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Breastfeeding with HIV in a high-income setting: equipoise and beyond – time to question the zero-risk policy

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Summary

With the use of combined antiretroviral therapy (cART), it has become possible to completely and permanently suppress human immunodeficiency virus (HIV) replication. Successful treatment with combined antiretroviral therapy not only makes HIV infection a treatable chronic disease with a near-normal life expectancy, but also reliably prevents horizontal and also vertical virus transmission. In principle, this allows us to dispense with certain preventive measures from the pre-cART era. However, HIV prevention recommendations tend not to be adjusted until it has been proven beyond any doubt that there is no associated risk. This zero-risk strategy still makes HIV infection a special case and contradicts standard medical practice, which almost always also entails some acceptable risk. This hesitant attitude delays adaptations of care and contributes to the stigmatisation of those affected. In addition, it might even violate the ethical principles of beneficence and justice.

In this context, there is still an ongoing debate as to whether the credo "U = U" (undetectable = untransmittable) applies to all aspects of vertical transmission. While there is consensus about the safety of vaginal delivery in case of an undetectable maternal viral load, Switzerland is still the only country that has also refrained from providing post-exposure prophylaxis to newborns since 2016 in such cases.

Furthermore, when we last revised our Swiss recommendations for the prevention of vertical transmission in 2018, we assumed a balance (equipoise) between the benefits and potential risks of breastfeeding with HIV under optimal conditions. We proposed a shared decision-making process to allow the expectant mother to make her own well-considered decision which is then unconditionally supported by the care team. However, the decision and the associated responsibility is basically left to the woman. Most high-income countries have meanwhile adopted this procedure.

Based on a literature review summarised in this article, the question arises as to whether this approach is still justified. We came to the conclusion that the potential risks of breastfeeding with HIV are being overemphasised, as benefits of breastfeeding, including reductions in morbidity and mortality for both mother and child appear to clearly outweigh these apparently very low risks, even in high-income settings. We therefore believe that breastfeeding with HIV should be favoured and encouraged and not just supported under optimal circumstances and that the care teams should take a clear position in this regard. This will facilitate decision-making for affected women, reduce stigma, relieve the parent(s) of taking on primary responsibility for the decision and further "normalise" HIV infection.

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Introduction

Forty years after the discovery of the Human Immunodeficiency Virus (HIV) as the cause of Acquired Immune Deficiency Syndrome (AIDS) in 1983 [1], HIV infection has evolved from a fatal condition to a chronic, treatable disease. If it is treated early (when the CD4 cell count is still high) and successfully, the life expectancy of those affected differs only slightly from that of the general population [2]. More than 30 antiretroviral drugs from different substance classes are currently available for the treatment of HIV infection [3]. With combined antiretroviral therapy (cART), complete suppression of HIV replication can be

achieved in most people living with HIV. Completely suppressed viral replication is now recognised and accepted as one of the best options for preventing HIV transmission ("treatment as prevention"). This was assumed early on by representatives of the Swiss HIV Cohort Study (SHCS) [4, 5] and in 2008, based on the evidence available at the time, Vernazza et al. published the so-called "Swiss Statement" [6], according to which people living with HIV with an undetectable viral load and no additional sexually transmitted diseases (STD) could not transmit HIV sexually. This statement led to an international outcry, much opposition and great scepticism at the time and it took eight years for this principle to be accepted and for the credo "U = U" (undetectable = untransmittable) to be launched by the "Prevention Access Campaign" in 2016 [7]. However, "U = U" has only been verified and generally accepted for horizontal HIV transmission [8, 9].

In vertical transmission prevention (VTP), (1) the administration of zidovudine (azidothymidine [AZT]) during pregnancy, delivery and as post-exposure prophylaxis in the newborn (neonatal PEP) (PACTG-076 protocol) [10], (2) elective caesarean delivery before the onset of labour and rupture of membranes [11, 12], and (3) withholding from breastfeeding led to a reduction of the transmission rate from 25–40% [13] to below 2% even before the availability of combined antiretroviral therapy.

It later became apparent that successful treatment of pregnant women with cART was at least as effective as this whole package of interventions in preventing vertical transmission of HIV. Accordingly, the need for these interventions was questioned again and some of them, mainly intra-partum zidovudine and elective caesarean delivery, were omitted from most guidelines, including those of Switzerland, in 2009 [14, 15].

Once again, representatives of the Swiss HIV Cohort Study and of the Swiss Mother and Child HIV Cohort Study (MoCHiV) [16] recognised early the need to also re-evaluate the remaining preventive measures from the pre-cART era, namely neonatal post-exposure prophylaxis and abstinence from breastfeeding. In fact, in 2016 Switzerland became the first country in the world to discontinue neonatal post-exposure prophylaxis in case of an undetectable maternal viral load [17]. Furthermore in 2018, the Swiss Federal Commission for Sexual Health (EKSG) went another step forward and came to the conclusion that, in an optimal scenario (undetectable maternal viral load throughout pregnancy, reliable adherence to combined antiretroviral therapy, regular follow-up), the benefits of breastfeeding with HIV balance the potential risks, and that there is a "clinical equipoise" [18]. Accordingly the healthcare provider's role could no longer be advising to not breastfeed and the autonomy of the pregnant woman regarding her own view of infant feeding became indispensable. The healthcare team currently should discuss all available information about benefits and risks of breastfeeding in a comprehensive and unbiased way with the woman (ideally also in the presence of her partner) in order to allow her to make her own well-considered decision. As a result of this so-called shared decision-making process, the woman's decision has to be unconditionally supported by all involved parties [18, 19].

This approach allowed women with HIV to breastfeed their children under optimal conditions. The responsibility for the decision to breastfeed and its consequences was essentially transferred to the expectant mother, while the care team did not have to prioritise any option and was therefore relieved of its responsibility.

The question arises as to whether this way of proceeding is still justified. This article aims to critically examine this approach from a variety of perspectives.

General medical and social considerations

Ethical principles and objectives of medical action

"Primum nil nocere" (first do no harm) is one of the oldest and most important dogmas of medical practice, matching a central element of the Hippocratic Oath. This fundamental medical promise also includes the principle of medical confidentiality. Evidence-based and patient-centred action, as well as a high degree of empathy, are also fundamental elements of medical practice. Ethical principles form the indispensable and binding basis for this.

Dealing with risks in society and medicine

A risk always exists when an action or situation can have a harmful effect on an individual. We then speak of risk behaviour or risk exposure. Both occur frequently in our society: for example, the former in the context of individual addictive behaviour (nicotine, alcohol) and the latter in road traffic.

Risk is also an important consideration in medicine. Virtually every medical procedure or intervention involves potential risks in addition to its benefits. Therefore, the benefits and risks of any medical intervention should be carefully weighed against each other and the benefits must always clearly outweigh the potential risks. In order to achieve a desired treatment goal, physicians and patients therefore usually accept a certain minimal risk.

HIV-specific considerations

Risk assessment and HIV infection

Unlike in other diseases, there is largely a lack of willingness to accept any residual risk of HIV transmission. Recommendations tend not to be adjusted until it has been proven beyond doubt that this will not lead to any additional case of HIV infection. This means that adjustments to recommendations, even if they would eliminate other potential risks, are often only made after years of hesitation and delay. This also becomes clear when comparing national and international guidelines for the prevention of vertical transmission. Switzerland, for example, finally resumed recommending vaginal delivery as a rule instead of elective caesarean delivery in case of fully suppressed viral replication 10 years later than the Netherlands [20]. Conversely, the Swiss abandonment of neonatal post-exposure prophylaxis has not been adopted by any other guideline (except Latvia) since 2016 [17, 21].

Stigmatisation and discrimination against people living with HIV

HIV infection has always been associated with significant stigma. This is primarily due to the fact that AIDS is such a devastating disease and that, in the early phase of the pandemic, men who have sex with men (MSM) and intravenous drug users were at a particularly high risk of infection. Even today, four decades later and despite enormous medical advances, HIV infection is still perceived and treated as a "special case" by both the public and healthcare professionals. Although it is meanwhile a treatable chronic disease, healthcare has failed to "normalise" the way it is dealt with. As a result, healthcare itself contributes to the continuation of the stigma of those affected [22]. This also applies to the prevention of vertical transmission and in particular to the issue of breastfeeding with HIV. On the one hand, in individual cases women with HIV have even been prosecuted for breastfeeding [23]. On the other hand, prohibiting breastfeeding stigmatises women in communities with high breastfeeding rates.

Specific breastfeeding considerations

Health benefits of breastfeeding in general and in different regions of the world

Breast milk is undoubtedly the best possible nutrition for newborns and infants in the first months of life and promotes the health of both the mother and the child [24–26]. However, commercial formula milk definitively eliminates the risk of HIV transmission. In a comprehensive review of breastfeeding, Victora and coworkers emphasised that possibly no other health behaviour can affect such varied outcomes in the two individuals who are involved: mother and child [26].

This is especially evident in low- and middle-income countries, where water supply is not guaranteed and safe [24], and where breastfeeding prevents an estimated half of all diarrhoea episodes and a third of respiratory infections, resulting in a 72% and a 57% reduction of hospital admissions for diarrhoea and respiratory infections, respectively. Accordingly, mortality of infants exclusively breastfed for six months was reduced by 88% as compared to those not breastfed [26]. It has been estimated that hundreds of thousands of children's lives (>820,000) per year could potentially be saved in low- and middle-income countries by universal breastfeeding [24]. This protection far outweighs the risk of HIV infection, which is why the World Health Organization (WHO) has always recommended breast milk as the only food in these countries for the first six months of life.

In women, breastfeeding has a pronounced psychological benefit (bonding, reduction of maternal depression). It also prolongs the duration of postpartum amenorrhoea and thus the interval until the next pregnancy [24, 26, 27].

Breastfeeding significantly reduces the incidence of gastrointestinal, pulmonary and ear infections in children, even in high-income countries [28, 29].

Albeit less pronounced, breastfeeding has also been shown to be associated with a 40% reduction (OR: 0.60, 95% CI: 0.54–0.67) in the overall risk of infant death (7–365 days of life) among multiple ethnic groups within the US population [30].

Ip and coworkers also analysed information about the health benefits of breastfeeding from high-income countries in their extensive evidence report. They concluded that even in these countries breastfeeding is associated with a significant reduction of many diseases in infants and mothers [31]. Meta-analyses of available data showed that ever-breastfeeding was associated with a 36% (95% CI: 0.51–0.81) reduction in sudden infant deaths. Furthermore, breastfeeding was associated with a 58% (95% CI: 0.18–0.96) decrease in necrotising enterocolitis associated with a high case-fatality rate. Exclusive breastfeeding, either for more than three or six months duration also resulted in a 50% (95% CI: 0.36–0.70) reduction in the risk of acute otitis media in infants younger than 24 months [31].

In the long term, ever-breastfeeders versus never-breastfeeders showed a 7–24% risk reduction of developing overweight and obesity in two independent meta-analyses [31–33]. In a third one, the duration of breastfeeding was significantly negatively related to the unadjusted risk of overweight, with a 4% risk decrease for each month of breastfeeding. It is also suggested that breastfeeding as compared with commercial formula feed results in a 39% reduction in the risk of developing type 2 diabetes. Furthermore, long-term breastfeeding (>6 months) was associated with a 20% risk reduction of acute lymphatic leukaemia (ALL) in later life [31]. It has even been shown to have a positive effect on mental development (intelligence quotient [IQ]) [26, 34].

As for women, results of two meta-analyses concluded that there was a reduction in the risk of breast cancer in women who breastfed their infants. In one study, there was a statistically significant reduction in the risk of breast cancer of 4.3% (95% CI: 2.9–5.8) for each year of breastfeeding [35]. In a longitudinal study of two large cohorts in the US with over 150,000 parous women, longer duration of lifetime breastfeeding was associated with a reduced risk of developing type 2 diabetes among women who did not have a history of gestational diabetes [31, 36].

In a later systematic review and meta-analysis not restricted to data from high-income countries, Chowdhury and coworkers found that breastfeeding >12 months reduced the risk of breast and ovarian cancer by 26% and 37%, respectively. Furthermore, breastfeeding women lowered their risk of developing type 2 diabetes by 32% [27].

Breastfeeding with HIV infection: risk of transmission

Without antiretroviral therapy or exposure prophylaxis, the risk of vertical HIV transmission by breastfeeding has been reported to be 14–29% [37].

In view of the current treatment options for pregnant women living with HIV, the question arises whether the credo "U = U" also applies to vertical transmission. For all other transmission routes, this seems to be largely established today. In general, vertical transmission rates of less than 0.4% are observed in many high-income countries [38]. In women taking combined antiretroviral therapy with undetectable viral load at conception and close to birth and with neonatal post-exposure prophylaxis administered to newborns, not a single HIV transmission to a

child occurred among over 5482 mother-child pairs of the French cohort during pregnancy or at birth [39].

In contrast, relatively little data is available on the risk of transmission during breastfeeding, but there is some evidence that, under optimal conditions, this risk is extremely low:

In the Mma Bana study from Botswana, 560 women with HIV and a CD4 cell count ≥200 cells/ml were randomly assigned to receive either abacavir/zidovudine/lamivudine (ABC/AZT/3TC) (nucleoside reverse transcriptase inhibitor [NRTI]-only group) or lopinavir-ritonavir (LPV/r) with zidovudine/lamivudine (proteinase inhibitor [PI] group) from 26 to 34 weeks of gestation and compared with a group of 170 women with a CD4 cell count <200 cells/ml treated with nevirapine (NVP) and zidovudine/lamivudine. The infants received a single dose of nevirapine at birth and then neonatal post-exposure prophylaxis with zidovudine for 4 weeks. The duration of breastfeeding was defined as six months. In all three groups, despite the short duration of antiretroviral therapy, viral suppression of <400 RNA copies/ml at birth was achieved in more than 90% of women. Only 8/709 infants (1.1%) were infected; six of these tested positive at birth, reflecting intrauterine transmission. Two infants in the nucleoside reverse transcriptase inhibitor-only group who tested negative at one month had a positive HIV DNA PCR at three months of life. At this time, the two mothers had been treated for 17 and 27 weeks, respectively. Both mothers had <50 HIV RNA copies/ml in blood and breast milk at one and three months after delivery while one mother still had 257 HIV RNA copies/ml at delivery [40].

The PROMISE study, conducted in resource-poor countries in Africa and India with 2431 mother-child pairs with uninfected babies at birth recruited post-partum with a relatively high maternal CD4 cell count of ≥350 cells/mm^3 showed extremely low transmission rates, regardless of whether the mother was being treated with combined antiretroviral therapy or the infant was receiving exposure prophylaxis with a daily dose of nevirapine during breastfeeding. After six months, only 0.3% of the infants were found to be infected, and after 12 months 0.6%. This was despite the fact that in the combined antiretroviral therapy group and the nevirapine group, only 41% and 31%, respectively, of the mothers had a viral load <400 copies/ml at entry into the study [41]. Of note, 95% of the women had participated in an antepartum component of the study and started antiretroviral treatment with either ZDV alone or a PI-based combined antiretroviral therapy at 14 weeks of gestation or later. Five percent of women were not treated during pregnancy. In two of seven infants in the combined antiretroviral therapy group, HIV infection was first recognised at the ages of 13 and 38 weeks, respectively. At that time, the mother of the first infant had an undetectable viral load (<40 copies/ml) and the second a measurable viral load of less than 40 copies/ml. However, both women had detectable virus at breastfeeding initiation [42].

In another cohort study (KIULARCO) from Tanzania, only 2 of 186 breastfed children tested positive for HIV: one when the mother had a high viral load and one after the mother had stopped treatment. When the viral load was undetectable (<100 copies/ml), no viral transmission occurred [43].

In the DolPHIN-2 study conducted in Cape Town (South Africa) and Kampala (Uganda), 250 women were treated from the third trimester of pregnancy with either an efavirenz (EFV)- or a dolutegravir (DTG)-based regimen and with tenofovir (TDF) as well as lamivudine or emtricitabine (FTC). A total of four vertical transmissions were registered, three of which had occurred intrauterine. One postpartum viral transmission occurred in an infant of the efavirenz group, whose mother always had an undetectable viral load (<50 copies/ml) after 12, 24, 48 and 72 weeks. Her antiretroviral treatment was started in the third trimester of pregnancy. The infant was fed exclusively with breast milk for 24 weeks and then also with supplementary food until the 48th week. HIV infection was diagnosed at the age of 72 weeks and the maternal and fetal viruses showed identical polymorphisms [44]. This case represents a possible breast milk transmission from a fully suppressed woman with HIV. However, the infant missed visits at 24 and 48 weeks (stored samples were used for diagnostics) and the interval between the end of breastfeeding at 48 weeks and the detection of the virus in the infant six months later (at 72 weeks) raises questions about the time point and the circumstances of transmission.

Given the specific characteristics of breast milk, certain conditions, namely combined antiretroviral therapy with absolutely reliable adherence to treatment and follow-up and an undetectable maternal viral load at conception and throughout pregnancy must be met to ensure safe breastfeeding with HIV. Only under such stringent conditions can it be assumed that U = U also applies to breastfeeding. These conditions were not met in any of the cases of possible virus transmission through breastfeeding mentioned above, even in those that happened with undetectable maternal viral loads. Accordingly, they cannot serve as evidence that safe breastfeeding with HIV under optimal conditions carries the risk of viral transmission.

As mentioned above, Switzerland introduced the shared decision-making process to allow for breastfeeding in 2018 [19]. Some countries in Europe (Austria, Denmark, Germany, Greece, Kyrgyzstan, Norway, Poland, the Netherlands, Sweden) now proceed in a similar way [45, 46], and a comparable approach is also recommended by the most important national and international guidelines, including those from Europe (EACS 2023), the UK (British HIV Association [BHIVA] 2020) and the USA (Department of Health and Human Services [DHHS] 2023) [47–49].

At the BHIVA Spring Conference in 2023, Francis and colleagues from the UK presented data of 150 breastfed infants. Mothers who chose to breastfeed had to have a fully suppressed HIV viral load for as long as possible, but certainly during the last trimester of pregnancy. To date, no transmission has occurred in the UK, and in 106 breastfed infants, HIV transmission has definitely been excluded by antibody testing at the age of ≥18 months [50]. In Switzerland, initial data from 41 mother-child pairs has been published, with 25 women deciding to breastfeed their children. No transmission has occurred [51]. Further case studies have been published in North America (10 and 68 mother-child pairs) [52, 53], Canada (three mother-child pairs) [54], Italy (13 mother-child pairs) [55] and Germany (42 and 77 mother-child pairs) [56, 57]. No vertical transmission through breastfeeding has been reported.

Based on data from Switzerland [51] and the Netherlands [58], it can be assumed that in high-income countries with corresponding recommendations, around half of pregnant women living with HIV decide to breastfeed their children as part of the participatory decision-making process with optimal conditions. Although only a few case studies have been published, it is likely that in these countries many mothers living with HIV have already breastfed or are breastfeeding their children. Nonetheless, to date not a single case of viral transmission to a child has been reported in high-income countries with well-established healthcare systems. If one considers breastfeeding similarly to sexual transmission (number of sexual intercourses leading to one transmission), then even in individual cases there is a very high number of corresponding feeds and an extremely small risk of viral transmission [59, 60].

Breastfeeding with HIV infection: open questions

There are still a number of unanswered questions about whether mothers living with HIV should or should not breastfeed their children. These are the reasons why experts are having such a hard time with this issue. Clarifying these questions however will certainly take a long time and may even be unrealistic in some cases.

Medications used for the mother's combined antiretroviral therapy pass into breast milk in varying amounts and lead to different plasma levels in the infant [61]. Some lead to high levels in the infant (rilpivirine [RPV], efavirenz, nevirapine, abacavir, lamivudine, emtricitabine, tenofovir alafenamide and raltegravir [RAL]), others to minimal values (tenofovir disoproxil, dolutegravir, bictegravir [BTG] and darunavir/ritonavir [DRV/r]) [38]. Concentrations that are too high increase the risk of toxicity, while too low concentrations promote the development of HIV resistance in the event of virus transmission. In addition, breastfeeding prolongs the exposure of infants to antiretroviral compounds. It is also conceivable that maternal therapy might influence the composition of breast milk or the infant's microbiome.

Human/breast milk is rich in cells and therefore contains cells that are potentially susceptible to HIV and thus also cell-bound viral DNA which carries the potential for viral reactivation in breast milk. This is particularly important in the case of mastitis, because even subclinical mastitis can increase the salt content, inflammatory cytokines and cell-associated and cell-free HIV in breast milk [62].

It is also unclear how long it takes during combined antiretroviral therapy until the breast milk is free of cell-free viruses in addition to the blood, or whether there are cases of persistent viral load discordance between plasma and breast milk [63]. To minimise this potential risk, Swiss recommendations support breastfeeding only if maternal viral load is suppressed throughout pregnancy. Of note, there is still no standardised method for determining viral load in breast milk.

Also unclear is the role of the integrity of the infant's gastrointestinal tract and the question of whether complementary feeding (mixed feeding with replacement formula or solid food) also plays a role in an ideal scenario in high-income settings, as shown in low- and middle-income countries [64].

The role of maternal virological blips (short periods of measurable minimal virus replication) and the question of how often mother and child should be checked during breastfeeding are also unclear. In the postpartum period, mothers are particularly vulnerable in many ways (postpartum depression or other affective disorders, irregular sleep, new living conditions), which might adversely affect optimal treatment adherence and follow-up [65].

Despite all these unresolved questions, there is currently no evidence that any of these potential risks might be so relevant that breastfeeding under optimal conditions cannot be unconditionally supported.

Further considerations

Decision for or against breastfeeding (opt-in versus opt-out)

The way in which a question is perceived by someone will undoubtedly influence the decision-making process. It is very important what decision an expectant mother has to make regarding breastfeeding. Currently, in the shared decision-making process, women have to decide whether they want to breastfeed and thereby take possible risks. On the other hand, if the care team explicitly advises breastfeeding under optimal conditions, women can follow this advice or decide not to breastfeed in order to exclude any possible associated risk. In some way, this is similar to the situation in the early years of the pandemic, when HIV tests became available. At that time, most recommendations advised healthcare workers to ask for explicit permission for the HIV test (opt-in). It took years to change this approach and to provide the test regularly with the option to refuse (opt-out), which significantly improved test uptake. The actual shared decision-making process about infant feeding is a kind of an opt-in procedure, which transfers the final decision and thus the responsibility of breastfeeding to the expectant mother. Furthermore, her decision remains influenced by individual concerns and attitudes within the care team which undoubtedly can unintentionally interfere with the shared decision-making process.

It will certainly take many years to resolve all the remaining concerns surrounding infant nutrition with HIV. The question therefore arises as to whether one should continue with the current approach or go a step further given the experience gained so far. By analogy with the approach taken in connection with potential risks associated with any surgery or medical treatment, it seems justifiable not only to support breastfeeding with HIV, but to declare it as the best way to feed the infant under clearly defined optimal circumstances. Even with such advice, the expectant mother would be informed about all open questions and possible risks and would retain the option of deciding against breastfeeding (in analogy with opt-out). This would take the burden of responsibility off women's shoulders and further reduce stigma.

Equipoise

The concept of "clinical equipoise" was established by Freedman in 1987. He developed this concept to overcome ethical barriers in clinical research. Equipoise in its theoretical sense ("theoretical equipoise") only exists when ev-

idence on behalf of two alternative treatment regimens is exactly balanced. Ethics requires that each clinical trial begins with an honest null hypothesis. If a physician knows that two treatments are not equivalent, ethics requires that the superior treatment be recommended. Clinical equipoise is a more common and weaker concept. It refers to situations where two different options of equal value are available. There might be disagreement among the clinical community, with some clinicians favouring one (A) and others another (B) treatment or approach. By definition, in case of clinical equipoise, "good medicine" judges the choice between A and B indifferent [66].

The ongoing debate about breastfeeding with HIV under certain conditions in high-income countries seems to correspond to the definition of clinical equipoise. However, although there is good evidence to suggest that the benefits of breastfeeding outweigh the potential risks, this debate gives much greater weight to the open questions and potential risks than to the much better documented benefits, which actually deserve much more attention. The question arises as to whether it is still justified to consider the potential risks and benefits of breastfeeding as equivalent under optimal conditions, given that breastfeeding can even reduce mortality in both mother and child.

The four principles of clinical ethics

Ultimately, our considerations are also about a balanced weighting of the four principles of biomedical ethics according to Beauchamp and Childress, namely autonomy (the right to make informed decisions about one's own healthcare), non-maleficence (do no harm), beneficence (do good) and justice (equality in medical care) [67]. The current approach, based on a balance (equipoise) between benefit and potential risks of breastfeeding with HIV under optimal conditions, strongly favours the autonomy of the expectant mother. However, the principles of beneficence (reduction of morbidity and mortality for both mother and child) and justice (equitable access to best medical care irrespective of HIV infection) also deserve appropriate consideration. Currently, there is no evidence that any of the open questions or potential risks of breastfeeding with HIV under optimal conditions might be relevant enough to outweigh the significant benefits of breastfeeding. Accordingly, breastfeeding with HIV infection under optimal conditions should primarily be considered under the principle of beneficence rather than that of non-maleficence.

Conclusion

We believe that the benefits of breastfeeding with HIV under optimal conditions are likely to outweigh the theoretical possible risks. While the potential risks can be considered very low, breastfeeding has multiple benefits including a reduction in morbidity and mortality for both mother and child. We should therefore not wait for all open questions related to breastfeeding with HIV to be fully resolved and question the zero-risk policy currently applied. If the benefits of breastfeeding with HIV under optimal conditions are judged to outweigh the possible risks, then breastfeeding should actually be favoured and encouraged. This should be clearly communicated to the expectant mother as part of the shared decision-making process. This approach would be consistent with standard medical practice and reduce stigma, while preserving the autonomy of women allowing them to give greater weight to the potential risks (which should always be mentioned) and choose to refrain from breastfeeding. This shift to favouring breastfeeding under optimal conditions also needs to be widely communicated among care teams, healthcare workers and the community. Of course, it must not lead to a diminished commitment to pursuing research to answer all open questions and clarify possible risks of breastfeeding with HIV.

Including breastfeeding mothers with HIV and their infants in observational studies is of utmost importance for collecting further data and gaining additional experience as quickly as possible.

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References

1. Barré-Sinoussi F, Chermann JC, Rey F, Nugeyre MT, Chamaret S, Gruest J, et al. Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS). Science. 1983 May;220(4599):868–71. http://dx.doi.org/10.1126/science.6189183.
2. Trickey A, Sabin CA, Burkholder G, Crane H, d'Arminio Monforte A, Egger M, et al. Life expectancy after 2015 of adults with HIV on long-term antiretroviral therapy in Europe and North America: a collaborative analysis of cohort studies. Lancet HIV. 2023 May;10(5):e295–307. http://dx.doi.org/10.1016/S2352-3018(23)00028-0.
3. Menéndez-Arias L, Delgado R. Update and latest advances in antiretroviral therapy. Trends Pharmacol Sci. 2022 Jan;43(1):16–29. http://dx.doi.org/10.1016/j.tips.2021.10.004.
4. Swiss HIV Cohort Study; Schoeni-Affolter F, Ledergerber B, Rickenbach M, Rudin C, Günthard HF, Telenti A, et al. Cohort Profile: The Swiss HIV Cohort study. Int J Epidemiol 2010; 39:1179-89. DOI: http://dx.doi.org/10.1093/ije/dyp321.
5. Scherrer AU, Traytel A, Braun DL, Calmy A, Battegay M, Cavassini M, et al.; Swiss HIV Cohort Study (SHCS). Cohort Profile Update: The Swiss HIV Cohort Study (SHCS). Int J Epidemiol. 2022 Feb;51(1):33–34j. http://dx.doi.org/10.1093/ije/dyab141.
6. Vernazza P, Hirschel B, Bernasconi E, Flepp M. HIV-infected people without other STDs are not sexually infectious under effective antiretroviral therapy. Swiss Med Wkly. 2008;89:165–9.
7. The Lancet Hiv. U=U taking off in 2017. Lancet HIV. 2017 Nov;4(11):e475. http://dx.doi.org/10.1016/S2352-3018(17)30183-2.
8. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, Degen O, et al.; PARTNER Study Group. Risk of HIV transmission through con-

domless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet. 2019 Jun;393(10189):2428–38. http://dx.doi.org/10.1016/S0140-6736(19)30418-0.

9. Rodger AJ, Cambiano V, Bruun T, Vernazza P, Collins S, van Lunzen J, et al.; PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. JAMA. 2016 Jul;316(2):171–81. http://dx.doi.org/10.1001/jama.2016.5148.
10. Connor EM, Sperling RS, Gelber R, Kiselev P, Scott G, O'Sullivan MJ, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. N Engl J Med. 1994 Nov;331(18):1173–80. http://dx.doi.org/10.1056/NEJM199411033311801.
11. Kind C, Rudin C, Siegrist CA, Wyler CA, Biedermann K, Lauper U, et al.; Swiss Neonatal HIV Study Group. Prevention of vertical HIV transmission: additive protective effect of elective Cesarean section and zidovudine prophylaxis. AIDS. 1998 Jan;12(2):205–10. http://dx.doi.org/10.1097/00002030-199802000-00011.
12. Andiman W, Bryson Y, de Martino M, Fowler M, Harris D, Hutto C, et al.; International Perinatal HIV Group. The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1—a meta-analysis of 15 prospective cohort studies. N Engl J Med. 1999 Apr;340(13):977–87. http://dx.doi.org/10.1056/NEJM199904013401301.
13. Luzuriaga K, Mofenson LM. Challenges in the elimination of Pediatric HIV-1 infection. N Engl J Med. 2016 Feb;374(8):761–70. http://dx.doi.org/10.1056/NEJMra1505256.
14. Expert Commission Clinic and Therapy HIV/AIDS of the FOH. Pregnancy and HIV: recommendations of the FKT for the prevention of vertical HIV transmission. Recommendations in the case of pregnancy to prevent HIV transmission to the child. Bulletin of the Federal Office of Public Health. 2004;53:1008–11.
15. Expert Commission Clinic and Therapy HIV/AIDS of the FOH. HIV, pregnancy and birth. An update of the recommendations for the prevention of vertical HIV transmission. Bulletin of the Federal Office of Public Health. 2009;5:69–75.
16. Paioni P, Capaul M, Brunner A, Traytel A, Aebi-Popp K, Crisinel P-A, et al. Cohort profile: the Swiss Mother and Child HIV Cohort Study (MoCHiV). BMJ Open 2024;14:e086543. doi: http://dx.doi.org/10.1136/bmjopen-2024-086543. . DOI: http://dx.doi.org/10.1136/bmjopen-2024-086543.
17. Ad hoc working group MoCHiV. Recommendations of the Federal Commission for Sexual Health (EKSG) for the prevention of HIV transmission from mother to child. Bulletin of the Federal Office of Public Health. 2016;4:80–1.
18. Kahlert C, Aebi-Popp K, Bernasconi E, Martinez de Tejada B, Nadal D, Paioni P, et al. Is breastfeeding an equipoise option in effectively treated HIV-infected mothers in a high-income setting? Swiss Med Wkly. 2018 Jul;148(2930):w14648. http://dx.doi.org/10.4414/smw.2018.14648.
19. Ad hoc working group. Recommendations of the Federal Commission for Sexual Health (EKSG) for the medical care of HIV-infected women and their children. Bulletin of the Federal Office of Public Health. 2018;50:10–22.
20. Aebi-Popp K, Mulcahy F, Rudin C, Hoesli I, Gingelmaier A, Lyons F, et al. National Guidelines for the prevention of mother-to-child transmission of HIV across Europe - how do countries differ? Eur J Public Health. 2013 Dec;23(6):1053–8. http://dx.doi.org/10.1093/eurpub/ckt028.
21. Fernandes G, Chappell E, Goetghebuer T, Kahlert CR, Ansone S, Bernardi S, et al. HIV postnatal prophylaxis and infant feeding policies vary across Europe: results of a Penta survey. HIV Med. 2025 Feb;26(2):207–17. http://dx.doi.org/10.1111/hiv.13723.
22. Yuvaraj A, Mahendra VS, Chakrapani V, Yunihastuti E, Santella AJ, Ranauta A, et al. HIV and stigma in the healthcare setting. Oral Dis. 2020 Sep;26(S1 Suppl 1):103–11. http://dx.doi.org/10.1111/odi.13585.
23. Symington A, Chingore-Munazvo N, Moroz S. When law and science part ways: the criminalization of breastfeeding by women living with HIV. Ther Adv Infect Dis. 2022 Sep;9:20499361221122481. http://dx.doi.org/10.1177/20499361221122481.
24. North K, Gao M, Allen G, Lee AC. Breastfeeding in a global context: epidemiology, impact, and future directions. Clin Ther. 2022 Feb;44(2):228–44. http://dx.doi.org/10.1016/j.clinthera.2021.11.017.
25. Masi AC, Stewart CJ. Role of breastfeeding in disease prevention. Microb Biotechnol. 2024 Jul;17(7):e14520. http://dx.doi.org/10.1111/1751-7915.14520.
26. Victora CG, Bahl R, Barros AJ, França GV, Horton S, Krasevec J, et al.; Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet. 2016 Jan;387(10017):475–90. http://dx.doi.org/10.1016/S0140-6736(15)01024-7.
27. Chowdhury R, Sinha B, Sankar MJ, Taneja S, Bhandari N, Rollins N, et al. Breastfeeding and maternal health outcomes: a systematic review and meta-analysis. Acta Paediatr. 2015 Dec;104(467):96–113. http://dx.doi.org/10.1111/apa.13102.
28. Quigley MA, Kelly YJ, Sacker A. Breastfeeding and hospitalization for diarrheal and respiratory infection in the United Kingdom Millennium Cohort Study. Pediatrics. 2007 Apr;119(4):e837–42. http://dx.doi.org/10.1542/peds.2006-2256.
29. Tromp I, Kiefte-de Jong J, Raat H, Jaddoe V, Franco O, Hofman A, et al. Breastfeeding and the risk of respiratory tract infections after infancy: The Generation R Study [Internet]. PLoS One. 2017 Feb;12(2):e0172763. http://dx.doi.org/10.1371/journal.pone.0172763.
30. Li R, Ware J, Chen A, Nelson JM, Kmet JM, Parks SE, et al. Breastfeeding and post-perinatal infant deaths in the United States, A national prospective cohort analysis. Lancet Reg Health Am. 2022 Jan;5:100094. http://dx.doi.org/10.1016/j.lana.2021.100094.
31. Ip S, Chung M, Raman G, Chew P, Magula N, DeVine D, et al. Breastfeeding and maternal and infant health outcomes in developed countries. Rockville, MD, USA: Agency for Healthcare Research and Quality, 2007. Evid Rep Technol Assess (Full Rep). 2007;153:1–186.
32. Owen CG, Martin RM, Whincup PH, Smith GD, Cook DG. Effect of infant feeding on the risk of obesity across the life course: a quantitative review of published evidence. Pediatrics. 2005 May;115(5):1367–77. http://dx.doi.org/10.1542/peds.2004-1176.
33. Arenz S, Rückerl R, Koletzko B, von Kries R. Breast-feeding and childhood obesity—a systematic review. Int J Obes (Lond). 2004 Oct;28(10):1247–56. http://dx.doi.org/10.1038/sj.ijo.0802758.
34. Prentice AM. Breastfeeding in the modern world. Ann Nutr Metab. 2022;78 Suppl 2:29–38. http://dx.doi.org/10.1159/000524354.
35. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and breastfeeding: collaborative reanalysis of individual data from 47 epidemiological studies in 30 countries, including 50302 women with breast cancer and 96973 women without the disease. Lancet. 2002 Jul;360(9328):187–95. http://dx.doi.org/10.1016/S0140-6736(02)09454-0.
36. Stuebe AM, Rich-Edwards JW, Willett WC, Manson JE, Michels KB. Duration of lactation and incidence of type 2 diabetes. JAMA. 2005 Nov;294(20):2601–10. http://dx.doi.org/10.1001/jama.294.20.2601.
37. Dunn DT, Newell ML, Ades AE, Peckham CS. Risk of human immunodeficiency virus type 1 transmission through breastfeeding. Lancet. 1992 Sep;340(8819):585–8. http://dx.doi.org/10.1016/0140-6736(92)92115-v. http://dx.doi.org/10.1016/0140-6736(92)92115-V.
38. Bamford A, Foster C, Lyall H. Infant feeding: emerging concepts to prevent HIV transmission. Curr Opin Infect Dis. 2024 Feb;37(1):8–16. http://dx.doi.org/10.1097/QCO.0000000000000986.
39. Sibiude J, Le Chenadec J, Mandelbrot L, Hoctin A, Dollfus C, Faye A, et al. Update of perinatal human immunodeficiency virus type 1 transmission in France: zero transmission for 5482 mothers on continuous antiretroviral therapy from conception and with undetectable viral load at delivery. Clin Infect Dis. 2023 Feb;76(3):e590–8. http://dx.doi.org/10.1093/cid/ciac703.
40. Shapiro RL, Hughes MD, Ogwu A, Kitch D, Lockman S, Moffat C, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. N Engl J Med. 2010 Jun;362(24):2282–94. http://dx.doi.org/10.1056/NEJMoa0907736.
41. Flynn PM, Taha TE, Cababasay M, Fowler MG, Mofenson LM, Owor M, et al.; PROMISE Study Team. Prevention of HIV-1 transmission through breastfeeding: Efficacy and safety of maternal antiretroviral therapy versus infant nevirapine prophylaxis for duration of breastfeeding in HIV-1-infected women with high CD4 cell count (IMPAACT PROMISE): a randomized, open label, clinical trial. J Acquir Immune Defic Syndr. 2018 Apr;77(4):383–92. http://dx.doi.org/10.1097/QAI.0000000000001612.
42. Flynn PM, Taha TE, Cababasay M, Butler K, Fowler MG, Mofenson LM, et al.; PROMISE Study Team. Association of maternal viral load and CD4 count with perinatal HIV-1 transmission risk during breastfeeding in the PROMISE postpartum component. J Acquir Im-

mune Defic Syndr. 2021 Oct;88(2):206–13. http://dx.doi.org/10.1097/QAI.0000000000002744.
43. Luoga E, Vanobberghen F, Bircher R, Nyuri A, Ntamatungiro AJ, Mnzava D, et al. No HIV transmission from virally suppressed mothers during breastfeeding in rural Tanzania. J Acquir Immune Defic Syndr. 2018 Sep;79(1):e17–20. http://dx.doi.org/10.1097/QAI.0000000000001758.
44. Malaba TR, Nakatudde I, Kintu K, Colbers A, Chen T, Reynolds H, et al.; DolPHIN-2 Study Group. 72 weeks post-partum follow-up of dolutegravir versus efavirenz initiated in late pregnancy (DolPHIN-2): an open-label, randomised controlled study. Lancet HIV. 2022 Aug;9(8):e534–43. http://dx.doi.org/10.1016/S2352-3018(22)00173-4.
45. Keane A, Lyons F, Aebi-Popp K, Feiterna-Sperling C, Lyall H, Martínez Hoffart A, et al. Guidelines and practice of breastfeeding in women living with HIV-Results from the European INSURE survey. HIV Med. 2024 Mar;25(3):391–7. http://dx.doi.org/10.1111/hiv.13583.
46. Navér L, Albert J, Carlander C, Gisslén M, Pettersson K, Soeria-Atmadja S, et al. Prophylaxis and treatment of HIV infection in pregnancy, Swedish guidelines 2024. Infect Dis (Lond). 2024 Aug;56(8):657–68. http://dx.doi.org/10.1080/23744235.2024.2360029.
47. Ambrosioni J, Levi L, Alagaratnam J, Van Bremen K, Mastrangelo A, Waalewijn H, et al.; EACS Governing Board. Major revision version 12.0 of the European AIDS Clinical Society guidelines 2023. HIV Med. 2023 Nov;24(11):1126–36. http://dx.doi.org/10.1111/hiv.13542.
48. British HIV Association guidelines for the management of HIV in pregnancy and postpartum 2018 (2020 third interim update). British HIV Association (BHIVA) 2020. https://www.bhiva.org/pregnancy-guidelines. [Accessed 18 June 2024].
49. Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. Department of Health and Human Services (DHHS) 2023. https://clinicalinfo.hiv.gov/en/guidelines/perinatal. [Accessed 18 June 2024].
50. Francis K, Sconza R, Thorne C, Peters H. Monitoring clinical practice of BHIVA-supported breastfeeding guidelines for women living with HIV in the UK. BHIVA 2023 spring conference Gateshead, UK. 2023. https://www.ucl.ac.uk/integrated-screening-outcomes-surveillance/sites/integrated_screening_outcomes_surveillance/files/o12_supported_breastfeeding_in_uk.pdf. [Accessed 18 June 2024].
51. Crisinel PA, Kusejko K, Kahlert CR, Wagner N, Beyer LS, De Tejada BM, et al. Successful implementation of new Swiss recommendations on breastfeeding of infants born to women living with HIV. Eur J Obstet Gynecol Reprod Biol. 2023 Apr;283:86–9. http://dx.doi.org/10.1016/j.ejogrb.2023.02.013.
52. Yusuf HE, Knott-Grasso MA, Anderson J, Livingston A, Rosenblum N, Sturdivant H, et al. Experience and outcomes of breastfed infants of women living with HIV in the United States: findings from a single-center breastfeeding Support Initiative. J Pediatric Infect Dis Soc. 2022 Jan;11(1):24–7. http://dx.doi.org/10.1093/jpids/piab116.
53. Levison J, McKinney J, Duque A, Hawkins J, Bowden EV, Dorland J, et al. Breastfeeding among people with human immunodeficiency virus in North America: A multisite study. Clin Infect Dis. 2023 Nov;77(10):1416–22. http://dx.doi.org/10.1093/cid/ciad235.
54. Nashid N, Khan S, Loutfy M, MacGillivray J, Yudin MH, Campbell DM, et al. Breastfeeding by women living with human immunodeficiency virus in a resource-rich setting: A case series of maternal and infant management and outcomes. J Pediatric Infect Dis Soc. 2020 Apr;9(2):228–31. http://dx.doi.org/10.1093/jpids/piz003.
55. Prestileo T, Adriana S, Lorenza DM, Argo A. From Undetectable Equals Untransmittable (U=U) to Breastfeeding: Is the Jump Short? Infect Dis Rep. 2022 Mar;14(2):220–7. http://dx.doi.org/10.3390/idr14020027.
56. Haberl L, Audebert F, Feiterna-Sperling C, Gillor D, Jakubowski P, Jonsson-Oldenbüttel C, et al. Not recommended, but done: breastfeeding with HIV in Germany. AIDS Patient Care STDs. 2021 Feb;35(2):33–8. http://dx.doi.org/10.1089/apc.2020.0223.
57. Feiterna-Sperling C, Krüger R, Bethke H, Siedentopf JP, von Weizsäcker K, Heinrich-Rohr M, et al. Breastfeeding in HIV-positive mothers under optimized conditions: 'real-life' results from a well-resourced healthcare setting. J Perinat Med. 2025 Apr;53(6):765–74. http://dx.doi.org/10.1515/jpm-2025-0170.
58. Bukkems VE, Finkenflügel RN, Grintjes K, Marneef M, de Haan M, Mielitz I, et al. Exploring the breastfeeding desires and decision-making of women living with HIV in the Netherlands: Implications for Perinatal HIV Management in Developed Countries. Breastfeed Med. 2023 May;18(5):356–61. http://dx.doi.org/10.1089/bfm.2023.0004.
59. Behrens GM, Aebi-Popp K, Babiker A. Close to zero, but not zero: what is an acceptable HIV transmission risk through breastfeeding. J Acquir Immune Defic Syndr. 2022 Apr;89(4):e42. http://dx.doi.org/10.1097/QAI.0000000000002887.
60. Waitt C, Low N, Van de Perre P, Lyons F, Loutfy M, Aebi-Popp K. Does U=U for breastfeeding mothers and infants? Breastfeeding by mothers on effective treatment for HIV infection in high-income settings. Lancet HIV. 2018 Sep;5(9):e531–6. http://dx.doi.org/10.1016/S2352-3018(18)30098-5.
61. Aebi-Popp K, Kahlert CR, Crisinel PA, Decosterd L, Saldanha SA, Hoesli I, et al.; Swiss Mother and Child HIV Cohort Study (SHCS). Transfer of antiretroviral drugs into breastmilk: a prospective study from the Swiss Mother and Child HIV Cohort Study. J Antimicrob Chemother. 2022 Nov;77(12):3436–42. http://dx.doi.org/10.1093/jac/dkac337.
62. Rutagwera DG, Molès JP, Kankasa C, Mwiya M, Tuaillon E, Peries M, et al. Recurrent severe subclinical mastitis and the risk of HIV transmission through breastfeeding. Front Immunol. 2022 Mar;13:822076. http://dx.doi.org/10.3389/fimmu.2022.822076.
63. Van de Perre P, Rubbo PA, Viljoen J, Nagot N, Tylleskär T, Lepage P, et al. HIV-1 reservoirs in breast milk and challenges to elimination of breast-feeding transmission of HIV-1. Sci Transl Med. 2012 Jul;4(143):143sr3. http://dx.doi.org/10.1126/scitranslmed.3003327.
64. Coovadia HM, Rollins NC, Bland RM, Little K, Coutsoudis A, Bennish ML, et al. Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. Lancet. 2007 Mar;369(9567):1107–16. http://dx.doi.org/10.1016/S0140-6736(07)60283-9.
65. Emmanuel E, St John W. Maternal distress: a concept analysis. J Adv Nurs. 2010 Sep;66(9):2104–15. http://dx.doi.org/10.1111/j.1365-2648.2010.05371.x.
66. Freedman B. Equipoise and the ethics of clinical research. N Engl J Med. 1987 Jul;317(3):141–5. http://dx.doi.org/10.1056/NEJM198707163170304.
67. Varkey B. Principles of clinical ethics and their application in practice. Med Princ Pract. 2021;30(1):17–28. http://dx.doi.org/10.1159/000509119.