



TECHNICAL REPORT

Antenatal screening for HIV, hepatitis B, syphilis and rubella susceptibility in the EU/EEA

ECDC TECHNICAL REPORT

Antenatal screening for HIV, hepatitis B, syphilis and rubella susceptibility in the EU/EEA

A Member State survey of policies and practices
in the prevention of mother-to-child transmission



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Abbreviations

| | |
|-------|---------------------------------------------------|
| AIDS | Acquired immune deficiency syndrome |
| ANS | Antenatal screening |
| ART | Antiretroviral therapy |
| ARV | Antiretroviral |
| EEA | European Economic Area |
| EIA | Enzyme immunoassay |
| ELISA | Enzyme-linked immunosorbent assay |
| GUM | Genito-urinary medicine |
| HAART | Highly active antiretroviral therapy |
| HBeAg | Hepatitis B envelope antigen |
| HBcAg | Hepatitis B core antigen |
| HBsAg | Hepatitis B surface antigen |
| HBV | Hepatitis B virus |
| HIV | Human immunodeficiency virus |
| MMR | Measles, mumps and rubella |
| MTCT | Mother-to-child transmission |
| NAAT | Nucleic acid amplification test |
| PWID | People who inject drugs |
| QALY | Quality-adjusted life year |
| STI | Sexually transmitted infection |
| TPHA | <i>Treponema pallidum</i> haemagglutination assay |
| WHO | World Health Organization |

Glossary

| | |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Antenatal | Before birth; during or relating to pregnancy. |
| Antenatal screening | Testing of pregnant woman to detect conditions in the woman that may threaten the health of the foetus or child. |
| Antenatal screening coverage | Proportion of pregnant women screened of the total eligible. |
| Infant | A child of less than 12 months of age. |
| Mother-to-child transmission | Transmission of an infectious agent from mother to child before birth, during labour and delivery, or during infancy (the first year of life). Also referred to as vertical transmission. |
| Newborn | A child of less than 1 month of age. |
| Neonatal | Of, relating to, or affecting the newborn during the first month after birth. |
| Notifiable infection | An infection that must be reported to health authorities. |
| Diagnostic testing | Applying a test for the purpose of identifying a health condition or disease. |
| Opt-in testing | Individuals seeking care are informed that testing is recommended. The individual is required to give explicit consent before the test is performed. |
| Opt-out testing | Testing is performed as part of routine care. Pre-test information is made available and consent is assumed unless the individual explicitly declines testing. |
| Prenatal | Before birth; during or relating to pregnancy (synonym for antenatal). |
| Screening | The systematic application of tests, examinations, or other procedures with the intention of identifying previously unrecognised health conditions. The relevant population is dependent on the condition to be identified. |
| Selective screening | Testing targeting subsets of the population, usually groups considered to be disproportionately affected or at increased risk. |
| Universal screening | Systematic testing applied to the entire relevant population, which can be either mandatory or voluntary. |
| Vertical transmission | See mother-to-child-transmission. |

Key findings

These findings are based on the analysis of an online survey taken in June and July 2013. The survey was filled in by national experts appointed by the Member State based on their expertise in antenatal screening programmes. A total of 26 EU/EEA countries participated in the survey.

Antenatal strategies and practices

National guidance, recommendations or strategy for antenatal care: The majority (25/26) of EU/EEA countries that responded to the survey, provide antenatal care services based on national guidance, recommendations or strategy, however compliance with such guidelines is suboptimal in some countries.

Implementation of antenatal screening for infections: A high proportion of EU/EEA countries implement antenatal screening for HIV (24/26), HBV (23/26) and syphilis (26/26). Fewer countries have implemented rubella susceptibility screening programmes (14/26).

Strategies for antenatal screening: Opt-out screening is the most common strategy for antenatal screening for HIV (15/23), HBV (14/23), syphilis (16/26) and rubella susceptibility (9/14) in EU/EEA countries.

Financing of antenatal screening: Antenatal screening programmes for infections are for the most part publicly funded and provided through national health services in the EU/EEA; in several countries, however, screening is only covered through a pre-existing health insurance policy.

Timing of screening and coverage: Countries that have antenatal screening policies for infections and rubella susceptibility most often recommend that this screening is undertaken in the first trimester of pregnancy for HIV (21/23), HBV (14/20), syphilis (22/24) and rubella susceptibility (10/11). Coverage of screening was estimated to be $\geq 95\%$ for HIV, HBV and syphilis in the majority of responding countries.

Laboratory methods for antenatal screening: HIV antibody/antigen (Ab/Ag) combination tests are used in 18/23 countries. HBsAg testing is used in the 20 countries that provided information on HBV antenatal screening. Both treponemal and non-treponemal tests are in use for antenatal screening for syphilis in 14/24 EU/EEA countries.

Diagnosis during pregnancy: 15/21 EU/EEA countries reported capacity to distinguish between HIV infections that were known before pregnancy and HIV infections newly diagnosed during the current pregnancy through screening. Eight of 13 countries reported that more than 30% of HIV-positive pregnant women were newly diagnosed through antenatal screening. Nine of 22 countries can identify whether HBV infection is newly diagnosed during the current pregnancy; the percentage ranged from 0.5 to 100 in six reporting countries.

Testing of children born to positive mothers: In all responding countries, children born to HIV-, HBV-, and syphilis-positive mothers, or mothers confirmed with rubella infection during pregnancy, are tested. Exceptions are Finland, where syphilis testing is not done if the mother has been treated during pregnancy, and Italy and Poland, who do not test children born to HBV-positive mothers.

Referral to healthcare: Antenatal screening in the EU/EEA is most often performed in specialist healthcare services (obstetricians and gynaecologists), with midwives and general practitioners also involved in screening in some countries.

Treatment/prophylaxis of the mother and the child: All responding EU/EEA countries recommend antiretroviral therapy for HIV-positive pregnant woman and antiretroviral prophylaxis for the newborn. Penicillin is the recommended treatment for both syphilis and congenital syphilis. Prevention of mother-to-child transmission of HBV is based on a combination of vaccination (first dose at birth) and administration of HBV immunoglobulin to the child in 18/21 responding countries.

Populations at risk of mother-to-child transmission: Ethnic minority pregnant women and migrants from high-prevalence areas outside the EU were identified by country responders as the population at highest risk of mother-to-child transmission of HIV, HBV, syphilis and rubella, followed by women presenting or being reached late for antenatal care. People who inject drugs and mobile populations like intra-EU-migrants were also identified as high-risk populations.

Challenges for effective antenatal screening: Common challenges for effective antenatal screening reported by EU/EEA countries were the deficiencies in data reporting and collection at the national level, insufficient capacity to reach groups at risk, and a general lack of resources for these activities.

Antenatal screening for infections in the EU/EEA

HIV: All surveyed countries with the exception of Hungary and Slovenia (24/26) implement antenatal HIV screening, with opt-out screening being the most common (15/24) strategy. Testing coverage is over 95% in the first trimester in 8/15 countries and over 95% for testing at any time during pregnancy in 12/18 countries. Ten countries reported repeat testing later in pregnancy, either as a general recommendation (Estonia, Lithuania, Romania, Slovakia and Spain) or among high-risk groups (France, Greece, Ireland, Italy and Norway).

In 2013, 19 countries reported a total of 91 HIV MTCT (mother-to-child transmission) cases in persons born in the reporting country, with MTCT rates per 100 000 births between 0.7 (Germany) and 43.7 (Latvia); ten countries had no MTCT reports in people born in the reporting country (Annex 2).

Hepatitis B: Antenatal screening for hepatitis B (HBV) is implemented in 23/26 countries (not in Lithuania, Norway and Romania); in the majority of countries that reported data (8/13), screening coverage was $\geq 95\%$. However, data from many countries were not collected at the national level, making it difficult to evaluate the screening situation. Identification of MTCT cases in EU/EEA residents was also difficult because datasets submitted to TESSy showed a low level of completeness.

Except for Denmark, Finland, Iceland, Norway, Sweden and the UK, where vaccination is targeted only at people at risk, all countries run universal childhood HBV vaccination programmes; coverage is between 74% and 99%. In countries where the first dose of vaccine is not routinely offered at birth, newborns of mothers from risk groups are targeted for vaccination.

Syphilis: All participating EU/EEA countries (26/26) implement antenatal screening. Most (22/24) countries test pregnant women for syphilis during the first trimester of pregnancy. Seven countries reported repeat testing during the third trimester of pregnancy as a general recommendation and another three countries offer repeat testing for women in risk groups. The reported coverage of antenatal screening of syphilis was high: 14/18 countries reported a coverage of $\geq 95\%$, while three reported a coverage of $\geq 90\%$.

In 2013, 64 cases of congenital syphilis were reported from nine countries, with rates per 100 000 live births between 0.3 (Germany) and 40.6 (Bulgaria); twelve countries reported zero cases of congenital syphilis (Annex 2).

Rubella: 14/26 countries implement national rubella susceptibility screening. In ten countries, screening was discontinued due to low incidence of rubella and high vaccination coverage. The countries that still screen for rubella susceptibility rarely keep a national database. Testing coverage was $\geq 95\%$ in 4/5 countries that reported data. A lack of available data describing MTCT of rubella and levels of population susceptibility was identified as the biggest challenge for the implementation of effective antenatal screening policies for rubella.

In 10/11 countries, antenatal screening for rubella susceptibility is recommended during the first trimester of pregnancy, but it can also be offered as preconception care. In 2013, 45 of the 49 cases of congenital rubella reported in the EU/EEA occurred in Romania, a country where antenatal screening is not implemented.

Conclusions

The results of this survey and the available surveillance data indicate that there is ongoing mother-to-child transmission of HIV, hepatitis B, syphilis and rubella, especially among certain high-risk populations. This suggests that the effectiveness of the antenatal screening practice – despite of considerable breaths – can be optimised. Factors that compromise effectiveness include low screening coverage, limited access to antenatal care services, and limited access to testing for several subpopulations.

While the case rates of MTCT of HIV and congenital syphilis are below the WHO global targets for the elimination in the EU/EEA (<50 cases per 100 000 live births), antenatal care coverage and testing still needs to be scaled up in several countries, with increased attention to be given to improving access to antenatal screening for vulnerable groups.

Few countries collect data robust enough for a comprehensive evaluation of antenatal screening programme effectiveness, and even fewer countries make the results of such evaluations publically available. It would therefore be helpful to develop a set of process and outcome indicators to guide countries in the monitoring and evaluation of antenatal screening programme effectiveness.

Several national surveillance systems in EU/EEA countries do not currently identify and record all MTCT cases in people born in the reporting country. Recording these cases is essential for the informative value of national screening programmes. In addition, the notification of congenital syphilis cases is not mandatory in some countries. Enhanced surveillance of MTCT cases with comprehensive collection of information about the mother and the child would improve the assessment of the incidence of MTCT and would provide valuable information on risk factors. This information could then be used to inform national policies and would probably lead to scaled-up antenatal screening for the most-at-risk subpopulations.

Ongoing mother-to-child transmission particularly affects certain vulnerable groups that are not adequately reached by, or do not have access to, testing services and prevention interventions that are available to the majority of the population. Member States should consider targeted interventions for such populations at risk, based on an assessment of disease epidemiology and risk profile.

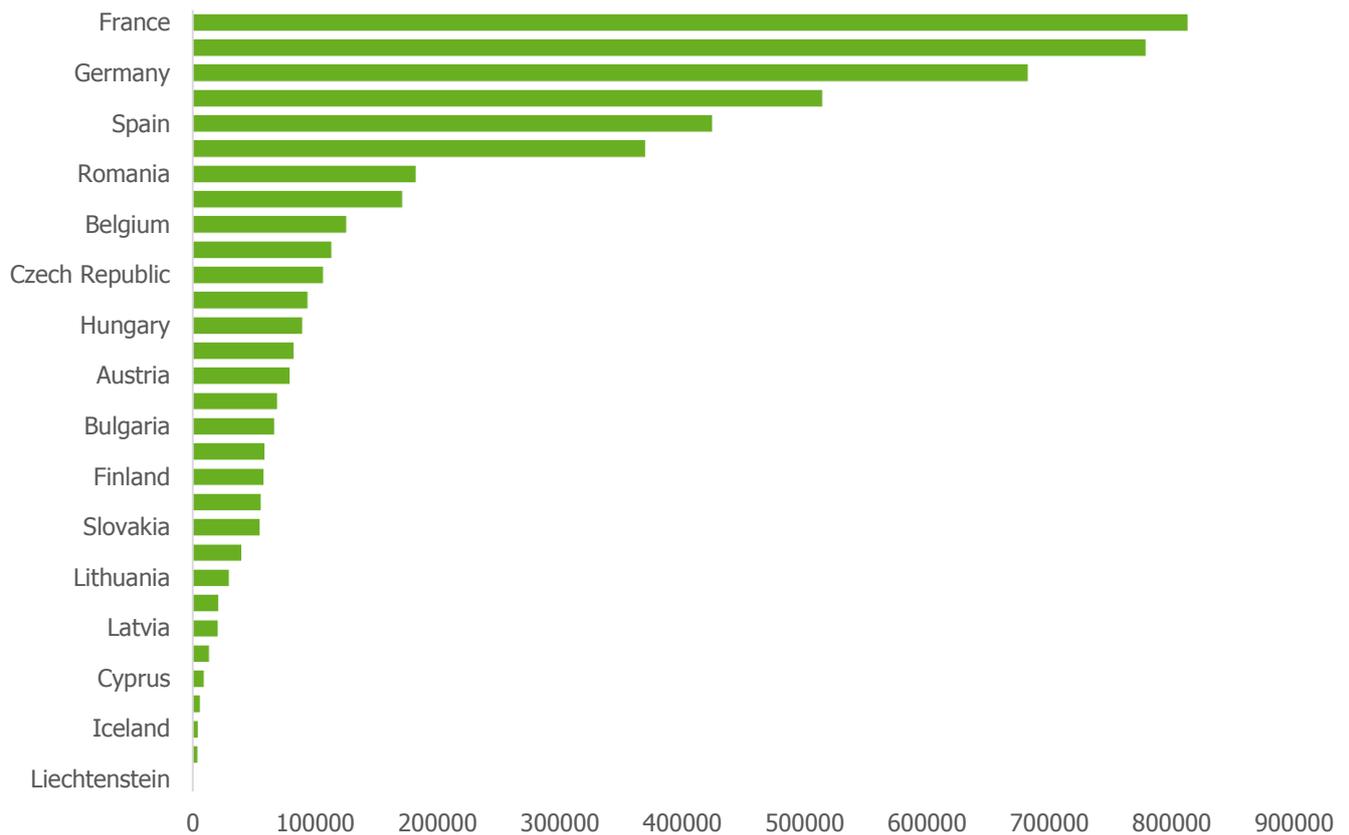
ECDC is currently developing an evidence-based guidance to strengthen antenatal screening among vulnerable groups. The guidance will answer two central questions: a) What are the decisive elements of national programmes for antenatal infection screening with regard to their effectiveness and b) how can vulnerable groups be reached to increase the uptake of prenatal care in order to prevent or reduce mother-to-child transmission of infectious diseases.

1 Background

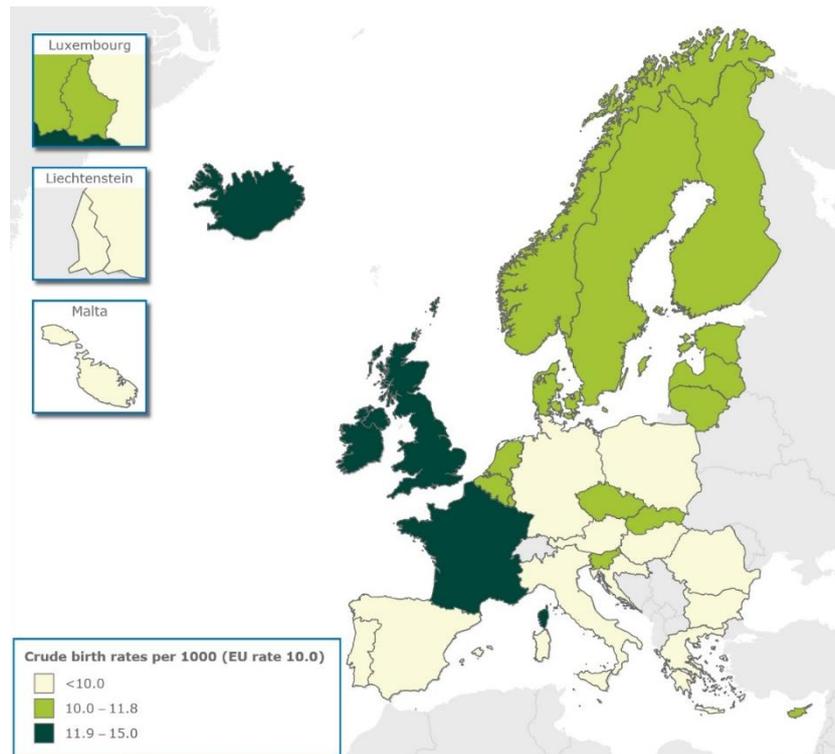
1.1 Demographics

In 2013, 5.1 million children were born in EU countries, a crude birth rate of 10.0 live births per 1 000 inhabitants (Eurostat). The number of live births was highest in France (820 830) and the lowest in Malta (4 032) (Figure 1). Ireland had the highest birth rate (15.0) and Portugal the lowest (7.9) (Figure 2) [1]. Among the European Economic Area (EEA) countries, Iceland and Norway had birth rates above the EU rate (10.0), 13.4 and 11.6, respectively.

Figure 1. Number of live births in EU/EEA countries, 2013



Source: Eurostat [1]

Figure 2. Crude birth rate per 1 000 inhabitants, EU/EEA, 2013

Note: The crude birth rate relates the number of births during the year to the average population in that year.

Source: Eurostat [1]

Despite the existence of effective preventive interventions, the transmission of infections from mother to child before birth, during the birthing process and in infancy still occurs in several European countries [2,3].

1.2 Epidemiological context

The vertical transmission of HIV, syphilis, HBV and rubella, as shown by surveillance data, is characterised by different patterns in the EU/EEA countries. These patterns are a result of the heterogeneity in case reporting, differences in antenatal screening policies and practices, prevalence rates of infections in women of reproductive age, and vaccination policies. Antenatal screening programmes may also vary across countries and may be affected by a number of factors such as programme implementation, access to antenatal care, integration of antenatal screening in overall antenatal care, timeliness, frequency of testing, and notification of the results.

HIV

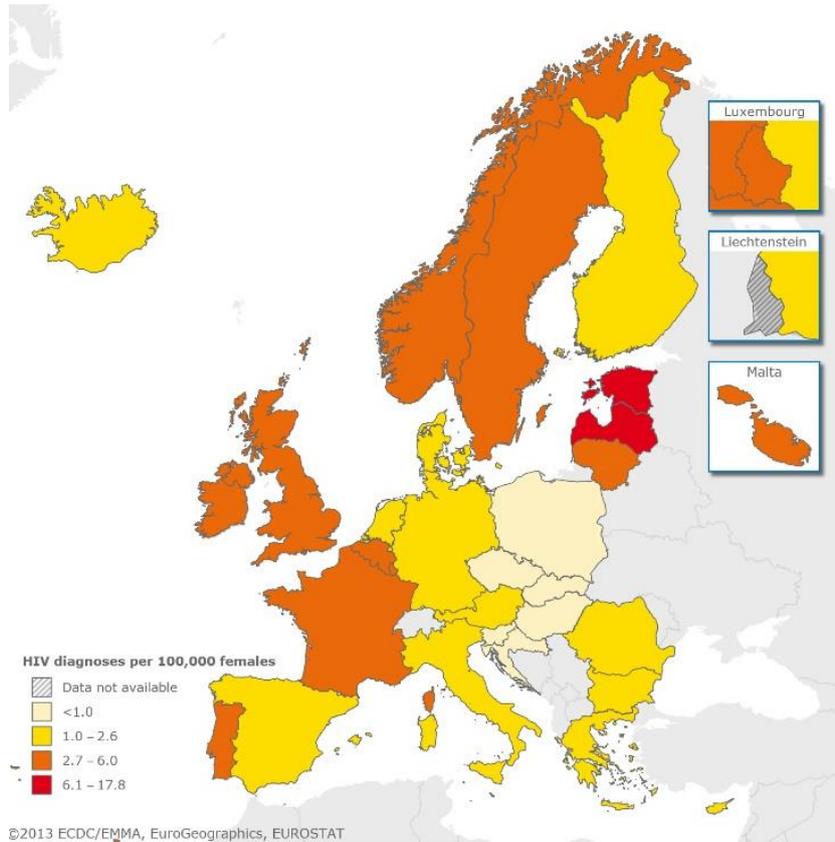
Mother-to-child transmission (MTCT) is the most significant mode of HIV infection in children worldwide [4]. Without intervention, the risk of HIV transmission from infected mother to child ranges from 15% to 30% during pregnancy/delivery to between 10% and 20% during breastfeeding. Risk factors for MTCT are high viral load, low CD4 cell count, and advanced clinical stage of the mother. With a combination of appropriate interventions including anti-retroviral therapy (ART) for the mother, anti-retroviral prophylaxis for the newborn, and avoidance of breastfeeding, the risk of MTCT of HIV can be reduced to 1–2% [5].

In 2013, 29 157 new HIV diagnoses were reported in the 30 EU/EEA countries, a rate of 5.7 per 100 000 population. The overall rate for women was 2.6 per 100 000 population (range: 0.3 in Hungary, 17.8 in Estonia) (Figure 3 a). Among pregnant women, HIV prevalence was the highest in Estonia and Ireland (over 0.3%); between 0.1% and 0.2% in Latvia, Romania, Spain and the UK; and below 0.1% in 16 European countries (numbers are from 2000 to 2004) [6].

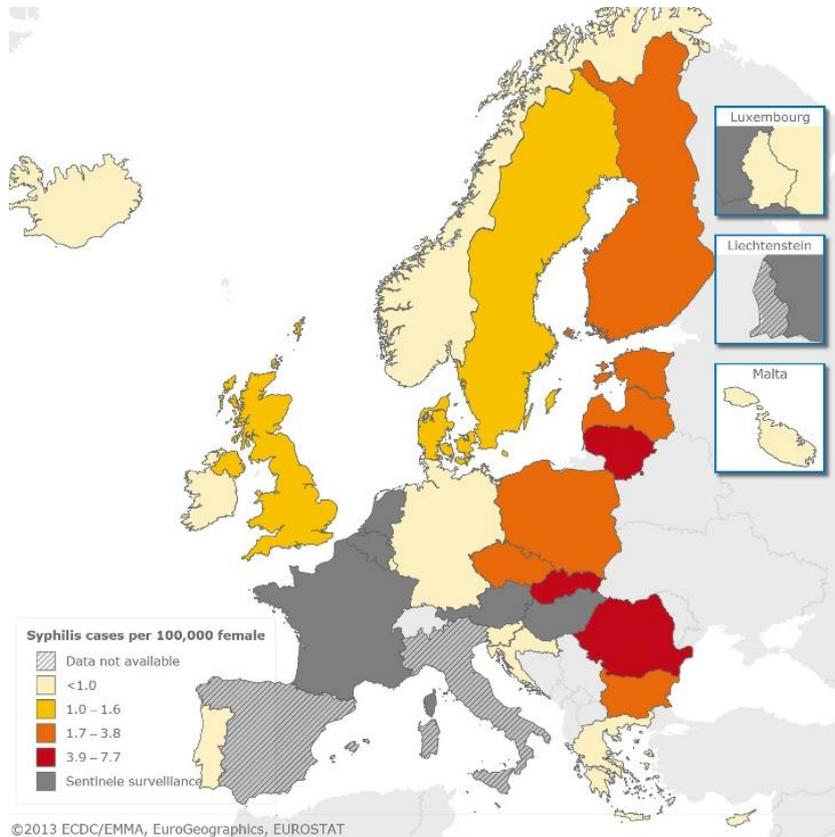
Although policies regarding antenatal HIV screening are implemented in the majority of EU/EEA countries [7], MTCT accounted for 0.7% (218 cases) of all new HIV diagnoses [2]. While 25% of the individuals infected through MTCT originated from countries with generalised epidemics, 39% (85/218) originated from an EU/EEA reporting country. This indicates remaining challenges for the existing antenatal screening programmes [2].

Figure 3. Notification rates of HIV and syphilis per 100 000 women, EU/EEA, 2013

a) HIV



b) Syphilis



HBV

High maternal viral load is the most important factor in vertical transmission of HBV and is significantly correlated with e-antigen (HBeAg) positivity. Without intervention, the risk of transmission from an HBeAg-positive mother is between 70% and 90%, and <10% for an HBeAg-negative/HBsAg-positive mother [8].

MTCT is preventable in 95% of all cases through the administration of vaccine and immunoglobulin to the baby at birth [8]. With no immunoprophylaxis, more than 90% of infants infected by their HBeAg-/HBsAg-positive mothers will go on to develop chronic infection. The earlier in life the infection occurs, the higher is the risk for chronicity. The chronicity rate after HBV infection decreases to approximately one quarter (23%) in children infected at preschool age and to 2.7% in young adults. Approximately 25% of those who become chronically infected during childhood will die prematurely from cirrhosis or liver cancer [9].

In 2013, 2 896 cases of acute HBV and 13 629 cases of chronic HBV were reported by 28 EU/EEA countries, with an overall male-to-female ratio of 1.5:1 [10]. MTCT was the most common route of transmission for chronic HBV (43.5%), with a high proportion of these cases being imported. Comparison of rates of HBV in women is difficult due to the heterogeneity in the case definitions used by each country. Rate comparisons are further complicated by the largely asymptomatic nature of the infection (especially chronic), which means that reported cases are more indicative of differences in testing than the underlying epidemiology. Among pregnant women, the reported HBV prevalence ranges between 0.14% (Finland) and 1.15% (Greece) [11].

Syphilis

Transmission of syphilis from mother-to-child depends upon the extent of bacteraemia in the pregnant woman, which declines gradually during the course of infection. The risk of vertical transmission is 70% for primary and secondary syphilis, 40% for early latent and 10% for late latent syphilis [12]. Penicillin is an effective treatment for syphilis during pregnancy; infants born to treated mothers have only a 1–2% risk of infection [13].

Adverse outcomes of untreated pregnancies include: early foetal loss or stillbirth (21%), neonatal death (9%), prematurity or low birth weight (6%), and clinical evidence of syphilis in the newborn (16%) [14]. Globally, MTCT of syphilis may contribute to up to one quarter of all stillbirths and 11% of neonatal deaths [15].

In 2013, 22 227 syphilis cases were reported in 29 EU/EEA countries, resulting in an overall syphilis rate of 5.5 per 100 000 population. The rate among women was 1.6 per 100 000, ranging between 0.3 (Croatia, Slovenia) and 7.7 (Lithuania) (Figure 3 b). In 2013, 64 cases of congenital syphilis were reported from 9 countries; 12 countries reported zero cases. The overall rate in the EU/EEA was 2.0 per 100 000 live births. The majority of the cases were reported by Bulgaria (27), Poland (19) and Portugal (5) [3]. These numbers appear to be relatively low, but it is likely that congenitally transmitted syphilis infections are underreported [16].

Rubella

Rubella virus is spread in airborne droplets and through respiratory secretions. If infected during pregnancy, women may transmit the infection to their foetus. Transmission of infection is highest, up to 80%, during the first trimester, declining to a minimum of 25% at the end of the second trimester. There is no treatment for rubella but MTCT can be prevented by ensuring that all women who plan to get pregnant are immune or have been immunised against rubella [17].

Infection with rubella has severe adverse outcomes such as miscarriage, stillbirth and a series of birth defects. Children with a congenital rubella syndrome can suffer hearing impairments, eye and heart defects and other lasting disabilities, including autism, diabetes mellitus and thyroid dysfunction. Rubella is most damaging during the first trimester. After the fourth month, infection of the mother with rubella is less likely to harm the foetus [17].

In 2013, 38 847 rubella cases were reported from 27 EU/EEA countries, with 12.6% of cases in females. Most (99%) cases were associated with the large rubella outbreak in Poland where two cases of congenital rubella were reported in 2013 [18]. In Romania, 45 cases of congenital rubella were reported in 2013 after an outbreak in 2011 and 2012 when 119 rubella cases were reported among pregnant women [19].

Vaccination against rubella is part of routine childhood immunisation schedules in Europe. However, year of introduction, vaccination strategies, schedules and coverage vary by country, which leaves parts of the population susceptible to rubella infection. The increased circulation of rubella among young adults in Europe inevitably increases the risk of congenital rubella syndrome [20].

1.3 Antenatal screening for infections

Screening is defined as the systematic application of tests, examinations, or other procedures with the intention of identifying previously unrecognised health conditions [21]. Antenatal screening involves the testing of pregnant women for evidence of infection, or in the case of rubella, for lack of protective immunity, in an effort to prevent vertical transmission through specific interventions, reducing harm to both mother and child.

Guidelines, recommendations and regulations that govern the organisation and implementation of antenatal screening and intervention services may vary between countries and regions and even between service providers. Antenatal screening can be implemented in many ways; it can be targeted (selective) or population-based (universal or mass-screening), depending on the structure of maternal and child health services in different countries or regions. Testing in pregnancy is rarely mandatory; opt-out and opt-in screening are the most common forms of voluntary antenatal screening [7]. The funding, division of labour between public and private health services and cost to the patient may vary widely depending on how healthcare and social welfare services are organised. Access to antenatal services may differ by country in accordance to national laws and regulations, as well as health insurance coverage.

1.4 Effectiveness of antenatal screening programmes

The effectiveness of an antenatal screening programme is measured through monitoring of how well the system performs in preventing the MTCT of the infections that the screening and subsequent interventions target. This can be done by comparing the predicted/estimated number of infections among newborns that would occur without the interventions to those that actually occur. To be able to measure this, reliable estimates of the occurrence of disease among pregnant women are needed, as well as equally reliable estimates of the occurrence of disease among their offspring. Effectiveness can also be described as a function of the success at the different stages of the continuum of antenatal care: how many pregnant women at risk are linked into and retained in care, offered antenatal screening, are notified of their test results and subsequently are treated, or, in the case of rubella, vaccinated to prevent MTCT in future pregnancies.

To ensure optimal effectiveness, antenatal preventive interventions should be based on the best scientific evidence and cost effectiveness analyses and take into account the local epidemiology of specific infections, priorities in public health, and resources. A list of evidence-based effective interventions for the prevention of MTCT was published by the World Health Organization in 2005 [22]. Recent reports from Denmark and the Netherlands suggest that replacing selective screening programmes based on risk factors with universal screening programmes with an opt-out strategy are effective in reducing the transmission rates of HIV, HBV and syphilis [23-25].

2 Survey in the Member States

2.1 Aims and objectives

Data needed to evaluate the effectiveness of antenatal screening programmes of HIV, HBV, syphilis and rubella susceptibility in the EU/EEA were collected through a Member State survey. The survey had the following objectives:

- Describe current practice and map existing policies for the antenatal screening of infections in EU/EEA countries.
- Define the effectiveness of antenatal screening in terms of proportion of pregnant women screened, proportion of follow-up of positive test results, and provision of mother-to-child transmission prevention services.
- Identify subpopulations vulnerable to MTCT of HIV, HBV, syphilis and rubella.
- Understand the current challenges for antenatal screening in Member States in order to inform the development of ECDC guidance for effective antenatal screening.

2.2 Methods

Survey roll-out

An online survey was undertaken in June and July 2013 [26]. To identify survey responders, a letter was sent to the ECDC Coordinating Competent Body¹ in each Member State, inviting them to nominate national experts who could best provide information on national policies and practices. Depending on country arrangements, up to five experts were appointed in each country to answer the survey, based on their involvement and expertise in antenatal screening programming.

The survey questionnaire was developed in English and consisted of five sections: one general part (Annex 3) and four infection-specific questionnaires (Annexes 4–7). The *general questionnaire* included questions on antenatal care policies, implementation of antenatal screening for HIV, HBV, syphilis and rubella susceptibility and type of strategies, as well as on vaccination programmes for HBV. The *specific questionnaires* covered the following items for each infection:

- Organisation of antenatal screenings, including details on antenatal care providers, testing methods, timing of testing, funding
- Management of infection during pregnancy, type of interventions to prevent mother-to-child transmission during antenatal and neonatal period
- Indicators for antenatal screening effectiveness (i.e. either raw data or country estimates for testing coverage, uptake of MTCT interventions)
- List of populations groups at risk for not being reached by antenatal screening and thus vulnerable to MTCT
- Country self-assessment of challenges in achieving MTCT elimination.

Responses were stored on a Webropol platform on a secure space managed by THL Helsinki and transferred to an Excel file at the end of the survey.

The survey was piloted by experts from Denmark, the Netherlands and Northern Ireland (UK) in April 2013. Comments and suggestions were incorporated in the revised version of the questionnaires.

Screening strategies definitions

The survey responders were invited to select the type of antenatal screening implementation that best described their national profile. The following options were available: *opt-in* screening – ‘pregnant woman is offered testing and if she agrees to testing, she must provide explicit consent’, *opt-out* screening – ‘pregnant woman is informed that testing will take place as part of the antenatal care, the test will be performed unless she explicitly declines’ and *universal* screening – ‘testing offered to all, none of the previous strategies apply’. If a country offered screening for *selective* risk groups, responders were asked to specify which groups.

¹ http://www.ecdc.europa.eu/en/aboutus/Competent%20bodies/Pages/Competent_bodies.aspx

Data on mother-to-child transmission in the reporting country

HIV and HBV cases attributed to MTCT and congenital syphilis cases were retrieved from The European Surveillance System (TESSy) for the reporting year 2013 (Annex 2). Country of birth, country of nationality, region of origin, probable country of infection and importation status were used to identify HIV and HBV MTCT cases in persons born in the reporting country.

Indicators of effectiveness

Testing coverage and coverage of prevention interventions in the mother or in the child were collected as part of the assessment of the effectiveness of antenatal screening. The antenatal screening testing coverage, defined as the proportion of pregnant women tested, was reported by survey responders based on existing national data; if no national data were available, responders estimated the coverage. The same approach was used to determine the coverage for interventions.

3 Results

3.1 Member States responses to survey

Responses to the general section of the questionnaire on antenatal screening were received from 26/30 countries (86.7%). For the infection-specific questionnaires, number were slightly lower: 25 countries (83.3%) filled in questionnaires for HIV, 22 countries (73.3%) for HBV, 24 countries (80%) for syphilis, and 22 countries (73.3%) for rubella susceptibility (Annex 1).

Austria, Bulgaria, Cyprus and Liechtenstein did not respond to the survey and are not included in the analysis. At the time of the survey, Croatia was not part of the EU/EEA.

All country-specific responses refer to the situation in the entire country, with the exception of Ireland where the responses on syphilis only refer to Dublin. Northern Ireland participated in the pilot project; the Northern Irish results were later merged with those of other UK countries. If there were differences in results between the four UK countries are always indicated.

3.2 Antenatal screening programmes: organisation and integration

With the exception of Romania, all responding EU/EEA countries confirmed that they have released a national guidance or recommendations on antenatal care, including pregnancy, antenatal, neonatal and post-natal care (Table 1). In Romania, in the absence of a comprehensive national guidance, various professional bodies have issued recommendations on antenatal care.

Furthermore, 25 of 26 responding countries (all but Hungary) confirmed that they have a national guidance document, recommendations or a strategy for antenatal screening of infectious diseases. Antenatal screening is recommended for HIV in 24 countries (not in Hungary and Slovenia), for HBV in 23 countries (not in Lithuania, Norway and Romania), for syphilis in all 26 responding countries, and for rubella susceptibility in 17 countries (not in Denmark, Estonia, Finland, Hungary, Latvia, Lithuania, the Netherlands, Romania and Slovenia) (Table 1).

In the vast majority of EU/EEA countries, screening of infectious diseases is integrated into overall antenatal care. Luxembourg does not integrate screening for any of the four infectious diseases covered by this report.

Table 1. Availability of national guidance/recommendations/strategy for antenatal care/antenatal screening for HIV, HBV, syphilis and rubella susceptibility in the EU/EEA, 2013

| Country | National guidance for antenatal care | National guidance for antenatal screening of infections | National screening recommended for | | | |
|----------------|--------------------------------------|---------------------------------------------------------|------------------------------------|-------|----------|------------------------|
| | | | HIV | HBV | Syphilis | Rubella susceptibility |
| Belgium | Yes | Yes | Yes | Yes | Yes | Yes |
| Czech Republic | Yes | Yes | Yes | Yes | Yes | No |
| Denmark | Yes | Yes | Yes | Yes | Yes | No |
| Estonia | Yes | Yes | Yes | Yes | Yes | No |
| Finland | Yes | Yes | Yes | Yes | Yes | No |
| France | Yes | Yes | Yes | Yes | Yes | Yes |
| Germany | Yes | Yes | Yes | Yes | Yes | No |
| Greece | Yes | Yes | Yes | Yes | Yes | Yes |
| Hungary | Yes | No | No | Yes | Yes | No |
| Iceland | Yes | Yes | Yes | Yes | Yes | Yes |
| Ireland | Yes | Yes | Yes | Yes | Yes | Yes |
| Italy | Yes | Yes | Yes | Yes | Yes | Yes |
| Latvia | Yes | Yes | Yes | Yes | Yes | No |
| Lithuania | Yes | Yes | Yes | No | Yes | No |
| Luxembourg | Yes | Yes | Yes † | Yes † | Yes † | Yes † |
| Malta | Yes | Yes | Yes | Yes | Yes | Yes |
| Netherlands | Yes | Yes | Yes | No | Yes | No |
| Norway | Yes | Yes | Yes | Yes | Yes | Yes |
| Poland | Yes | Yes | Yes | Yes | Yes | Yes |
| Portugal | Yes | Yes | Yes | Yes | Yes | Yes |
| Romania | No± | Yes | Yes | No | Yes | No |
| Slovakia | Yes | Yes | Yes | Yes | Yes | Yes |

| Country | National guidance for antenatal care | National guidance for antenatal screening of infections | National screening recommended for | | | |
|----------|--------------------------------------|---------------------------------------------------------|------------------------------------|-----|----------|------------------------|
| | | | HIV | HBV | Syphilis | Rubella susceptibility |
| Slovenia | Yes | Yes | No | Yes | Yes | No |
| Spain | Yes | Yes | Yes | Yes | Yes | Yes |
| Sweden | Yes | Yes | Yes | Yes | Yes | No |
| UK | Yes | Yes | Yes | Yes | Yes | Yes |

† Screening not integrated in overall antenatal care

± Romania: no national guidance on antenatal care exists, but separate recommendations have been issued by various professional bodies.

3.3 Antenatal HIV screening: survey results

Responses to the questionnaire on antenatal HIV screening were received from 25/26 countries, with Portugal the one country that did not fill in the HIV-specific questionnaire. Instead, Portugal provided information on the implementation of HIV screening in the general questionnaire.

Implementation of antenatal HIV screening

Antenatal screening for HIV is implemented in 24/26 (92%) countries (Table 1). Hungary and Slovenia do not offer national antenatal screening for HIV; Slovenia stated that the primary reason for not offering antenatal HIV screenings was the fact that HIV epidemiology did not support the need for a national screening programme; Hungary cited limited resources.

Funding of antenatal HIV screening

Antenatal screening for HIV is publicly funded (and offered free of charge) in 15/25 (60%) countries. A further eight countries (32%) offer antenatal HIV screening through various health insurance schemes (Table 2).

Table 2. Financing of antenatal HIV screening, EU/EEA, 2013

| Publicly funded | Health insurance | No HIV screening |
|------------------------------------------------------------|---------------------------------|------------------|
| n=15 | n=8 | n=2 |
| DK, FI, FR, IS, IE, IT, LV, LT, MT, NL, NO, RO, ES, SE, UK | BE, CZ, EE, DE, GR, LU, PL*, SK | HU†, SI†† |

† HIV screening not provided due to limited resources

†† Epidemiology does not support the need for HIV screening

* Poland reported that antenatal screening for uninsured pregnant women was funded through the public health budget.

Country names use ISO 3166-1 country codes

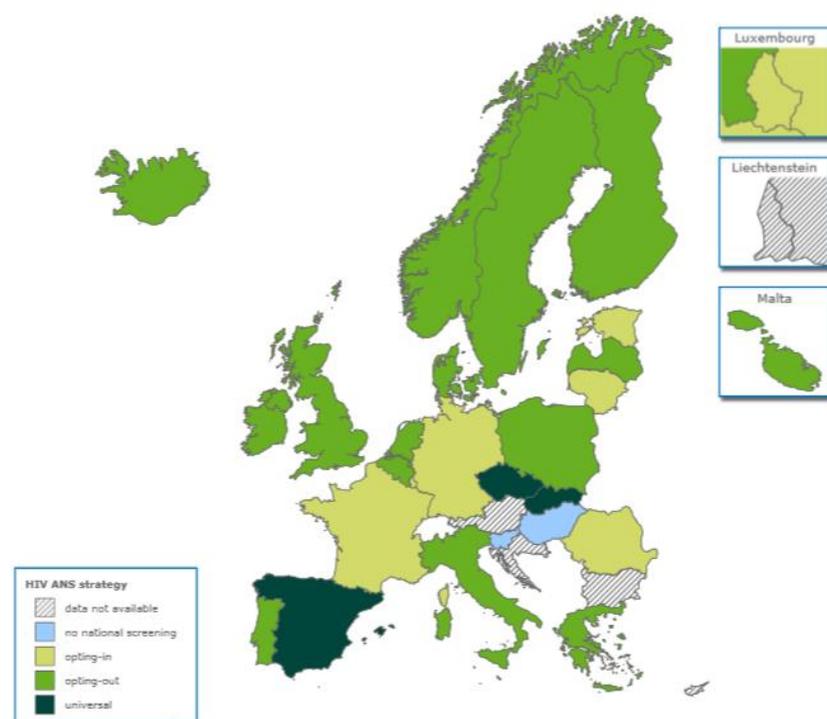
Data collection, storage and analysis

Data on antenatal screening for HIV are collected, stored and analysed at a national level in 11 countries (Czech Republic, Denmark, Estonia, Finland, France, Ireland, Lithuania, the Netherlands, Romania, Slovakia and the UK).

Monitoring or evaluation of the effectiveness of antenatal screening programmes for HIV was reported by Denmark [27], Finland, [28] France, [29] Ireland, Italy, the Netherlands [24,30] Romania [31], Slovakia and the UK.

Strategies for antenatal HIV screening

The most common strategy (15/24) of antenatal screening for HIV in EU/EEA countries is opt-out screening, where pregnant women are tested as part of routine antenatal care unless they explicitly decline. Opt-in screening is the chosen strategy in six countries (as well as in Northern Ireland (UK)), where pregnant women are offered testing and must provide explicit consent. The Czech Republic, Slovakia and Spain reported universal screening for HIV with systematic testing of all pregnant women (Figure 4). Romania and Slovenia reported that they operated targeted antenatal HIV screening among women who inject drugs.

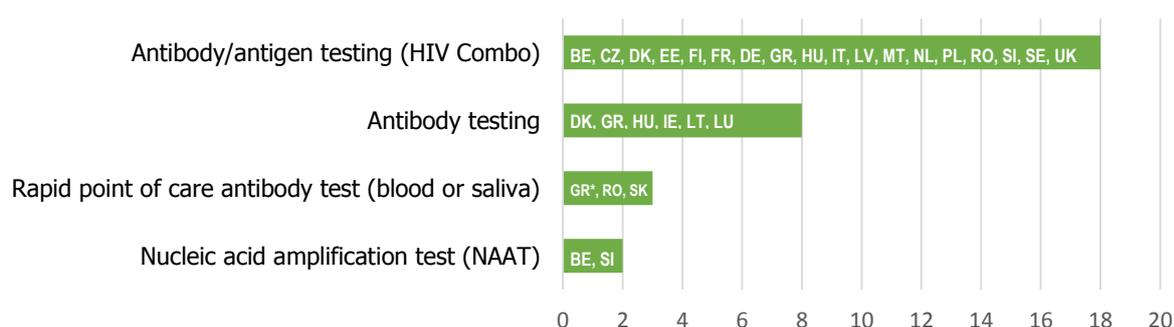
Figure 4. Antenatal HIV screening strategies, EU/EEA, 2013 survey

Note: Opt-in antenatal screening for HIV is implemented in Northern Ireland (UK).

Laboratory methods for antenatal HIV screening

There are three main categories of tests used for antenatal HIV screening in the EU/EEA: antibody tests, combination tests, and nucleic acid amplification tests (NAATs). While combination tests detect both HIV antibody and antigen, NAATs detect the genetic material of the virus. Both test types are able to detect HIV infections relatively early compared to antibody tests. However, NAATs allow for an even earlier detection of infection. NAATs, however, are more expensive and technically more demanding [32].

Eighteen of 23 countries reported that they use an HIV combination test for antenatal screening; Belgium and Slovenia reported the use of NAATs for antenatal screening (Figure 5).

Figure 5. Tests used for antenatal HIV screening, EU/EEA, 2013 survey

* If the mother's HIV status is unknown, rapid tests are used at delivery.

Timing of screening and testing coverage

Antenatal screening for HIV is recommended during the first trimester of pregnancy in 21/23 EU/EEA countries. In Ireland and Malta, testing is done at the time of booking antenatal care (Table 3).

In addition, Estonia, Lithuania, Romania, Slovakia and Spain reported recommendations on repeated HIV testing during the third trimester of pregnancy. In France, Greece, Ireland, Italy and Norway only women belonging to nationally defined risk groups are re-tested later in pregnancy. The risk groups tested in Ireland include: pregnant women that are active injecting drug users, pregnant women with known HIV infected partner, pregnant women

whose partner is from a high-prevalence country, or pregnant women whose partner is at risk for HIV infection and of unknown HIV status.

For women not tested earlier in pregnancy, antenatal screening for HIV is recommended at delivery in Denmark, France, Germany, Greece, Ireland, Latvia, Romania, Spain and the UK.

Screening coverage during the first trimester was reported to be 95% or higher in almost half (8/15) of the countries providing data (Table 3). Iceland reported the lowest coverage (50%), ahead of Romania which reported 60% coverage.

Overall coverage – the percentage of women tested at least once during pregnancy – was high among respondent countries, with the majority (12/18) estimating 95% or higher. Iceland provided the lowest overall coverage estimate at 50% (Table 3).

Table 3. Implementation of antenatal HIV screening in the EU/EEA and coverage data for 2011 (or most recent year available), as reported by survey responders

| Country | Antenatal screening during 1st trimester | Antenatal screening coverage 1st trimester [†] | Repeated screening | Antenatal screening coverage overall ^{††} |
|----------------|------------------------------------------|---------------------------------------------------------|-------------------------------|----------------------------------------------------|
| Belgium | Yes | | | 73%–78%± |
| Czech Republic | Yes | 80% | | >99% |
| Denmark | Yes (D) | | | 98% |
| Estonia | Yes | >80% | 3rd trimester | >80% |
| Finland | Yes | 98% | | 98% |
| France | Yes (D) | 99% | At delivery, in risk groups | 99% |
| Germany | Yes (D) | 87%–93% | | 87% - 93% |
| Greece | Yes (D) | | 3rd trimester, in risk groups | |
| Iceland | Yes | 50% | | 50% |
| Ireland | Yes¥ (D) | | 3rd trimester, in risk groups | 98.6% |
| Italy | Yes | 90% | At delivery, in risk groups | 90% |
| Latvia | Yes (D) | 88%–89% | | |
| Lithuania | Yes | | 3rd trimester | 93% |
| Luxembourg | Yes | 98% | | 100% |
| Malta | Yes¥ | | | ~100% |
| Netherlands | Yes | 99.8% | | 99.8% |
| Norway | Yes | 95% | At delivery, in risk groups | 95% |
| Poland | Yes | * | | |
| Romania | Yes (D) | ~60% | 3rd trimester | |
| Slovakia | Yes | 98% | 3rd trimester | 99% |
| Spain | Yes (D) | | 3rd trimester | ~100% |
| Sweden | Yes | >95% | | |
| UK | Yes (D) | 95% | | >95% |

[†] Country data for 2011 or for the most recent year; if no monitoring data were available, survey responders were invited to provide estimates

^{††} Percentage of pregnant women tested at least once

¥ At time of booking of antenatal care

D Testing at delivery if not done earlier

± Belgium: higher coverage value refers to pregnant women with high-risk profile (the risk is based on age – under 16 or above 40 years of age, socio-economic status, and medical comorbidities)

* Poland reported a 66.6% coverage in Mazowieckie region in 2013, based on a sample of 1 111 pregnant women

Note: Hungary and Slovenia do not implement national antenatal HIV screening. In Northern Ireland, HIV screening is repeated at delivery, with 98.5% of women tested at least once during pregnancy.

HIV diagnosis during pregnancy

Fifteen of 21 countries reported that they were able to distinguish between HIV infections that were known before pregnancy and HIV infections newly diagnosed during the current pregnancy (Table 4). The percentage of pregnant women newly diagnosed with HIV during their current pregnancy ranged between 0% and 63% and was over 30% in eight of the 13 countries where this estimation was possible (Table 4). The survey did not include additional questions on the procedures used.

Table 4. HIV-positive pregnant women and timing of HIV diagnosis in relation to current pregnancy, EU/EEA countries

| Country | Number of HIV-positive pregnant women (S) | Ability to distinguish between HIV infections diagnosed during current pregnancy vs. infection diagnosed before pregnancy | Pregnant women diagnosed during current pregnancy | |
|----------------|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-------|
| | | | N (S) | % (C) |
| Belgium | 250 | Yes | NR | |
| Czech Republic | 8 | Yes | 3 | 38% |
| Denmark | 39 | Yes | 12 | 31% |
| Estonia | 20 | No | | |
| Finland | 22 | Yes | 9 | 41% |
| France | 1500 | Yes | ~200 | 13% |
| Germany | | No | | |
| Greece | 21 | Yes | 10 | 48% |
| Iceland | 2 | Yes | 0 | 0% |
| Ireland | 109 | Yes | 17 | 16% |
| Latvia | 25 | No | | |
| Lithuania | 8 | Yes | 5 | 63% |
| Luxembourg | 14 | Yes | 7 | 50% |
| Malta | 6 | No | | |
| Netherlands | 89 | Yes | | *40% |
| Norway | 11 | Yes | | |
| Poland | 67 | No | | |
| Romania | 259 | Yes | 95 | 37% |
| Slovakia | 2 | Yes | 0 | 0% |
| Slovenia | 0 | | | |
| Spain | 0 | | 0 | |
| Sweden | 13 | No | | |
| UK | 1114 | Yes | 223 | 20% |

(S) Survey data provided by survey responders for 2011 or for the most recent year

(C) Calculated

* Responder's estimate

Note: Numbers in italics represent 2012 data or, in the case of Poland, 2013 data.

Vertical transmission of HIV

In 2013, 19 countries reported a total of 91 cases of MTCT in persons born in the reporting country (data retrieved from TESSy). Ten countries reported zero MTCT. The HIV MTCT case rate per 100 000 live births ranged between 0.7 in Germany and 43.7 in Latvia (Annex 2). When the age of reported cases was restricted to less than two years, the total number of MTCT cases in persons born in the reporting country was 53, and the MTCT rate ranged between 0.3 (Germany and the UK) and 29.1 (Latvia) (Annex 2).

Testing of children born to HIV-positive mothers

All 25 responding countries recommend HIV testing of children born to an HIV-positive mother. NAATs are used for diagnosis in 23/25 responding countries; HIV combination tests are used in Hungary and Spain. Eleven countries (Czech Republic, Finland, Estonia, Ireland, Malta, the Netherlands, Norway, Poland, Romania, Slovakia and Slovenia) use both HIV combination tests and NAATs.

Belgium, Hungary, Italy and Spain recommend that children should be tested once, at birth. In all other EU/EEA countries, children are tested more than once (Table 5). The estimated percentage of children tested at least once varied between 91% and 100% in the responding countries.

Table 5. Children born to HIV-positive mothers: age at last HIV test, EU/EEA, 2013

| At birth n=4 | 3–6 months n=6 | 12–18 months n=13 | 20–24 months n=2 |
|-------------------------------|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------|
| BE, HU , IT, ES | DK, <i>IE</i> , IS, FR, GR, LU, <i>NO</i> | <i>CZ</i> , <i>EE</i> , <i>FI</i> , DE, IS, LV, LT, <i>MT</i> , <i>NL</i> , <i>PL</i> , <i>RO</i> , <i>SI</i> , UK | SE, <i>SK</i> |

Note: Countries in bold only use HIV combination tests for diagnosis; all other countries use NAATs alone or in association with HIV combination tests (countries in italic).

HIV: referral and retention in care

HIV-positive pregnant women are referred to specialised HIV treatment and care services in 21 of the 24 countries (not in Finland, France and the UK). Sexually transmitted infection (STI)/genito-urinary medicine (GUM) clinics are the primary places for referral in Finland and the UK. A multi-disciplinary team was reported to be involved in the HIV care for pregnant women in France, Finland and the UK. To a lesser extent, HIV-positive pregnant women are referred to gynaecologists/obstetricians (Iceland, Italy, Latvia, Norway, Slovenia and Spain).

Data on the proportion of pregnant women with HIV who receive antiretroviral treatment (ART) or prophylaxis during pregnancy are available in six countries (Finland, Greece, Luxembourg, Malta, Slovakia and the UK). In these six countries – and in a further 12 countries with estimated data – between 95% and 100% of pregnant women with HIV are on ART.

In the majority of countries, the infection status of the newborn/infant is monitored through collaboration between HIV clinics/treatment centres and neonatologists/paediatricians (Belgium, Denmark, France, Iceland, Italy, Latvia, Poland, Slovakia, Slovenia, Spain and the UK). Monitoring via HIV treatment centres/clinics occurs in the Czech Republic, Estonia, Hungary, Ireland and Lithuania and by neonatologists/paediatricians in Germany, Luxembourg, Malta, Norway and Northern Ireland (UK). Specialised HIV treatment centres for children provide care in the Netherlands, and in Romania, children are monitored in infectious disease hospitals/wards that specialise in HIV. Finland, Greece and Ireland have paediatric infectious disease clinics/centres.

Data on the proportion of newborn children who go on to be enrolled in HIV care are reported by only a few countries (Czech Republic, Estonia, Greece, Iceland, Lithuania, Malta, Poland and Romania). Several countries reported that 98–100% of all children of HIV-positive pregnant women receive HIV care (Belgium, Denmark, France, Germany, Italy, the Netherlands, Norway, Slovenia, Spain and the UK – reported and estimated data).

Treatment/prophylaxis of mother and child

Antiretroviral therapy (ART) for HIV-positive pregnant women (who have not been in treatment before the pregnancy) is implemented as a combination of three drugs in 23/24 countries. In the Czech Republic, the treatment is implemented as a combination of two drugs. Monotherapy was reported to be considered in some cases in Ireland and the UK. In Latvia all options are considered. The coverage of ART in HIV-positive pregnant women was estimated at between 95 and 100% in 6/23 countries (Finland, Greece, Luxembourg, Malta, Slovakia and the UK).

Caesarean section is recommended to HIV-positive mothers in 8/25 countries (Czech Republic, Italy, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia) while in 14/25 countries (Belgium, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Luxembourg, Spain, Sweden and the UK), this option depends on the mother's viral load. Caesarean section is not recommended in Malta, the Netherlands and Norway.

All responding countries recommend that HIV-positive mothers refrain from breastfeeding.

Between 90 and 100% of children born to HIV-positive mothers receive antiretroviral prophylaxis in 9/23 reporting countries (Estonia, Greece, Iceland, Italy, Lithuania, Luxembourg, Malta, Slovakia and the UK). The number of drugs used for HIV prophylaxis of children varies between countries; national guidelines can recommend one or more drugs based on a case-based assessment of the risk of MTCT (Table 6).

Table 6. The number of drugs used for the HIV prophylaxis of the child, EU/EEA, 2013

| One drug* | One drug | Two drugs | Three drugs |
|--------------------------------------------|--------------------------------------------|--------------------|------------------------------------------------------------|
| BE, EE, FR, DE, GR, IE, LV, MT, PL, SI, UK | <i>CZ</i> , <i>FI</i> , IS, IT, LT, LU, SE | DE, GR, IE, NL, RO | BE, DK, EE, FR, DE, GR, IE, LV, MT, NL, NO, PL, SK, ES, UK |

* Dependent on mother's treatment and viral load

Populations at risk of mother-to-child transmission of HIV and challenges for effective antenatal screening

The most commonly recognised risk groups reported as not being reached by antenatal HIV screening programmes in the responding countries were: migrants from high-prevalence areas outside the EU, pregnant women presenting late for screening, pregnant women who inject drugs, mobile populations within the EU, women whose partners belong to risk groups (including migrants from high-prevalence areas, PWIDs, mobile populations) (Figure 6).

The two most common challenges for implementing effective antenatal screening policies for HIV were: insufficient capacity for reaching risk groups and low-quality national data (lack or incomplete data) (Figure 6).

Figure 6. Population groups reported as not being effectively reached by antenatal HIV screening programmes and vulnerable to MTCT of HIV, EU/EEA, 2013

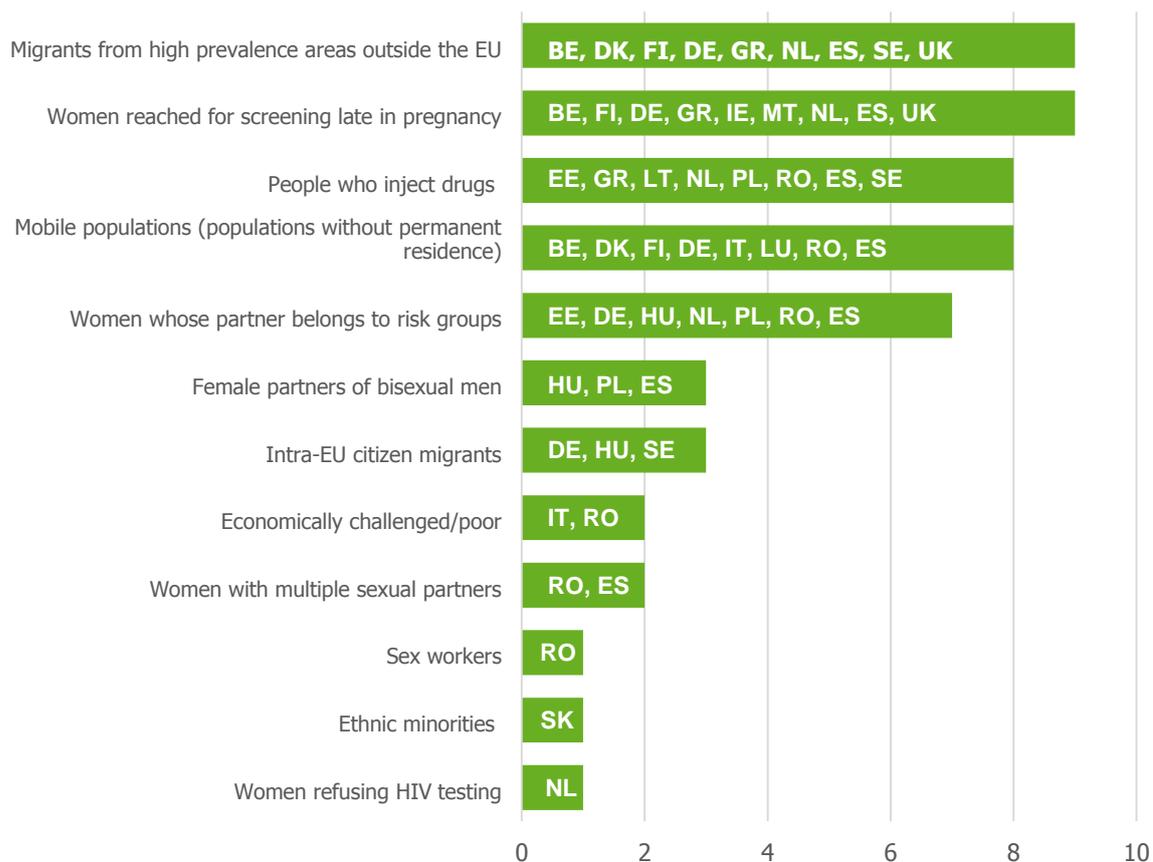
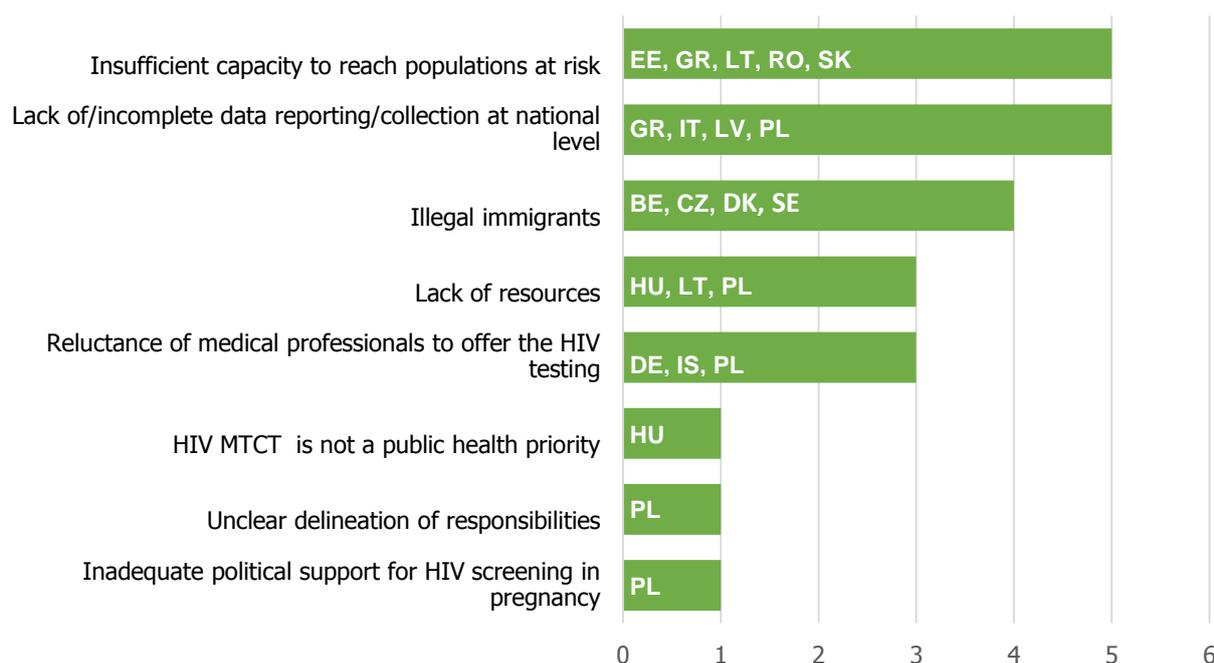


Figure 7. Challenges for the implementation of effective antenatal HIV screening policies, EU/EEA, 2013



3.4 Antenatal HBV screening: survey results

Responses to the HBV antenatal screening questionnaire were received from 22/26 countries, - Portugal, Slovenia and Slovakia did not respond; Belgium partially responded in the validation phase.

Implementation of antenatal HBV screening

Antenatal screening for HBV is implemented in 23/26 (88%) countries. Lithuania, Norway and Romania do not implement national antenatal HBV screening. Lithuania and Romania state limited resources as the main reason for not offering antenatal HBV screening, while Norway cites a low HBV incidence that does not warrant universal antenatal HBV screening.

Funding of antenatal HBV screening

HBV antenatal screening is publicly funded (and free of charge) in 14/20 countries; another six countries offer antenatal HBV screening through health insurance schemes (Table 7).

Table 7. Financing of HBV antenatal screening, EU/EEA, 2013

| Publicly funded n=14 | Health insurance n=6 |
|--------------------------------------------------------|-------------------------|
| DK, FI, FR, HU, IE, IS, IT, LV, MT, NL, PL, ES, SE, UK | BE, CZ, EE, DE, GR, LU |

Information not provided by Portugal, Slovenia and Slovakia.

Data collection, storage and analysis

Collection, storage and analysis of data on antenatal HBV screening occur at a national level in eight responding countries (Czech Republic, Denmark, Finland, France, Malta, the Netherlands, Slovakia and the UK).

Monitoring or evaluation of the effectiveness of antenatal screening programmes for HBV has been performed in Denmark [27], Finland [28], France [33], Italy [34], the Netherlands [24,30], Slovakia and the UK.

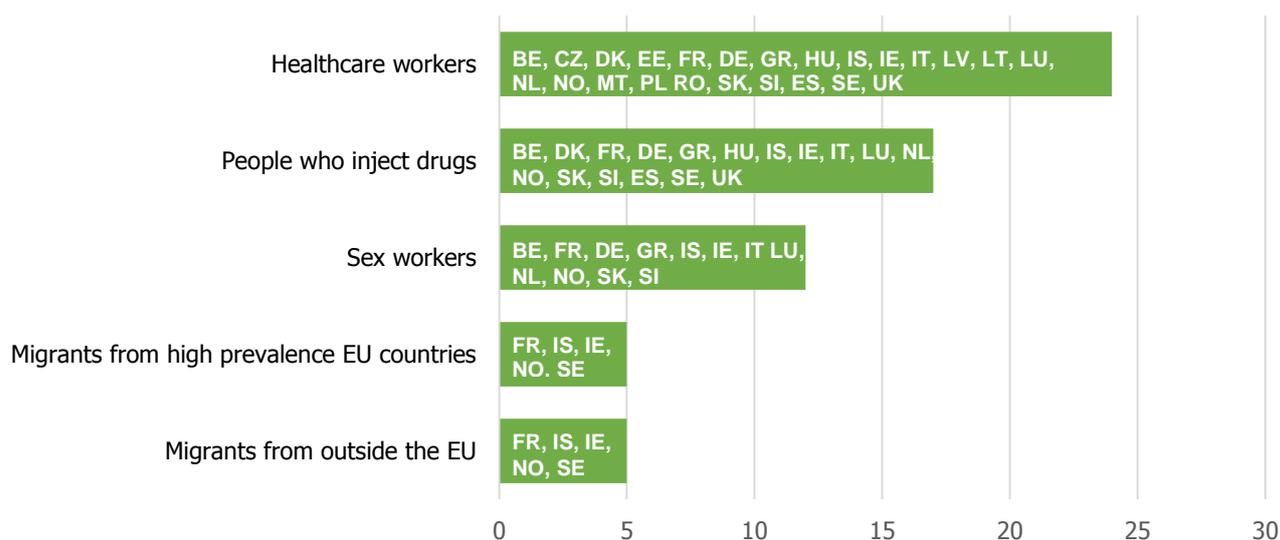
Vaccination policies and coverage

HBV vaccination is part of the national childhood vaccination programme in 20 of the 26 responding EU/EEA countries. Coverage varies from 74% to 99%. Denmark, Finland, Iceland, Norway, Sweden and the UK offer vaccine to babies born to HBV-infected mothers or mothers from risk groups.

All but one (Slovakia) of the 26 responding countries offer one dose of HBV vaccine at birth (within the first 12 to 24 hours). This is based either on a general recommendation or because these children were born to HBV-infected mothers or to mothers from risk groups.

In addition to childhood vaccination, many countries implement vaccination programmes in selected population groups at risk, e.g. healthcare workers, people who inject drugs, sex workers and migrants (Figure 8). Other risk groups mentioned were: close contacts of HBV carriers and confirmed cases, travellers to high-prevalence areas, prison workers, prisoners, families adopting from endemic countries, security and police forces, patients with chronic diseases and mobile populations.

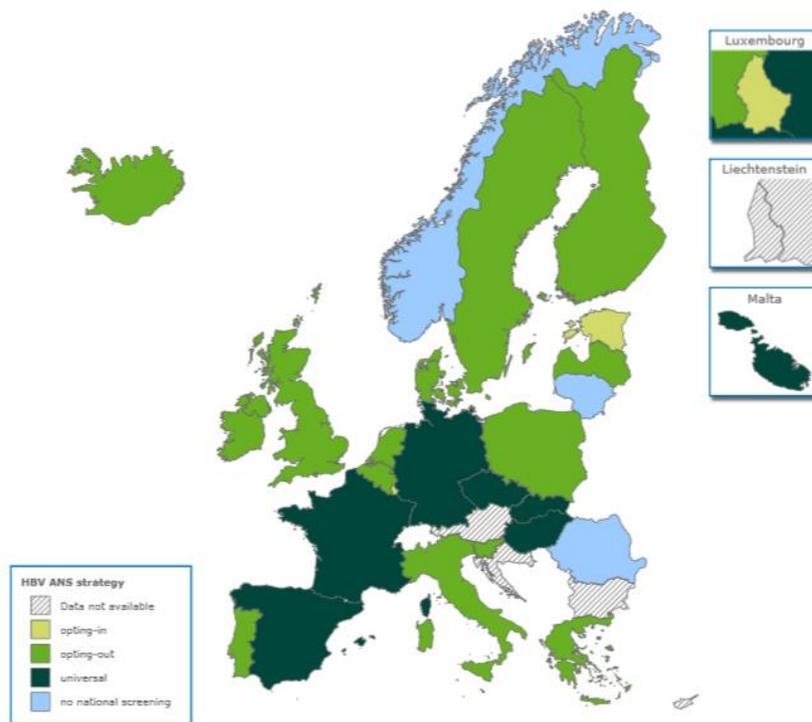
Figure 8. HBV vaccination programmes in population groups at risk, EU/EEA, 2013



Strategies for antenatal HBV screening

The most common (14/23, 61%) antenatal HBV screening strategy in the EU/EEA is opt-out screening, followed by universal screening (7/23, 30%). Estonia and Luxembourg use opt-in screening. In the absence of a national programme, antenatal HBV testing is offered to selected pregnant women based on a doctor's/midwife's assessment in Norway and to women who inject drugs in Romania (Figure 9).

Figure 9. Antenatal HBV screening strategies, EU/EEA, 2013

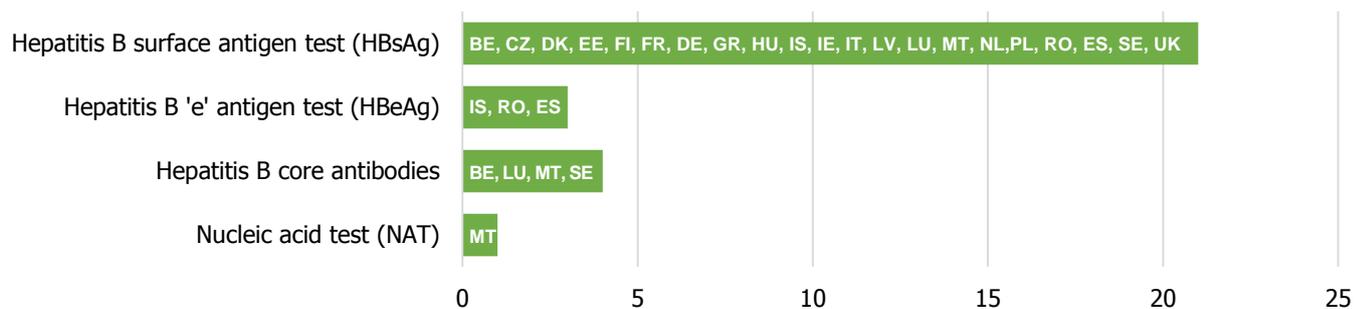


Note: Opt-in antenatal HBV screening is implemented in Northern Ireland (UK); testing is offered to selected pregnant women in Romania (PWID) and in Norway (based on clinician's assessment)

Laboratory methods for antenatal HBV screening

HBsAg testing is used in all the 20 countries that provided information. In addition, three countries (Estonia, Iceland and Romania) reported HBeAg testing. Belgium, Luxembourg, Malta and Sweden use anti-HBc testing (Figure 10).

Figure 10. Tests used for antenatal HBV screening, EU/EEA, 2013



Timing of screening and testing coverage

Antenatal HBV screening is recommended during the first trimester of pregnancy in 14/20 of the responding countries. In France, screening is recommended at six months of pregnancy; in Estonia, Germany, Iceland, Italy and Poland it is recommended during the third trimester (Table 8).

The Czech Republic recommends repeated HBV testing during the third trimester of pregnancy.

Germany, Greece, Latvia, Poland, Spain and Northern Ireland (UK) recommend HBV screening at delivery, if it was not performed during pregnancy.

The percentage of women tested at least once during pregnancy was estimated at over 95% in 8 of 13 of the responding countries. Estonia and Hungary estimated the coverage to be around 90%, while Iceland estimated that only 50% of the pregnant women are tested (Table 8).

Table 8. Implementation of antenatal HBV screening in the EU/EEA and coverage data for 2011 (or most recent year available), as reported by survey responders

| Country | First screening test recommended | Pregnant women tested at least once |
|----------------|----------------------------------|-------------------------------------|
| Belgium | 1st trimester | 80%–85%± |
| Czech Republic | 1st trimester | 99.8% |
| Denmark | 1st trimester | 99% |
| Estonia | 3rd trimester | >90% |
| Finland | 1st trimester | 98% |
| France | 6 months | ~87.5% (2010) |
| Germany | 3rd trimester† | |
| Greece | 1st trimester† | |
| Hungary | 1st trimester | 90% |
| Iceland | 3rd trimester | 50% |
| Ireland | 1st trimester | >95% |
| Italy | 3rd trimester | 97.7% (2008–2009) |
| Latvia | 1st trimester | |
| Lithuania | - | |
| Luxembourg | 1st trimester | ~95% |
| Malta | 1st trimester‡ | 100% |
| Netherlands | 1st trimester | 100% |
| Poland | 3rd trimester† | |
| Romania | - | |
| Spain | 1st trimester† | |
| Sweden | 1st trimester | |
| UK | 1st trimester | |

† Screening offered at delivery if not performed earlier

‡ At time of booking of antenatal care

± Belgium: higher coverage value refers to pregnant women with high-risk profile (the risk is based on age – under 16 or above 40 years of age, socio-economic status, and medical comorbidities)

Northern Ireland offers screening during the first trimester and at delivery if not done earlier. 98.5% of pregnant women were tested at least once for HBV.

Note: Lithuania, Norway and Romania do not offer national HBV antenatal screening.

HBV diagnosis during pregnancy

Nine of 22 countries reported that they were able to distinguish between HBV infections that were known before pregnancy and HBV infections newly diagnosed during the current pregnancy. This distinction is possible in the Czech Republic, Denmark, Hungary, Latvia, Norway, Romania, Spain, Sweden and the UK. In Finland, this is possible if the pregnant woman was tested during an earlier pregnancy. The percentage of newly diagnosed infections ranged from 0.5% in the Czech Republic to 100% in Denmark. In Finland it was 54%, 55% in England (UK), 73% in Estonia, and 97% in Latvia.

Vertical transmission of HBV

Six cases of MTCT of HBV were reported in children below the age of two. All six cases were identified as 'non-imported' (TESSy data, 2013): Germany (1), Ireland (1), Latvia (2), Romania (1) and Slovakia (1). Another six HBV infections in 2013 were reported – also in children under the age of two – as 'non-imported' but with an 'unknown' transmission mode: Austria (2), Spain (1) and Romania (3). The relevance of these cases for the performance of antenatal screening is unclear.

Testing of children born to HBV-positive mothers [35]

Maternal HBeAb can be transmitted through the placenta. However, in the absence of HBV viraemia, most infants who are HBeAg positive at birth will lose the HBeAg by the time they reach six to 12 months of age. Therefore, the most important predictor of infant infection and immunoprophylaxis failure is detectable HBV DNA in the infant's serum at birth. Anti-HBc testing of infants born to HBV-infected mothers is not recommended, as passively acquired maternal anti-HBc may be detected up to the age of 24 months.

Testing of children born to HBV-infected mothers is recommended in 18/20 countries, the exceptions being Italy and Poland (Table 9). In Poland, although testing is not officially recommended, it is routinely offered at 9 to 13 months of age by primary care practitioners.

HBsAg testing is used for the diagnosis of HBV in children born to HBV-positive mothers in all countries that perform this testing; eight of which also use NAATs (Table 10).

Table 9. HBV testing among children born to HBV-infected mothers and age at the time of the last test, EU/EEA, 2013

| Number of HBV tests given to child | Age of child at last test <9 months | Age of child at last test >9 months |
|------------------------------------|-------------------------------------|-------------------------------------|
| 1 test | EE, FR, RO | DK, ES, FI, GR, HU, IE, MT, NL, UK |
| 2 tests | DE, IS | LV, NO, SE |
| >2 | LU | |

Table 10. Diagnostic tests used to detect HBV infection in children born to HBV-positive mothers, EU/EEA, 2013

| HBsAg | NAAT | Anti-HBc | Anti-HBs | HBeAg |
|----------------------------------------------------------------------------|---------------------------------|----------------|--------------------|-------|
| CZ, EE, FI, FR, DE, GR, HU, IS, IE, LV, LU, MT, NL, NO, PL, RO, ES, SE, UK | CZ, EE, FI, GR, LV, NO, SE, UK† | CZ, DE, IE, NO | FR, IE, DE, LU, NL | DE |

† Northern Ireland

Confirmatory testing of seroconversion after vaccination (anti-HBs) of children born to HBV-positive mothers is done in 15 countries (Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Spain and Sweden); confirmatory testing is not performed in the Czech Republic, Estonia, Poland, Romania and the UK. Ireland reported very low implementation rates of existing recommendations on follow-up testing.

HBV: referral and retention in care

National data about the proportion of pregnant women with positive HBV results that were referred to specialist care were only available from Malta. Denmark, Finland and Northern Ireland (UK) gave estimates: 60%, <5% and 100%, respectively.

HBV-infected pregnant women are referred for care to hepatologists/gastroenterologists in 13/21 countries (Czech Republic, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Luxembourg, the Netherlands, Poland and the UK). Women in Iceland can also be referred to a gynaecologist/obstetrician and/or a STI/GUM clinic; in Czech Republic and Poland to a gynaecologist/obstetrician; and in Luxembourg to a STI/GUM clinic.

In Denmark, Italy, Romania and Sweden pregnant women are referred to an infectious disease specialist/unit; in Finland and Malta to STI/GUM clinic; in Norway women are provided care by a primary care practitioner and can be referred to a gynaecologist/obstetrician.

The infection status of the newborn/infant born to an HBV-positive mother is monitored by paediatricians in the majority (16/22) of countries. In Denmark, Estonia, Hungary, the Netherlands and the UK, monitoring is done in primary care. There is no child monitoring in Luxembourg. A specialist in hepatology is involved in the Czech Republic, France, Latvia and Poland. In Ireland, Latvia and the UK, the primary care provider is supported by a hepatologist and a paediatrician.

Treatment/prophylaxis for the child [36]

WHO guidelines recommend that infants should receive a first dose of HBV vaccine as soon as possible after birth, preferably within 24 hours of birth, followed by completion of the HBV vaccine series during the first year of life. Administration of HBV immunoglobulin in conjunction with HBV vaccination may be of benefit for infants born to mothers who are both HBsAg and HBeAg positive. No recommendation for the routine use of antiviral therapy to prevent HBV MTCT has been formulated.

The prevention of MTCT for children born to HBV-positive mothers is implemented as a combination of vaccination (first dose administered within 24 hours of birth) and administration of HBV immunoglobulin in 18/21 responding countries. In Estonia, Latvia and Romania only vaccination is used. Norway and Sweden use antiviral prophylaxis (therapy administered to the mother) in certain case-based circumstances, in addition to vaccination and immunoglobulin.

Populations at risk of mother-to-child transmission of HBV and challenges for effective antenatal screening

According to the responding countries, the following population groups were at risk of being missed by antenatal HBV screening programmes: migrants from high-prevalence areas outside the EU, women presenting late in pregnancy, pregnant women who inject drugs, and mobile populations (Figure 11).

The three most common challenges for implementing effective antenatal screening policies for HBV were: lack of reporting and collection of data at the national level, insufficient capacity for reaching populations at risk and a lack of resources (Figure 12).

Figure 11. Population groups at risk of not being (entirely/effectively) reached by antenatal HBV screening programmes and still vulnerable to MTCT of HBV, EU/EEA, 2013

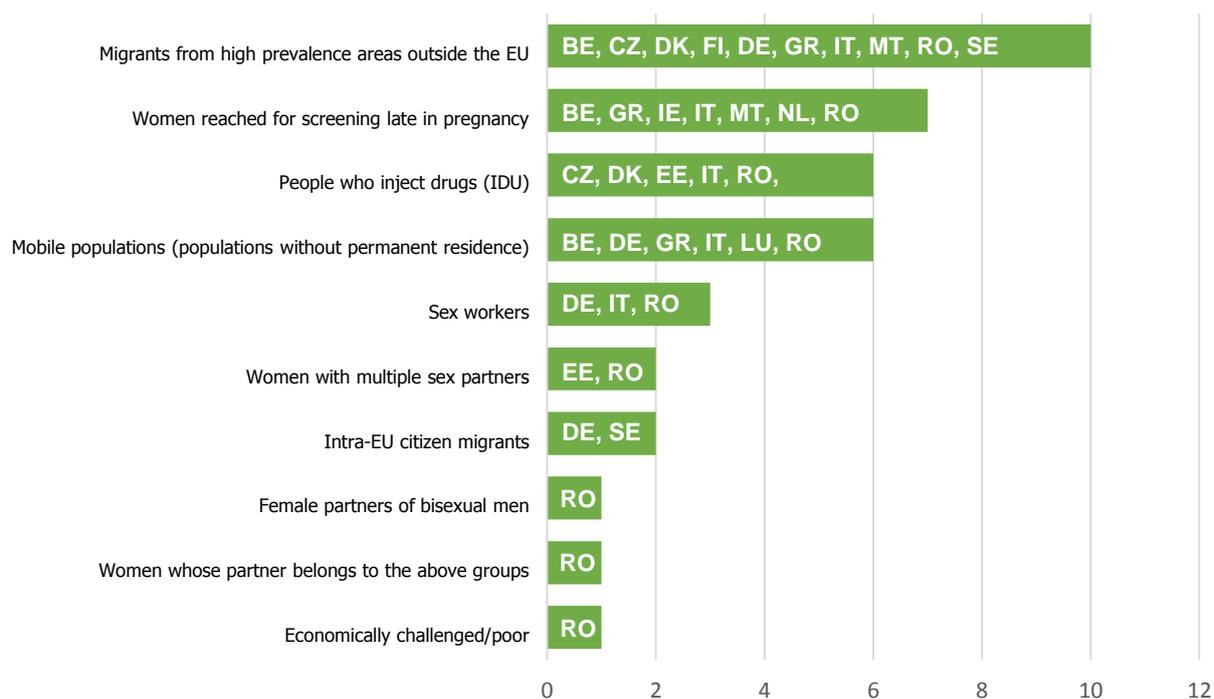
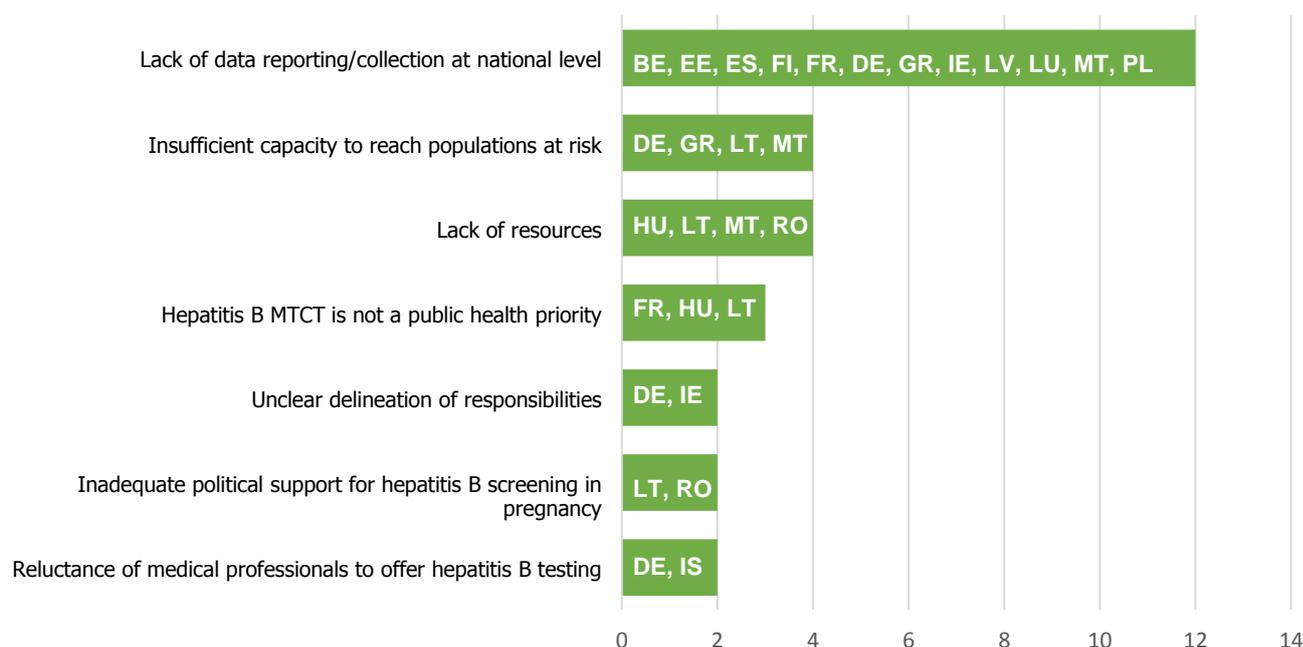


Figure 12. Challenges for the implementation of effective antenatal screening policies for HBV, EU/EEA, 2013



3.5 Antenatal syphilis screening: survey results

Responses to the syphilis antenatal screening questionnaire were received from 24/26 countries; Portugal and Poland did not respond.

Implementation of antenatal screening for syphilis

Antenatal screening for syphilis is implemented in all 24 responding countries: Belgium, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Romania, Slovakia, Slovenia, Spain, Sweden and the UK.

Funding of antenatal screening for syphilis

Antenatal syphilis screening is publicly funded (free of charge) in 15/24 countries. Another 9/24 countries offer antenatal syphilis screening through health insurance schemes (Table 11).

Table 11. Financing of antenatal screening for syphilis, EU/EEA, 2013 survey

| Publicly funded n=15 | Health insurance n=9 |
|------------------------------------------------------------|------------------------------------|
| DK, FI, HU, IS, IE, IT, LV, LT, MT, NL, NO, RO, ES, SE, UK | BE, CZ, EE, FR, DE, GR, LU, SK, SI |

Data collection, storage and analysis

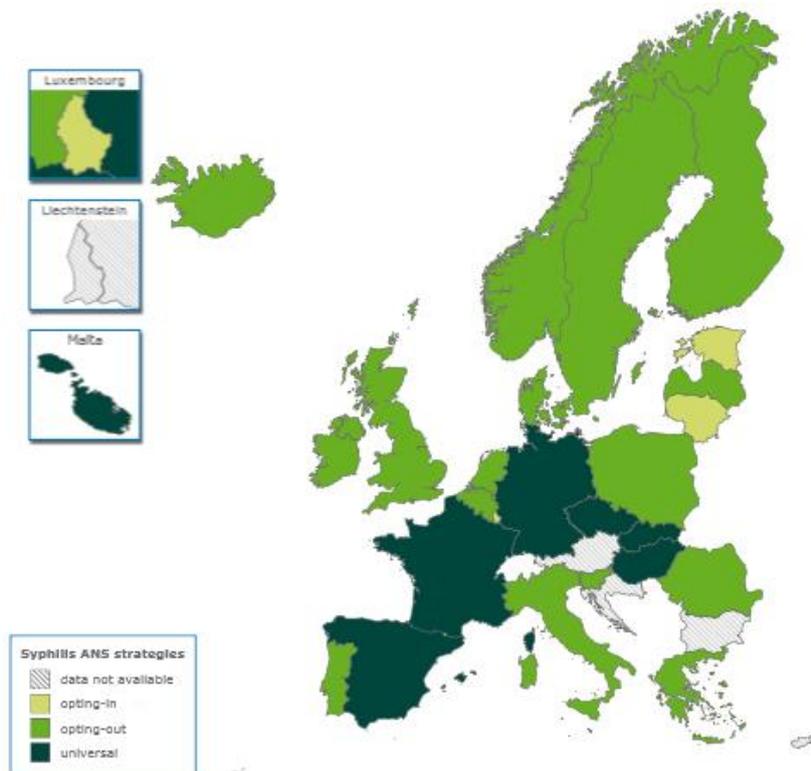
Data on antenatal screening for syphilis are collected, stored and analysed at the national level in eight countries: Denmark, Finland, Lithuania, Malta, the Netherlands, Romania, Slovakia and the UK.

Monitoring or evaluation of the effectiveness of antenatal screening programmes for syphilis have been performed in Denmark [30], Finland [28], Italy, the Netherlands [24], Slovakia and the UK.

Strategies for antenatal syphilis screening

Data on the type of screening strategy were available for 26 countries, including Portugal and Poland. The most common strategy (16/26, 62%) of antenatal screening for syphilis in EU/EEA countries is an opt-out strategy, followed by universal screening (7/26, 27%). Estonia, Lithuania and Luxembourg reported opt-in screening for syphilis (Figure 13). Antenatal syphilis screening targeting sex workers on an irregular basis was reported by Romania.

Figure 13. Syphilis antenatal screening strategies, EU/EEA, 2013



Note: Opt-in antenatal screening for syphilis is implemented in Northern Ireland (UK)

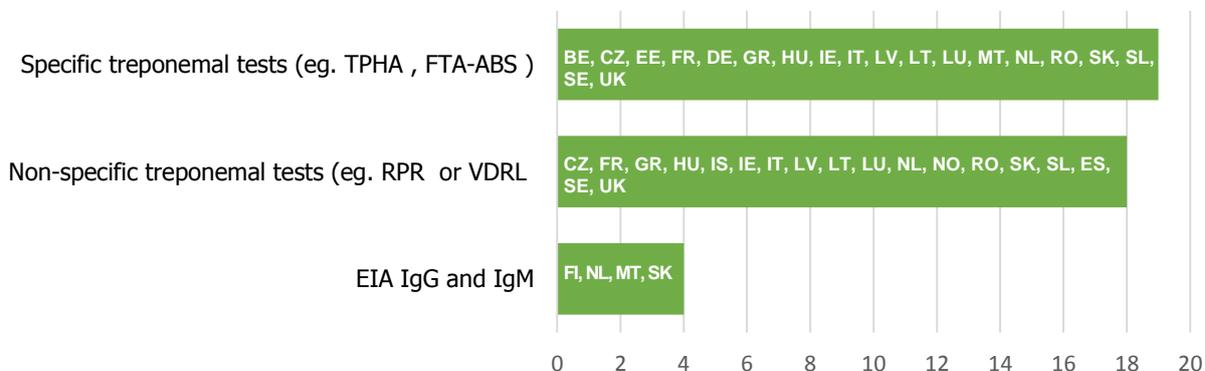
Laboratory methods for antenatal syphilis screening

Antenatal screening for syphilis is carried out with specific and nonspecific treponemal tests (specific: *Treponema pallidum* particle agglutination test (TPPA), *Treponema pallidum* haemagglutination, enzyme immunoassay vs. nonspecific: rapid plasma reagin and venereal disease research laboratory).

Traditionally, non-treponemal tests are used for syphilis screening; however, during the last decade, non-treponemal tests have been replaced by highly sensitive and specific enzyme immunoassays.

Both treponemal and non-treponemal tests are in use for the antenatal screening of syphilis in most EU/EEA countries (15/24). In Iceland, Norway and Spain only non-specific treponemal tests are used. In Belgium, Estonia and Germany only specific treponemal tests are in use. IgM/IgG enzyme immunoassays are in use in Finland, Malta and Slovakia (Figure 14). Testing methods in Denmark are selected by individual laboratories.

Figure 14. Tests used for antenatal screening of syphilis, EU/EEA, 2013



Timing of screening and testing coverage [37]

The timing of antenatal interventions has a significant impact on the risk of becoming infected with syphilis. Women who were tested and received appropriate treatment during the first two trimesters of pregnancy were 2.24 times (95% CI 1.28, 3.93) more likely to have a healthy baby than those receiving syphilis treatment during their third trimester.

Antenatal screening for syphilis is recommended during the first trimester of pregnancy in 22/24 countries that provided this information. In Malta, testing is done at the time of booking antenatal care. Syphilis screening is recommended during the second trimester of pregnancy in Hungary.

In addition, the Czech Republic, Estonia, Latvia, Lithuania, Romania, Slovakia and Spain reported having recommendations on repeated syphilis testing during the third trimester of pregnancy. In Belgium, France and Italy, women from risk groups are re-tested during the third trimester (Table 12).

Denmark, Estonia, Latvia, Lithuania, Spain and Romania mentioned that antenatal screening for syphilis is recommended at delivery if not already done earlier in pregnancy.

The estimated coverage of syphilis screening during the first trimester of pregnancy was over 95% in four countries (Finland, Ireland, Netherlands, Sweden) and between 80% and 95% in another nine (Czech Republic, Estonia, Germany, Iceland, Latvia, Luxembourg, Norway, Slovakia, Slovenia) (Table 12).

The percentage of women tested at least once during pregnancy was estimated as 95% or higher in 14 of 18 responding countries. Hungary estimated the coverage at between 90% and 100%, Slovenia and Iceland estimated 90%, and Belgium cited a coverage of between 63% and 74%.

Table 12. Implementation of antenatal syphilis screening in the EU/EEA and coverage data for 2011 (or most recent year available), as reported by survey responders

| Country | Antenatal screening during 1st trimester | Antenatal screening coverage 1st trimester | Repeated screening | Antenatal screening coverage overall |
|----------------|------------------------------------------|--------------------------------------------|----------------------------|--------------------------------------|
| Belgium | Yes | | 3rd trimester, risk groups | 63%–74%± |
| Czech Republic | Yes | 80% | 3rd trimester | 99.8% |
| Denmark | Yes (D) | | | 98% |
| Estonia | Yes (D) | >90% | 3rd trimester | >95% |
| Finland | Yes | 98% | | 98% |
| France | Yes | | 3rd trimester, risk groups | >95% |
| Germany | Yes | 95% | | |
| Greece | Yes | | 3rd trimester | |
| Hungary | No (16th week) | | | 90%–100% |
| Iceland | Yes | 90% | | 90% |
| Ireland | Yes | 98% | | 95% |
| Italy | Yes | | 3rd trimester, risk groups | |
| Latvia | Yes (D) | 88–89% | 3rd trimester | 98% |
| Lithuania | Yes (D) | | 3rd trimester | |
| Luxembourg | Yes | 95% | | 95% |
| Malta | * | | | 100% |
| Netherlands | Yes | >95% | | >99% |
| Norway | Yes | 95% | | 95% |
| Romania | Yes (D) | | 3rd trimester | |
| Slovakia | Yes | 95% | 3rd trimester | 99% |
| Slovenia | Yes | >80% | | >90% |
| Spain | Yes (D) | | 3rd trimester | ~100% |
| Sweden | Yes | >98% | | |
| UK** | Yes | | | 97% |

(D) Tested at delivery if not tested earlier

± Belgium: higher coverage value refers to pregnant women with high-risk profile (the risk is based on age – under 16 or above 40 years of age, socio-economic status, and medical comorbidities)

* At time of booking of antenatal care

** England only. In Northern Ireland, syphilis screening is recommended during the 1st trimester and at delivery if not tested earlier; overall coverage 98.5%.

Policies for partner notification

In 21/24 EU/EEA countries, there is an official policy for partner tracing and treatment of all sexual contacts of a syphilis-positive pregnant woman. There is no such official policy for partner tracing in Belgium, France and Germany.

Vertical transmission of syphilis

In 2013, 64 cases of congenital syphilis were notified by nine of the 21 countries that reported data to TESSy. The congenital syphilis rate per 100 000 live births ranged between 0.3 in Germany and 40.6 in Bulgaria. Twelve countries reported no congenital syphilis cases in 2013 (Annex 2).

Testing of children born to syphilis-positive mothers [38]

Treatment is recommended to newborns diagnosed with congenital syphilis. Asymptomatic neonates born to a mother diagnosed with syphilis during pregnancy receive a prophylactic single dose of penicillin. Follow-up tests should be arranged at 1, 2, 3, 6 and 12 months to assess response to treatment. Infants with negative serology should still have follow-ups at three and six months.

All 24 responding countries recommend testing of children born to mothers diagnosed with syphilis, except for Finland, where testing is not done if the mother has been treated during pregnancy. Most of the responding countries use both non-specific and specific treponemal tests in the diagnosis of congenital syphilis. Belgium, France, Hungary and Norway also use nucleic acid testing or a direct antigen detection method for diagnostics. The number of tests and the age of the child at testing varies between countries (Table 13). In the UK, children are tested repeatedly, beginning with birth and then during follow-ups. Follow-ups depend on factors such as the presence of symptoms in the mother or the baby or the type of treatment that the mother received.

Table 13. Syphilis testing among children born to infected mothers and age at the time of the last test, EU/EEA, 2013

| Number of syphilis tests given to the child | Age of child at time of last test | | | | | | |
|---------------------------------------------|-----------------------------------|-------------|--------------------|-----------|------------------------------------|------------------------|--------------|
| | At birth | 6-12 months | >12 and <24 months | 24 months | Until negative or fourfold decline | On an individual basis | No age given |
| 1 test | ES | NL | RO | | | | |
| 2 tests | | IT, LU, MT | FR | | MT | | |
| 2+ tests | | | | SK, SI | | | NO |
| 3 tests | | IS | IE | | | | |
| 3+ tests | | | | HU | | | |
| 5 tests | | | | | | | FI* |
| 7 tests | | | | CZ | | | |
| No number specified | | | | | DK, EE, GR | DE, LV, LT | UK |

Countries in bold use NAATs or a direct antigen detection method for diagnostics.

* If the mother was not treated during pregnancy

Syphilis: referral and retention in care

Pregnant women diagnosed with syphilis are referred to STI/GUM clinics in 13/24 countries (Denmark, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Norway, Romania, Sweden and the UK) and to a gynaecologist/obstetrician in Estonia, Germany, Netherland and Slovenia. Shared care by STI/GUM clinics and gynaecologists/obstetricians was reported in Greece, Latvia and Norway. Cases are referred to dermatology/venereology clinics in the Czech Republic and Greece, or to infectious diseases specialists in Denmark. In Spain, cases are treated by neonatologists/paediatricians and gynaecologists/obstetricians. In Sweden, a specialist in antenatal care collaborates with a venereologist.

In 20/23 countries, newborns/infants of a syphilis-positive mothers are monitored in a hospital secondary care ward (paediatrics/neonatology). In Hungary and Ireland, the monitoring is done in a hospital outpatient clinic/ambulatory war, and in Luxembourg the newborn/infant is monitored by a general practitioner. Denmark and Estonia reported that the hospital wards and the outpatient/ambulatory clinics are jointly responsible for monitoring the outcome of syphilis exposure or congenital infection in infants. Dermatology/venereology clinics (Czech Republic) and paediatric infectious disease units (Greece) support neonatology/paediatric hospital wards in the monitoring of infants of syphilis-positive mothers. In the UK, outpatient clinics are responsible for monitoring these infants, unless the child's condition requires inpatient care.

Treatment/prophylaxis of the mother and the child [39]

Effective treatment regimens of maternal and fetal infection exist. Penicillin G, administered parenterally, is the preferred drug for treating syphilis. Maternal treatment can be inadequate if delivery occurs within 30 days of therapy, or if the maternal antibody titer at delivery is four times higher than the pre-treatment titer.

Penicillin is the treatment of choice for syphilis in pregnant women in all 24 responding countries. Data about the proportion of pregnant women diagnosed with syphilis who are treated during pregnancy were only available from Luxembourg and Malta, both reporting a treatment coverage of 100%. Nine other countries (Czech Republic, Denmark, Estonia, Finland, Iceland, Slovakia, Slovenia, Spain and Northern Ireland (UK)) provided estimates ranging between 80% and 100%. Eleven countries (Belgium, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Romania and the UK) do not collect data on the proportion of women with syphilis who are treated during pregnancy.

All 24 responding countries treat congenital syphilis with penicillin.

Populations at risk of mother-to-child transmission of syphilis and challenges for effective antenatal screening

The most commonly recognised risk groups reported by the responding countries as not being reached by antenatal syphilis screening programmes were: women reached for screening late in pregnancy, migrants from high-prevalence countries outside the EU and PWID (Figure 15).

The three most common challenges for implementing effective screening policies for syphilis were: the lack of data reported and collected at the national level, insufficient capacity to reach groups at risk, and a lack of resources (Figure 16).

Figure 15. Population groups at risk of not being reached by syphilis antenatal screening programmes, vulnerable to MTCT of syphilis, EU/EEA, 2013

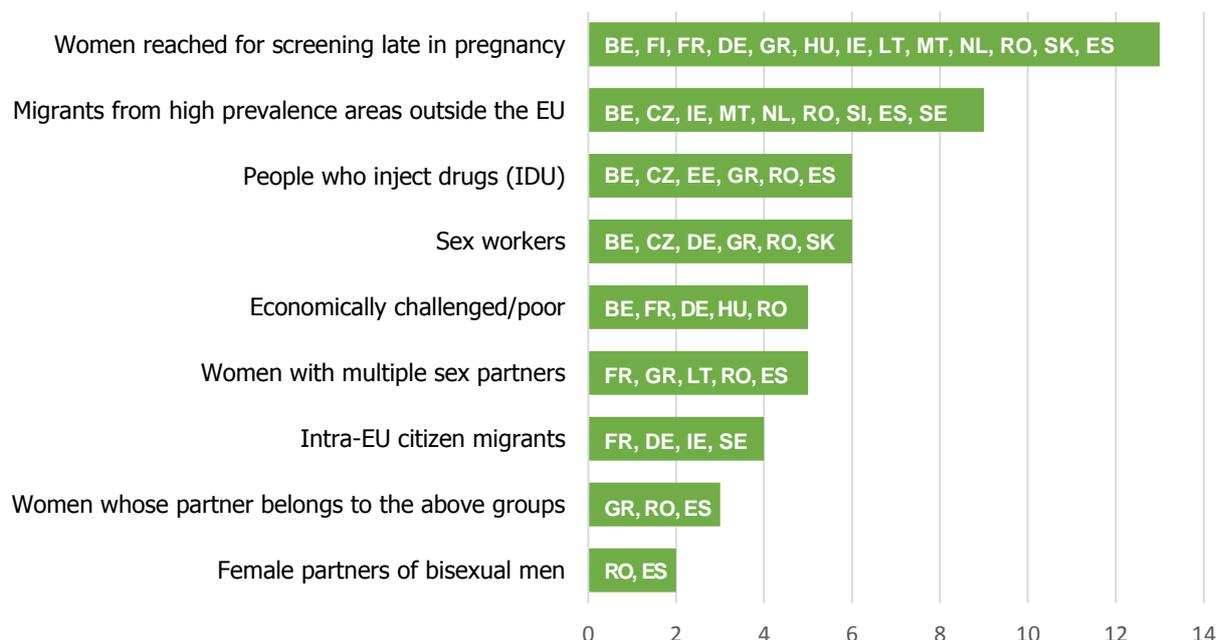
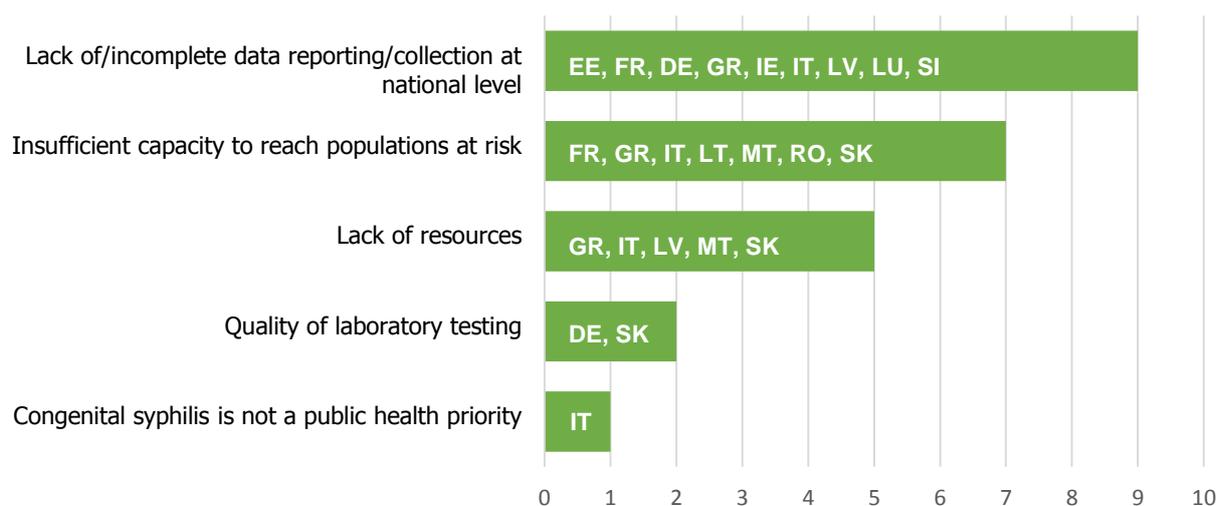


Figure 16. Challenges for the implementation of effective antenatal screening policies for syphilis, EU/EEA, 2013

3.6 Rubella susceptibility screening: survey results

Responses to the rubella questionnaire were received from 22/26 countries. Belgium, Portugal, Slovakia and Slovenia did not respond. Rubella is a notifiable infection in 24/26 responding EU/EEA countries. Exceptions are Denmark (but both rubella infection during pregnancy and congenital rubella are notifiable) and France. In Belgium, rubella is notifiable in the Brussels capital region and congenital rubella in the Walloon region. Congenital rubella is not notifiable in France.

Implementation of antenatal screening for rubella susceptibility

Antenatal rubella susceptibility screening is implemented in 14/26 (59%) countries: Belgium, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Slovakia, Spain and UK.

Rubella susceptibility screening has been discontinued due to low incidence of rubella and the high vaccination coverage in several countries such as Denmark, Finland, Hungary and Slovenia. Limited resources were mentioned by Latvia, Lithuania and Romania as a reason for not recommending susceptibility screening. In the Netherlands, although there are no national antenatal screening recommendations, rubella susceptibility testing is offered on the recommendation of a doctor or midwife: about 60% screened all pregnant women, 25% offered testing to high-risk groups including the unvaccinated, and 15% did not offer screening to pregnant women at all. Estonia, Germany, Slovenia and Sweden also reported testing of 'pregnant women in specific groups'.

The overall aim of antenatal rubella susceptibility testing in Iceland, Ireland, Malta, Norway and Sweden is to identify susceptible women who would benefit from post-partum rubella immunisation. The main aim in Luxembourg, Poland and Spain is to assist diagnosis in subsequent pregnancies and investigation of the neonate in case of maternal exposure to rubella. Both aims are considered equally important in France, Greece and Italy.

The management of viral rash illness (or exposure to viral rash illness) during pregnancy is addressed in guidance for antenatal rubella susceptibility screening in the Czech Republic, Germany, Greece, Luxembourg and Malta. In Denmark, France, the Netherlands, Romania, Sweden and the UK, the management is addressed in a separate guidance document. No guidance on this topic exists in Estonia, Hungary, Iceland, Ireland, Italy, Norway and Poland.

Funding of antenatal screening for rubella susceptibility

Rubella susceptibility screening is publicly funded (free of charge) in seven countries. Another 4/11 countries offer antenatal syphilis screening through health insurance schemes (Table 14).

Table 14. Financing of antenatal screening for rubella susceptibility, EU/EEA, 2013

| Publicly funded n=7 | Health insurance n=4 |
|----------------------------|-------------------------|
| IS, IE, IT, MT, NO, ES, UK | FR, GR, LU, PL* |

* Poland reported that antenatal screening for uninsured pregnant women was funded through the public health budget. No information reported from Belgium, Portugal and Slovakia.

Data collection, storage and analysis

Data on antenatal screening for rubella susceptibility is collected, stored and analysed at the national level in Ireland, Slovakia and the UK.

Monitoring or evaluation of the effectiveness of antenatal screening programmes for rubella susceptibility has been performed in Ireland, Slovakia and the UK.

Vaccination policies and coverage

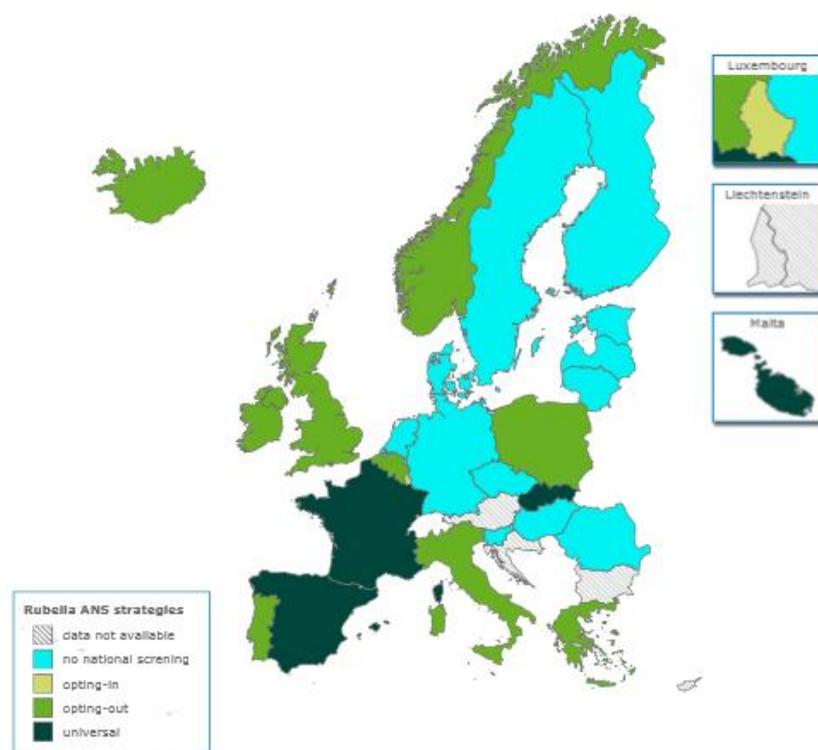
All EU/EEA countries have childhood vaccination programmes in place for rubella. All programmes administer two doses of the measles, mumps and rubella (MMR) vaccine. The year of programme implementation varies, as does vaccination coverage: in 2013, national estimates ranged between 86% and 99% for the first dose in 2013 [40].

Selective rubella vaccinations are recommended for healthcare workers in six countries (Finland, France, Ireland, Italy, Norway and Spain) and for migrants from high-prevalence countries inside and outside the EU (Ireland and Slovakia). Rubella vaccinations can also be offered to close contacts of confirmed rubella cases, mobile populations, to people in pre-conceptual care and to people at risk for occupational reasons.

Strategies for rubella susceptibility antenatal screening

The most common (9/14, 64%) strategy of antenatal screening for rubella susceptibility in the EU/EEA is opt-out screening, followed by universal screening (4/14, 29%). Luxembourg reported using an opt-in strategy (Figure 17).

Targeted antenatal rubella susceptibility screening is offered in the case of clinical suspicion or contact with a rubella case (Estonia), to those whose immunity is unknown or non-existent (Germany), to the unvaccinated (Slovenia) and to those unvaccinated in their the first pregnancy (Sweden). Testing is recommended by doctors or midwives in the Netherlands.

Figure 17. Antenatal rubella susceptibility screening strategies, EU/EEA, 2013

Note: Opt-in strategy in Northern Ireland (UK); Estonia, Germany, Netherlands, Slovenia and Sweden: testing targeted to pregnant women in specific population groups

Timing of screening and testing coverage

Antenatal screening for rubella susceptibility is recommended during the first trimester of pregnancy in 10/11 countries (France, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Poland, Spain, and the UK). Malta recommends testing as part of pre-conceptual care. Testing during pre-conceptual care is also possible in France, Greece, Italy and Spain.

Rubella susceptibility testing can be done as part of pre-conceptual care in the Czech Republic, Hungary and Latvia, three countries that do not run national screening programme. In Germany testing is recommended both as part of pre-conceptual care and during the first trimester.

The percentage of women tested at least once during pregnancy was estimated at over 95% in Ireland, Luxembourg, Malta and the UK. Norway estimated the coverage to be 90%, while the Netherlands provided an estimate of 60%.

The proportion of negative tests, reflecting rubella susceptibility in tested pregnant women, was only available from Ireland, Malta and the UK: 3.70%, 9.50% and 5.35%, respectively.

Congenital rubella

Number of congenital rubella cases reported in the EU/EEA have remained low. Between 2007 and 2012, the highest numbers were reported by Italy (26) and Romania (58). In 2013, 49 cases of MTCT of rubella were reported by four countries, with 45 by Romania (Table 22) [41].

Table 15. Congenital rubella cases, EU/EEA 2007–2013

| Country | Congenital rubella cases 2013 | Congenital rubella cases 2007–2012 |
|----------------|-------------------------------|------------------------------------|
| Belgium | 0 | 1 |
| Czech Republic | 0 | 2 |
| Denmark | 0 | 0 |
| Estonia | 0 | 0 |
| Finland | 0 | 1 |
| France | - | 3 |
| Germany | 1 | 4 |

| Country | Congenital rubella cases 2013 | Congenital rubella cases 2007–2012 |
|-------------|-------------------------------|------------------------------------|
| Greece | 0 | 0 |
| Hungary | 0 | 0 |
| Iceland | 0 | 0 |
| Ireland | 0 | 0 |
| Italy | - | 26 |
| Latvia | 0 | 0 |
| Lithuania | 0 | 0 |
| Luxembourg | 0 | 0 |
| Malta | - | 0 |
| Netherlands | 0 | 0 |
| Norway | 0 | 0 |
| Poland | 2 | 3 |
| Portugal | 0 | 2 |
| Romania | 45 | 58 |
| Slovakia | 0 | 0 |
| Slovenia | 0 | 0 |
| Spain | 1 | 6 |
| Sweden | 0 | 1 |
| UK | 0 | 2 |

Source: adapted from WHO [41]

Testing of children born to mothers with rubella infection during early pregnancy

The EU case definition requires that an infant with congenital rubella was laboratory-confirmed with rubella infection and shows clinical manifestations suggestive of congenital rubella syndrome, or was born to a woman with a laboratory-confirmed rubella infection during pregnancy [42]. Children born to a mother diagnosed with rubella during pregnancy are tested for rubella in all 21 responding countries.

All 21 countries, except Denmark and the UK, use anti-rubella IgM antibody testing to confirm diagnosis of congenital rubella. Hungary and Poland also use virus isolation. Denmark uses only NAATs. A combination of virus isolation, IgM antibody and nucleic acid testing is used in the Czech Republic, Germany, Ireland, Italy, Latvia, Luxembourg, the Netherlands and Spain. IgM antibody testing, together with nucleic acid testing is used in Estonia, Finland, France, Greece, Norway and Sweden (Table 23). The UK utilises both NAAT and virus isolation testing.

In addition, anti-rubella IgG tests are done at six months of age in Romania; in France, this test is conducted at 12 months. Italy monitors IgG levels in the first year of life, while Spain monitors persistence of IgG antibodies from 6 to 12 months of age.

Table 16. Diagnostic tests used to detect congenital rubella, EU/EEA, 2013

| IgM antibody | NAAT | IgG antibody | Virus isolation |
|--------------------------------------------------------------------------------|----------------------------------------------------------------|----------------|--------------------------------------------|
| CZ, EE, FI, FR, DE, GR, HU, IS, IE, IT, LV, LT, LU, MT, NL, NO, PL, RO, ES, SE | CZ, DK, EE, FI, FR, DE, GR, IE, IT, LV, LU, NL, NO, ES, SE, UK | FR, IT, RO, ES | CZ, DE, HU, IE, IT, LV, LU, NL, PL, ES, UK |

Note: Northern Ireland uses IgM antibody testing for congenital rubella.

Rubella: Referral and retention in care

Pregnant women who are rubella antibody negative are recommended to be vaccinated in the post-partum period in all 15 countries that responded (Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Poland, Spain and Sweden). In addition, six countries (France, Germany, Greece, Iceland, Italy and Spain) recommend additional laboratory investigations during pregnancy. Denmark, France, Ireland, Poland and the UK perform additional laboratory investigations during pregnancy, but only in the in case of rubella exposure or if there are clinical signs suggestive of rubella. France recommends an additional antibody test at the 20th week of gestation. None of the responding EU/EEA countries had data on the proportion of women with a negative rubella antibody test that were vaccinated against rubella after delivery.

Newborns/infants suspected of congenital rubella are monitored in a hospital secondary care ward (paediatrics/neonatology) in the Czech Republic, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Romania, Spain and Sweden. In nine countries (Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy and Sweden) the monitoring is done jointly with the hospital outpatient clinic/ambulatory ward. In Germany, Hungary and Italy, newborns can also be

monitored in a well-baby clinic in primary care or by a general practitioner. In Norway and the UK, monitoring depends on clinical signs and symptoms; in Romania, referral to an infectious disease hospital/ward involvement depends on the pathology.

Populations at risk of mother-to-child-transmission of rubella and challenges for effective antenatal screening

Due to the high vaccination coverage in Europe, vertical transmission of rubella is rare. However, unvaccinated cohorts remain still susceptible to infection, particularly migrants from rubella endemic countries and women following certain beliefs (Figure 18).

The three most commonly cited challenges for implementing effective antenatal screening policies for rubella susceptibility were: the lack of reporting and deficiencies in data collection at the national level, a lack of resources, and insufficient capacity to reach risk groups. Other challenges included difficulties reaching migrant populations. Unvaccinated migrant women, for example, may be less likely to seek screening. Also, there are smaller population groups who missed MMR vaccination or whose parents refused vaccination. In addition, offering and promoting rubella susceptibility tests is often not standard practice among healthcare workers. In some countries, data on post-partum vaccination are not collected (Figure 19).

Figure 18. Population groups reported to be at risk of not being reached by antenatal rubella susceptibility screening programmes or vulnerable to MTCT of rubella, EU/EEA, 2013

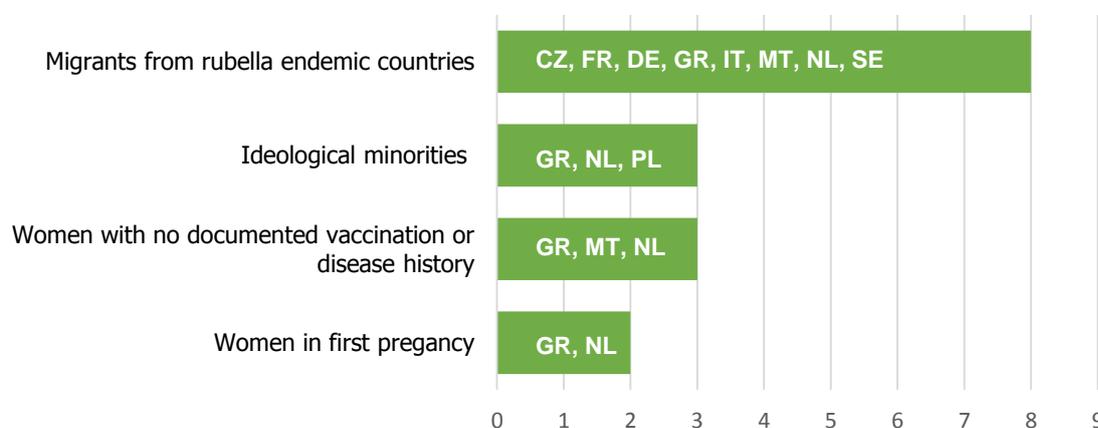
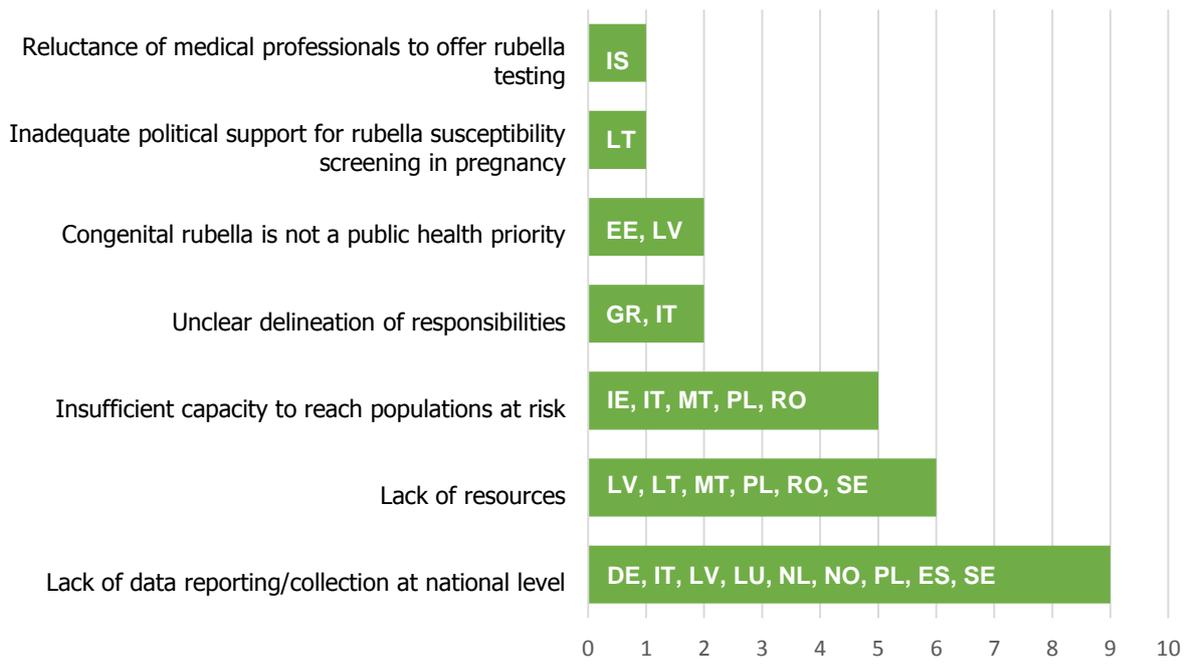


Figure 19. Challenges for the implementation of effective antenatal screening policies for rubella, EU/EEA, 2013 survey



4 Discussion and conclusions

Antenatal screening for HIV, HBV, syphilis and rubella susceptibility is widely implemented in the EU/EEA and can effectively prevent or reduce mother-to-child transmission. Nonetheless, challenges to programme implementation remain, which may explain why mother-to-child transmission is still reported in many European countries.

4.1 Effectiveness of antenatal screening

In the vast majority of EU/EEA countries (96%), the provision of antenatal care to pregnant women is based on national guidance, screening recommendations or a prevention strategy, sometimes as part of a wider programme of antenatal screening for infectious diseases. Antenatal HIV screening programmes are implemented in 24 countries (all but Hungary and Slovenia). HBV screening programmes are carried out in 23 countries (not in Lithuania, the Netherlands and Romania; in Romania screening is recommended but not implemented). Antenatal syphilis screening is implemented in all 26 responding countries, whereas rubella susceptibility screening is done in 14 countries (not in the Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Latvia, Lithuania, the Netherlands, Romania, Slovenia and Sweden). Despite the existence of national recommendations, compliance with existing guidelines is reported to be less than optimal in several countries [43-48]: in the survey, several free-text responses highlighted that implementation is highly variable and often depends on the local general practitioners and public health nurses who perform the screening tests.

Access to antenatal screening for pregnant women is further restricted by insufficient programme funding and inadequate preventive measures. Public funding, the strategy adopted by the majority of EU/EEA countries, is aimed at easy access to screening, but some subgroups (e.g. undocumented migrants) are not always entitled to benefit from public services, which increases their vulnerability to MTCT. Nonetheless, pregnant women from newly arrived migrants and asylum seekers may not be aware of their options with regard to antenatal care.

Opt-out programmes are the most commonly used programmes for the antenatal screening of HIV, HBV, syphilis and rubella susceptibility in Member States, followed by universal screening. An opt-out strategy is considered an effective way to reach pregnant women – a reasonable compromise between a fully informed consent and universal screening [14,23,24,43,49,50]. Some countries targeted women at higher risk of MTCT (i.e. PWID or women showing high-risk behaviours). Survey respondents pointed out that these population groups presented a significant challenge to the successful prevention of MTCT of HIV, HBV and syphilis.

The results of this survey clearly show that MTCT – despite all screening strategies and programmes – still occurs, albeit at a low level. Reasons for ongoing MTCT in Europe could be that the effectiveness of antenatal screening strategies is compromised by factors such as incomplete screening coverage, poor access to antenatal care, or inadequate HIV and hepatitis testing among groups at high risk. However, rates of MTCT in EU/EEA countries are low across all countries and cases of MTCT are clustered in high-risk subpopulations.

Evidence from other surveys indicates that the healthcare system fails to recognise and meet the complex needs of pregnant women from ethnic minorities: this – in addition to cultural, language and communication barriers – can hinder early initiation of antenatal care in this subgroup [51]. The UK NICE Guideline Developing Group has published guidance for antenatal care services for women with complex social factors (defined as women with substance misuse, recent arrival as a migrant, asylum seeker or refugee status, difficulty speaking or understanding English, age under 20, domestic abuse, poverty and homelessness) [52].

The high coverage of ART in HIV-positive pregnant women, the EU/EEA-wide recommendation for avoiding breastfeeding, and the almost complete antiretroviral prophylaxis coverage in infants born to HIV-positive mothers (98–100%, 10/23 countries), may have contributed to the very low rates of HIV MTCT in EU/EEA countries.

In 2011, the global community defined the elimination of HIV and syphilis MTCT as a public health priority. The WHO document 'Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis', outlines processes and criteria for validation of elimination of mother to child transmission of HIV and/or syphilis in a country [53]. Overall, the EU/EEA countries that responded to the survey, showed that they had either reached, or were very close to reaching, the WHO Global targets for the elimination of MTCT of HIV and syphilis.

According to current survey findings, the proportion of HIV-positive pregnant women newly diagnosed through antenatal screening was over 30% in 6/11 countries. If detected late during pregnancy, this considerable proportion of women with undiagnosed infection may further contribute to ongoing MTCT transmission. A similar figure was reported in a recent publication from the UK: 32% (19/60) of the HIV-positive pregnant women were diagnosed during their current pregnancy [54].

A major challenge to antenatal screening identified by the Member States in the survey was the lack of systematic collection of specific operational and outcome data on antenatal screening programmes; data on antenatal

screening of HIV are not collected or analysed in half of the surveyed countries, with the percentage even smaller for HBV, syphilis and rubella susceptibility screening. Without surveillance data, countries are unable to monitor rates of MTCT, properly assess the effectiveness of their antenatal screening strategies, and are limited in their ability to respond and adapt to changes in the epidemiology of vertically transmitted infections. Collection, storage and analysis of antenatal screening data needs to be strengthened at both national and regional levels. Routine monitoring and evaluation of national antenatal screening programmes, including auditing programme implementation and measurement of testing coverage seem beneficial.

Reluctance of medical professionals to offer HIV testing was identified as an obstacle to successful antenatal screening by several countries, reflecting that attitudes towards HIV infection still differ from other infectious diseases. Reluctance to offer testing can be due to the healthcare professional's discomfort when approaching the subject of HIV, lack of training to increase competence in conducting HIV testing, lack of knowledge on local HIV prevalence and transmission routes, unawareness of or lack of local guidance and policies on HIV testing, and logistical barriers such as cost, time constraints and consent procedures [55].

Finally, a challenge specific to reducing MTCT of HBV is the relationship between screening programmes and vaccination policy. Some countries, for example Romania, do not implement antenatal HBV screening, as HBV is included in the childhood vaccination programme. However, coverage of HBV vaccination among women of child-bearing age in several EU/EEA countries has not yet reached a sufficiently high level to be used as a justification for discontinuing antenatal screening. If screening is discontinued, it is still necessary to have targeted antenatal screening programmes for various vulnerable subpopulations in which vaccination coverage may be substantially lower. The six countries (Denmark, Finland, Iceland, Norway, Sweden and the UK) that lack national childhood vaccination programmes have a very low population prevalence of HBV (<0.5%). With the exception of Norway, all countries report universal screening for HBV, as the vast majority of HBV diagnoses are among migrant populations infected in their country of origin.

4.2 Strengths and limitations of the survey

Participation in this antenatal screening survey was high, with 26 of 30 (87%) EU/EEA countries responding. Only Austria, Bulgaria, Cyprus and Liechtenstein did not participate. Questions were kept short and to the point to ensure the survey could be completed in a reasonable amount of time. Disease-specific questionnaires were similar in content to assure comparability of the results between diseases. A pilot phase ensured the survey was optimised prior to rolling out to all countries.

However, there are limitations inherent to the survey methodology, which limits the conclusions that can be drawn from these data. The response rate for each of the five general or disease-specific questionnaires (HIV, HBV, syphilis, rubella) varied. Missing responses could have been due to the unavailability of the appointed responder or limited/unavailable/missing data.

Data accuracy further relied on the interpretation of the questions and the responders' knowledge or awareness of antenatal screening policies. As the questionnaires were filled in by public health officials rather than clinicians, the data may reflect policy rather than practice. A recent audit of clinical practice in Ireland showed very low rates of compliance with the recommendations for follow-up testing of infants born to HBV-positive mothers in primary care [56].

Because of the time delay between data collection and publication of this report, some of the information may be outdated, e.g. advances in lab testing technologies for HIV and wider access to new testing methods in the Member States.

In terms of the limitations to the numerical data, the low completeness of variables in TESSy for HIV and hepatitis B (e.g. country of birth and probable country of infection) made it difficult to identify all MTCT cases born in the reporting country, leading to likely underascertainment of mother-to-child transmission in some countries.

4.3 Final considerations

Since the rates of MTCT of HIV and congenital syphilis are below the WHO global targets for the elimination in most EU/EEA countries, the development of stricter European targets may better fit the low levels of transmission.

Few countries collect data robust enough for a comprehensive evaluation of antenatal screening programme effectiveness and even fewer make the results of such evaluations publically available. As such, the development of a set of indicators to guide countries in the monitoring and evaluation of antenatal screening programme effectiveness would help.

In several EU/EEA countries, national surveillance systems do not currently collect all the variables needed to identify nationally acquired MTCT infections; in addition, notification of congenital syphilis is not always mandatory. The introduction of enhanced surveillance of vertical transmission may improve completeness of reporting and

reduce underestimation of MTCT in Europe. Development of MTCT databases may further help identification of the risk factors associated with the transmission.

Ongoing MTCT affects some vulnerable groups that are not reached by or do not have access to testing services and prevention interventions available to the general population. Targeted interventions for such populations at risk, based on the epidemiological and risk profile of each country settings, should be considered by the Member State.

Reacting to survey findings, ECDC is currently developing evidence-based guidance for strengthening antenatal screening among vulnerable groups for the use of national programme coordinators and policy makers. The guidance will aim at responding two main questions: which elements of a national antenatal screening programme for infections influence effectiveness and which are the specific approaches to be used for reaching the vulnerable groups in order to increase the uptake of prenatal care and reduce/prevent MTCT.

Annex 1. Responses to the Member State survey on antenatal screening

| Country | Survey questionnaires | | | | |
|-------------------------------------------|-----------------------|-----|-----|----------|---------|
| | General | HIV | HBV | Syphilis | Rubella |
| Austria | | | | | |
| Belgium | x | x | * | x | |
| Bulgaria | | | | | |
| Cyprus | | | | | |
| Czech Republic | x | x | x | x | x |
| Denmark (pilot) | x | x | x | x | x |
| Estonia | x | x | x | x | x |
| Finland | x | x | x | x | x |
| France | x | x | x | x | x |
| Germany | x | x | x | x | x |
| Greece | x | x | x | x | x |
| Hungary | x | x | x | x | x |
| Iceland | x | x | x | x | x |
| Ireland | x | x | x | x | x |
| Italy | x | x | x | x | x |
| Latvia | x | x | x | x | x |
| Liechtenstein | | | | | |
| Lithuania | x | x | x | x | x |
| Luxembourg | x | x | x | x | x |
| Malta | x | x | x | x | x |
| Netherlands (pilot) | x | x | x | x | x |
| Norway | x | x | x | x | x |
| Poland | x | x | x | | x |
| Portugal | x | | | | |
| Romania | x | x | x | x | x |
| Slovakia | x | x | | x | |
| Slovenia | x | x | | x | |
| Spain | x | x | x | x | x |
| Sweden | x | x | x | x | x |
| United Kingdom | x | x | x | x | x |
| United Kingdom (Northern Ireland) (pilot) | x | x | x | x | x |

Note: Denmark, Netherlands and Northern Ireland (UK) participated in the pilot phase of the survey.

** Belgium provided answers to several questions during the validation phase.*

Annex 2. Mother-to-child transmission of HIV: number of cases and rates per 100 000 births in persons identified as born in the reporting country and cases of congenital syphilis

| Country | HIV MTCT | | | | Congenital syphilis | |
|-------------------|-----------|------------|---------------|------------|---------------------|------------|
| | All ages | | 0–1 year olds | | Cases | Rate |
| | Cases | Rate | Cases | Rate | | |
| Austria | 1 | 1.3 | 1 | 1.3 | - | - |
| Belgium | 1 | 0.8 | 0 | 0.0 | - | - |
| Bulgaria | 5 | 7.5 | 2 | 3.0 | 27 | 40.6 |
| Cyprus | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Czech Republic | 0 | 0.0 | 0 | 0.0 | 1 | 0.9 |
| Denmark | 0 | 0.0 | 0 | 0.0 | - | - |
| Estonia | 2 | 14.8 | 2 | 14.8 | 0 | 0.0 |
| Finland | 1 | 1.7 | 1 | 1.7 | - | - |
| France | 13 | 1.6 | 9 | 1.1 | - | - |
| Germany | 5 | 0.7 | 2 | 0.3 | 2 | 0.3 |
| Greece | 0 | 0.0 | 0 | 0.0 | - | 0 |
| Hungary | 1 | 1.1 | 0 | 0.0 | 2 | 2.2 |
| Iceland | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Ireland | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Italy | 5 | 1.0 | 3 | 0.6 | - | 0.0 |
| Latvia | 9 | 43.7 | 6 | 29.1 | 0 | 0.0 |
| Liechtenstein | - | - | - | - | - | - |
| Lithuania | 1 | 3.3 | 1 | 3.3 | 2 | 6.7 |
| Luxembourg | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Malta | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Netherlands | 2 | 1.2 | 1 | 0.6 | - | - |
| Norway | 1 | 1.7 | 1 | 1.7 | 0 | 0.0 |
| Poland | 4 | 1.1 | 4 | 1.1 | 19 | 5.1 |
| Portugal | 1 | 1.2 | 0 | 0.0 | 5 | 6.0 |
| Romania | 16 | 9.1 | 13 | 7.4 | 3 | 1.7 |
| Slovakia | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Slovenia | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| Spain | 5 | 1.2 | 4 | 0.9 | 3 | 0.7 |
| Sweden | 2 | 1.8 | 1 | 0.9 | 0 | 0.0 |
| United Kingdom | 16 | 2.0 | 2 | 0.3 | 0 | 0.0 |
| Total: EU and EEA | 91 | 1.8 | 53 | 1.0 | 64 | 2.0 |

–: data not available, country does not report to TESSy

Source: Data retrieved from The European Surveillance System (TESSy), EU/EEA, 2013

Annex 3. General questionnaire: antenatal screening

This antenatal screening 2013 survey aims to identify current policies and practices for the antenatal screening for HIV, HBV, syphilis and rubella and to recognise points of vulnerability within current systems.

Please fill in all questions applicable to your country. Leave empty those questions where data are not available. At the end of the questionnaire an additional space is provided for comments.

Use the 'Break' buttons to pause at any time; your answers will be saved. To continue the survey, a link will be provided by the system, which can be either saved or sent to your email address.

1. Country

2. In the event that your responses will apply only to a region of your country, please specify the region.

3. Background information

First name

Last name

Email

Phone

Organization

4. Does your country have national guidance/recommendation on antenatal care (including pregnancy, antenatal, neonatal and post- partum care)?

- Yes, please provide a reference or link to the document(s)
 No

5. Does your country have national guidance/recommendations/a strategy for antenatal infectious disease screening?

- Yes
 No

6. Which of the following infections are covered by the guidance/ recommendations/strategy?

- HIV
 HBV
 Syphilis
 Rubella

7. Is the screening of infectious diseases integrated into the overall antenatal care?

| | Yes | No |
|------------------------|-----|----|
| HIV | | |
| HBV | | |
| Syphilis | | |
| Rubella susceptibility | | |

8. Which of the following infections are notifiable in your country? Please indicate where the reporting of the transmission mode (mother-to-child transmission, MTCT) is required, if applicable

| | Notifiable | MTCT reported |
|-----------------------------|------------|---------------|
| HIV | | |
| HBV | | |
| Syphilis | | |
| Congenital syphilis | | |
| Rubella susceptibility | | |
| Congenital rubella syndrome | | |

9. How is the antenatal screening for infectious diseases implemented in your country?

| | HIV | HBV | Syphilis | Rubella |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----|-----|----------|---------|
| Universal screening (no questions asked) | | | | |
| Screening, opting-in (pregnant woman is offered testing, and if she agrees to testing, she must provide explicit consent) | | | | |
| Screening, opting-out (pregnant woman is informed that testing will take place as part of the antenatal care, unless she explicitly declines) | | | | |
| Selective screening for groups at risk for HIV, please specify | | | | |
| Selective screening for groups at risk for HBV, please specify | | | | |
| Selective screening for groups at risk for syphilis, please specify | | | | |
| Selective screening for groups at risk for rubella, please specify | | | | |
| Voluntary testing (screening not offered, but available) | | | | |
| Screening not recommended | | | | |

10. If the antenatal screening for a given infectious disease is not recommended in your country, please provide reasons for this policy.

| | HIV | HBV | Syphilis | Rubella |
|------------------------------------------------------|-----|-----|----------|---------|
| Epidemiology does not support the need for screening | | | | |
| Cost-effectiveness studies do not support screening | | | | |
| Limited resources | | | | |
| Other, please specify | | | | |

11. Is vaccination against the following diseases part of a national childhood vaccination programme in your country? Please provide the year of comprehensive implementation, that is, when the targeted/effective coverage was reached.

| | Yes | No |
|---------|-----|----|
| HBV | | |
| Rubella | | |

12. What is the vaccination coverage of HBV in the national childhood vaccination programme in your country? Please provide data from 2011, if available.

13. In the event that you have an additional policy for vaccinating selected population groups, please choose relevant groups targeted for vaccinations.

| | HBV | Rubella |
|------------------------------------------------------|-----|---------|
| Epidemiology does not support the need for screening | | |
| People who inject drugs (IDU) | | |
| Sex workers | | |
| Migrants from high prevalence areas outside the EU | | |
| Migrants from high prevalence areas inside the EU | | |
| Healthcare workers | | |
| Other, please specify? | | |
| Additional information, if needed | | |

14. Are data for antenatal screening of infectious diseases collected, stored and analysed in your country

| | HIV | HBV | Syphilis | Rubella |
|-------------------------------------------|-----|-----|----------|---------|
| Nationally | | | | |
| Regionally | | | | |
| Data from the private sector are included | | | | |
| Data are not collected | | | | |
| Other, please specify | | | | |

15. Has the effectiveness of antenatal screening for infectious diseases been monitored or evaluated in your country?

| | Yes | No |
|------------------------|-----|----|
| HIV | | |
| HBV | | |
| Syphilis | | |
| Rubella susceptibility | | |

16. Please provide any additional information you consider important regarding the antenatal screening for infectious diseases in your country. You can also add here the links you could not fit in the previous boxes.

Annex 4. Questionnaire: antenatal HIV screening

This antenatal screening 2013 survey aims to identify current policies and practices for the antenatal screening for HIV and to recognise points of vulnerability within current systems.

Please fill in all questions applicable to your country. Leave empty those questions where data are not available. At the end of the questionnaire an additional space is provided for comments.

Use the 'Break' buttons to pause at any time; your answers will be automatically saved. To continue the survey, a link will be provided by the system, which can be either saved or sent to your email address.

1. Country
2. In the event that your responses will apply only to a region of your country, please specify the region
3. Background information

First name

Last name

Email

Phone

Organization

Section 1: Antenatal assessment and screening for HIV

4. Is antenatal screening for HIV implemented in your country?

- Yes
- No

5. How is the antenatal screening for HIV financed?

- Publicly funded (the test is offered free of charge)
- Funded by health insurance (the test is funded through pre-existing health insurance)
- At the personal cost of the person screened
- Other, please specify

6. In which healthcare settings (or by which medical professionals) the antenatal screening is routinely offered? Please rank in the order of importance (1=most important , 6=least important) from the following options. You can add your own, if necessary, and leave irrelevant options empty

| | 1 | 2 | 3 | 4 | 5 | 6 |
|--------------------------------|---|---|---|---|---|---|
| General practitioner | | | | | | |
| Midwives | | | | | | |
| Family planning clinics | | | | | | |
| Obstetrician/gynaecologist | | | | | | |
| Any other specialist physician | | | | | | |
| Other, please specify | | | | | | |

7. During antenatal care visits, is the following information regarding the risks of HIV transmission recommended to be communicated to the pregnant woman?

- Risk of in utero transmission of HIV
- Risk of transmission of HIV during birth
- Risk of transmission of HIV during breastfeeding

8. What is the test used for antenatal screening of HIV?

- Antibody testing
- Antibody/antigen serology (HIV Combo)
- Nucleic acid test (NAT)
- Rapid point of care antibody test (blood or saliva)
- Other, please specify

9. When during pregnancy is the screening test for HIV recommended?

- During the first trimester
- During the second trimester
- During the third trimester
- During delivery, if not tested earlier
- Other, please specify

10. Please provide an estimate of the proportion (%) of pregnant women tested early in pregnancy (during the first trimester)

11. In your national/regional data collection on HIV infection and pregnancy, can you distinguish between newly diagnosed HIV infection and HIV infections diagnosed before the current pregnancy?

- Yes
- No

Please, provide explanation, if needed

12. How many pregnant women are tested for HIV? Please provide data from 2011, if available, or choose the most recent year

Number of women tested and explanation, if needed

13. To the best of your knowledge, what proportion of pregnant women are tested for HIV at least once during pregnancy? Please provide data from 2011, if available, or choose the most recent year

% and explanation, if needed

14. How many tests were performed in antenatal screening for HIV? This number will be used when information on the number of pregnant women tested is not available. Please provide data from 2011, if available, or choose the most recent year

Number of HIV tests and explanation, if needed

15. How many HIV-positive pregnant women were reported in your country? Please provide data from 2011, if available or choose the most recent year

Number of HIV-positive pregnant women and explanation, if needed

16. How many of the pregnant women tested were newly diagnosed HIV cases? Please provide data from 2011, if available or choose the most recent year

Number of newly diagnosed HIV-positive pregnant women

17. Is the child born to a HIV-positive mother tested for HIV?

- Yes, at birth
- Yes, when the infant is aged (specify in months)
- Yes, more than once. Please specify the age at the time of the last test (in months)
- Other, please specify
- No

18. To the best of your knowledge, what proportion of children born to HIV-positive mothers are tested for HIV at least once after birth? Please provide data from 2011, if available, or choose the most recent year

19. What is the test method used for the diagnosis of HIV infection in a child born to a HIV-positive mother?

- Antibody/antigen serology (HIV Combo)
- Nucleic acid test (NAT)
- Other, please specify
- There is no testing for HIV for children born to HIV-positive mothers in my country

Section 2: Intervention and management of HIV during pregnancy, antenatal and neonatal period.

20. To whom or where is the HIV-positive pregnant woman referred to for HIV infection care?

- Sexually transmitted infections (STI)/genito-urinary medicine (GUM) clinic
- Gynaecologist/obstetrician
- HIV treatment centre/clinic
- Other, please specify

21. Is the antiretroviral treatment of HIV-positive pregnant women (who have not been in treatment before the pregnancy) for the prevention of mother-to-child transmission implemented as

- Monotherapy
- Combination treatment of two drugs
- Combination treatment of three drugs

Other, please specify

22. What is the proportion of all pregnant women with HIV infection who receive antiretroviral treatment or prophylaxis during pregnancy?

- Reported proportion
- Estimated proportion
- Data is not available

23. Is Caesarean section recommended in your country for the prevention of mother-to-child transmission of HIV during birth?

- Yes
- No
- Other, please specify

24. Is avoiding breastfeeding recommended in your country for the prevention of mother-to-child transmission of HIV?

- Yes
- No

25. Is the antiretroviral prophylaxis for children born to HIV-positive mothers implemented as

- Monotherapy
- Combination treatment of two drugs
- Combination treatment of three drugs
- Other, please specify

26. What is the proportion of children born to HIV-positive mothers who receive antiretroviral prophylaxis?

- Reported proportion
- Estimated proportion
- Data is not available

27. Where is the infection status of the newborn/infant born to a HIV-positive mother monitored?

- Neonatologist/paediatrician
- HIV treatment centre/clinic
- Combination of the two
- Other, please specify

28. What is the proportion of newborn children with confirmed HIV infection who have become enrolled in HIV care?

- Reported proportion
- Estimated proportion
- Data is not available
- Additional explanation, if needed

29. How many vertical transmissions of HIV were there in children born in your country during the last five years? If possible, please exclude any children who were born abroad. Otherwise provide the total number and indicate below that your data may include children born abroad.

- 2011
- 2010
- 2009
- 2008
- 2007
- We cannot distinguish vertical transmissions of HIV based on the country the child was born in

30. When cases of mother-to-child transmission are reported and the information is available, please list factors which are frequently associated with vertical transmission

Section 3: Vulnerable populations and determinants for mother-to-child transmission.

31. From the list below, which are the population groups at risk of not being reached by the antenatal screening for HIV, and can be considered vulnerable to mother-to-child transmission of HIV in your country? For those you consider vulnerable population groups, please fill in your own estimate for the screening coverage percentage.

- Women reached for screening late in pregnancy
- Economically challenged/poor

- People who inject drugs (IDU)
- Sex workers
- Female partners of bisexual men
- Migrants from high prevalence areas outside the EU
- Intra-EU citizen migrants
- Mobile populations (populations without permanent residence)
- Ethnic minorities not part of the above groups, please specify
- Ideological minorities, e.g. based on faith and conviction
- Women with multiple sexual partners
- Women whose partner belongs to above groups
- Healthcare workers
- Other, please specify?

Section 4: Self-assessment of challenges for effective antenatal screening and mother-to-child transmission elimination.

32. What are the challenges (if any) for the implementation of effective antenatal screening policies for HIV in your country?

- Lack of resources
- Lack of data reporting/collection at national level
- Unclear delineation of responsibilities
- HIV mother to child transmission is not a public health priority
- Inadequate political support for HIV screening in pregnancy
- Reluctance of medical professionals to offer the HIV testing
- Insufficient capacity to reach populations at risk
- Other, please specify

33. Please provide any additional information you consider important regarding the antenatal screening of HIV in your country (e.g. what works well or provide an example of good practice). Links to antenatal screening audit reports or effectiveness studies are welcomed.

Annex 5. Questionnaire: antenatal HBV screening

This antenatal screening 2013 survey aims to identify current policies and practices for the antenatal HBV screening and to recognise points of vulnerability within current systems.

Please fill in all questions applicable to your country. Leave empty those questions where data are not available. At the end of the questionnaire an additional space is provided for comments.

Use the 'Break' buttons to pause at any time; your answers will be automatically saved. To continue the survey, a link will be provided by the system, which can be either saved or sent to your email address

1. Country
2. In the event that your responses will apply only to a region of your country, please specify the region
3. Background information

First name

Last name

Email

Phone

Organization

Section 1: Antenatal assessment and screening for HBV

4. Is antenatal HBV screening implemented in your country?

- Yes
- No

5. How is the antenatal HBV screening financed?

- Publicly funded (the test is offered free of charge)
- Funded by health insurance (the test is funded through pre-existing health insurance)
- At the personal cost of the person screened
- Other, please specify

6. In which healthcare settings (or by which medical professionals) the antenatal screening is routinely offered? Please rank in the order of importance

(1= most important , 6= least important) from the following options. You can add your own, if necessary, and leave irrelevant options empty

| | 1 | 2 | 3 | 4 | 5 | 6 |
|--------------------------------|---|---|---|---|---|---|
| General practitioner | | | | | | |
| Midwives | | | | | | |
| Family planning clinics | | | | | | |
| Obstetrician/gynaecologist | | | | | | |
| Any other specialist physician | | | | | | |
| Other, please specify | | | | | | |

7. During antenatal care visits, is the risk of in utero transmission of HBV recommended to be communicated to the pregnant woman?

- Yes
- No

8. What is the test used for antenatal screening of HBV?

- HBV surface antigen test (HBsAg)
- HBV 'e' antigen test (HBeAg)
- Nucleic acid test (NAT)
- Other, please specify

9. When during pregnancy is the screening test for HBV recommended?

- During the first trimester
- During the second trimester
- During the third trimester
- During delivery, if not tested earlier
- Other, please specify

10. In your national/regional data collection on HBV infection and pregnancy, can you distinguish between newly diagnosed HBV infection and HBV infections diagnosed before the current pregnancy?

- Yes
- No

Please, provide explanation, if needed

11. How many pregnant women are tested for HBV? Please provide data from 2011, if available, or choose the most recent year

Number of women tested and explanation if needed

12. To the best of your knowledge, what proportion of pregnant women are tested for HBV at least once during pregnancy? Please provide data from 2011 if available or choose the most recent year.

13. How many tests were performed in antenatal HBV screening? This number will be used when information on the number of pregnant women tested is not available. Please provide data from 2011, if available, or choose the most recent year

Number of HBV tests and explanation, if needed

14. How many HBV positive pregnant women were reported in your country? Please provide data from 2011, if available, or choose the most recent year

Number of HBV positive pregnant women and explanation, if needed

15. How many of the pregnant women tested were newly diagnosed HBV cases? Please, provide data from 2011, if available or choose the most recent year

Number of newly diagnosed HBV positive women

16. Is the child born to a HBV positive mother tested for HBV?

- Yes, once. At when the infant is aged (specify in months)
- Yes, twice. The last test is made when the infant aged (specify in months)
- Yes, more than twice. Please specify the number of tests and the infant's age at the time of the last test (specify in months)
- Other, please specify
- No

17. To the best of your knowledge, what proportion of children born to mothers with HBV (chronic carriers or acute infections) are tested for HBV at least once after birth? Please provide data from 2011, if available or choose the most recent year.

18. What is the test method used for the diagnosis of HBV infection in a child born to a HBV positive mother?

- HBV surface antigen test (HBsAg)
- Nucleic acid test (NAT)
- Other, please specify
- There is no testing for hepatitis for children born to HBV positive mothers in my country

19. Is any testing performed to confirm the seroconversion as a result of vaccination of the child born to a HBV positive mother?

- Yes
- No

Please, provide explanation, if needed

Section 2: Intervention and management of HBV during pregnancy, antenatal and neonatal period.

20. To whom or where is the HBV positive pregnant woman referred to for the HBV infection care?

- Sexually transmitted infections (STI)/ genito-urinary medicine (GUM) clinic
- Gynaecologist/obstetrician
- Hepatologist/gastroenterologist
- General physician
- Other, please specify

21. What is the proportion of pregnant women with positive HBV test result referred on to specialist care?

- Reported proportion
- Estimated proportion
- Data is not collected

22. Where is the infection status of the newborn/infant born to a HBV positive mother monitored?

- Obstetrician
- Paediatrician
- Hepatology specialist

- Other hospital service
- Primary care
- Other, please specify
- No monitoring

23. Is the prevention of mother-to-child transmission for children born to HBV positive mothers implemented as

- Vaccination, the first dose administered within 24 hours of birth
- Administration of HBV immunoglobulin
- Administration of antiviral drug prophylaxis, please specify

Additional explanation, if needed

24. How many vertical transmissions were there of HBV in children born in your country during the last five years? If possible, please exclude any children who were born abroad. Otherwise provide the total number and indicate below whether your data includes children born abroad

- 2011
- 2010
- 2009
- 2008
- 2007

We cannot distinguish vertical transmissions of HBV based on the country the child was born in or in the event of late manifestation

25. When cases of mother-to-child transmission are reported and the information is available, please list factors which are frequently associated with vertical transmission

Section 3: Vulnerable populations and determinants for mother-to-child transmission.

26. From the list below, which are the population groups at risk of not being reached by the antenatal HBV screening, and can be considered vulnerable for the mother-to-child transmission of HBV in your country? For those you consider vulnerable population groups, please fill in your own estimate for the screening coverage percentage.

- Women reached for screening late in pregnancy
- Economically challenged/poor
- People who inject drugs (IDU)
- Sex workers
- Female partners of bisexual men
- Migrants from high prevalence areas outside the EU
- Intra-EU citizen migrants
- Mobile populations (populations without permanent residence)
- Ethnic minorities not part of the above groups, please specify
- Ideological minorities, e.g. based on faith and conviction
- Women with multiple sexual partners
- Women whose partner belongs to above groups
- Healthcare workers
- Other, please specify

Section 4: Self-assessment of challenges for effective antenatal screening and mother-to-child transmission elimination.

27. What are the challenges (if any) of implementing policies on antenatal HBV screening?

- Lack of resources
- Lack of data reporting/collection at national level
- Unclear delineation of responsibilities
- HBV mother to child transmission is not a public health priority
- Inadequate political support for HBV screening in pregnancy
- Reluctance of medical professionals to offer HBV testing
- Insufficient capacity to reach populations at risk
- Other, please specify

28. Please provide any additional information you consider important regarding antenatal screening of HBV in your country (e.g. what works well or provide an example of good practice). Links to antenatal screening audit reports or effectiveness studies are welcomed.

Annex 6. Questionnaire: antenatal syphilis screening

This antenatal screening 2013 survey aims to identify current policies and practices for the antenatal screening for syphilis and to recognise points of vulnerability within current systems.

Please fill in all questions applicable to your country. Leave empty those questions where data are not available. At the end of the questionnaire an additional space is provided for comments.

Use the 'Break' buttons to pause at any time; your answers will be automatically saved. To continue the survey, a link will be provided by the system, which can be either saved or sent to your email address.

1. Country
2. In the event that your responses will apply only to a region of your country, please specify the region
3. Background information

First name

Last name

Email

Phone

Organization

Section 1: Antenatal assessment and screening for syphilis

4. Is antenatal screening for syphilis implemented in your country?

- Yes
 No

5. How is the antenatal screening for syphilis financed?

- Publicly funded (the test is offered free of charge)
 Funded by health insurance (the test is funded through pre-existing health insurance)
 At the personal cost of the person screened
 Other, please specify

6. In which healthcare settings (or by which medical professionals) the antenatal screening is routinely offered? Please rank in the order of importance (1= most important , 6= least important) from the following options. You can add your own, if necessary, and leave irrelevant options empty

| | 1 | 2 | 3 | 4 | 5 | 6 |
|---------------------------------------------------------------------------|---|---|---|---|---|---|
| General practitioner | | | | | | |
| Midwives | | | | | | |
| Family planning clinics | | | | | | |
| Obstetrician/gynaecologist | | | | | | |
| Specialist physician (sexually transmitted illness or infectious disease) | | | | | | |
| Other, please specify | | | | | | |

7. During antenatal care visits, is the risk of in utero transmission of syphilis recommended to be communicated to the pregnant woman?

- Yes
 No

8. Is there a policy for partner tracing and treatment for the sexual contact(s) of a pregnant woman found positive for syphilis?

- Yes
 No
 Please, provide explanation, if needed

9. What is the test used for antenatal screening of syphilis?

- Non-specific treponemal tests (e.g. RPR (rapid plasma reagin) or VDRL (venereal disease research laboratory))
 Specific treponemal tests (e.g. TPHA (*Treponema Pallidum* Hemagglutination Assay, FTA-ABS (fluorescent treponemal antibody absorption assay)
 Nucleic acid test (NAT)
 Rapid point of care test
 Other, please specify

10. When during pregnancy is the screening test for syphilis recommended?

- During the first trimester
- During the second trimester
- During the third trimester
- During delivery, if not tested earlier
- Other, please specify

Additional explanation, if needed

12. How many pregnant women are tested for syphilis? Please provide data from 2011, if available, or choose the most recent year

Number of women tested and explanation if, needed

13. To the best of your knowledge, what proportion of pregnant women are tested for syphilis at least once during pregnancy? Please provide data from 2011, if available, or choose the most recent year

% and explanation, if needed

14. How many tests were performed for antenatal screening for syphilis? This number will be used when information on the number of pregnant women tested is not available. Please provide data from 2011, if available, or choose the most recent year

Number of syphilis tests and explanation, if needed

15. How many syphilis positive pregnant women were reported in your country? Please provide data from 2011, if available, or choose the most recent year

Number of syphilis positive pregnant women and explanation, if needed

16. Is the child born to a mother diagnosed with syphilis during pregnancy tested for syphilis?

- Yes, once. When the infant is aged (specify in months)
- Yes, twice. The last test is made when the infant is aged (specify in months)
- Yes, more than twice. Please specify the number of tests and the infant's age at the time of the last test (in months)
- Other, please specify
- No, if the mother has been treated for syphilis
- No

17. What is the test method used for diagnosis of congenital syphilis?

- Non-specific treponemal tests (e.g. RPR (rapid plasma reagin) or VDRL (venereal disease research laboratory))
- Specific treponemal tests (e.g. TPHA (*Treponema Pallidum* Hemagglutination Assay, FTA-ABS (fluorescent treponemal antibody absorption assay))
- Nucleic acid test (NAT)
- Rapid point of care test
- Other, please specify
- There is no testing for syphilis for children

Section 2: Intervention and management of syphilis during pregnancy, antenatal and neonatal period.

18. To whom or where is the syphilis positive pregnant woman referred to for the syphilis infection care?

- Sexually transmitted infections (STI)/ genito-urinary medicine (GUM) clinic
- Gynaecologist/obstetrician
- Combination of the two
- Other, please specify

19. What is the drug of choice for the treatment of syphilis in pregnant women?

- Penicillin
- Other, please specify

20. What is the proportion of pregnant women diagnosed with syphilis who are treated during pregnancy?

- Reported proportion
- Estimated proportion
- Data is not collected

21. What is the drug of choice for the treatment of congenital syphilis?

- Penicillin
- Other, please specify

22. Where is the newborn/infant born to a syphilis positive mother monitored when congenital syphilis is suspected?

- Hospital outpatient clinic/ambulatory care ward
- Well-baby clinic in primary care or general practitioner (GP)
- Hospital secondary care ward (paediatrics/neonatology)

- No monitoring recommended
- Other, please specify

23. How many congenital syphilis cases were there in children born in your country during the last five years? If possible, please exclude any children who were born abroad. Otherwise, provide the total number and indicate below that your data may include children born abroad.

- 2011
- 2010
- 2009
- 2008
- 2007
- We cannot distinguish congenital syphilis cases based on the country the child was born in

24. When cases of congenital syphilis are reported and the information is available, please list factors which are frequently associated with vertical transmission

Section 3: Vulnerable populations and determinants for mother to child transmission.

25. From the list below, which are the population groups at risk of not being reached by the antenatal screening for syphilis, and can be considered vulnerable to mother to child transmission of syphilis in your country? For those you consider vulnerable population groups, please fill in your own estimate for the screening coverage percentage.

- Women reached for screening late in pregnancy
- Economically challenged/poor
- People who inject drugs (IDU)
- Sex workers
- Female partners of bisexual men
- Migrants from high prevalence areas outside the EU
- Intra-EU citizen migrants
- Women with multiple sexual partners
- Women whose partner belongs to above groups
- Other, please specify?

Section 4: Self-assessment of challenges for effective antenatal screening and mother-to-child transmission elimination.

26. What are the challenges (if any) of implementing policies on antenatal screening for syphilis?

- Lack of resources
- Lack of data reporting/collection at national level
- Unclear delineation of responsibilities
- Congenital syphilis is not a public health priority
- Inadequate political support for syphilis screening in pregnancy
- Reluctance of medical professionals to offer the syphilis testing
- Insufficient capacity to reach populations at risk
- Other, please specify

27. Please provide any additional information you consider important regarding antenatal screening of syphilis in your country (e.g. what works well or provide an example of good practice). Links to antenatal screening audit reports or effectiveness studies are welcomed.

Annex 7. Questionnaire: rubella susceptibility screening in pregnancy

This antenatal screening 2013 survey aims to identify current policies and practices for the antenatal screening for rubella susceptibility and to recognise points of vulnerability within current systems.

Please fill in all questions applicable to your country. Leave empty those questions where data are not available. At the end of the questionnaire an additional space is provided for comments.

Use the 'Break' buttons to pause at any time; your answers will be automatically saved. To continue the survey, a link will be provided by the system, which can be either saved or sent to your email address.

1. Country

2. In the event that your responses will apply only to a region of your country, please specify the region

3. Background information

First name

Last name

Email

Phone

Organization

Section 1: Antenatal assessment, screening for rubella susceptibility, intervention and management of rubella during pregnancy, antenatal and neonatal period

4. Is antenatal screening for rubella susceptibility implemented in your country?

Yes

Yes, in some regions of the country, please specify

No

5. What is the overall aim of antenatal care for rubella in your country?

To identify susceptible women who would benefit from rubella immunisation post-partum

To assist diagnosis in later pregnancy and investigation of the neonate in case of maternal exposure to rubella

Other, please specify

6. Is the management of viral rash illness or exposure to viral rash illness in pregnancy addressed in the guidance for antenatal rubella susceptibility screening?

Yes, in the same guidance

No, in a separate guidance, please provide a reference or link to the document

No guidance related to the management of viral rash illness or exposure to viral rash illness in pregnancy exists.

7. How is the antenatal rubella susceptibility screening financed?

Publicly funded (the test is offered free of charge)

Funded by health insurance (the test is offered based on a pre-existing health insurance)

At the personal cost of the person screened

Other, please specify

8. In which healthcare settings (or by which medical professionals) the antenatal screening is routinely offered?

Please rank in the order of importance (1=most important, 6=least important) from the following options. You can add your own, if necessary, and leave irrelevant options empty

| | 1 | 2 | 3 | 4 | 5 | 6 |
|----------------------------|---|---|---|---|---|---|
| General practitioner | | | | | | |
| Midwives | | | | | | |
| Family planning clinics | | | | | | |
| Obstetrician/gynaecologist | | | | | | |
| Specialist physician | | | | | | |
| Other, please specify | | | | | | |

9. When is the rubella susceptibility screening test recommended?

As part of preconceptual care

During the first trimester

During the second trimester

During the third trimester

10. How many pregnant women are tested for rubella antibodies? Please provide data from 2011, if available, or choose the most recent year
Number of women tested and explanation, if needed
11. To the best of your knowledge, what proportion of pregnant women undergo antenatal screening for rubella at least once during pregnancy? Please provide data from 2011, if available, or choose the most recent year % and explanation, if needed
12. How many tests were performed for antenatal screening for rubella antibodies? This number will be used when information on the number of pregnant women tested is not available. Please provide data from 2011, if available, or choose the most recent year
Number of tests and explanation, if needed
13. What proportion of the tested women were negative for rubella antibodies? Please provide data from 2011, if available, or choose the most recent year
- 2011
 - 2010
 - 2009
14. What is the follow-up of the rubella antibody negative pregnant women? Please, leave empty in case there is no antenatal rubella susceptibility screening in your country.
- No particular follow-up
 - Need for additional laboratory investigation during pregnancy
 - Need for additional laboratory investigation during pregnancy only in case of exposure to a case or clinical signs suggestive of rubella
 - Recommendation for vaccination in the post-partum period
 - Other, please specify
15. What proportion of the pregnant women with a negative test result for rubella antibodies are not vaccinated against rubella after delivery?
- Reported proportion
 - Estimated proportion
16. During antenatal care visits, are the risk factors for rubella infection during pregnancy (including travel to endemic countries) recommended to be communicated to the pregnant woman?
- Yes
 - No
17. Is the child born to a mother diagnosed with rubella during pregnancy tested for rubella?
- Yes
 - No
18. What is the test method used for confirmation of a diagnosis of congenital rubella?
- Virus isolation
 - Antibody testing (IgM)
 - Nucleic acid test (NAT)
 - Other, please specify
19. Is termination of pregnancy recommended in cases of confirmed rubella infection during pregnancy?
- Yes, during the first trimester
 - Yes, during the second trimester
 - No
- Additional explanation, if needed
20. Where is the newborn/infant monitored when congenital rubella is suspected?
- Hospital outpatient clinic/ambulatory care ward
 - Well baby clinic in primary care or general practitioner (GP)
 - Hospital secondary care ward (paediatrics/neonatology)
 - Other, please specify
21. How many congenital rubella syndrome cases were there in children born in your country during the last five years? If possible, please exclude any children who were born abroad. Otherwise, provide the total number and indicate below that your data may include children born abroad.
- 2011
 - 2010
 - 2009

- 2008
- 2007
- We cannot distinguish congenital rubella cases based on the country the child was born in

Section 2: Vulnerable populations and determinants for mother-to-child transmission.

22. From the list below, which are the population groups at risk of not being reached by the antenatal rubella susceptibility screening, and can be considered vulnerable to mother-to-child transmission of rubella in your country? To those you consider vulnerable population groups, please fill in your own estimate for the screening coverage percentage.

- Women in first pregnancy
- Women with no documented vaccination or disease history
- Migrants from rubella endemic countries
- Ideological minorities, e.g. based on faith and conviction
- Other, please specify

Section 3: Self-assessment of challenges for effective antenatal screening and mother-to-child transmission elimination.

23. What are the challenges (if any) of implementing policies on rubella susceptibility screening?

- Lack of resources
- Lack of data reporting/collection at national level
- Unclear delineation of responsibilities
- Congenital rubella is not a public health priority
- Inadequate political support for rubella susceptibility screening in pregnancy
- Reluctance of medical professionals to offer rubella testing
- Insufficient capacity to reach populations at risk
- Other, please specify

24. Please provide any additional information you consider important regarding rubella susceptibility screening in your country (e.g. what works well or provide an example of good practice). Links to antenatal screening audit reports and effectiveness studies are welcome

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