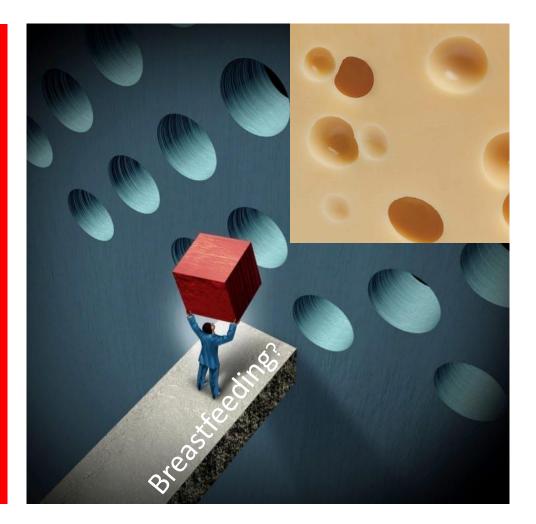
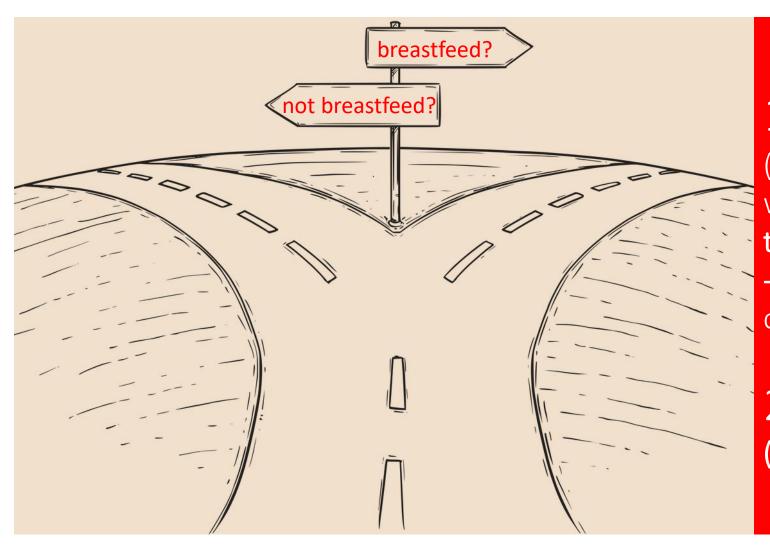
How to counsel women living with HIV who are breastfeeding in high-income settings?



Breastfeeding challenges?

- Setting: virtually no HIV MTCT risk
 - maternal HIV infection is diagnosed
 - cART is implemented
 - HIV pVL suppressed
- Globally, breastfeeding recommended
 - · evidence for lifelong benefits mother/child
- Safety? Evidence from PROMISE (Flynn, 2018)
 - risk HIV MTCT 0.3% for 6 months of breastfeeding, however, HIV pVL data missing
 - acceptable in high-income settings?
- Undetectable = Untransmittable message
 - women want to breastfeed in high-income settings too (e.g. personal, social, cultural)
- Many additional unknowns
 - e.g. toxicity maternal cART

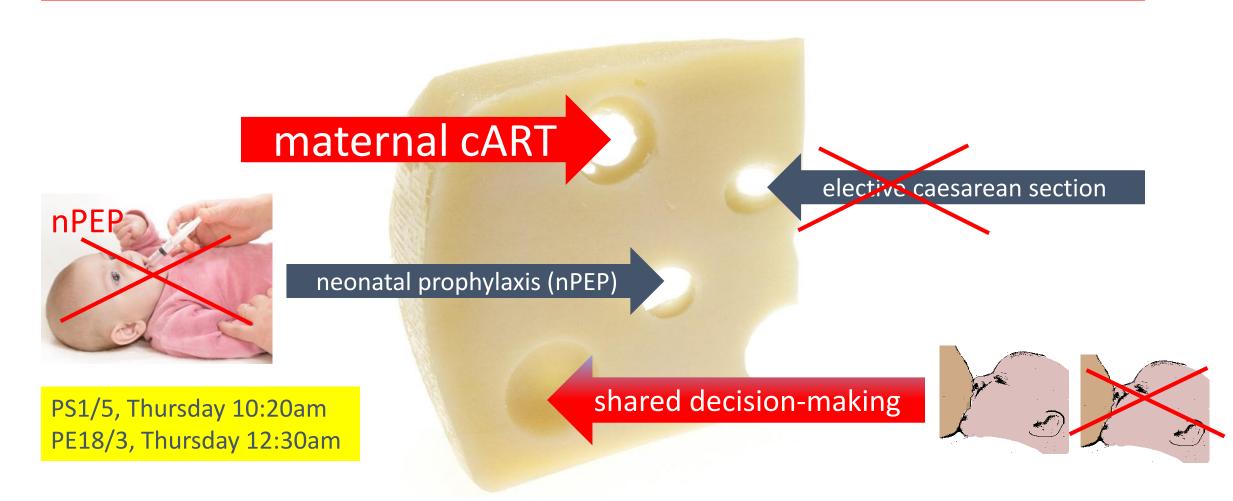




1) clinical EQUIPOISE

- (...) when the clinical **potential risk** as well as the **benefit** of an intervention **tend towards zero**
- -> balancing risk and benefit is utmost challenging, or even impossible. (...)
- 2) patient's AUTONOMY
- (...) based on ethical principles (...)

Update Swiss Recommendations 2019



Guidance for a shared decision-making

- Prerequisite conditions to minimise HIV MTCT risk ("optimal scenario")
 - HIV pVL < 50 RNA copies/ml throughout pregnancy (regular follow-up)
 - All HCW involved: open, non-judgemental, unbiased towards breastfeeding, final decision after shared decision-making will be accepted
- Shared decision-making process
 - Interdisciplinary (adult HIV specialist, paediatrician and obstetrician/gyn.),
 - start early in pregnancy, comprehensive information and discussion on benefits- and risks, written decision in the medical records
- Follow up mother and child
 - Mother: initially monthly follow-up, pVL >50 RNA copies/ml -> stop breastfeeding, immediate contact if issues e.g. mastitis, impaired adherence etc.
 - Infants: routine testing by PCR month 1, 2 (or 4), 6, serology month 18-24

Benefit/risk consultation with future parents

Benefits

- Uniform global recommendation to breastfeed newborns, virtually no contraindications e.g. maternal HIV
- Simple, easy and free way of providing nutrition, psychologically essential!
- **Child**: microbiome, atopic disease (eczema, wheezing, asthma), infectious diseases (airways, gut)
- Mother: postpartum recovery (involution uterus, depression), breast cancer, glucose homeostasis

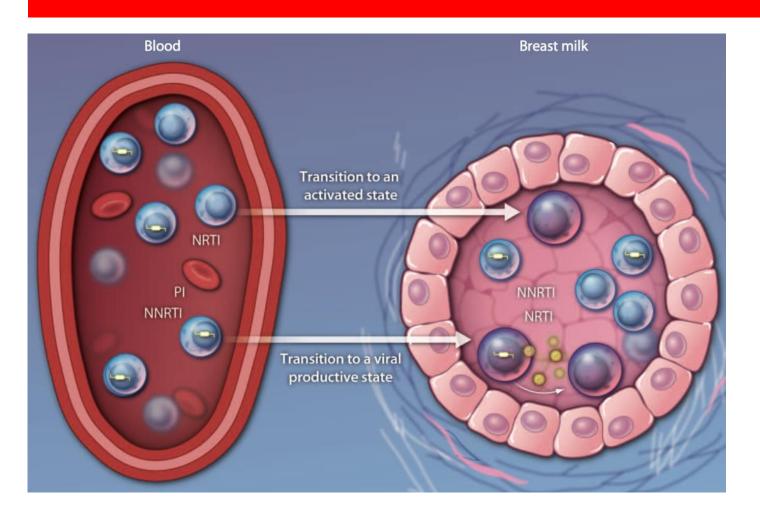
Risks

- **HIV MTCT** cannot be ruled out
- Postpartum vulnerable period e.g. irregular sleep, adherence!
- Infant: extended cART exposure
 -> toxicity, risk of ART resistance?
- Mastitis known as increased risk
- Exclusive breastfeeding lower risk of HIV MTCT versus mixed breastfeeding
- Cell-associated virus, HIV MTCT risk not fully understood

Extended cART exposure

- Infant toxicity due to antiretroviral therapy
 - serious adverse events in infants exposed to ARVs through breast milk appear to be relative uncommon
 - data from older drugs suggest low drug levels in breastmilk, experience with new substances largely missing
- Development of ART resistance
 - suboptimal levels of ART -> risk of mutations in the infected infant?

HIV-1 reservoir present in breastmilk



cell-associated (DNA) virus in breastmilk even when HIV pVL

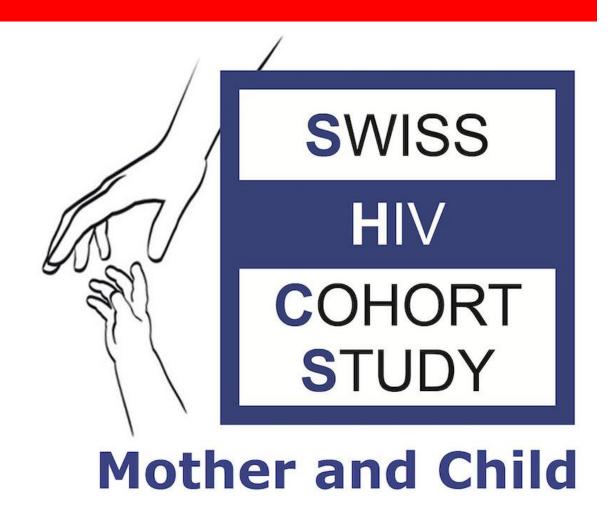
suppressed, depend on duration of suppression relevance with regard to HIV MTCT unclear, nevertheless this is a concern

Detectable virus in body fluids relates to transmission?

- Yes, of course, but...
- Results PARTNER 1 (2016, Rodger, JAMA) and PARTNER 2 (2019, Rodger, Lancet) study confirmed U = U message
 - -> suppression of HIV pVL is key!
- Genital shedding in 5.8% of about 1000 women on cART with suppressed HIV pVL (2017, King, JID)
- -> elective cesarean section abandoned without signal of elevated HIV MTCT transmission!

Current Situation CH?

- Breastfeeding mothers
 - recommendations implemented 12/2018
 - 5 women with HIV breastfeeding documented in SHCS database
- Research project
 - Breastfeeding in HIV-positive women: Evaluating the shared decision making process and prospective cohort evaluation (SHCS817, PI K. Aebi-Popp)



Lessons from the implementation

- Ensure that the mother can decide freely
 - separate discussion with the mother
- Implement clear communication, involve stakeholders e.g. midwives, obstetrical/neonatal ward, neonatologist
 - written documentation of decision
 - motivation to support women with HIV
 - clarify infection control issues e.g. cleaning of breastmilk pumps in advance
- Provide uncomplicated support for the mother
 - encourage mother to get immediately in contact in case of problems e.g. unstable adherence, breastfeeding support...

Conclusion

- Shared decision-making approach accepted and feasible in Switzerland
 - breastfeeding supported (no active recommendation!)
 - optimal scenario
 - informed parental decision
 - "intermediate approach" until robust safety data available
 - years in CH to detect HIV MTCT!
- innovative ideas needed until U = U in breastfeeding
 - Hypothesis: "The chance of HIV MTCT from a breastfeeding suppressed mother is ZERO!"
- Need for common action!
 - collect and contribute data on breastfeeding with HIV in high—income settings!



Christian R. Kahlert, WAVE Workshop EACS 2019, Basel