Human Immunodeficiency Virus (HIV)
Infection in the Netherlands

HIV Monitoring

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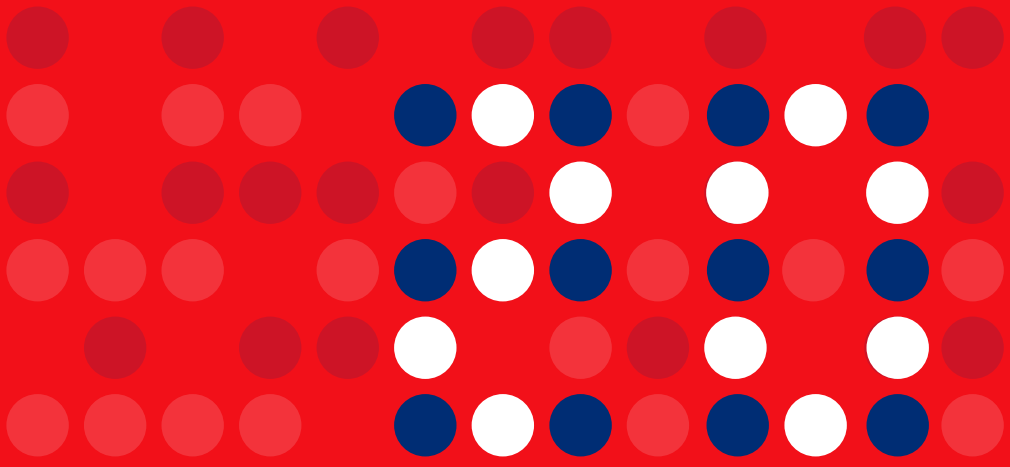

6. Pregnancies in women living with HIV in the Netherlands

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Introduction

The most common mode of HIV acquisition for children aged 0 to 15 years worldwide is transmission from an HIV-positive mother to her child[1]. Mother-to-child transmission (MTCT) of HIV mostly occurs perinatally during labour and delivery, less commonly *in utero*, or postnatally during breastfeeding. Without intervention, the risk of MTCT varies between 15% and 45%[2,3]. Since the introduction of combination antiretroviral therapy (cART) in pregnant women, the risk of MTCT has been dramatically reduced to less than 1%[4,5].

Recommendations for the treatment of HIV during pregnancy have changed over time. Previously, the initiation of combination antiretroviral therapy (cART) was based on the maternal CD4 cell count. As a result, a substantial proportion of women who did not need to start cART according to these early guidelines, started it for the first time during pregnancy, with the sole purpose of reducing maternal HIV RNA to limit the MTCT risk. In many of these cases, cART was discontinued after delivery. After 2015, general treatment guidelines were revised, and treatment for all individuals was recommended, regardless of CD4 cell count[6]. As a result, these days pregnant women are advised to continue cART postpartum.

To ensure timely initiation of cART, and reduce the risk of MTCT, it is important to ascertain pregnant women's HIV status. In January 2004, the Netherlands introduced standardised voluntary HIV antibody testing for pregnant women during the first trimester of pregnancy[7]. This has resulted in a sharp decline of MTCT of HIV in the Netherlands, as described in further detail in Chapter 5: Children living with HIV in the Netherlands.

The follow up and treatment outcomes of all pregnant women in care during the period 1996 to 2018 were described in detail in the 2019 SHM Monitoring report[8].

For the purpose of this year's report, we have decided to focus on the women who were pregnant during the years 2016 to 2019, as this population better reflects current treatment guidelines.

Demographics

Maternal characteristics

Table 6.1: Characteristics of HIV-positive pregnant women registered and monitored by Stichting HIV Monitoring between 2016-2019. It should be noted that data on the number of registered pregnancies in 2019 may be incomplete due to a delay in data collection.

	Total n (%)	Dutch n (%)	Non-Dutch n (%)
Maternal characteristics	303	87 (29)	216 (71)
HIV diagnosis before pregnancy (%)	264 (87)	11 (13)	28 (13)
Age at start of first pregnancy occurring in HIV infection (years*)	32 (28-36)	30 (25-35)	33 (28-37)
HIV transmission route			
Heterosexual contact (%)	278 (92)	80 (92)	198 (92)
Other (%)	25 (8)	7 (8)	18 (8)
Total number of pregnancies	387	112	275
Number of pregnancies among women registered between 2016-2019			
1	105 (35)	31 (36)	74 (34)
2	84 (28)	27 (31)	57 (27)
≥3	114 (37)	29 (33)	85 (39)
Pregnancy outcome			
Partus (%)	237 (64)	74 (66)	163 (59)
Miscarriage (%)	92 (24)	22 (20)	70 (26)
Abortion (%)	55 (14)	16 (14)	39 (14)
Unknown (%)	3 (1)		1 (1)
Total number of partus	237	74	163
Mode of delivery			
Vaginal	165 (70)	55 (74)	110 (67)
Caesarean	70 (30)	19 (36)	51 (31)
Unknown	2 (1)	0	2 (1)
Pregnancy duration			
≥37 weeks	195 (82)	59 (80)	136 (83)
32-37 weeks	27 (11)	13 (18)	14 (9)
<32 weeks	14 (6)	2 (3)	12(7)
Unknown	1 (<0.5)	0	1 (<1)
Birth weight (grammes, IQR*)	3,042 (2,743-3,357)	3,137 (2,625-3,335)	3,024 (2,776-3,405)

	Total n (%)	Dutch n (%)	Non-Dutch n (%)
Perinatal deaths	3 (1)	0	3(2)
Combination antiretroviral therapy started			
Before pregnancy	194 (82)	61 (82)	133 (82)
During pregnancy	43 (18)	13 (18)	30 (18)
No combination antiretroviral therapy during pregnancy	0	0	0
HIV RNA plasma levels before delivery HIV			
HIV RNA available	235/237^(98)	73/74^(99)	162/163 (99)
Undetectable	217 (92)	69 (95)	148 (91)
Detectable#	18 (8)	4 (5)	14 (9)

** Median, Interquartile Range (IQR)*

^ number of pregnancies after HIV diagnosis that resulted in birth

 # based on the detection limit of the assay

Table 6.1 shows the characteristics of the 303 HIV-positive women who had a registered pregnancy in the Netherlands between 2016 and 2019. Of these women, 216 (71%) were of non-Dutch origin and 87 (29%) originated from the Netherlands. The majority of women of non-Dutch origin were born in sub-Saharan Africa (n=139, 64%) or the Caribbean/Latin America region (n=42, 20%).

The majority of the 303 women (264 women, 87%) were aware of their HIV infection before becoming pregnant and this proportion did not differ between women of Dutch and non-Dutch origin. Their median age at the time of the first registered pregnancy was 32 years (interquartile range [IQR] 28-36).

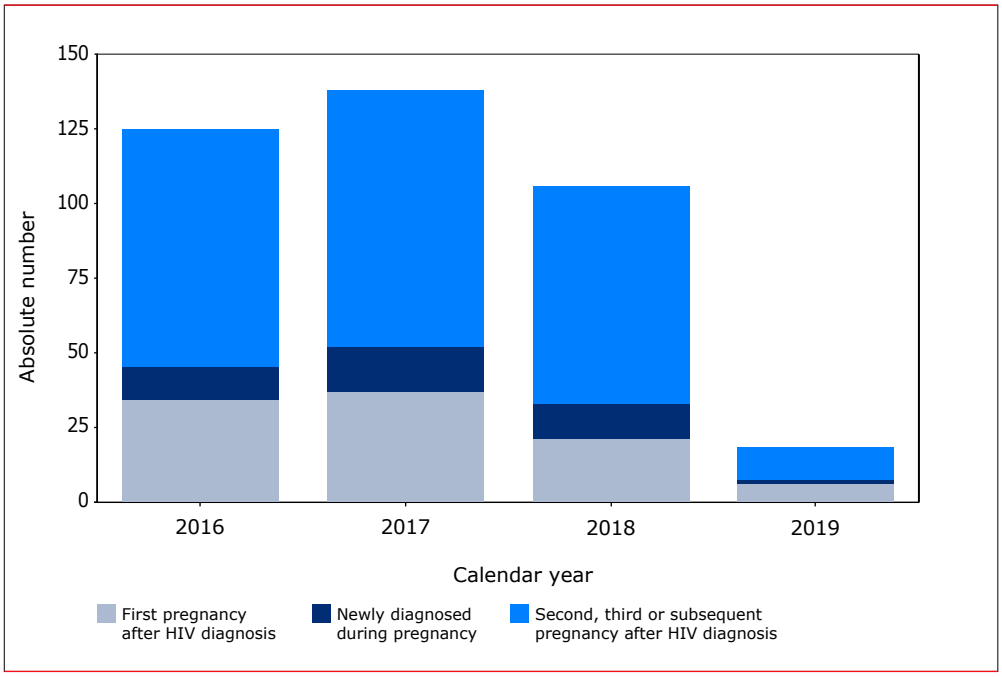
Looking at the 303 women, we see that in women of both Dutch and non-Dutch origin, heterosexual contact was the most common mode of HIV acquisition (92%). Injecting drug use (IDU) was not a reported mode of HIV acquisition. Eleven pregnant women acquired HIV through MTCT themselves.

Between 2016 and 2019, none of the mothers were documented to have died during follow up. A total of 20 women were no longer in care; of these, seven were known to have moved abroad and 13 were lost to follow up. Being lost to follow up was relatively somewhat more common in women of non-Dutch origin (5%) than in those of Dutch origin (3%).

Trends in number of pregnancies in HIV-positive women

The absolute annual number of pregnancies in women in care in the Netherlands varied between 125 pregnancies in 2016, a maximum of 137 pregnancies in 2017, 106 pregnancies in 2018, and, to date, 18 reported pregnancies in 2019[a] (*Figure 6.1*). The number of women newly diagnosed with HIV during pregnancy varied between 11 in 2016 and 15 in 2019. The number of second, third or subsequent pregnancies in women already known to be HIV positive was approximately 80 annually (*Figure 6.1*).

Figure 6.1: *Absolute number of first and subsequent pregnancies per year, stratified by whether HIV infection was already known at the time of conception, or newly diagnosed during pregnancy. It should be noted that our data on the number of registered pregnancies in 2019 may be incomplete due to a delay in data collection.*



a *It should be noted that data of the number of registered pregnancies in 2019 may be incomplete due to a delay in data collection.*

Pregnancy-related characteristics

Overall, 303 women accounted for 387 registered pregnancies: 34% of the women had one registered pregnancy, 28% had two registered pregnancies, and 38% of the women had three or more registered pregnancies (*Table 6.1*).

Pregnancy outcome

The 387 pregnancies resulted in 237 (71%) births (including both live and stillbirths). A total of 92 pregnancies (24%) ended in a miscarriage, and 54 (14%) were ended by abortion. However, this may be an underestimation as not all miscarriages or pregnancy terminations may have been reported. For the remaining three (1%) pregnancies, the outcome was unknown.

Pregnancy duration, preterm birth and perinatal death

A total of 237 pregnancies lasted at least 24 weeks and were therefore counted as a birth. The duration of pregnancy is known for 236 of these pregnancies. Overall, 195 (82%) pregnancies lasted at least 37 weeks, whereas 41 (15%) pregnancies resulted in preterm birth (defined as a pregnancy duration between 24 and 37 weeks). This preterm birth rate of 15% is higher than would be expected, based on figures from the general Dutch population, where preterm birth is reported in 7% of pregnancies[9].

Perinatal death, including antepartum death, occurred in three (1%) births. Congenital disorders were registered for five infants and none of these were fatal.

Mode of delivery

If viral suppression during pregnancy can be achieved with cART, vaginal delivery is recommended for HIV-positive women[10,11]. However, in the presence of detectable HIV RNA levels at, or near the time of delivery, elective Caesarean section is recommended to minimise the risk of MTCT: the European AIDS Clinical Society (EACS) guidelines state that elective Caesarean section should be carried out if HIV RNA levels are above 50 copies/ml in weeks 34-36 of pregnancy[12].

Overall, 70% of newborns were delivered vaginally; 74% of the women of Dutch origin delivered vaginally compared to 67% of women of non-Dutch origin. Thirty percent of newborns were delivered by Caesarean section, which was elective in 51% of cases.

Looking at the mode of delivery, we see that 98% of the women who delivered vaginally had an HIV RNA <50 copies/ml. This figure was 88% for women who delivered by elective section.

Combination antiretroviral therapy (cART) use and response to treatment in pregnant women

From 2016 onwards, cART was used during all 237 pregnancies that lasted at least 24 weeks: in 194 (82%) pregnancies, women were already using cART at the time of conception, while in 43 (18%) pregnancies, use of cART began during pregnancy.

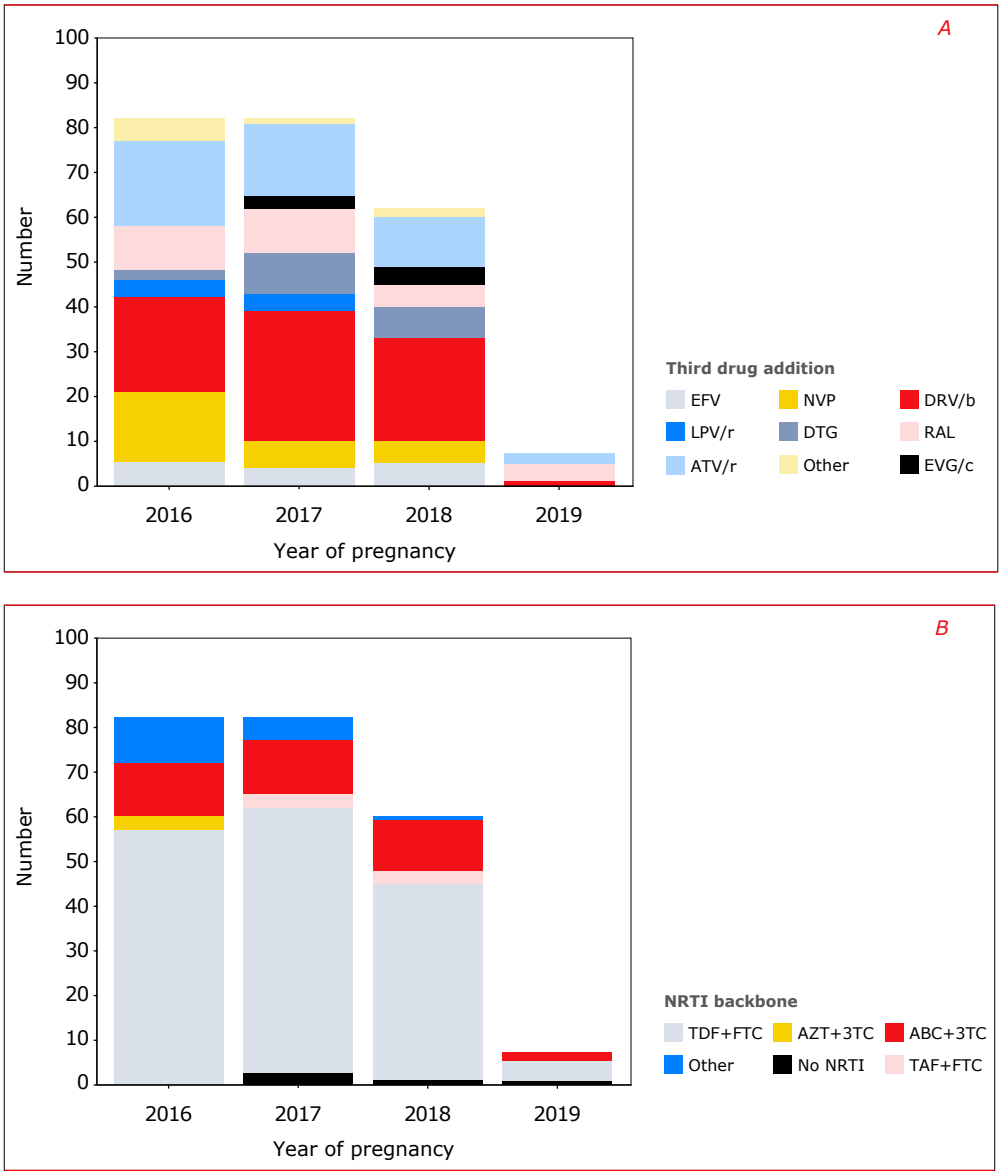
Figure 6.2A shows the most commonly used third-drug additions to the nucleoside analogue reverse transcriptase inhibitor (NRTI) backbone as part of cART in pregnant women between 2016 and 2019. The most commonly used regimens were darunavir-containing (32%) and atazanavir-containing regimens (21%).

In May 2018, a potential safety signal was reported regarding dolutegravir and a possible relation with neural tube defects[13]. Between 2016 and 2019, dolutegravir was used *around the time of conception* by 29 women in the Netherlands, 17 of whom switched to another regimen during pregnancy (median time between conception and the switch was seven weeks [IQR 5-9]). The remaining 12 women continued with dolutegravir for the duration of their pregnancies. These 29 pregnancies resulted in 28 live births and one stillbirth. An additional six women initiated dolutegravir *during pregnancy* at a median of 27 weeks pregancy duration (IQR 19-31). These six pregnancies resulted in six live births. No neural tube defects were documented in any of the infants, including the one stillborn.

Figure 6.2B provides an overview of the components of the NRTI backbone used during pregnancy between 2016 and 2019. The most commonly prescribed backbone was the combination of tenofovir and emtricitabine (TDF+FTC) (70%), followed by a combination of abacavir and lamivudine (ABC+3TC) (16%).

Because of reduced serum levels of cobicistat during the second third trimesters of pregnancy, and thereby also reduced levels of darunavir and elvitegravir when boosted with cobicistat, from 2018 onwards, cobicistat-containing regimens were no longer recommended during pregnancy[14]. In the Netherlands, cobicistat at the time of delivery was used in in eight pregnancies between 2016 and 2019, all women had an HIV RNA <50 copies/ml at time of delivery.

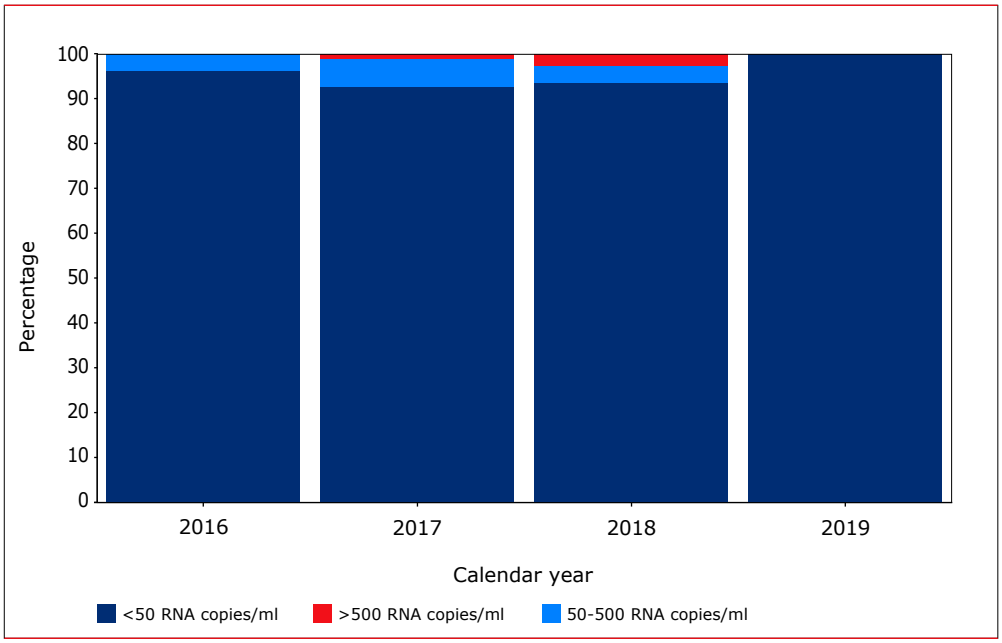
Figure 6.2: A) Third-drug additions and B) the nucleoside reverse transcriptase backbone used as part of the cART regimens during pregnancy in 2016-19.



Legend: 3TC=lamivudine; /r=ritonavir-boosted; /c=cobicistat-boosted; ABC=abacavir; ATV=atazanavir; AZT=zidovudine; DRV=darunavir; DTG=dolutegravir; EFV=efavirenz; EVG=elvitegravir; FTC=emtricitabine; IDV=indinavir; LPV=lopinavir; NFV=nelfinavir; NVP=nevirapine; RAL=raltegravir; SQV=saquinavir; TDF=tenofovir disoproxil fumarate; TAF=tenofovir alafenamide; NRTI=nucleoside analogue reverse transcriptase inhibitor.

Figure 6.3 shows the percentage of women on cART and their latest available plasma HIV RNA level prior to delivery; HIV RNA levels were categorised as <50 copies/ml, 50-500 copies/ml, and >500 copies/ml. In 94% of the overall births, the mothers had an HIV RNA level <50 copies/ml at the time of delivery, and 4% had an HIV RNA level between 50 and 500 copies/ml. The proportion of women with an HIV RNA <500 copies/ml at the time of delivery was 100% in 2016 and 2019, but it was 99% in 2017 and 97% in 2018. These lower proportions were driven by three women with HIV RNA > 500 copies/ml. One of these women had been diagnosed with HIV after 36 weeks of pregnancy. The remaining two women had initiated cART in the past, but both had previously reported treatment interruptions and one of them briefly interrupted cART during pregnancy. Another ten women had HIV RNA levels between 50 and 500 copies/ml (median RNA=94 copies/ml, minimum: 53, maximum= 491). Five of these ten women had first been diagnosed with HIV during their pregnancy, three other women initiated cART in the second trimester, and the remaining two women in the third trimester of pregnancy. No MTCT was reported among the infants born to mothers who had HIV RNA levels >50 copies/ml at time of delivery

Figure 6.3: Distribution of women using cART with their latest HIV RNA levels prior to delivery <50 copies/ml, 50-500 copies/ml, and >500 copies/ml.



Mother-to-child transmission in children born in the Netherlands

Between 2016 and 2019, 237 births were registered among mothers in whom HIV was known either prior to conception or was first diagnosed during pregnancy. Vertical transmission occurred in a single infant, resulting in a MTCT transmission rate in pregnant women using cART in the Netherlands of 0.42% (1/237), which is in line with low reported MTCT rates in other countries[15,16,17,18]. Further investigation of this case of MTCT revealed that the mother was not screened for HIV as part of the national pregnancy screening and was newly diagnosed with HIV during the 35th week of the pregnancy. The mother started cART in the 36th week. At time of cART initiation, the mother had a detectable HIV RNA level, but the last available HIV RNA measurement one day before delivery was undetectable (<40 copies/ml).

Postpartum follow up

Postpartum follow up was defined as the first 12 months after delivery and was considered for all pregnancies with a minimum duration of 24 weeks. Here we describe treatment and virological suppression rates during the postpartum period, as well as breastfeeding rates.

Treatment

Of the 237 pregnancies lasting 24 weeks or longer, 52 were excluded from this analysis: 44 because of insufficient follow up between delivery and the time of database closure, and eight because they were no longer in care (two had moved abroad and six were reported as lost to follow up during the postpartum period). For the remaining 185 pregnancies in 173 women, cART was initiated before conception or during pregnancy in 83% and 17% of cases, respectively. In 15 of these 185 pregnancies, treatment was discontinued postpartum. In five of these 15 pregnancies, treatment was restarted after a median of nine weeks (IQR 3-11 weeks). In the remaining ten pregnancies, the women did not restart cART postpartum; four women restarted cART after the postpartum period and six women did not have any documented restart.

Virological outcome

Detectable viraemia postpartum was defined as at least one HIV RNA measurement above 50 copies/ml during the postpartum period. On the basis of this definition, detectable HIV RNA was observed in 19% of the 185 pregnancies we analysed. For the subset of women with documented continued postpartum use of cART, 25 women (15%) had at least one HIV RNA level above 50 copies/ml (median HIV RNA=250 copies/ml, minimum 65 and maximum 85900 copies/ml). 12 out of the 25 women had one HIV RNA level above 50 copies/ml and 13 had more than one HIV RNA level above 50 copies/ml. In the 15 women who discontinued the use of cART postpartum, 11 experienced viral rebound (median HIV RNA=19800 copies/ml, minimum 617 and maximum 118579 copies/ml), but 4 remained suppressed. These four women had ongoing high CD4 cell counts, although for two women low compliance to treatment was reported.

Breastfeeding

For the above-mentioned 185 pregnancies, data on breastfeeding were available for 163 of them. Breastfeeding was reported in nine women, all of whom were on cART with an undetectable HIV RNA level postpartum. No cases of vertical transmission were documented in any of these breastfeeding women.

Summary and conclusions

All women with a registered pregnancy since 2016 have received cART during their pregnancy, and more than 90% had an undetectable HIV RNA level around the time of delivery. The MTCT rate in pregnant women using cART was 0.42% during the period 2016 to 2019, which is comparable to the low figures reported in other western European countries[15,16,17,19].

Despite the high proportion of women with undetectable viraemia near the time of delivery, we did observe a somewhat increased proportion with detectable HIV RNA levels in 2017 and 2018. To ensure continued zero vertical transmissions of HIV, this increase needs to be closely monitored, particularly in women who are newly diagnosed with HIV after conception, and therefore start cART only during pregnancy.

Results of earlier studies analysing exposure to cART as an increased risk factor for preterm birth were conflicting[20]. However, more recent studies have reported declines in preterm births in women living with HIV, attributed partly to the reduction in Caesarean sections to prevent vertical transmission of HIV[21,22]. Nevertheless, the proportion of preterm births in HIV-positive women in the Netherlands remains higher than that seen in the general population[9]. Because of the safety signal regarding dolutegravir and a possible relation with neural tube defects, we looked at women who used dolutegravir around time of conception and during pregnancy and no neural tube defects were reported among their infants.

Finally, since 2015, cART has been recommended for all individuals, regardless of CD4 cell count and, as such, is also recommended for women postpartum. From 2016 onwards, 15% of women who continued to use cART postpartum had at least one episode of viraemia, of whom half of them had more than one HIV RNA level above 50 copies/ml . This is possibly due to poorer adherence, which has previously been reported to deteriorate during the postpartum period[23,24,25,26,27,28].

Recommendations

As a result of changes to guidelines concerning HIV and pregnancy, cART is more likely to be started earlier in pregnancy. This is expected to result in a greater number of women becoming virally suppressed earlier in their pregnancy and around the time of delivery. Women with HIV who first start cART when already pregnant, require a higher degree of support, not only during pregnancy to ensure suppressed HIV RNA levels at the time of delivery, but also after delivery to maintain adherence to cART. Finally, although breastfeeding should not be actively recommended, women who decide to breastfeed need to be closely monitored clinically and virologically, along with their infants[29,30]. They need continuous adherence support in order to ensure sustained viral suppression and prevention of MTCT of HIV while breastfeeding.

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