
| Soungalo et al. 1997 [36]       | Does not include pregnant women                                         |
| Stephenson et al. 2000 [37]     | Provides general information on anthelmintic treatment.                 |
| Taylor et al. 2010 [38]         | General review on lymphatic filariasis and onchocerciasis.              |
| Taylor et al. 2014 [39]         | Does not include pregnant women.                                        |
| Vaidyanathan et al. 2001 [40]   | Review of ivermectin in scabies, mentions that safety in pregnant women must be established. |
| Walker et al. 2000 [41]         | Review of Interventions for treating scabies.                           |
| Whitworth et al. 1996 [42]      | Does not include pregnant women.                                        |
### Supplementary Table 4: Source of funding

| Reference           | Source of funding                                                                                                                                 |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Chippaux et al. 1993 | This work received financial support from the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (ID no. 870336) |
| Doumbo et al. 1992  | Onchocerciasis Controle Programme (OCP), Département d’Épidémiologie des Affections Parasitaires (DEAP) de l’École Nationale de Médecine et Pharmacie du Mali (ENMP), Project MOS/OCP/OCT nº 86010) |
| Gyapong et al. 2003 | This investigation received financial support from the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and GlaxoSmithKline |
| Makene et al. 2003  | Not available                                                                                                                                 |
| Ndyomugenyi et al. 2008 | Funding for the study was provided by DBL-Centre for Health Research and Development. The American Society of Tropical Medicine and Hygiene (ASTMH) assisted with publication expenses |
| Pacque et al. 1990  | This study was supported by funds by the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (ID no 870096 and TDR 890525) and the National Institutes of Health (ID no 510-RR04060) |
Supplementary Table 5: certainty of assessment using GRADE for observational studies

| Certainty of assessment using GRADE approach | Risk of bias | Inconsistency | Indirectness | Imprecision | Certainty of evidence (GRADE) | Comments |
|--------------------------------------------|--------------|---------------|--------------|-------------|-------------------------------|----------|
| Spontaneous abortions and stillbirths      | HIGH         | LOW           | LOW          | HIGH        | VERY LOW ⊕⊕⊕⊕                 | There is not enough evidence to assess whether ivermectin increases the risk of abortions and stillbirths. |
|                                           | Downgrade by 1² | No downgrade³ | No downgrade⁴ | Downgrade by 1⁵ |
| Congenital anomalies                       | HIGH         | LOW           | LOW          | HIGH        | VERY LOW ⊕⊕⊕⊕                 | We do not know if the exposure to ivermectin during pregnancy increases the risk of congenital anomalies. |
|                                           | Downgrade by 1² | No downgrade³ | No downgrade⁴ | Downgrade by 1⁵ |

Legend:

1 Observational studies start as “low quality of evidence”.

2 Considerable risk of bias was detected using the Newcastle-Ottawa scale (NOS) (See Table 3).

3 There was no statistical heterogeneity ($I^2 = 0\%$).

4 The studies were all conducted in a way that directly addresses the review question.

5 We downgraded for imprecision given the low number of events in the group that had received ivermectin during pregnancy and the pooled estimate crossed the point of no effect (OR=1) and significant harm.
Supplementary Table 6: certainty of assessment using GRADE for RCT

| Certainty of assessment using GRADE approach¹ | Risk of bias | Inconsistency | Indirectness | Imprecision | Certainty of evidence (GRADE) | Comments |
|---------------------------------------------|--------------|---------------|--------------|-------------|------------------------------|----------|
| Spontaneous abortions and stillbirths       | HIGH         | LOW           | LOW          | HIGH        | VERY LOW ⊕⊕⊕⊕                 | We do not know if the exposure to ivermectin during pregnancy increases the risk of abortions and stillbirths. |
|                                             | Downgrade by 1² | No downgrade³ | No downgrade⁴ | Downgrade by 1³ |                             |          |
| Congenital anomalies                        | HIGH         | LOW           | LOW          | HIGH        | VERY LOW ⊕⊕⊕⊕                 | We do not know if the exposure to ivermectin during pregnancy increases the risk of congenital anomalies. |
|                                             | Downgrade by 1² | No downgrade³ | No downgrade⁴ | Downgrade by 1³ |                             |          |

Legend:

¹ Randomised controlled trials start off as high quality of evidence.

² Risk of bias was judged as high because of an undescribed allocation concealment method and the absence of blinding, which may have increased performance bias.

³ Only one RCT was included.

⁴ The study directly addresses the review question.

⁵ Downgraded for imprecision because the study was underpowered to measure a difference in adverse events between study arms. The numbers of participants and events were very low, the point estimates for both risk of spontaneous abortion and stillbirths and congenital anomalies crossed both the point of no effect (OR=1) and substantial harm.
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