Maternal infections: revisiting the need for screening in pregnancy

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Abstract

The decision to implement screening for infections during pregnancy depends upon epidemiological, economic, therapeutic and test performance criteria. It therefore varies with public health priorities from country to country. When screening is implemented, first trimester has become the best time slot to build individual care pathways also in this field. This is most relevant for evaluating the risk of embryonic consequences, plan diagnostic testing, initiate primary or secondary prevention and increase the accuracy of ultrasound follow-up. This is a critical appraisal of epidemiological data and current international screening recommendations for infections in pregnancy.

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Running head : Early Pregnancy Infection Screening

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Introduction

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Pregnancy: an opportune time for women to be screened and receive appropriate care for the mother and the unborn child

Hepatitis C

Hepatitis C affects 1% of the adult population (HCV RNA–positive)[1] and 0.38% of live born infants are born from HCV–infected women in the USA[1,3]. The risk of vertical transmission is around 5.8% and up to 10.8% when women are co-infected with HIV. In contrast, this risk was negligible in women with HCV antibodies but negative for HCV-RNA [2]. Neither mode of delivery nor breastfeeding seem to affect vertical transmission[3]. However, invasive testing, internal fetal monitoring, and prolonged rupture of membranes have been empirically discouraged in the USA[4].

International recommendations have long been to offer screening to high risk women only (Table 1). However, since April 2020, the CDC and the American Association for the Study of Liver Diseases (AASLD)[5] have ruled in favor of universal screening in pregnancy when the prevalence of HCV infection is $> 0.1\%$. This should be done at booking using HCV antibody assay and confirmatory RNA testing for positive serologies.

This is in line with recent epidemiologic and cost-effectiveness evaluations as well as the development of new direct-acting antiviral (DAA) therapy[5]. Infected women should be referred for specialized medical evaluation. DAA is not yet approved for use in pregnancy but when introduced post-partum, it treats infected women and reduces the risk of HCV transmission to future offspring[5,6].

Hepatitis B

Up to 6% of pregnant women are infected with hepatitis B in high-prevalence areas such as Western Pacific and African Regions[7]. In the absence of prophylaxis, hepatitis B is passed to the child at birth from 90% and 10-20% of mothers who are both (HBsAg) and (HBeAg)-positive and (HBsAg) positivity alone respectively[8,9]. The risk for the infected neonate to develop chronic infection is 80-90 %. Infected offspring becomes a reservoir for horizontal transmission during the first 5 years of life.[7] Universal screening in pregnancy is recommended worldwide[13] and should be repeated in the 3rd trimester in high risk-women (Table 1).

Prophylaxis is obtained through hepatitis B vaccination and hepatitis B immunoglobulin (Ig) administration at birth in neonates born from HBsAg-positive mother.

Antiviral treatment with telbivudine, lamivudine, and tenofovir is safe in pregnancy[11,12] and is indicated in cases with high viral load (HBV DNA >200,000 IU/mL or 10^6copies/mL). It improves HBV suppression and reduces perinatal transmission (RR=0.3)[11,12]. This strategy proved cost-effective in the USA[13]. Vaccination remains a goal and can be safely offered to seronegative women in early pregnancy[7,10,14].

Human Immunodeficiency Virus (HIV)

Around 1.3 million HIV positive women become pregnant every year[15] and in the US, 1 in 9 women with HIV are unaware they have it [16]. The highest prevalence of HIV among adults aged 15 to 49 reaches

3.9% in Africas[17]. Perinatal transmission occurs during pregnancy, at delivery, but also in the postpartum period through breastfeeding. Without medical intervention 15–30% of infants born to HIV-positive women will become infected during gestation and delivery, with a further 5–15% becoming infected through breastfeeding[15]. Universal screening in pregnancy is recommended although not mandatory in any country for ethical reasons (Table 1). In order to encourage its implementation, some countries opted for systematic screening unless the woman explicitly refuses (opt-out approach)[18].

The performance of the HIV-1/2 antigen/antibody test is excellent with 99.8% to 100% sensitivity and 99.5% to 100% specificity and the results are available within hours with rapid HIV-tests[19]. Screening should be carried out as early as possible in pregnancy, at best pre-conceptionally.

In the event of positive serology, immediate initiation of antiretroviral treatment has proven effective to reduce MTCT down to 1.5%[20,21] and virtually zero when treatment is initiated before conception[22]. When maternal viral load is significant, planned caesarean section covered by intravenous Zidovudine is recommended across the board. However the viral load threshold above which a planned caesarean section may be beneficial is difficult to establish, which explains the discrepancy between recommendations ranging between 50, < 1000, and < 400 copies/mL in the British, American and French recommendations respectively[23 2425].

Finally, serial screening in 1st and 3rd trimesters also benefits high-risk seronegative women to discuss pre-exposure prophylaxis (PrEP)[26] to reduce the risk of MTCT[27].

Chlamydia trachomatis (ChT)

ChT is the most common sexually transmitted pathogen affecting up to 4.3% of sexually active women in the US and infections are largely asymptomatic[28] . In pregnancy, 1.7% of mostly asymptomatic women were diagnosed with ChT[29].

A review of 614,892 cases suggested that ChT infection in pregnancy increases the odds of several adverse outcomes: preterm premature rupture of membranes (OR = 1.81) endometritis (OR=1.69) low birthweight (OR= 1.34), small for gestational age (SGA) (OR=1.14) and intrauterine fetal demise (OR=1.44)[30] . However, authors highlighted that the literature in this review was complicated by heterogeneity and that the association may not hold in higher quality and prospective studies or those that use more contemporary nucleic acid testing. In the largest recent prospective screening study it was found similar outcomes in women who tested positive and were treated and those who tested negative [31]. Finally, the relationship between ChT infection and miscarriage is unclear[29,32].

Pregnant women infected with chlamydia can also pass the infection to their infants during delivery. With regard to neonatal consequences, some studies have estimated that 50–70% of infants born to mothers with ChT will become infected with ChT, and 30–50% of these infants will then develop chlamydial conjunctivitis, and 10–20% will develop pneumonia[33,34].

The evidence for screening and treatment in pregnancy is thin and there is no international consensus on ChT screening in pregnancy and clinical trials are still needed. It is recommended to screen at the first prenatal visit In the US and Canada[35] but this is seldom in Europe (Table 1) [33]. However, when a vaginal swab shows positive for ChT in a symptomatic woman, there is a consensus to treat.

Screening for infections that carry a risk of congenital anomaly

Syphilis

In 2012, approximately 930,000 maternal syphilis caused 350,000 adverse pregnancy outcomes including 143,000 fetal deaths/stillbirths, 62,000 neonatal deaths, 44,000 preterm/low weight births, and 102,000 infected infants worldwide[36]. Those outcomes were respectively 21%, 9.3% and 5.8% more frequent than

among women without syphilis[37]. This led WHO to establish guidelines to prevent vertical transmission, aiming for complete eradication of CS by 2030 [15]. The CDC raised awareness about the resurgence of cases of congenital syphilis (CS) in the US having more than doubled in 4 years, reaching a 20-year high[38].

There are two types of serological tests: non-treponemal, (Venereal Diseases Research Laboratory (VDRL); and treponemal (Treponema pallidum haemagglutination assay (TPHA), and fluorescent treponemal antibody absorbed (FTA-ABS) tests). A rapid syphilis treponemal test (RST) is also available with antibody results in 15 minutes. This RST can be performed in any setting without laboratory equipment unlike the other tests. Screening at booking is recommended worldwide for effective maternal treatment and WHO has issued empirical decision-making flowcharts for screening and treatment [39]. Serologic testing is also recommended while exploring cases of intrauterine fetal death[38,39].

Benzathine penicillin G 2.4 million units is given once intramuscularly in primary, secondary and latent syphilis of not more than two years. This should be repeated weekly for 3 weeks in infections ongoing more two years without evidence of treponemal infection [40].

Making syphilis screening universal, or even mandatory, may seem excessive, particularly in low prevalence populations, but WHO argues that this should be maintained and reinforced because it increases equity, is cost-effective, acceptable to patients, correctly performed by laboratories and, above all, it prevents severe obstetric complications in the event of proven infection (Table 1).

Toxoplasmosis

Maternal primary infection (MPI) with Toxoplasma gondii is mostly asymptomatic [41], but it carries a risk of neurological and ocular sequelae in the offspring. Although congenital toxoplasmosis (CT) poses a substantial burden of poor health with around 190,100 cases worldwide per year [42], seroprevalence has dropped in many countries over the last 20 years. In French pregnant women , it decreased, from 54 % in 1995 to 37% in 2010[43] and a similar decrease was observed in the US, down to 9.1%[44]. In France, the rate of seroconversion during pregnancy was between 0.2% and 0.25% in 2015[45] and since 2007 an overall prevalence was estimated around 3 to 4 cases per 10,000 live births (prevalence of severe forms: 0,1 in 10,000). However, 10% of CT infections are symptomatic, 25% of those are severe and over 10% lead to medical terminations of pregnancy following prenatal diagnosis[45].

Few countries offer routine screening for CT during pregnancy, and France and Austria have been most proactive since the 1970s[46,47](Table 1). Both programs have witnessed a decline in the incidence of CT and in fetal and pediatric damage[48,49].

The rationale for not offering screening includes low incidence of the disease, cost of screening and lack of evidence regarding effectiveness of antenatal treatment. However, recent publications from France and Austria suggest that prenatal screening for prevention was cost-saving and led to maintain current policies[47,48].

Classically , it is assumed that cat and food hygiene and cooking, particularly consumption of rare or raw meat are the main risk factors for infection with toxoplasma [50],[41]. However, the only two randomized clinical trials (RCT) testing education approaches, showed no difference in seroconversion in relation with any of those risk factors[51,52].

MPI is the appearance of specific G globulins (IgG) in a previously seronegative patient or by marked elevation of specific IgG in the presence of specific Ig M (IgM). The difficulty rests in the interpretation of positive IgM. Indeed, IgM may persist for years following acute infection; therefore isolated positive IgM are not absolute evidence of recent toxoplasmosis[53]. Algorithms of interpretation, using different assays to measure Ig titers, IgG avidity and sequential serological testing should be used to date MPI within expert laboratories[47].

MTCT is by transplacental passage of the parasite and the rate increases with gestational age at seroconversion (OR= 1.17 for each additional week)[54]. In one meta-analysis the rate of MTCT by gestational age at

seroconversion was 15% , 44%, 71% at 13, 26, 36 weeks respectively [55]. The risk of maternal seroconversion in the first weeks of pregnancy is < 5 %[56,57].

Gestational age at maternal seroconversion is the major prognostic factor in CT. The number of fetuses showing CT-related abnormalities on ultrasound is higher in infections early in pregnancy, and in up to 78% in the first trimester[58]. The proportion of symptomatic infants before the age of 3 falls from 61% to 25% and 9% following MPI at 13, 26 and 36 weeks respectively [59].

Infected fetuses can be asymptomatic or bear multisystemic damage including brain injury [60] and even die in-utero[61]. Normal antenatal ultrasound follow-up is associated ,with a negligible risk of abnormal neurological outcome, even following first-trimester infection [57,62]. However normal ultrasound monitoring cannot exclude the risk of chorioretinitis[62]. CT treated prenatally carries an overall risk of chorioretinitis of 26 %, although mainly peripheral.[57]. Long-term follow-up is recommended since only 39% of chorioretinitis are diagnosed at birth [57].

The rationale for antenatal treatment in CT is controversial. Treatment regimens vary but are based upon spiramycin and pyrimethamine–sulfamides (PS) (Figure 1)[47,46].

None of the recent prospective [63], or randomized studies [54] reported a significant effect of antenatal treatment on MTCT or on the fetal prognosis although none could exclude clinical benefits. The SYROCOT study reviewed 26 cohorts with 1,438 cases following prenatal screening and reported that treatment started within 3 weeks of seroconversion reduced MTCT compared with late (>8 weeks) treatment (p=0.05) [55]. The EMSCOT study found that prenatal treatment of infected fetuses, adjusted for gestational age at MPI , reduces the risk of serious neurological sequelae by 75% [64]. In addition, in 300 infants with CT, an interval > 8 weeks between MPI and intrauterine treatment initiation was associated with an increased risk of chorioretinitis [65]. Finally, in the only RCT comparing the two antenatal drug regimens, the incidence of prenatal cerebral signs of CT following prophylactic administration was lower with PS than with spiramycin [54].

Although CT can cause severe complications in the fetus, its decline in prevalence and incidence and controversial data on the efficacy of antenatal therapy explain that only a few countries in the world offer screening in pregnancy. However, primary prevention and screening for toxoplasmosis at first prenatal care visit is easy to implement with cost-benefit studies pointing in this direction.

Cytomegalovirus

Cytomegalovirus is the most common congenital infection (cCMV), affecting 0.5–2% of live births. It is the main non-genetic cause of congenital sensorineural hearing loss and of neurological damage[6667]. In high-income countries, about half of infected newborns are infected as a result of MPI and the other half as a result of non-MPI (reactivation or re-infection) [68]. Seroprevalence is high (50% in the USA and Europe, up to 100% in southern countries) and women at higher risk for MPI during pregnancy in high-income countries are typically young, multiparous, with high income[68]. In addition, it has recently been shown that women delivering again within 3 years of a previous baby who is in childcare have a 7% risk of MPI in the first trimester of the new pregnancy[69].

The risk of MTCT depends upon the trimester of MPI. Summarizing the results of the most relevant studies, it appears that the risk of transmission after MPI in the 1st, 2nd and 3rd trimester, is 38% (158/418), 40% (107/264), and 66% (78/118) respectively[70–73].

Following MPI, only first-trimester infections can lead to sequelae[74,75]. In the natural history, approximately 30-35% of newborns infected after first-trimester infection develop neurological sequelae, and 25% suffer hearing loss, mostly unilateral[76].

Despite the high burden of cCMV infection, , screening for MPI during pregnancy is not recommended by any public health authority but Germany[77,78]. This is due to older concerns about sensitivity and specificity

of serological tests, difficulty in establishing the prognosis of an infected fetus, and the lack of validated prenatal treatment options[79]. However, some issues need an update:

First, MPI is reliably identified by serologic testing based on IgG and IgM followed by IgG avidity testing in IgM positive cases. Low CMV IgG avidity indicates MPI within the preceding 3–4 months. Sensitivity and specificity of this algorithm depends mainly on the performance of the IgM kits used, the accuracy of the "low" range of IgG values, and the timing of serology screening[80,81]

Secondly, the prognosis of fetal infection relies upon standardized prenatal assessment[82]. Although gestational age at infection is a major prognostic factor[75,76,83], other parameters including sequential ultrasound (US) examinations in second and third trimesters, platelet count in fetal blood, and prenatal Magnetic Resonance Imaging (MRI) have all been shown to independently predict the outcome of infected fetuses in different studies[70,84–89] . The combination of ultrasound and MRI has a negative predictive value of 95 to 99 % [82,83,90].

Finally, the first indication of antivirals in fetal cCMV infection was to reduce the risk of sequelae in a fetus with proven fetal infection. In a phase II open-label trial, oral valaciclovir (8 g/d) given in pregnancies with mildly symptomatic fetuses was associated with a higher chance of delivering an asymptomatic neonate (82%), compared with an untreated historical cohort (43%)[91]. CMV-hyperimmune globulins did not prove to be effective in this indication[92]. The focus has recently addressed the efficacy of secondary prevention by giving treatment as soon as MPI is biologically proven in the first trimester in order to reduce the risk of MTCT and therefore the risk of sequelae. In a randomized double-blind, placebo-controlled study , Valaciclovir at a dose of 8 g/day reduced the rate of fetal infection by 71%[93]. CMV-hyperimmune globulins have been studied in this indication and there was a statistically significant difference when compared to untreated historical cohorts [94] (MTCT= 2.5% vs 35.2% in the treatment and historical groups respectively). However, this could not be shown through RCT including cases up to 28 weeks' which may have decreased the impact of hyperimmune globulins [92].

Maternal screening in early pregnancy would also benefit seronegative women, since individual primary prevention measures in these women have proven to be effective in significantly preventing MPI.

The recent and solid data highlighting 1) the typical profile of the pregnant women at risk of MPI, 2) the first trimester of pregnancy as the only one at risk of sequelae 3) the reduction of MTCT with antenatal valaciclovir, bring new perspectives for implementation of screening in early pregnancy.

Rubella

Rubella is a leading vaccine-preventable cause of birth defects since the early 1970s. Before the introduction of the vaccine, up to 4 babies per 1,000 live births were born with congenital rubella syndrome (CRS), an often devastating condition [95]. This includes low birth weight, deafness, mental retardation, cardiac and eye malformations [96,97] . The risk of MTCT is 80-90%, 54% and 25% when maternal rash occurs before 12 ,at 13-14 and after 20 weeks of pregnancy respectively [95,98].[98]. The risk of sequelae is constant before 12 weeks and nil after 16 weeks; in-between, a third of the fetuses develop sequelae, particularly deafness[96,98].

In 2015, the WHO Region of the Americas became the first in the world to be declared free of endemic transmission of rubella[103]whereas CRS rates are highest in the WHO African and South-East Asian regions where vaccination coverage is lowest. However, even in countries where endemic virus has disappeared, cases emerge, mainly due to non-immune migratory human flows[97,99],[100]. Screening with rubella specific antibodies during pregnancy is not/no longer recommended in some industrialized countries such as the United Kingdom or the US. It remains mandatory in France (Table 1).

The search for proof of immunity at the very beginning of pregnancy seems essential both to set up primary prevention measures and, above all, to consider vaccination after delivery, even before discharge from maternity ward.

Varicella

The incidence of varicella zoster virus (VZV) infection in pregnancy is around 1.2/10,000 [101] and the MTCT is 25%[102]. Sequelae have only been observed in 2 % of infected fetuses and only before 20 weeks [103]. The damage is ubiquitous including IUGR, skin lesions, neurological, eye, skeletal, gastrointestinal and genitourinary anomalies[104]. Maternal VZV infection also carries a risk of severe neonatal varicella in an estimated 17%-30% when it occurs between d-5 and d+2 relative to the date of delivery[105]. Non-immune pregnant women exposed to VZV (household contact, face-to-face contact > 5 minutes or in the same room > 1 hour) should receive post-exposure prophylaxis with anti-VZV-immunoglobulins, ideally within 96 hours, and no later than 10 days after infection[105]. The effect of this therapy has mostly been studied in order to reduce the risk of maternal morbidity that exists in case of MPI. The live attenuated VZV vaccine is contraindicated in pregnant women. Care givers should enquire about the immunological status of pregnant women for VZV (personal history of chickenpox, vaccination, or serology if in doubt) to prevent from exposing themselves to a situation as trivial as a child who has chickenpox in the first part of their pregnancy.

Conclusion

Infections during pregnancy can impact the prognosis of the fetus, the newborn and the infant. Young healthy pregnant women are often not aware of those risks, and first prenatal care visit is a key time slot in the obstetrical calendar to also raise those issues. Hepatitis B and C, HIV, genital Chlamydia infection are not rare diseases and should no longer be suspected only in precarious or marginal populations. Vertical transmission of these infections, from women who do not know they are carriers, maintains a significant incidence of chronic diseases.

Rubella, syphilis, VZV, Toxoplasma Gondii and CMV infections can lead to severe birth defects, especially when the fetus is in contact with the pathogen in early pregnancy. These infections are preventable by primary prevention measures implemented early enough. The WHO criteria validating the implementation of screening may not all strictly be met for these infections. However, the duty to provide accurate information, which frequently goes hand in hand with the maternal request to search for immunity, is in agreement with the principles of benevolence and non-malevolence guiding our practice.

Disclosure of Interests

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