Management of pregnancy and breastfeeding in WLWH:
Updates on Belgian guidances

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On behalf of the working group

BREACH
Belgian Research Aids&HIV Consortium

12th BREACH Symposium
Palais des Académies, Bruxelles

Working group: methodology

After the Breach meeting in November 2021: set up a working group on pregnancy in WLWH

- ✓ **4 groups**: Pregnancy (Deborah Konopnicki), Infants (Marc Hainaut), Breastfeeding (Dimitri Van der Linden), Ethical issues

- ✓ Created a shared drive with literature and consensus drafts
- ✓ Online meetings
- ✓ November 2023: presented at the 11th Breach Metting

Working groups

- Pregnancy Group

BARLOW Patricia
LAURENT France
KONOPNICKI Deborah
GILLES Christine
PELGROM Jolanda
ROELENS Kristien
CALUWAERTS Séverine
DE GREEF Julien
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- Infants Group

GOETGHEBUER Tessa
STOFFELS Karolien
VAN DER LINDEN Dimitri
DELFORGE Marie-Luce
ADLER Catherine
SCHMITZ Veronique
HAINAUT Marc
EERDEKENS An
KONOPNICKI Deborah
NAGEL Julie
ROUSSEAU Charlotte

- Breastfeeding group

NOESTLINGER Christiana
WILLEMS Myriam
KONOPNICKI Deborah
STOFFELS Karolien
GILLES Christine
VAN DER LINDEN Dimitri
DELFORGE Marie-Luce
AMEYE Annick
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HAINAUT Marc
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VANDERSCHUEREN Patricia
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NAGEL Julie
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2024

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Kristien Roelens UZ Gent
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Jessa Van Praet AZ St Jan
Roland Thomas Helora

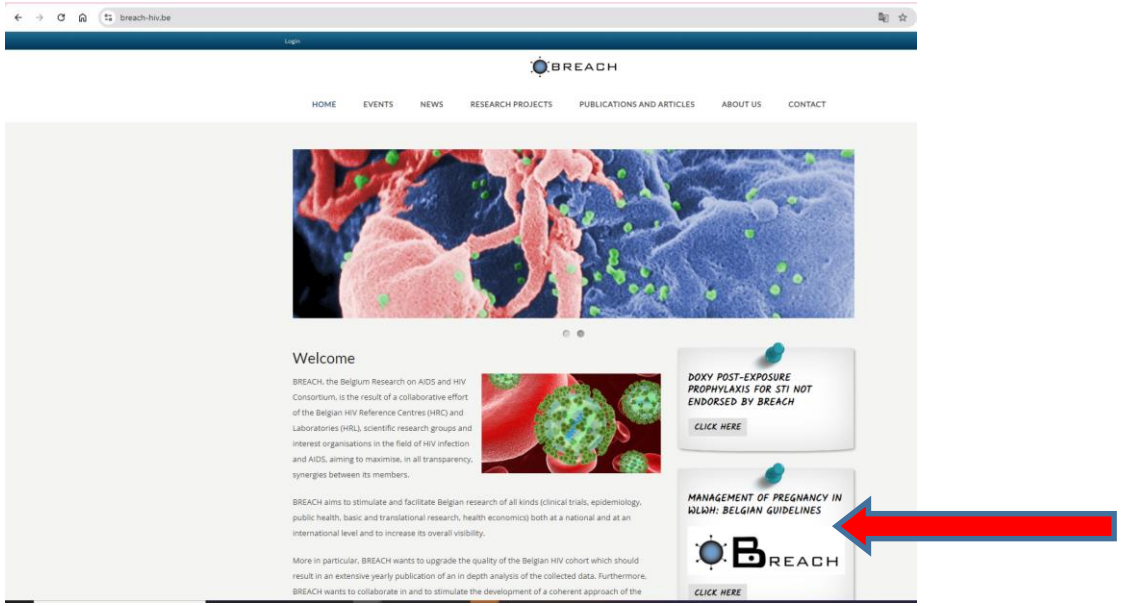
37 Virologists, Infectiologists, gynecologists, obstretricians, pediatricians, neonatologists, mid-wives, nurses, psychologists, public health researchers.

CHU Saint-Pierre, Cliniques Universitaires Saint Luc, Hôpital Ambroise Paré, Helora, Hôpital de la Citadelle, Hopital Erasme, ITG, LHUB-ULB, UZ Antwerp, UZ Brussel, UZ Gent, UZ Leuven

Belgian guidance

- Available
  - On the BREACH web site
  - Pediatric society?

- Project
  - BVIKM?
  - Sciensano?
  - VVOG?



- Presented at AfraVIH Yaoundé 2024 as poster and today

- should be submited to publication: Acta clinica belgica

- Reviewed by the group at least once a year and whenever there will be a breaking change:

Last meeting: October 1st

ARV therapy during pregnancy 2023

1. Insufficient data - Safety - Pharmacokinetic - Bitherapy as opposed to the 3 drugs dogma	**Bictegravir** **Doravirine** Raltegravir 1200 mg QD Cabotegravir/rilpivirine Dolutegravir/lamivudine Dolutegravir/rilpivirine	• Discussion with the patient to inform her: **shared decision** ➢ If VL<50 cp/ml, therapy well tolerated, and the patient wishes to continue her therapy, continue During pregnancy: monitoring VL frequently (at least at T1, T2, every month during T3) ➢ If VL >50 cp/ml, or if the patient prefer to have cART with sufficient data background: switch for a recommended therapy (See EACS guidelines)
2. Not recommended - Pharmacokinetic - Risk of viral rebound	Elvitegravir Cobicistat (significant decrease in blood concentrations at T3) Atazanavir (risk of hyperbilirubinemia, risk of viral failure)	• Discussion with the patient to inform her: **shared decision** and based on a case to case evaluation ➢ Propose to switch to another regimen **BEFORE T3** (as there are a lot of alternatives) ➢ If VL<50 cp/ml and well tolerated, continue and during pregnancy: monitoring VL frequently (at least at T1, T2, every month during T3)
3. Not recommended Risk of congenital abnormalities	Efavirenz	Propose to switch to another regimen as soon as possible at first T1 but until the end
4. Drugs that are ok		Dolutegravir based triple ***(or double regimen)*** to be started or continued Raltegravir 400 bid based triple regimen to be started or continued Prezista /rito based triple regimen to be started or continued Rilpivirine based triple regimen to be started or continued (Viramune based triple regimen to be continued, not started)

ARV therapy during pregnancy 2024

1. Insufficient data - Safety - Pharmacokinetic - Bitherapy as opposed to the 3 drugs regimen dogma	Raltegravir 1200 mg QD Cabotegravir/rilpivirine Dolutegravir/lamivudine Dolutegravir/rilpivirine	• Discussion with the patient to inform her: **shared decision** ➢ If VL<50 cp/ml, therapy well tolerated, and the patient wishes to continue her therapy, continue During pregnancy: monitoring VL frequently (at least at T1, T2, every month during T3) ➢ If VL >50 cp/ml, or if the patient prefer to have cART with sufficient data background: switch for a recommended therapy (See EACS guidelines)
2. Not recommended - Pharmacokinetic - Risk of viral rebound	Elvitegravir Cobicistat Atazanavir (risk of hyperbilirubinemia, risk of viral failure) (Doravirine: concerns for significant decrease in blood concentrations at T3)	• Discussion with the patient to inform her: **shared decision** and based on a case to case evaluation ➢ Propose to switch to another regimen **BEFORE T3** (as there are a lot of alternatives) ➢ If VL<50 cp/ml and well tolerated, continue and during pregnancy: monitoring VL frequently (at least at T1, T2, every month during T3)
3. Not recommended Risk of congenital abnormalities	Efavirenz	Propose to switch to another regimen as soon as possible at first T1 but until the end
4. Drugs that are ok	To be started →	Dolutegravir based or Bictegravir based triple drugs regimen
	To be continued	Dolutegravir based triple ***(or double regimen)*** or Bictegravir Triple Raltegravir 400 bid based triple regimen Prezista /rito based triple regimen Rilpivirine based triple regimen (Viramune based triple regimen)

The rest of the guidances are unchanged

2. Management of infants/children born from a mother living with HIV

Risk stratification

Lowest risk

- Full VL suppression before and throughout pregnancy

Intermediate risk

- Maternal VL detectable at some point during the pregnancy but <50 copies/mL before birth

High risk

- Maternal VL known or suspected to be >50 copies/mL at delivery

VL = viral load

Breastfeeding is not routinely recommended

When women decide to breastfeed, despite having been informed about the potential harms, as professionals it is our duty to offer proper guidance and follow-up in a supportive environment

Belgian registry for breastfeeding and HIV

- Belgian registry collecting prospectively breastfeeding cases

- Breastfeeding and HIV: a multicenter cohort study in Belgium
  - Study designed by St-Pierre University Hospital multidisciplinary team
  - Presented and approved by the working groups on October 1st
  - Submitted and approved by BREACH, provided financial support to be defined

Update on the Guidance and Management of pregnancy and breastfeeding in WLWH

Deborah KONOPNICKI

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Saint-Pierre University Hospital

On behalf of the working group

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Breastfeeding and HIV : Key messages

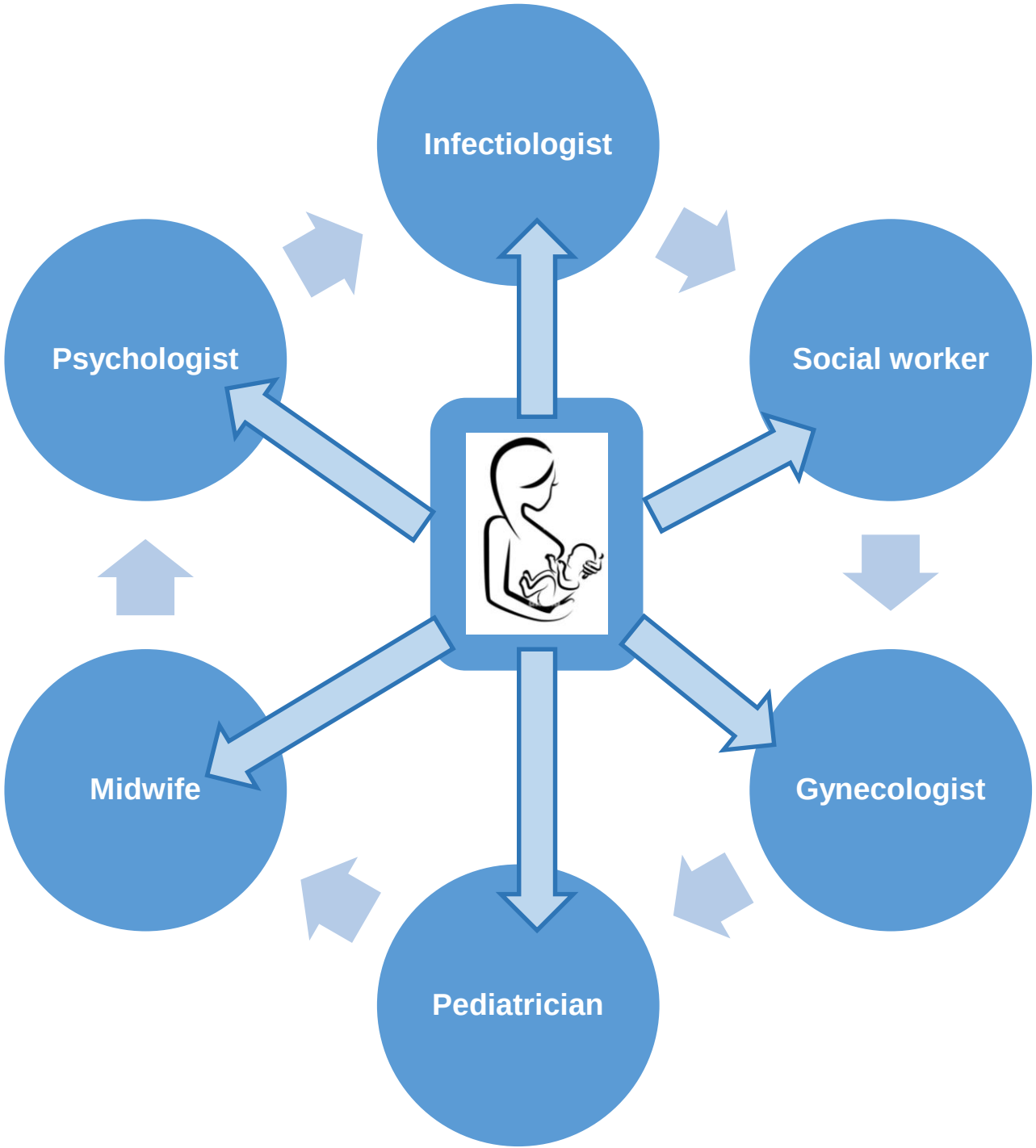
1. U=U ==> No evidence in the context of BF.

- Risk of transmission is very low, less than 1%.
- Residual risk of transmission even with effective ART
- No data available for ideal situation

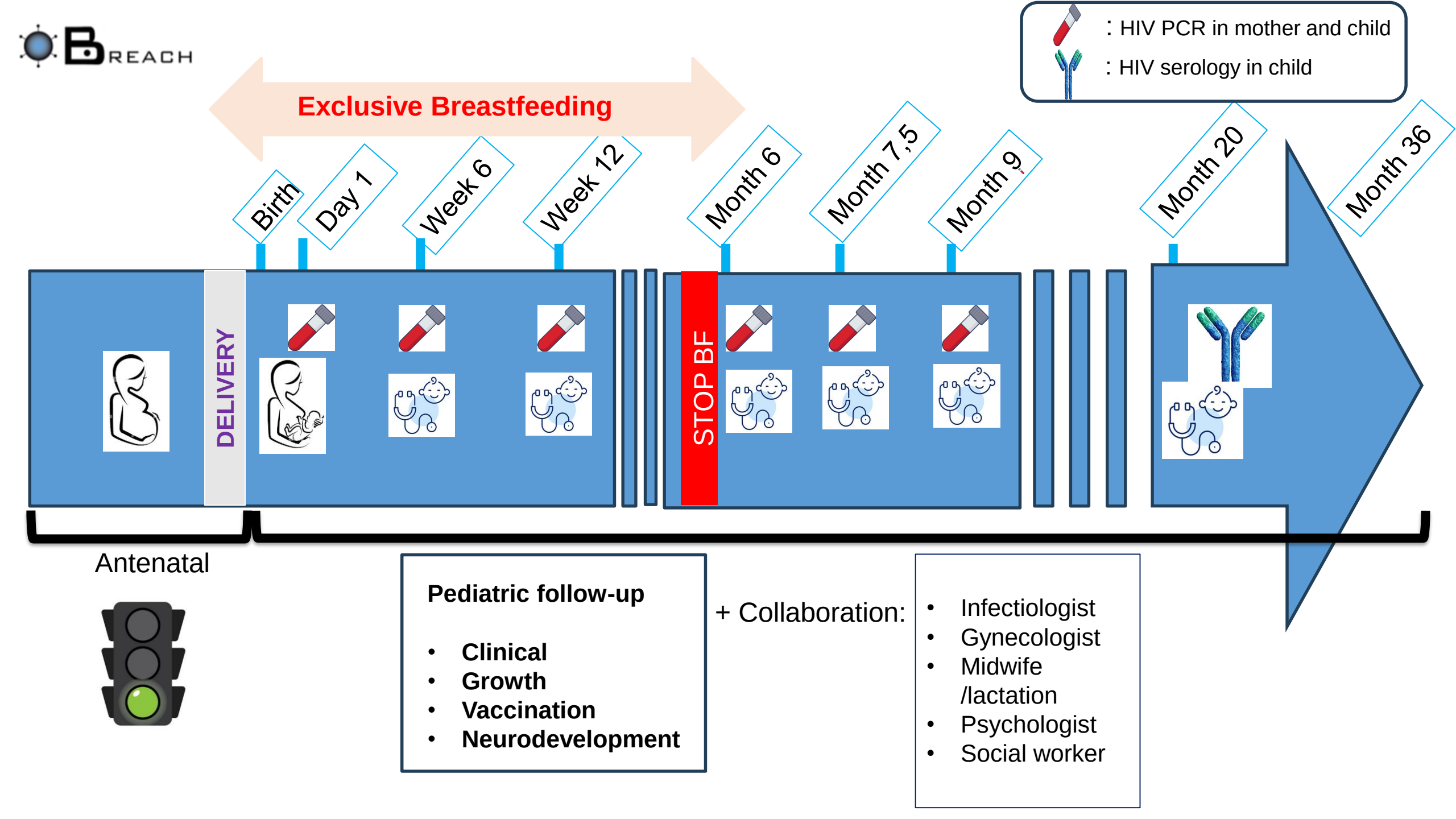
2. Risk linked to duration of breastfeeding .

3.Testing after breastfeeding cessation

4.Concern about exposure to drugs in breastfed infants : **HIV resistance** and **long term toxicities**



- Maternal viral suppression during pregnancy
- Healthy breasts and nipples
- Digestive mucosal integrity of the mother/newborn


: HIV PCR in mother and child
: HIV serology in child
Exclusive Breastfeeding
Birth
Day 1
Week 6
Week 12
Month 6
Month 7,5
Month 9
Month 20
Month 36
DELIVERY
STOP BF
Antenatal
Pediatric follow-up
Clinical
Growth
Vaccination
Neurodevelopment
+ Collaboration:
Infectiologist
Gynecologist
Midwife /lactation
Psychologist
Social worker

Breastfeeding and HIV: a multicenter cohort study in Belgium

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Aims of the study

- To **implement the new recommendations** about breastfeeding in WLWH in Belgium through BREACH
- To **support at best WLWH** who wants to breastfeed
- To **build medical knowledge** about breastfeeding in WLWH

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Material and method

- **Prospective multicentric cohort study**
- Criteria for inclusion
  - **All pregnant WLWH** followed in Belgium wishing to breastfeed
  - In an HIV reference clinic or in an affiliated hospital
- **Standardized information** about breastfeeding
  - Information given in writing / translated into different languages
  - Information given during ante-natal consultation
- **Specialized consultations**
  - With a paediatrician, an obstetrician and an infectiologist
  - If the women choose to breastfeed, with specialized breastfeeding midwives

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Material and method – After Birth

- Assessment of **the viral load** of both mother and child
  - every 6 weeks during the time of breastfeeding
  - 3 months after the cessation
- Assessment of **ARV concentration**
  - in the plasma of the mother, the baby, and in the milk
  - at weeks 6, 18, 36
- Assessment of **the HIV viral load in the milk** coincidentally

Statistics

- **All subjects will be included** in the statistical evaluation:
  - All demographics, maternal, neonatal and biological data
  - Ex : the duration of breastfeeding, breastfeeding interruptions, the mother's ARV treatment, AZT prophylaxis, …

- Statistical analysis and descriptive statistics will be used:
  - **Profile description of WLWH mothers** who breastfeed their baby
  - Trying to assess **the rate of HIV transmission via milk and the impact of antiretroviral drugs**

Register

- Creation of **a register including all pregnant WLWH followed in Belgium** and wishing to breastfeed, in an HIV reference clinic or in an affiliated hospital

HIV breastfeeding data collection form in Belgium

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[Dessin]

HIV breastfeeding data collection form- Belgium

Form date 10/24

PART 1: HOSPITAL INFORMATION

Hospital from data collection: _____

Name of data collector: _____

Hospital of birth: _____

PART 2: CHILD INFOMATION

Date of birth: ___/___/___ Sex: ☐ Male or ☐ Female Reference number: _____
Preterm birth before 37 weeks : ☐ No ☐ Yes ☐ Not known Gestational age: _____
Neonatal prophylaxis: ☐ No ☐ Yes* ☐ Not known
*If Yes:
☐ AZT during 4 weeks
☐ Other:
_____

PART 3: INFANT FEEDING HISTORY

Period of exclusive breastfeeding, i.e., without introduction of formula/other liquids or food:

_____ day(s) OR _____ week(s) OR _____ month(s) OR ☐ Never exclusively breastfed

Which statement best describes the infant feeding practices during the breastfeeding period?

☐ Exclusively breastfed (i.e., without use of any formula milk/other liquids or food), with no interruption
☐ Exclusively breastfed with some interruption(s) (e.g., stopped and re-started following a hiatus)
☐ Breastfed with some period(s) of mixed feeding (breast milk with formula milk/other liquids or food)
☐ Mixed feeding throughout
☐ Other:
_____

Reason(s) for any breastfeeding interruption(s):

_____
_____
_____

Reason(s) for any period(s) of mixed feeding:

☐ Temporary supplementation with formula milk whilst establishing breastfeeding in neonatal period
☐ Switching from breastmilk to formula milk (i.e., weaning)
☐ Other:
_____

Liquids/foods introduced during period(s) of mixed feeding:

☐ Formula milk
☐ Water
☐ Baby rice/cereal
☐ Donor milk
☐ Other: _____

Were solid foods introduced during breastfeeding before the age of 6 months? ☐ No ☐ Yes* ☐ Not known
* If yes, date (range or exact): _____
Reason: _____
_____
_____

Additional details of interruptions and/or mixed feeding (with approximate timings, if known):

_____
_____
_____
_____

Child age when all breastfeeding stopped or date :

_____ day(s) OR _____ week(s) OR _____ month(s) OR Dd/mm/yyyy:_____

Main reason for stopping all breastfeeding:

☐ Part of plan to stop
☐ Difficulties establishing breastfeeding (e.g., unable to latch) (avoidance of mixed feeding)
☐ Infant required supplementation (avoidance of mixed feeding)
☐ Clinical concerns in mother (e.g., maternal viraemia, mastitis, gastroenteritis):
_____
☐ Clinical concerns in infant (e.g., gastroenteritis):
_____
☐ Other:
_____

PART 4: CLINICAL COMPLICATIONS DURING BREASTFEEDING

At any point during the breastfeeding period, was there evidence of any of the following?

Maternal HIV viraemia ☐ No ☐ Yes* ☐ Not known
* Details, including clinical management and any changes to infant feeding:
_____
_____
_____
_____
_____

* Was additional HIV post-exposure prophylaxis given to the infant following evidence of maternal HIV viraemia during breastfeeding? ☐ No ☐ Yes** ☐ Not known

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HIV breastfeeding data collection form

General information (Hospital,...)

- Birth informations
- Infant feeding history
- Complication during BF
- Clinical and biological child's monitoring during BF
- Maternal treatments and VL during BF

⚠ The form will be filled in via Red cap online, which will be posted on the Breach web page

⚠ Possibility of participating in the registry without measuring CV in milk or drugs in baby

⚠ Need to sign 2 ICs: one for the register, one for the study