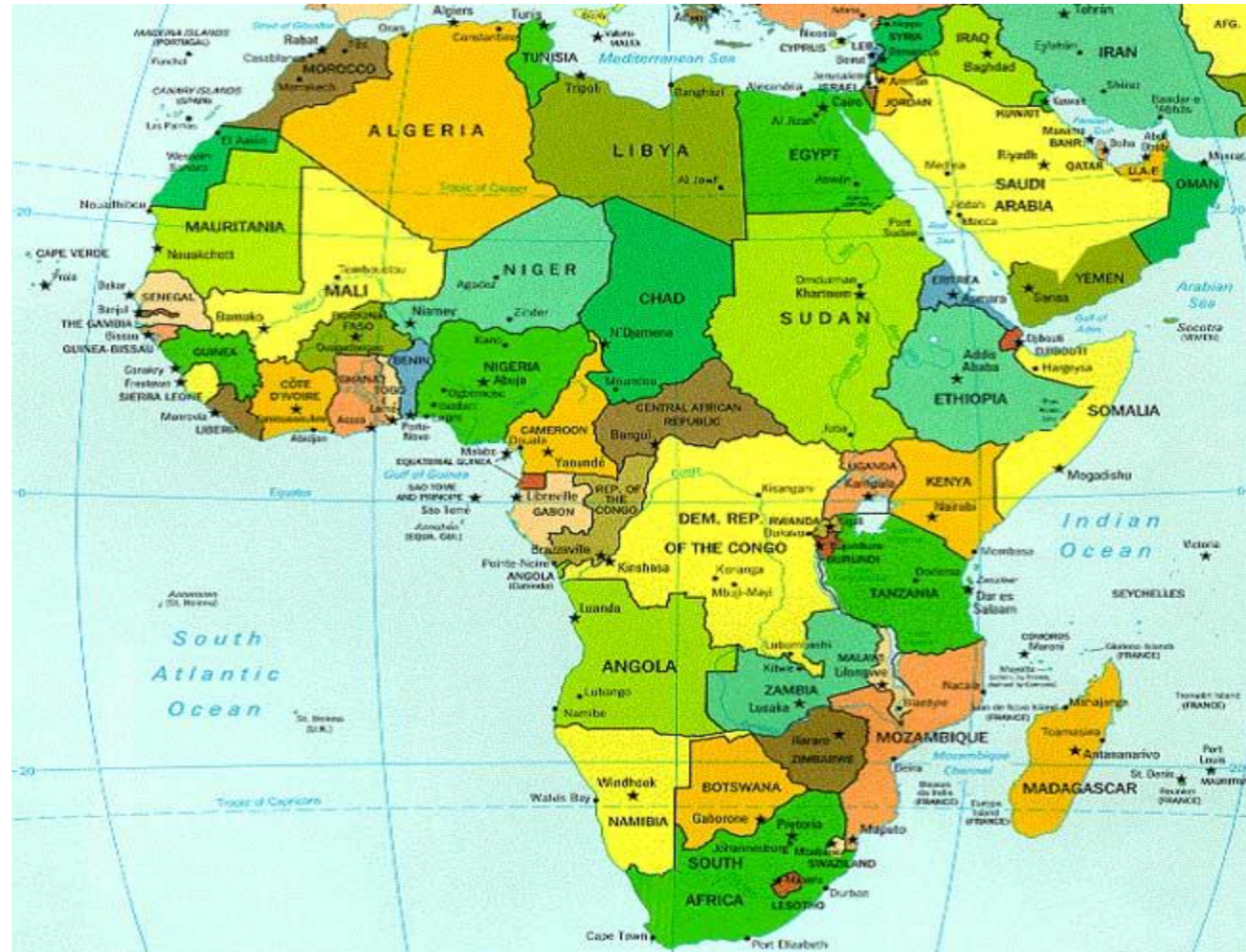


Considerations for ART interruption in African Infants participating in P1115



Outline

- Enrolment into Step 3
- Communicating the message
- Life after STI
- Follow up visits
- Navigating the science
 - Issues for consideration

Enrolment requirements for STI in P1115 (step 3)

- 2 Negative Antibody **AND**
- 2 Negative HIV DNA PCR **AND**
- No detectable HIV RNA **AND**
- CD4 \geq 25% and normal for age cell counts **AND**
- Permanent cessation of breastfeeding for > 6 weeks

Counselling Considerations

- 2 Negative Antibody **AND**
- 2 Negative HIV DNA **AND**
- No detectable HIV RNA

- Counselling
 - Meaning of results vs Community messaging
- Message in the Community is

“ART is for Life”

Infant feeding

- Permanent cessation of breastfeeding for > 6 weeks



- Screening procedures for step 3 may be delayed if breastfeeding is ongoing even though other criteria have been met
- WHO recommendations
 - Continue breastfeeding for 2yrs

Co-morbidities

- TB
 - Malnutrition
 - Pneumonia
 - Malaria
- Caregivers likely to present to local clinic/hospital
 - Care will be determined by non-study staff
 - Potential to “rescue” the child

Follow-up Visits

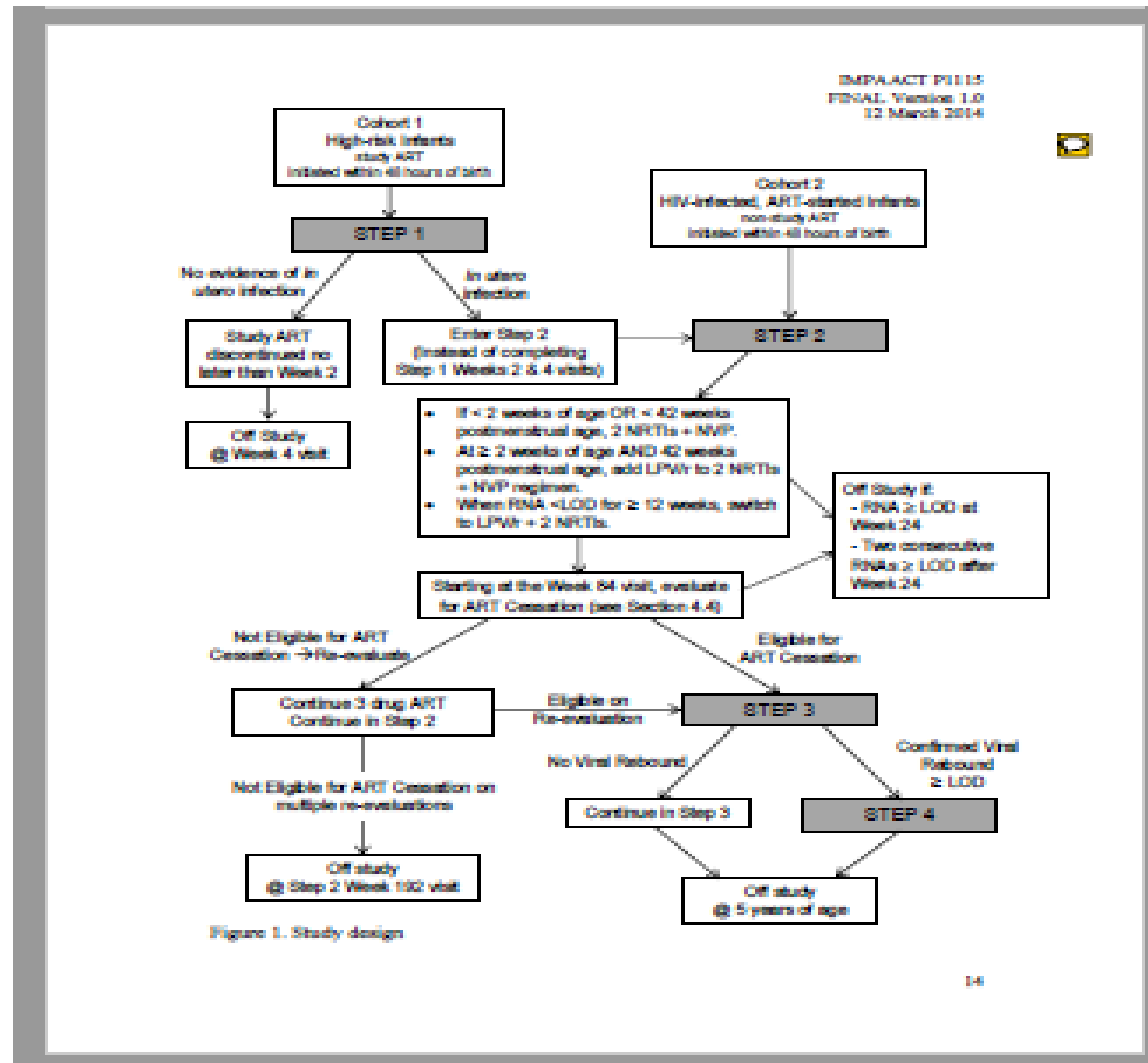
- Every week for first 4 weeks
- Then 2 weekly up to 12 weeks
- Increased frequency from usual 12-weekly which they would have been accustomed to
 - may lead to missed visits
 - Disruption in daily activities
- Initial increase in frequency of blood draws (weeks 1-4, 6,8,12,16)
 - “finishing the child’s blood”

Recommendations

- Communication with health care workers
 - Card or certificate explaining that this participant has had treatment intentionally interrupted for the purposes of P1115 study
- Site preparedness
 - Development of standardised counselling tools to manage STI in P1115
 - Intensive step 3 counselling prior to week 84
- Infant feeding practices
 - Continued breastfeeding counselling support

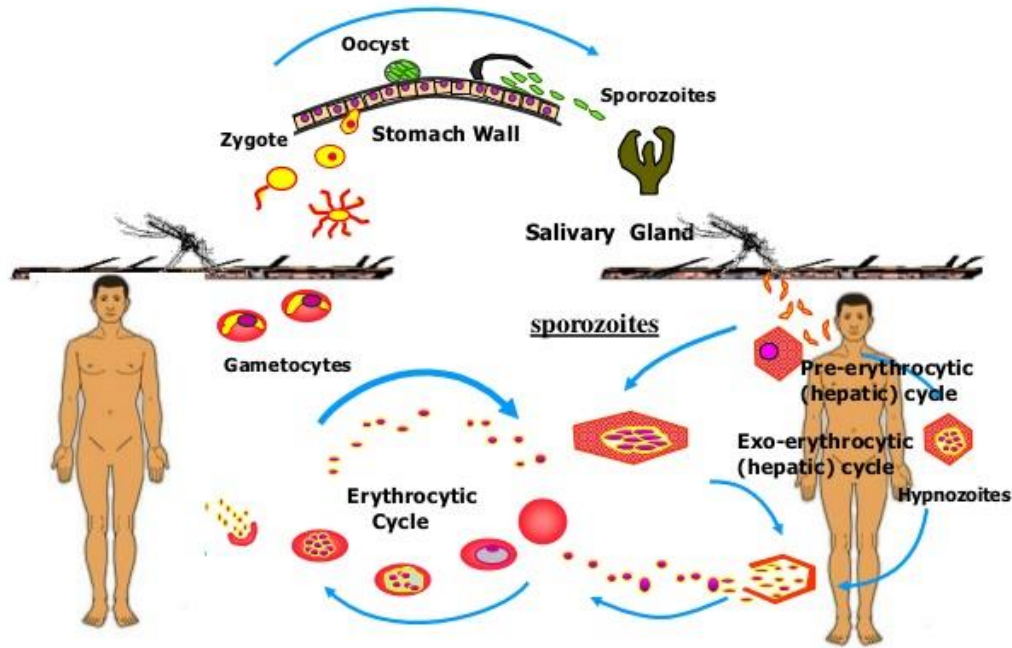
Navigating the Science

P1115 Study Design



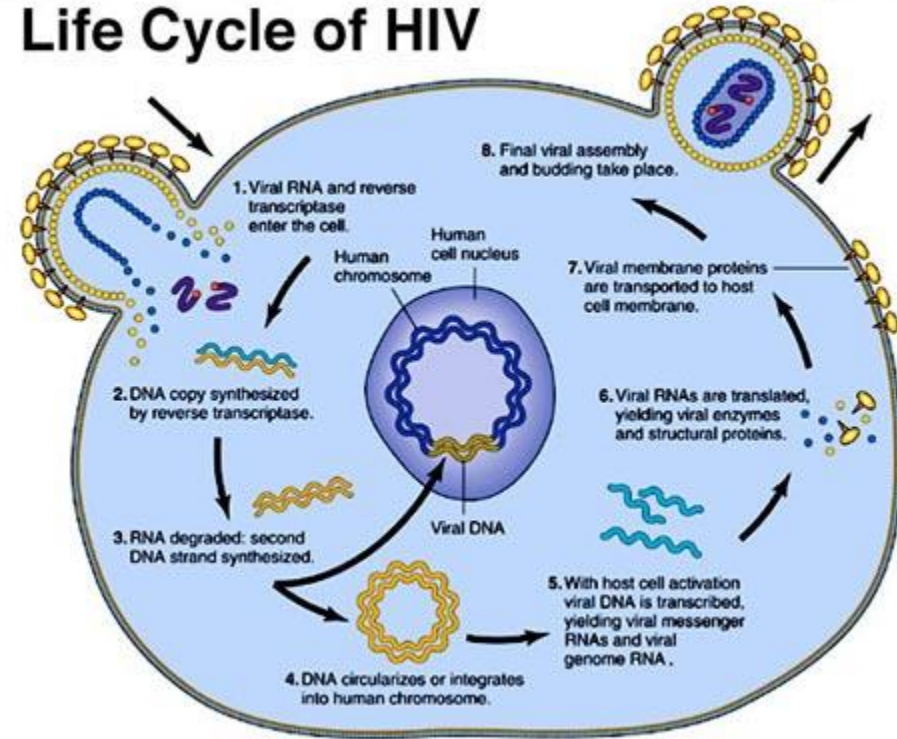
Wish list: "P1115 for dummies"

LIFE CYCLE OF MALARIA

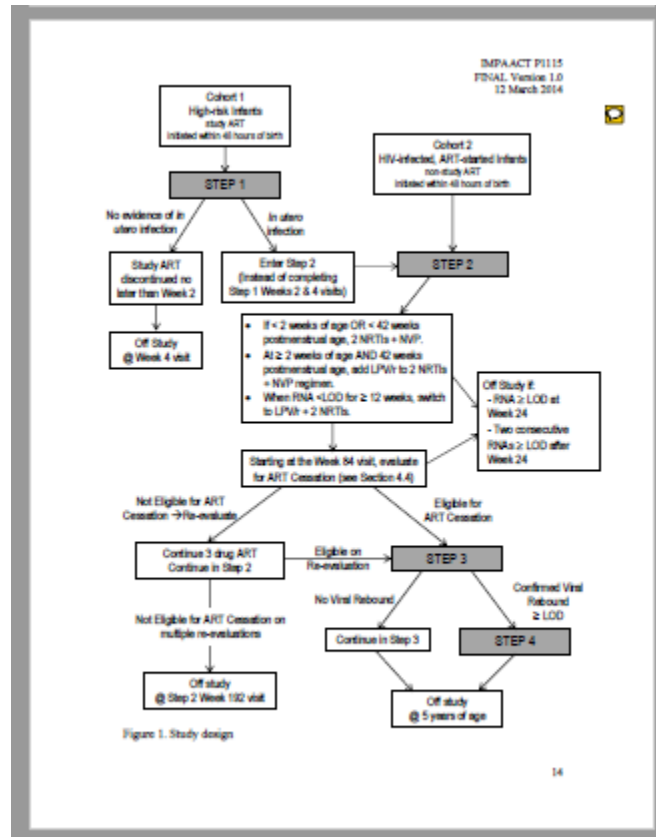


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Life Cycle of HIV



P1115 Study Design



- Pictorial study design for
 - Study staff
 - Participants
 - Stakeholders
 - Other health care workers

Recommendations

- Communication with health care workers
 - Card or certificate explaining that this participant has had treatment intentionally interrupted for the purposes of P1115 study
- Site preparedness
 - Development of standardised counselling tools to manage STI in P1115
 - Consider a flipchart or something similar
 - Intensive step 3 counselling prior to week 84
- Infant feeding practices
 - Continued breastfeeding counselling support

THANKS
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