**Lyme Disease and Pregnancy and Congenital Lyme.**

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Maternal-fetal transmission of Lyme disease, adverse pregnancy outcomes, and congenital infection have been documented over the last 35 years since the pioneering findings of transplacental transmission of the Lyme disease spirochete were first reported by Schlesinger et al in 1985.[[1]](#footnote-1) This initial case-report triggered widespread notification of the risk of this alternate mode of transmission through epidemiological bulletins issued by the Centres for Disease Control[[2]](#footnote-2) (CDC), World Health Organization[[3]](#footnote-3) and Canadian Federal health authorities.[[4]](#footnote-4) The CDC has recently updated their online public guidance to address the risk of maternal-fetal transmission of Bb.[[5]](#footnote-5) Vertical transmission of Bb also been reported by the U.S. Tick-borne Working Group 2018 Federal Report to Congress[[6]](#footnote-6) and by the US National Institutes of Health[[7]](#footnote-7) in an informational booklet on Lyme disease titled, ‘Lyme Disease, The Facts, The Challenge.’

In 1991, Dr. Willy Burgdorfer, the world-renowned scientist[[8]](#footnote-8) attributed for the discovery of Bb authored a detailed summary[[9]](#footnote-9) on the findings of the spirochete that had been characterized and documented up to that date. He stated, ‘after ten years of intensive investigations and more than 2500 scientific publications, Lyme borreliosis is now recognized as the most prevalent tick-borne disease that every year affects thousands of people – children and adults alike. Indeed, in many regions where it is endemic, the disease itself has been considered second only to AIDS in public interest and concern.’ He also addressed the issue of in-utero transmission of Bb, discussing the ‘well-documented’ invasion of the placenta by spirochetes and both favourable and adverse pregnancy outcomes including neonatal death that had been reported up to that time. Dr. Burgdorfer had also co-authored an important case-report[[10]](#footnote-10) with pathologist Dr. Alan Macdonald, reporting histologic and culture positive findings of Bb in fetal autopsy tissue of a stillborn infant whose mother had been infected with Lyme in her first trimester and not received medical treatment. This report among several others set the foundation for expanding the clinical spectrum of Lyme disease from a purely zoonotic disease, to one which could also be transmitted from human-to-human,[[11]](#footnote-11) from a mother to her baby in pregnancy.

Three separate groups of experts authored papers reviewing the clinical aspects and spectrum of Lyme disease, also recognizing congenital infection with Bb. One paper [[12]](#footnote-12) stated, “Like syphilis, Lyme disease during pregnancy may be associated with congenital infection of the infant and resulting clinical illness. Several reports describe infants who died shortly after delivery, or were stillborn, to mothers who had Lyme disease during pregnancy. Spirochetes were found in autopsy specimens from some of these babies.” A second review[[13]](#footnote-13) titled *Clinical Features of Lyme borreliosis* listed congenital disease as part of the main clinical spectrum of Lyme borreliosis, also highlighting similarities to syphilis. A third paper[[14]](#footnote-14) by authors who had also reported on the first documented case of transplacental transmission of Bb[[15]](#footnote-15) stated: ‘It is clear that B. burgdorferi can be transmitted in the blood of infected pregnant women across the placenta into the fetus. This has now been documented with resultant congenital infections and fetal demise. Spirochetes can be recovered or seen in the infant’s tissues including the brain, spleen and kidney..’

Thirty years after Dr. Burgdorfer’s 1991 report, the prevalence of new cases of Lyme disease continues to dramatically rise in North America and globally, with the US CDC estimating 470,000 yearly cases[[16]](#footnote-16) and estimates from Germany of over 300,000 new yearly cases.[[17]](#footnote-17) Epidemiological reports from China[[18]](#footnote-18) [[19]](#footnote-19) identify an average infection rate of 5.06% in the human population per year. It is currently unknown and unstudied what percentage of new cases of Lyme disease attributable to maternal-fetal transmission of the spirochete, could be contributing the rising global prevalence. There is no epidemiological mechanism in place to identify or track these cases, even if considered rare.[[20]](#footnote-20) In a recent publication on tickborne infections in pregnancy[[21]](#footnote-21), the author, an infectious disease specialist, highlights that an ICD-11 code for congenital Lyme infection would allow for ‘better science and improved understanding’ of this alternate mode of transmission and in turn, result in ‘improved maternal and child health.’

Evidence for transmission of B. burgdorferi in pregnancy, from mother to placenta and/or fetus/neonate/child includes:

* 20 cases whereby Borrelia was identified via autopsy of fetal[[22]](#footnote-22) [[23]](#footnote-23) [[24]](#footnote-24) or neonate tissue [[25]](#footnote-25) [[26]](#footnote-26) utilizing culture[[27]](#footnote-27) [[28]](#footnote-28), immunohistochemistry[[29]](#footnote-29), indirect immunofluorescence, PCR[[30]](#footnote-30) and microscopy. (8 neonatal deaths, 4 cases of stillbirth and 7 cases of miscarriage).
* 15 cases of live-birth, neonatal infection [[31]](#footnote-31) [[32]](#footnote-32) [[33]](#footnote-33) [[34]](#footnote-34) [[35]](#footnote-35) [[36]](#footnote-36) [[37]](#footnote-37) [[38]](#footnote-38) and adverse outcomes [[39]](#footnote-39) including two cases where Bb specific antibodies were identified in the cerebral spinal fluid (CSF) of infected symptomatic neonates.[[40]](#footnote-40) [[41]](#footnote-41)
* 2 cases of live-birth, Bb identified by PCR in cordblood of infants whose mothers were treated.[[42]](#footnote-42)
* 1 case of a child who died at age 7 because of cerebral complicaitons of congenital Lyme borreliosis.[[43]](#footnote-43)
* 20 cases Bb identified by histological methods or PCR in placentas of treated[[44]](#footnote-44) [[45]](#footnote-45) [[46]](#footnote-46) [[47]](#footnote-47) [[48]](#footnote-48)(18) and untreated [[49]](#footnote-49) (2) women.

Evidence for in-utero transmission of Borrelia burgdorferi sl has also been reported in mice[[50]](#footnote-50) [[51]](#footnote-51) [[52]](#footnote-52) [[53]](#footnote-53) [[54]](#footnote-54), rats[[55]](#footnote-55), cows [[56]](#footnote-56) [[57]](#footnote-57), horses[[58]](#footnote-58), vixens, dogs,[[59]](#footnote-59) [[60]](#footnote-60) and coyotes[[61]](#footnote-61) with direct detection of Borrelia spirochetes in tissues by various methods including culture, PCR and immunofluorescent staining. Four other experimental animal studies did not show transplacental transmission [[62]](#footnote-62) [[63]](#footnote-63) [[64]](#footnote-64) although in one experimental study[[65]](#footnote-65) despite not identifying transplacental transmission, authors identified sexual and contact transmission as possible alternate routes of Bb infection in mice.

A 1991 committee opinion [[66]](#footnote-66) by The American College of Obstetricians and Gynecologists (ACOG) acknowledges spirochetes can cross the placenta with resultant stillbirth. The UK Royal Society of Obstetricians and Gynecologists[[67]](#footnote-67) has listed Lyme disease as one of the infectious organisms which can cross the placenta leading to late intrauterine fetal death and stillbirth. Expert reviews on stillbirth in the American Journal of Obstetrics and Gynecology, [[68]](#footnote-68) Obstetrical and Gynecological Survey,[[69]](#footnote-69) Seminars in Fetal and Neonatal Medicine[[70]](#footnote-70), and the Lancet[[71]](#footnote-71) have identified Borrelia burgdorferi as being either associated with, or etiologic for stillbirth.

A paper published on the histopathology of Lyme borreliosis[[72]](#footnote-72) states, ‘Uterine involvement in stage II Lyme borreliosis is a significant factor in pregnancysince it may result in transplacental transmission of B. burgdorferi to the fetus. One of us has recently encountered cases of decidual necrosis with inflammation in patients with intrauterine infection due to B. burgdorferi (de Koning, unpublished data).’

Recent Infectious Disease Society (IDSA) 2020 guidelines[[73]](#footnote-73) on Lyme disease state, ‘to date, Lyme disease in pregnancy has not been found to result in congenital infection or a syndrome of congenital abnormalities, and no additional treatment or monitoring of the mother or infant is recommended beyond the standard of care.’ There are no citations for this statement. In a 2020 review on Lyme disease in the BMJ [[74]](#footnote-74)authors state, ‘During spirochetemia in the acute phase of infection, B burgdorferi sl may spread transplacentally, and evidence for congenital infection has indeed been reported in a few cases where Borrelia species were cultured from the newborn post-mortem.’

Several expert reviews specifically addressing Lyme disease and Pregnancy, [[75]](#footnote-75) [[76]](#footnote-76) [[77]](#footnote-77) [[78]](#footnote-78) [[79]](#footnote-79) [[80]](#footnote-80) [[81]](#footnote-81) [[82]](#footnote-82) [[83]](#footnote-83) [[84]](#footnote-84)

[[85]](#footnote-85) zoonotic,[[86]](#footnote-86) vector borne,[[87]](#footnote-87) or tickborne[[88]](#footnote-88) infections in pregnancy, fetal /congenital infections,[[89]](#footnote-89) [[90]](#footnote-90) epidemiology of Lyme disease[[91]](#footnote-91) and Lyme disease in general[[92]](#footnote-92) [[93]](#footnote-93) [[94]](#footnote-94) [[95]](#footnote-95) [[96]](#footnote-96) [[97]](#footnote-97) [[98]](#footnote-98) [[99]](#footnote-99) [[100]](#footnote-100) acknowledge maternal-fetal transmission of the Lyme disease spirochete and risk of adverse pregnancy outcomes.

A heterogeneous range of adverse pregnancy outcomes reported with gestational Lyme disease includes spontaneous miscarriage, stillbirth, premature delivery, neonatal death, intrauterine growth retardation and varying clinical manifestations in the newborn ranging from low birth weight and hyperbilirubinemia to hypotonia, cortical blindness, developmental delay, cardiac and urinary tract defects, syndactyly, respiratory distress and newborn rash.[[101]](#footnote-101) [[102]](#footnote-102) [[103]](#footnote-103) A meta-analysis performed in a recent systematic review by Waddell et al[[104]](#footnote-104) identified treated Lyme in pregnancy is associated with fewer adverse outcomes (11%, 95%CI 7–16) versus untreated (50%, 95%CI 30–70). A study by Lakos et al[[105]](#footnote-105) reviewed data from 95 women with Lyme borreliosis during pregnancy over a 22 year span. Adverse outcomes were identified in 12.1% of parentally treated women, 31.6% of orally treated women and 60% of untreated women, thus drawing attention to a significantly higher rate of adverse pregnancy outcomes in untreated cases.

No defined pattern of teratogenicity, causal association or clearly defined congenital syndrome has been associated with gestational Lyme, [[106]](#footnote-106) [[107]](#footnote-107) yet, according to Infectious Diseases pediatrician Dr. Tessa Gardner, ‘it is possible that B. burgdorferi gestational infection with transplacental dissemination could cause fetal pathology simply by causing Lyme borreliosis with the same manifestations (cutaneous, musculoskeletal, neurologic, neuropsychiatric, neurocognitive and urologic) that it produces in children and adult patients.’[[108]](#footnote-108) Dr. Gardner also outlined a framework to identify congenital Lyme borreliosis by categorizing the ‘incidence, time of presentation, and clinical manifestations of the various adverse outcomes associated with gestational Lyme borreliosis, including miscarriage, early severe congenital Lyme borreliosis, early mild congenital Lyme borreliosis and late chronic congenital Lyme borreliosis.’

Various case reports of maternal infection with subsequent vertical transmission have been published highlighting the labyrinthine complexity and diversity of clinical presentations with some authors identifying parallels to congenital syphilis.[[109]](#footnote-109) [[110]](#footnote-110) Two retrospective cases identified women who recalled tick-bites, had an EM rash and remained untreated with positive serology post-partum. In these cases, congenital heart defects and Bb spirochetes were identified upon fetal autopsy following neonatal death[[111]](#footnote-111) and stillbirth.[[112]](#footnote-112)

Cases of untreated, asymptomatic, seropositive maternal infection without recall of tick-bite or EM rash have resulted in reports of a term stillbirth with spirochetes identified in fetal tissue by dark-field microscopy,[[113]](#footnote-113) and in two cases whereby infants were diagnosed with congenital Lyme borreliosis; a 3-day-old infant with septic illness with IgG and IgM Borrelia antibody titres detected in blood and cerebrospinal fluid,[[114]](#footnote-114) and a male infant who manifested with relapsing/remitting episodes of multiple erythematous patches, fever and lymphadenopathy, starting at 3 weeks of birth and recurring over 3 years despite repeated courses of oral antibiotics. The rash was subsequently biopsied, and Bb identified through PCR. Seroconversion by IgG-WB was observed in the child at 13 months.[[115]](#footnote-115) A 1992 publication titled, *Current Perspectives on Lyme Borreliosis*, authored by Dr. Richard Kaslow from the Epidemiology and Biometry Branch, Division of Microbiology and Infectious Diseases, NIAID (NIH)[[116]](#footnote-116) stated ‘instances of severe illness in infants following transmission from untreated mothers has already lowered the threshold for more aggressive treatment of pregnant woman.’

Cases of neonatal death[[117]](#footnote-117) [[118]](#footnote-118) and diagnosis of congenital Lyme borreliosis[[119]](#footnote-119) have been reported whereby the mothers recalled a tick-bite, manifested an EM rash and were treated with varying courses of antibiotics, thus calling into question appropriate treatment strategies for gestational Lyme. A 1990 publication on treatment of Lyme disease[[120]](#footnote-120) stated, ‘the precise risk to the developing fetus of maternal Lyme disease during pregnancy is unknown although it is well documented that fetal infection can occur and may have deleterious outcomes including malformations and death. Since anecdotal experience has suggested that oral antibiotic therapy does not invariably protect the fetus, I prefer to use high-dose intravenous penicillin for pregnant women with active Lyme disease.’ Another expert[[121]](#footnote-121) also opined on appropriate treatment for gestational Lyme, ‘In one instance in which oral penicillin was administered during the fIrst trimester of pregnancy, the erythema migrans disappeared, but autopsy of the newborn, who died 1 day after birth, showed an infection of brain and liver with B. burgdorferi (Weber et al. 1988b). Thus, oral penicillin is not recommended during pregnancy, although several women on this regimen have delivered normal children (Berger 1984; Weber et al. 1986; Neubert 1987).’

A case of a woman with a four-month history of migratory joint pain and a positive IgG Western Blot was treated with several months of antibiotics, had symptom resolution, and later became pregnant but had a miscarriage at week 18.[[122]](#footnote-122) PCR testing of the placenta and fetus returned positive for Bb. In another case report, a baby was diagnosed with Lyme disease with a positive ELISA and Bb was also identified by PCR in placental tissue. His mother had been treated for serologically proven Lyme disease over a period of one year before pregnancy. At the age of seven, the child died ‘because of cerebral complications of congenital Lyme borreliosis.’ Histological/transmission electron microscopy revealed rare spirochetes in eye tissue. Bb was also identified in heart and kidneys upon autopsy.[[123]](#footnote-123)

Cases of asymptomatic, seronegative maternal infection have been reported, with a notable case of neonatal death at 8 days, resulting in autopsy which revealed Bb in neonate brain and heart.[[124]](#footnote-124) A report by Dattwyler et al [[125]](#footnote-125) highlighted the case of a mother diagnosed with Bb infection in her second trimester who was subsequently treated with antibiotics. She was asymptomatic and seronegative at time of birth and her child was born with neurologic dysfunction. Neonatal Bb infection was confirmed with serological evidence of antibodies specific to borrelia in infant CSF.

Macdonald[[126]](#footnote-126) reported a series of cases of gestational Lyme borreliosis with borrelia identified from pathologic examination of fetal tissues in 8 of 14 cases. 6 cases of live birth were reported with one infant developing respiratory distress and another developing neonatal sepsis. 9/14 mothers were seronegative for Lyme borreliosis with the author identifying that ‘most of the fatal cases of Lyme borreliosis in pregnancy were reactive in titres of the borderline region or were completely non-reactive in serologic tests,’ and ‘the tendency toward sero-negativity in pregnancy makes maternal serology a less satisfactory discriminator of maternal infection and useless as a practical tool to predict the state of the fetus.’ He also examined 10 cases of sudden infant death syndrome (SIDS) and identified two cases whereby spirochetes morphologically consistent with Bb were identified in two infant brains.

Epidemiological studies conducted to date offer limited information to support any association between maternal infection, congenital malformations and adverse outcomes. [[127]](#footnote-127) A prospective Bb serosurvey[[128]](#footnote-128) of pregnant women from high and low endemic areas in New York performed between 1988-1990, identified 11 women from a cohort of 2014 women (0.7%) who were seropositive at their first prenatal visit. The eleven pregnancies resulted in live births with three congenital defects noted but uniformly negative cord-blood IgM. Authors concluded that ‘having been diagnosed with Lyme disease or being at high risk of exposure to Lyme disease before conception or during pregnancy is not associated with fetal death, low birth weight, or congenital malformations as a whole.’ Authors identified a statistically significant association between past miscarriages and maternal tick bite and noted that cardiac defects were twice as high in children born to mothers in a endemic vs non-endemic area. They acknowledged that their study was underpowered and ‘the number of women too small to draw conclusions about the risk of a having a child with congenital malformation if a woman is seropositive.’ Neither cord-blood or neonatal serum of infants born to seropositive women was tested by culture or PCR and serological testing in these infants at later intervals was not done.

A second cord-blood sero-survey[[129]](#footnote-129) of infants in endemic versus non-endemic areas of New York was performed between 1986 -1988 in New York. There were 29 infants whose mothers had Lyme disease any time before or during pregnancy and 20 infants with positive IgG cord-blood samples. Authors indicated that ‘a positive serology and positive clinical history were not often present in the same individual’, in fact, none of the mothers of infants with a seropositive result gave a clinical history of past diagnosed Lyme disease. Authors reported a significantly greater incidence of heart defects as well as murmurs detected in the endemic cohort. Congenital defects of infants born to mothers who had Lyme disease prior to study pregnancy were described including a report of an infant who died of multiple congenital heart defects and another infant with hydrocele and laryngomalacia. Congenital anomalies including cardiac and urological defects were reported in 8/67 infants in the endemic cohort whose mothers identified a tick-bite in pregnancy. Authors concluded that the findings of this study combined with their previous study ‘indicate that having a past treated or untreated infection with Bb does not increase the risk of low birthweight, early fetal loss or congenital malformations as a whole.’ They identified considerable sample size constraints and ‘limited follow-up with respect to any long-term sequelae of prenatal exposure to Lyme’.

A third retrospective case-control study[[130]](#footnote-130) in 1999 was performed with the objective of determining whether maternal Lyme increases the risk of a congenital heart defect and with a conclusion that a ‘woman who has been bitten by a tick or is treated for Lyme disease during or before pregnancy is not at increased risk of giving birth to a child with a congenital heart defect.’ The risks associated with undiagnosed and untreated Lyme disease was not evaluated.

A large sero-survey from Russia[[131]](#footnote-131) enrolled 1039 women during routine pregnancy check-ups. There was a seropositivity rate of 5.5% (57 of 1039 women). Authors stated they did further clinical and serological observations in cases of seropositive women, and they also noted positive results in blood samples taken from umbilical blood in newborns. They also reported that histological and bacteriological study of placenta material had been undertaken and they were monitoring children of mothers with antibodies to the Lyme disease pathogen in their first year of life. They stated, ‘the data accumulated to date indicate that LD represents a serious risk factor in pregnancy: it increases the likelihood of miscarriage, has a teratogenic effect on the fetus in intrauterine infection and increases the indicators of perinatal mortality.’ Authors stated that specific results from their studies would be analyzed in separate reports. It appears these reports were not published.

A 2015 paper authored by Jasik and colleagues[[132]](#footnote-132) also addresses the ability for tick-borne diseases to pass through the placenta of infected animals and humans and the highlights the possibility of intergenerational infection. Regarding Borrelia burgdorferi infection, authors state: ‘It is possible that B. burgdorferi s.l. has a high ability to penetrate mammalian placentae due to its ability of active movement, antigenic and morphological variation, and many other features and causes diagnostic difficulties and problems. In cases of intrauteral fetal infections among patients with Lyme disease, symptoms are not homogeneous. Thus, confirming that B. burgdorferi s.l. is transmitted transplacentally may play important role in the spreading of these pathogens.’ Authors also highlight issues of persistence of infection despite antibiotic treatment and state: ‘The ability of long-term survival of B. burgdorferi s.l. in tissues and spreading of spirochetes in the body despite antibiotic treatment can contribute to intergenerational infection of Lyme disease.’

Since 1999, (over 20 years), there has been a lack of government funded research exploring maternal-fetal transmission of Borrelia burgdorferi in North America. NIH funded research exploring vertical transmission of Borrelia burgdorferi was published in 1996 [[133]](#footnote-133) and identified Bb by PCR in placentas of a small subset of women. Authors stated, ‘the presence of these spirochetes in placental tissue implies fetal transmission.’ The three women with spirochetes identified in their placentas had equivocal ELISAS, were asymptomatic and had no recall of tick-bite. There is no mention if these women were treated with antibiotics. Two women had a negative WB and the third was equivocal. Infants born to these women were healthy at birth, cord blood serology for IgG and IgM negative. There was no mention of longitudinal follow-up or re-evaluation of infant sero-status at a later date. Researchers at that time recommended further investigation: ‘long-term follow-up of infants born to mothers with placenta spirochetes is needed to determine what effect, if any, placental spirochetes may have on health and development of these individuals.’ The issue of discordance between findings placental spirochetes and borderline to negative maternal serology supports the earlier findings by MacDonald.

The 2020 US Tickborne Disease Working Group report to Congress[[134]](#footnote-134) has identified in Recommendation 8.3 ‘Further evaluation of non-tick bite transmission of Lyme disease, for example maternal-fetal transmission.’ The report also states, ‘Similarly, additional studies of potential congenital Lyme disease, and of persistent Lyme disease in undiagnosed and untreated infants resulting from maternal transmission of B. burgdorferi, could be helpful, as could patient registries.’

In a July 4, 1989, article in the New York Times titled *Medical Science Steps Up its Assault on Lyme Disease*, Dr. David Axelrod, the New York State Health Commissioner at the time was interviewed[[135]](#footnote-135) and quoted. When asked about Lyme and pregnancy, he stated: “We do know that the Lyme bacterium crosses the placenta. Most babies born of mothers with treated Lyme disease have been healthy, yet the long-term impact of this disease on the developing fetus and the newborn is not entirely clear.” Dr. Axelrod’s quote from over 30 years ago rings true today. It is known that the Lyme disease causing spirochete can cross the placenta and infect a fetus/baby, as has been acknowledged by many experts in the field.

Significant knowledge gaps remain regarding how Lyme disease impacts pregnancy in cases of acute versus chronic or subclinical illness, including best diagnostic approaches to identifying infection in both mother and baby, best treatment approaches in a pregnant woman or in an infant who is symptomatic at birth. Questions remain as how to identify a pregnant woman who may be infected but does not recall a tick-bite or EM rash, or the possibility of a latent or subclinical infection. Very little information exists on the potential for long-term health impacts of babies born to mothers with gestational Lyme. Clearly, the prevalence, incidence, clinical spectrum and potential long-term health consequences of infants exposed to Lyme in-utero must be further examined.[[136]](#footnote-136)

Due to multifold, heterogeneous, complex, and often confounding presentations of Bb infected mothers and their babies, it is clear that urgent re-investigation of transplacental transmission of Lyme disease be prioritized including development of pregnancy registries for mothers with gestational Lyme and implementation of well-designed prospective studies.[[137]](#footnote-137) Funding of non-human primate (NHP) studies are critical to providing a comprehensive, robust experimental platform to assess the risk of in-utero transmission of Bb and fetal outcomes within a controlled setting, as is done for other congenital infections.[[138]](#footnote-138) According to a recent review on the subject matter[[139]](#footnote-139), experts state, ‘NHP models are essential to determining the potential for fetal injury and teratogenesis due to new pathogens and the efficacy of therapeutics to prevent fetal damage.’

State of the art science is required to investigate the research gaps and complexities of this alternate mode of transmission and will require a collaborative multi-disciplinary, multi-stakeholder ‘relay-team’ approach, which values an integrative model of bringing together patients with lived experience, front-line clinicians, clinical researchers, and scientists to collectively identify, propose and carry out further investigation. This will inevitably open new doors for better diagnostics, treatment, healthcare professional education and resources, and ultimately much needed medical care, support and hope for families[[140]](#footnote-140) and children impacted.

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