

PROMISE 1077HS

Adherence Analysis

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Background slide

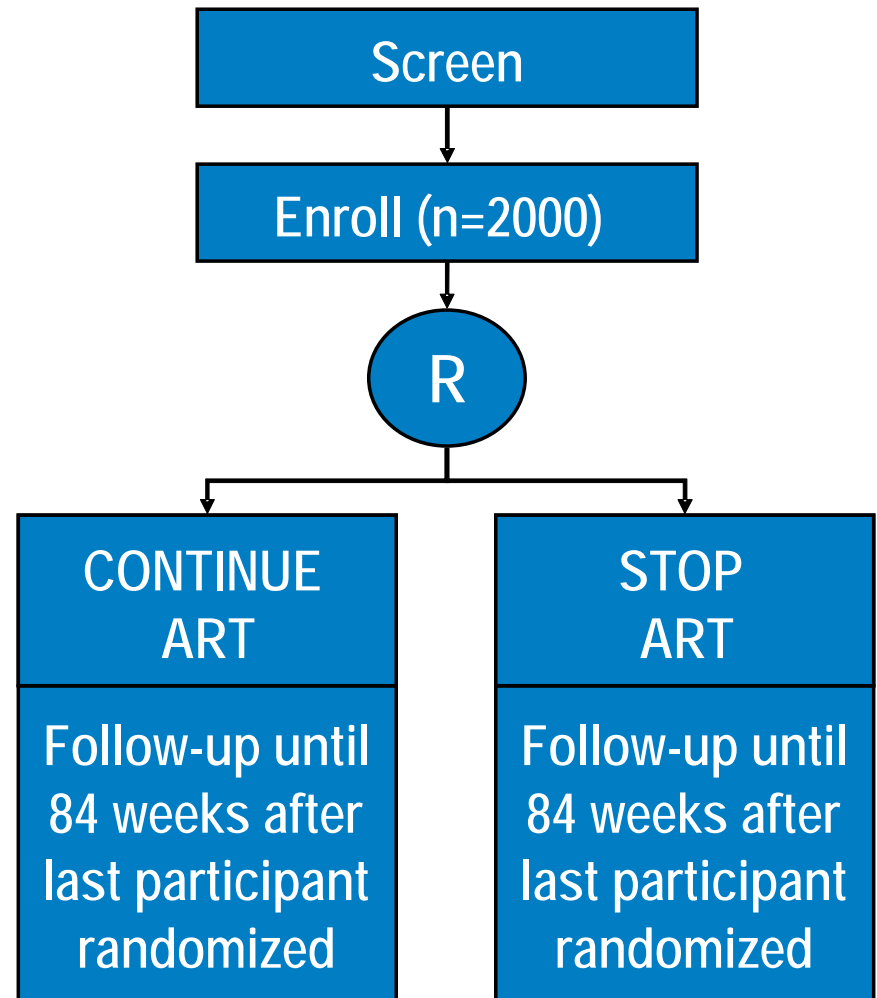
- A randomized strategy trial conducted among women who received highly active antiretroviral therapy (ART) during pregnancy for purposes of prevention of mother-to-child transmission (PMTCT) of HIV but do not otherwise meet criteria to initiate HAART for their own health

PROMISE 1077HS

- To determine whether continuation of HAART (Arm A) after delivery or other pregnancy outcome reduces morbidity and mortality compared to discontinuation and re-initiation of ART according to current standards of care (Arm B).
- The primary combined endpoint includes death, AIDS-defining illness, and serious non-AIDS-defining cardiovascular, renal, and hepatic events.

1077HS Research Question

Among women who do not meet criteria for ART for their own health, who received a triple ARV (ART) regimen during pregnancy for PMTCT, is long term health better served by continuing or stopping ART postpartum?



Primary Adherence Objective

- “To evaluate rates of self-reported adherence to ART and its association with the primary endpoint and with CD4+ cell count, HIV- 1 viral load, and HIV-1 resistance patterns at 1, 2, and 3 years following randomization.”

Adherence Objectives

- To compare adherence among those in the immediate treatment arm to those in the delayed treatment arm
- To compare Quality of Life data between those in the immediate versus delayed ART arms
- To determine which components of the QOL/Adherence/Resource use self report form are most predictive of nonadherence
- To look at geographic differences in adherence

Additional objective

- ~18 months into the study, addition of a detailed adherence questionnaire asking about barriers

- | | | | | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| 1. Side effects make me feel sick | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 2. Following dietary restrictions is hard (taking medicine with or without food)..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 3. Needing to share ART with other family members and friends... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 4. Not understanding how to take the medicine..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 5. Religious beliefs..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 6. Traveling away from home..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 7. Transportation problems getting to the clinic for refills..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 8. Pills getting lost, damaged, or stolen..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 9. It is hard to take so many pills..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 10. I am tired of taking pills every day..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 11. Remembering to take pills every day..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 12. I am busy taking care of my baby..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 13. I am busy doing other things (household work, childcare for older children, working)..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 14. Other health problems or illnesses get in the way..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 15. Fear or worry that other people <u>inside</u> of the home will find out I am sick | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 16. Fear or worry that other people <u>outside</u> of the home will find out I am sick | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 17. I don't feel sick so it is hard to take pills every day..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 18. I don't think the pills work and prefer other types of alternative treatment..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 19. I don't think I need the pills right now because my CD4 T-cell count is high (my immune system is strong)..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 20. If someone saw me taking my pills, they might start asking questions..... | <input type="checkbox"/>
0 | <input type="checkbox"/>
1 | <input type="checkbox"/>
2 | <input type="checkbox"/>
3 |
| 21. Of all the choices above, what is the MAIN reason it is difficult to take medication every day? NOTE: Choose one of the options checked above that is identified as the main reason and enter number here:..... | | | | |

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I. Have you disclosed your HIV status to your primary sex partner?

(Check one box)

Yes 1

No 2

I do not have a primary sex partner (husband or boyfriend) 3

J. Have you disclosed your HIV status to any of the following (outside of primary partner)?

(Check one box for each item below)

	Yes	No	Not applicable
1. Parent(s)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
2. Sibling(s)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
3. Children.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
4. Other relatives	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
5. One or more friends	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
6. Religious leader.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
7. Counselor.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
8. I have not disclosed my HIV status to anyone	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
9. Other, specify	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

NOTE: If you answer 'Yes' to this item, use the line below to specify the category (not name) of person to whom you have disclosed your status. (e.g., Teacher).

Specify [70]: _____

K. Does difficulty telling people about your HIV status (disclosing your HIV status to family and friends) make taking your HIV medications everyday a challenge?

(Check one box)

No, not at all 1

Yes, but rarely 2

Yes, sometimes 3

Yes, much or most of the time 4

Yes, all the time 5

Adherence Objectives

- Among those with evidence of virologic failure (VL > 1,000 copies) due to nonadherence, to characterize most common barriers
- To determine whether barriers vary between those who are adherent and those with episodes of virologic failure
- To determine whether barriers vary by geographic region

PROMISE General Overview: Sequential Randomized 2x2 Factorial Trial

~8,000 women who don't need treatment for own health (CD4 >350)

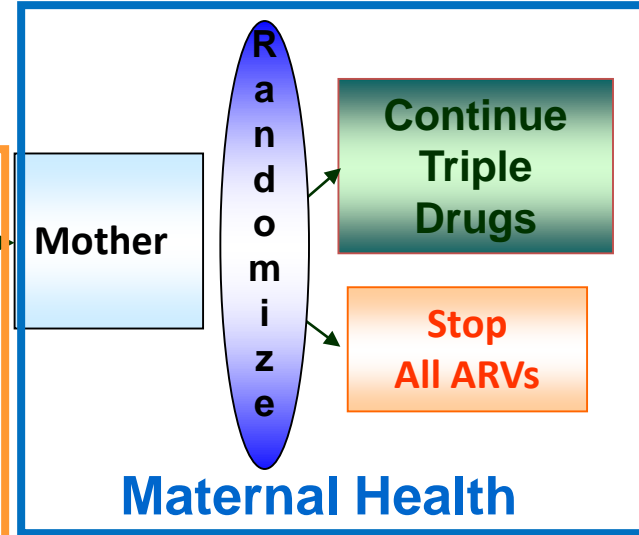
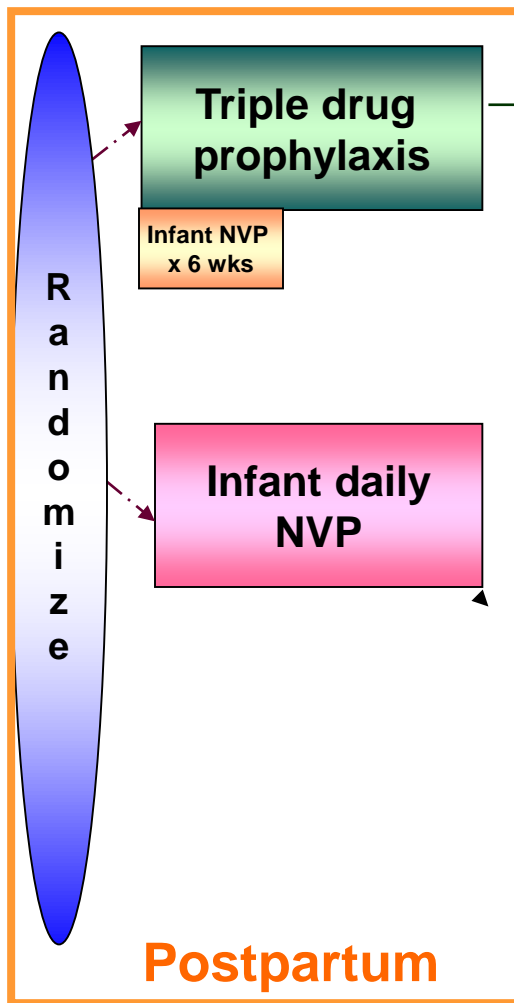
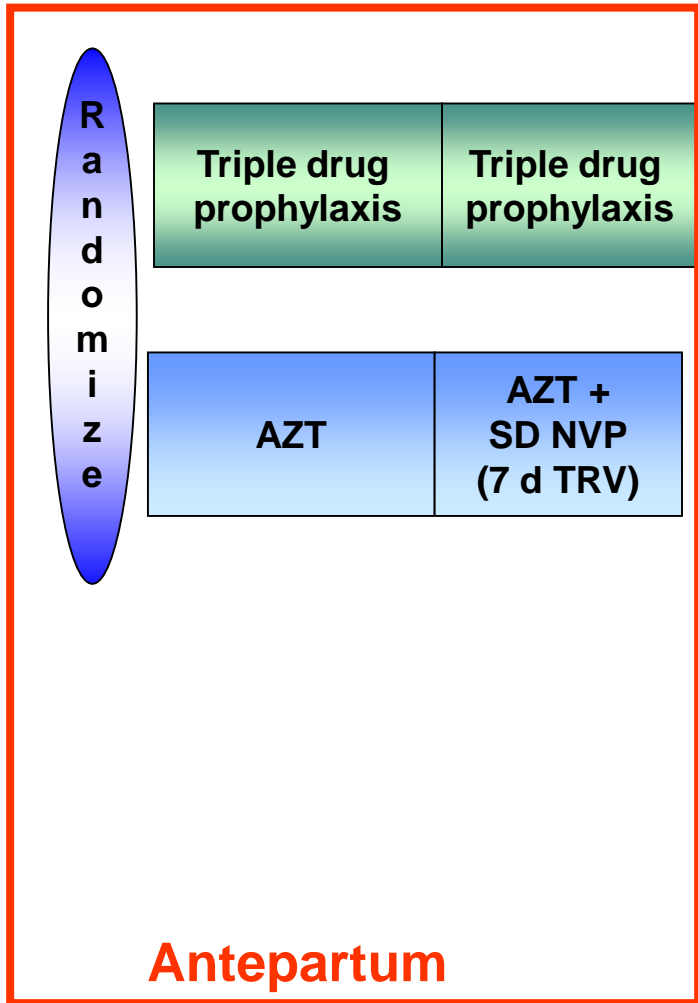
AP 14wk-term

IP

PP for Duration BF

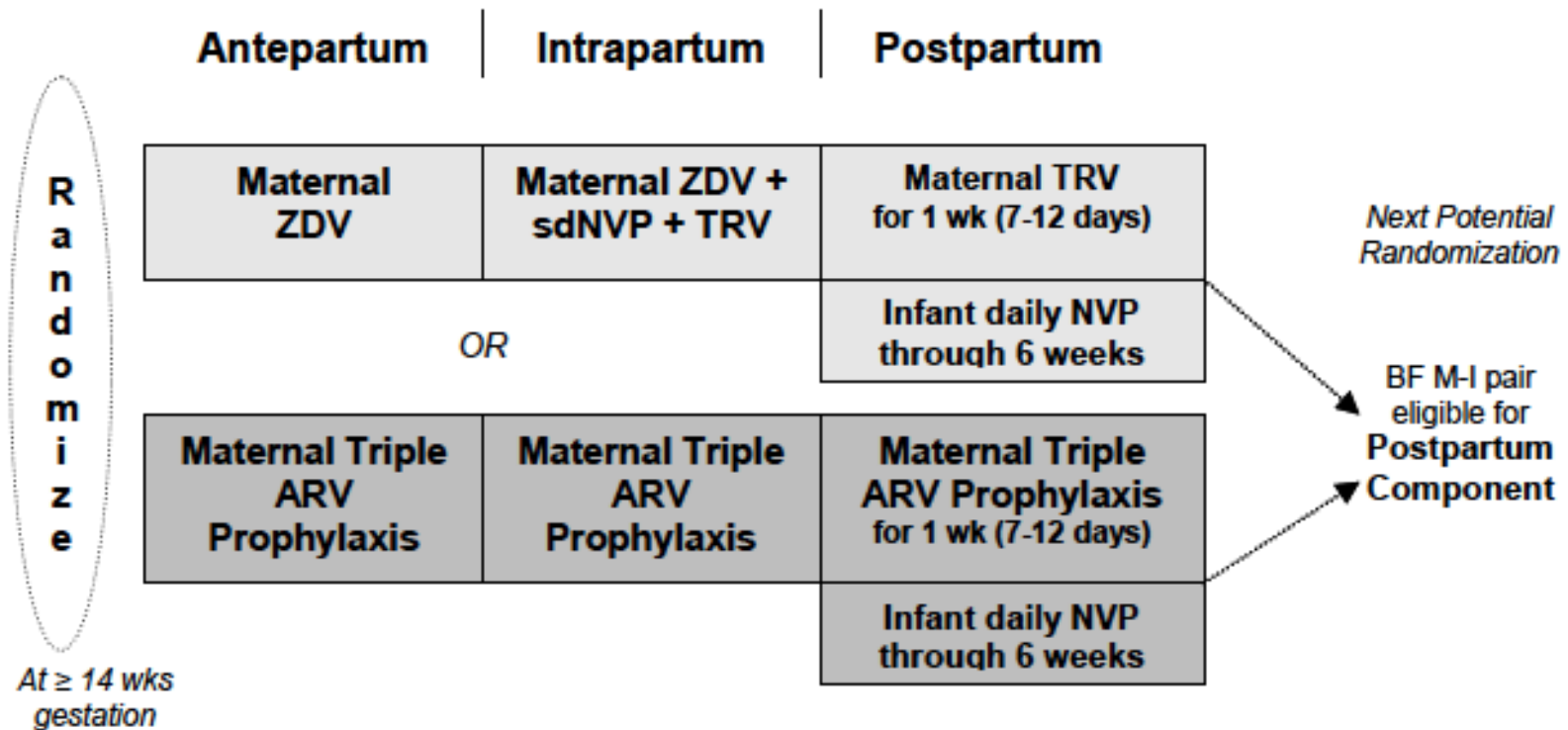
After Weaning

Infant uninfected
at birth



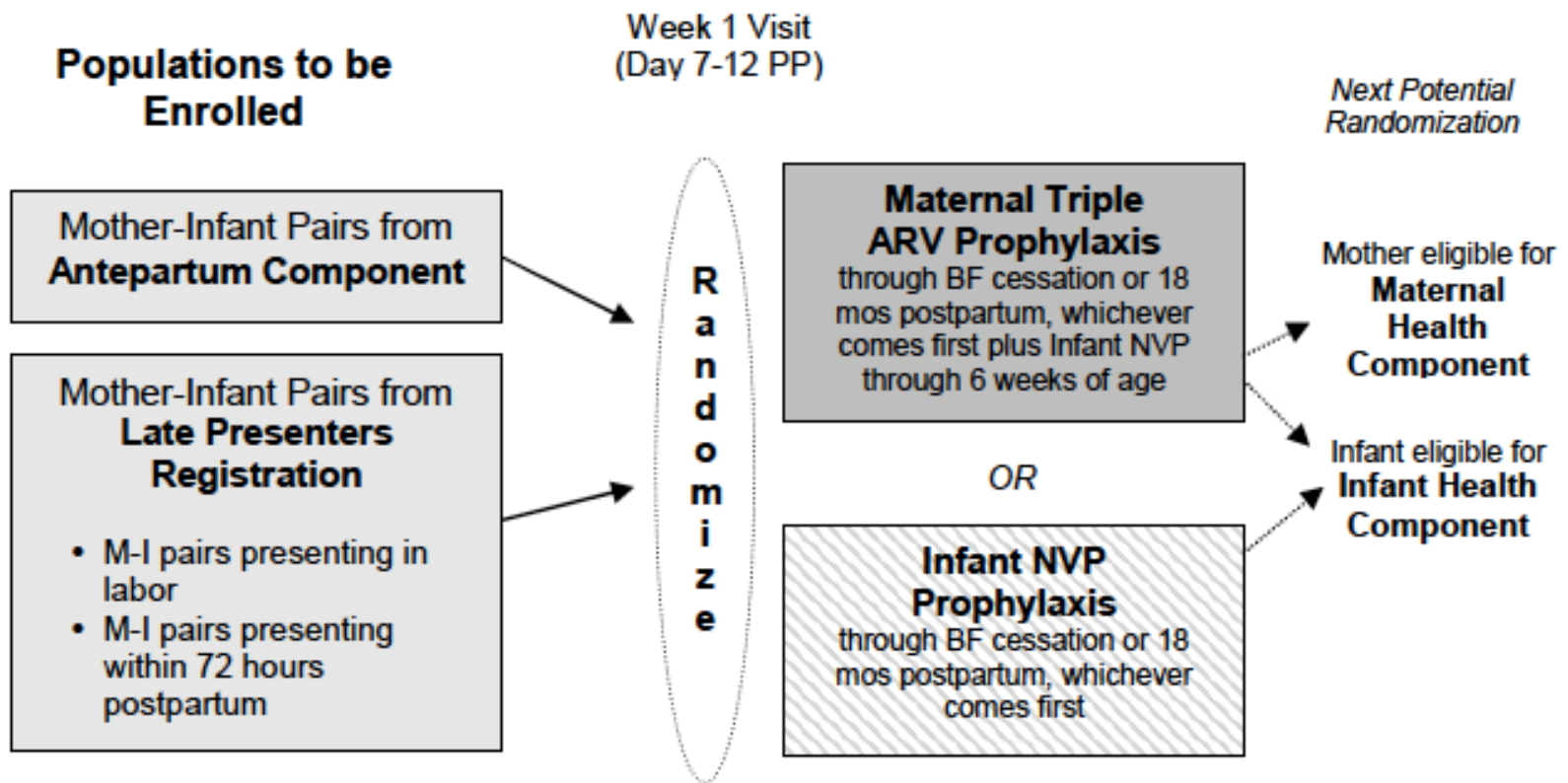
PROMISE 1077BF/FF

Antepartum Randomization: BF Settings (In Countries Where Non-triple ARV AP Regimens are Used for PMTCT)

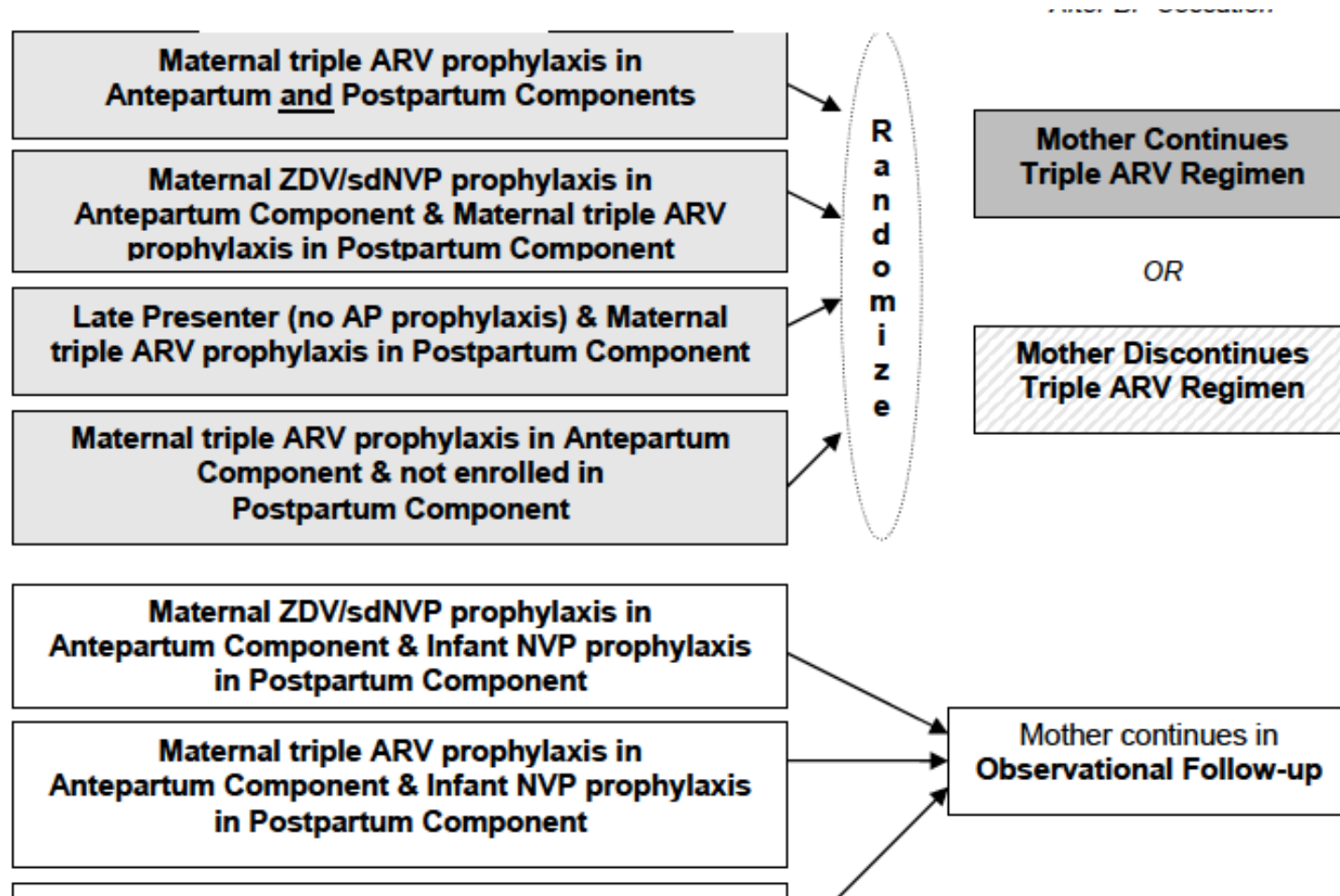


PROMISE 1077BF/FF

Postpartum Randomization: BF Settings



PROMISE 1077BF/FF



1077BF/FF Adherence Objectives

- Antepartum: To evaluate adherence to maternal ARV regimens
- Postpartum: To evaluate adherence to maternal and/or infant ARV regimens
- Maternal Health: To evaluate rates of self-reported adherence and its association with the primary endpoint, CD4 count, viral load, and resistance patterns 1, 2, and 3 years following randomization
- To compare quality of life between study arms at 1, 2, and 3 years
- Additional questions on barriers not added to BF/FF

Additional opportunities BF/FF

- To compare adherence in those in the maternal health arm among those who continue after cessation of breastfeeding versus those who d/c and restart later for maternal health
 - Are factors associated with nonadherence different by region (comparison using 1077HS)

Additional opportunities BF/FF

- To evaluate adherence at different stages (what factors predict high versus low adherence? What factors are associated with specific patterns of adherence: high on all, low on all, mixed)
 - Pregnancy
 - Postpartum up to 3 or 6 months
 - After cessation of breastfeeding among those who continue for maternal health

DISCUSSION