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**Poor evidence – big decisions; a tale of the evidence on congenital Lyme disease**

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**Objectives/aims**

Use systematic review (SR) to support an evidence-informed approach to addressing a highly politicized issue and support public health recommendations on the impact of gestational Lyme disease (LD) in humans.

**Methods**

A SR was conducted to summarize the global literature on adverse birth outcomes associated with gestational LD in humans. The SR followed an *a priori* protocol of pretested screening, risk of bias, and data extraction forms. Data were summarized descriptively and random effects meta-analysis (MA) was used where appropriate. The results of the SR were used to support discussions with stakeholders about the evidence and development of public health recommendations.

**Main findings**

The SR identified 45 relevant studies, 29 describing 59 cases reported as gestational LD in the United States, Europe, and Asia (1969-2017) and 17 observational studies. Adverse birth outcomes included abortion or fetal death (n=11), newborn death (n=9), and newborns with an abnormal outcome at birth (n=14). Only one case provided a full case description (clinical manifestations in the mother, negative outcome for the child, and laboratory detection of *Borrelia burgdorferi* sensu lato complex (*B. burgdorferi* in the child) that provides some evidence for negative consequences for the fetus as a result of vertical transmission of *B. burgdorferi*. No study provided pathological evidence for how the presence of *B. burgdorferi* may be associated with pathology seen in the fetus. Eight studies found no difference in the prevalence of adverse birth outcomes in an exposed population (defined by the authors as: gestational LD, history of LD, tick bites or residence in an endemic area) and an unexposed population. A meta-analysis of nine studies identified significantly fewer adverse birth outcomes in women reported to have been treated for gestational LD (11%, 95% CI 7 -16) compared to those who were not treated during pregnancy (50%, 95% CI 30 -70) providing indirect evidence of links between gestational LD and adverse birth outcomes. Other risk factors; trimester of exposure, length of LD during pregnancy, acute vs. disseminated LD at diagnosis, and symptomatic LD vs. seropositive and healthy during pregnancy were not significantly associated with adverse birth outcomes. Thus, there is limited evidence for transplacental transmission of *B. burgdorferi;* adverse birth outcomes of gestational LD were inconsistent however we cannot rule out uncommon consequences of gestational LD.

The current evidence supports recommendations of diagnosis and treatment of gestational LD during pregnancy, which is only partially in line with the wishes of the stakeholder groups. This presentation will include discussion on our experience with stakeholder engagement and the challenges that need to be overcome when taking an evidence-informed approach to help address a research poor - highly politicized topic.