



IMPACT OF AV2 ANTIVIRAL DRUG IN THE TREATMENT OF HPV-ASSOCIATED PRECANCEROUS LESIONS OF THE CERVIX : A Randomized Placebo-Controlled Clinical Trial (KINVAV Study)

Progress Report

Alex Mutombo

Supervisors: Yves Jacquemyn, Jean-Pierre Van Geertruyden, Bogers JP,
Simoens Cindy, Rahma Tozin



Investigational Product: AV2

- Essential natural oil mixed 50 % in olive oil
- Clear cervical lesions due to HPV

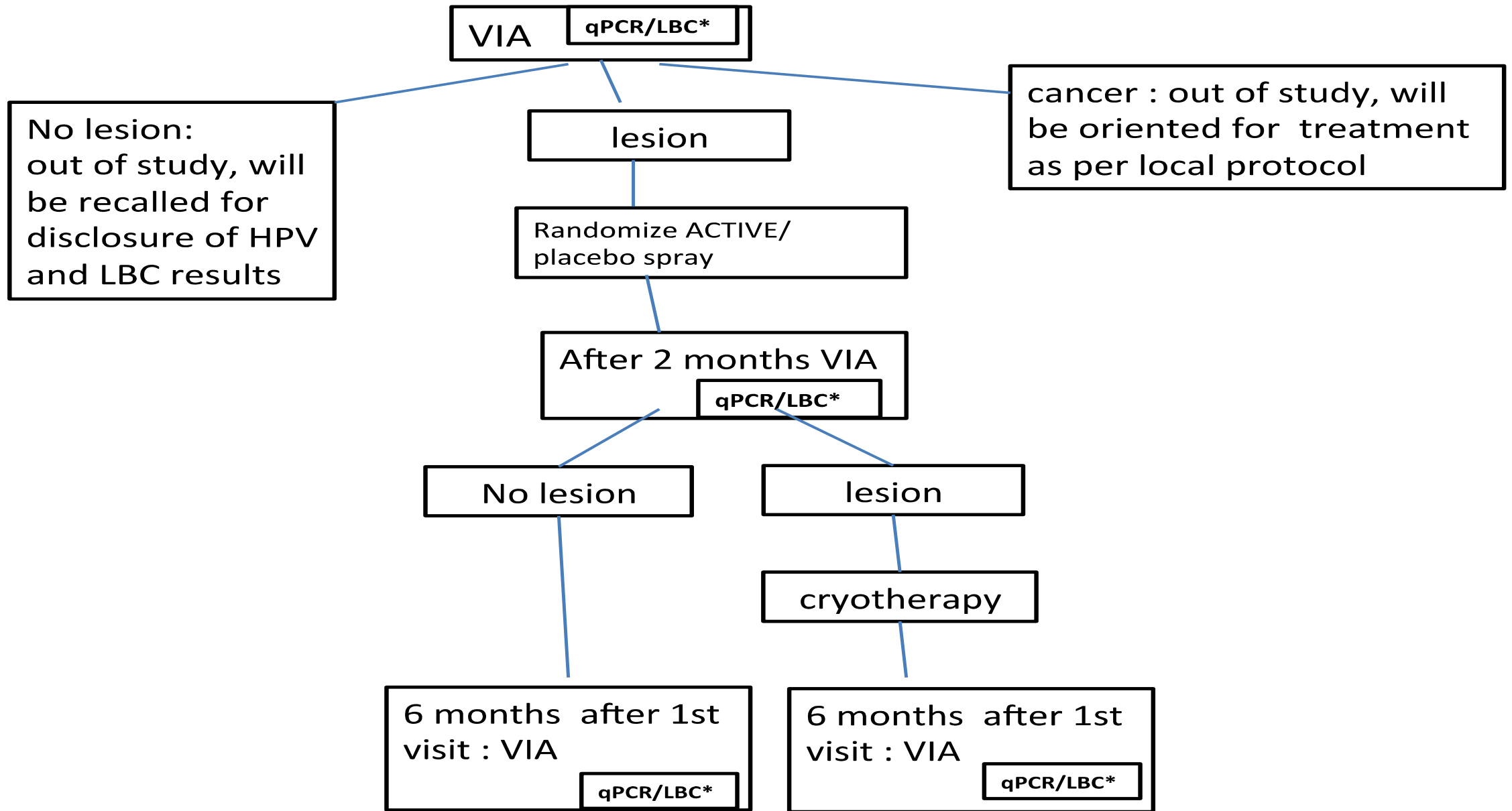
Objectives of the study

1. To evaluate the clinical efficacy of the local virucide AV2[®] in the treatment of HPV-associated lesions of the uterine cervix.
2. To identify the genotypes of HPV found in the Kinshasa region.
3. To test the impact of HPV screening followed by virucide treatment in a see-and-treat setting on HPV infection and associated cervical lesions.

Sponsors and Collaborators

- Universiteit Antwerpen/ VLIR-UOS
- Cesa Alliance
- AML: Prof Bogers, Benoy I
- Sefako Makgatho Health Sciences University: Lebelo RL, Meschack B
- University of Kinshasa

- Approved by IRB/IEC of both Antwerp University Hospital UZA and University of Kinshasa
- Registered in ClinicalTrials.gov: **NCT02346227**



* qPCR and LBC for later analysis not available at randomisation or treatment

Outcomes

- **Primary outcome:** change of lesions 2 months after treatment with AV2[®].
- **Secondary outcomes:**
 - absence of HPV DNA at month 2;
 - correlation between change of lesions and change in HPV DNA at month 2;
 - changes in HPV viral load at month 6;
 - number of participants with adverse effects.

Start inclusion 2
July 2015



YJ Supervising visits

- July 2015
- December 2015
- May 2016

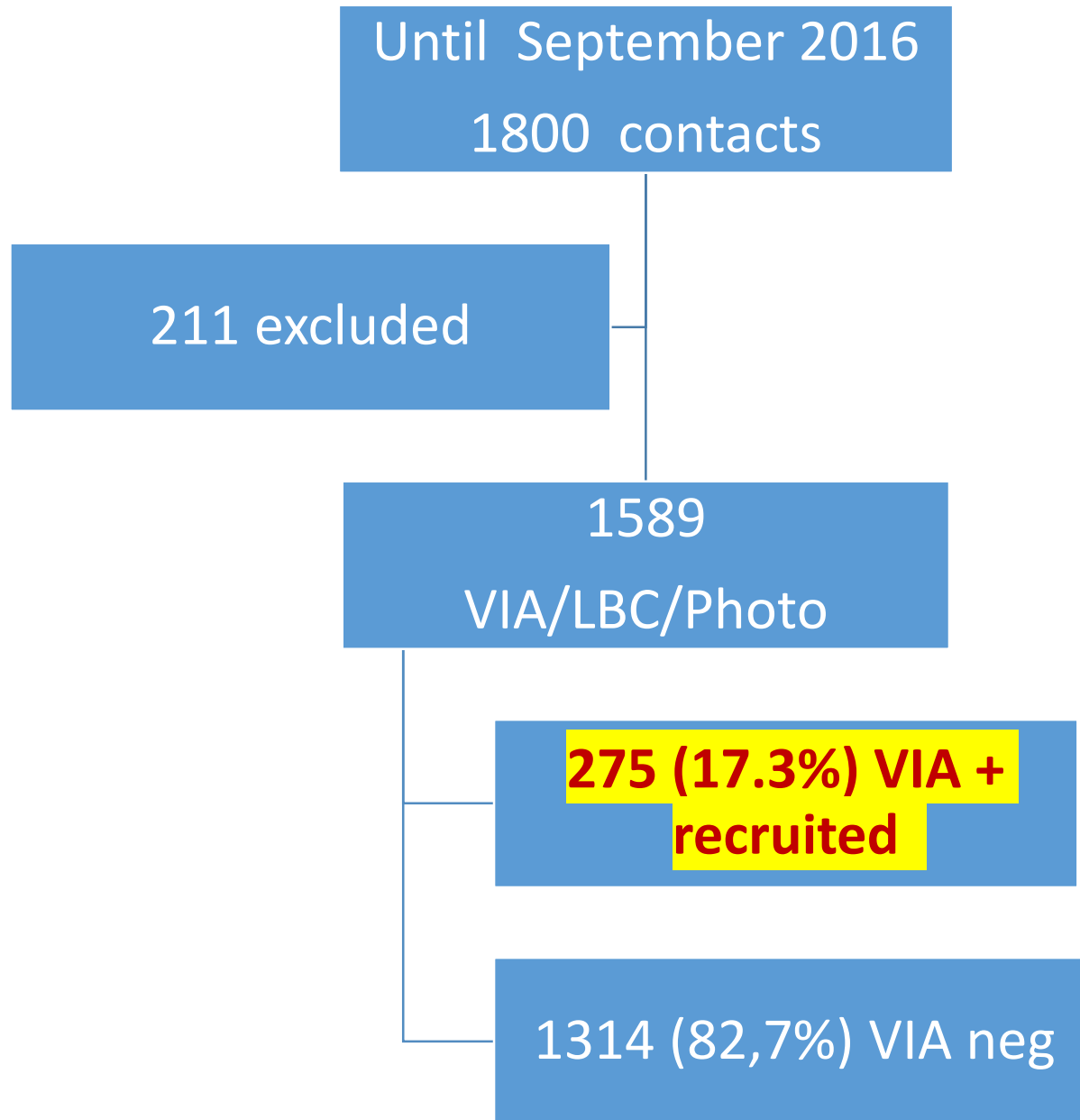


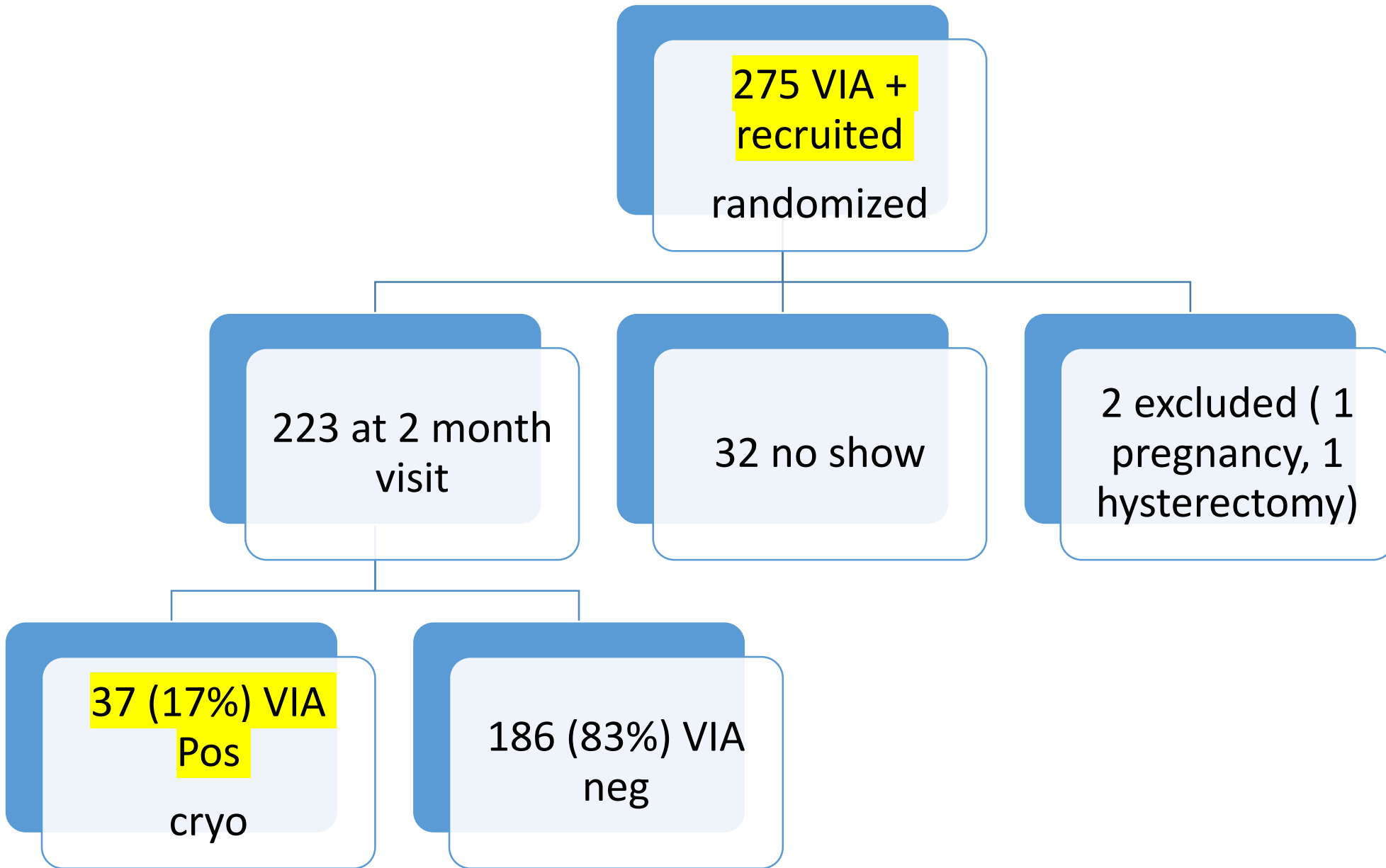
Logistical problems

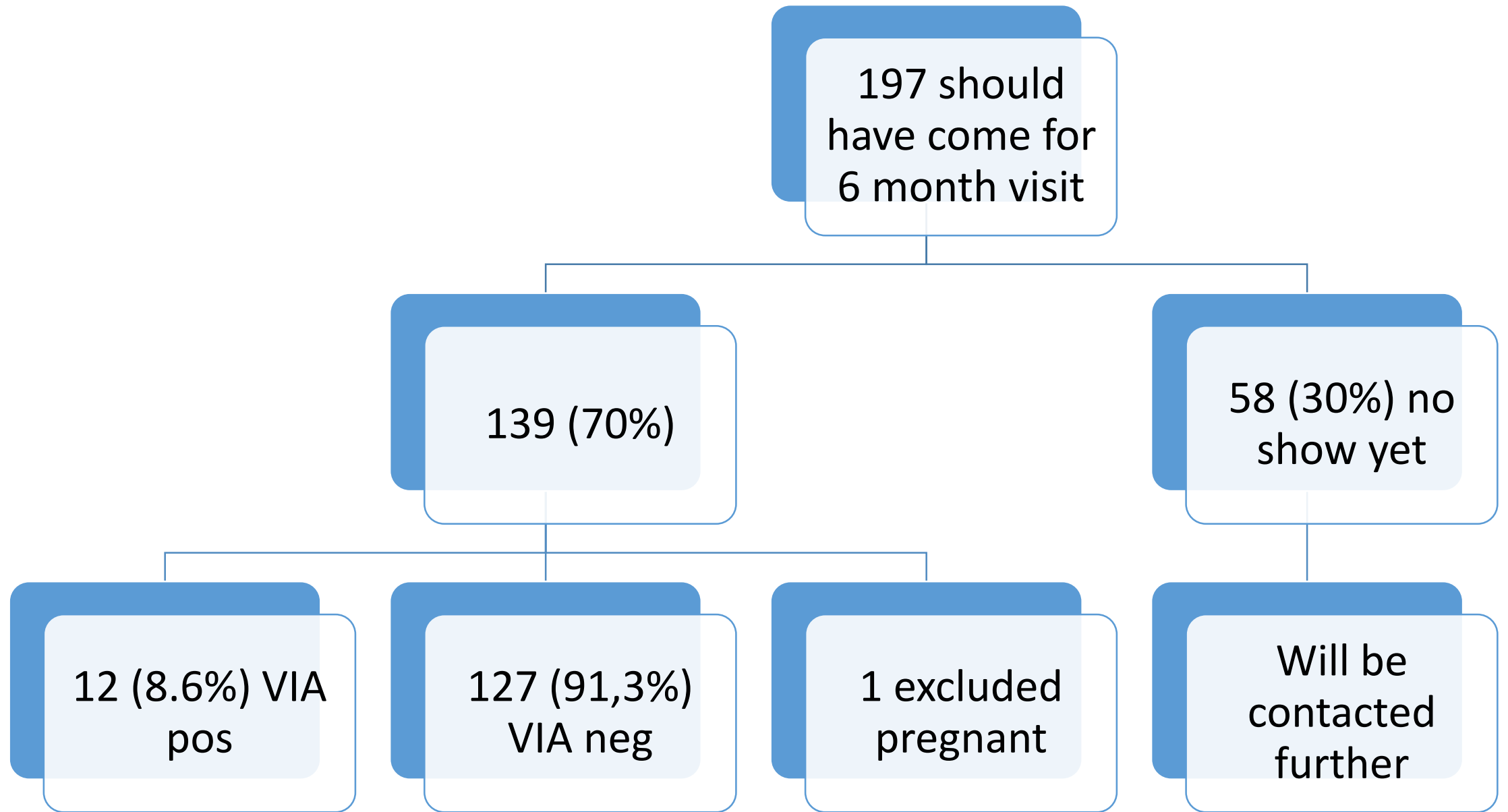
- Shipment of
Thinprep from South
Africa to DRC

- Shipment of
Thinprep samples
from DRC to South
Africa

- Difficulties to
reaching out women
for control visit
(diverse reasons)







Situation on 22 September 2016

Cytology results SMU

| Results | n=500 | % |
|-----------|-------|------|
| NILM | 471 | 94,2 |
| ASCUS | 6 | 1,2 |
| LSIL | 22 | 4,4 |
| HSIL CIN2 | 1 | 0,2 |
| HISL CIN3 | 0 | 0 |

Cytology results AML

| Results | n=45 | % |
|---------|------|-------|
| NILM | 43 | 95,6 |
| ASCUS | 2 | 4,4 |
| LSIL | 0 | 0,0 |
| HSIL | 0 | 0,0 |
| TOTAL | 45 | 100,0 |

Cytology Results: Overall

| | | |
|-------|-----|-------|
| NILM | 514 | 94,3 |
| ASCUS | 8 | 1,5 |
| LSIL | 22 | 4,0 |
| HSIL | 1 | 0,2 |
| TOTAL | 545 | 100,0 |

Qualitative HPV (SMU)

| HPV | N | % |
|----------|-----|-------|
| positive | 7 | 3,8 |
| HR HPV | 20 | 10,8 |
| negative | 159 | 85,5 |
| Total | 186 | 100,0 |

Qualitative HPV testing (AML)

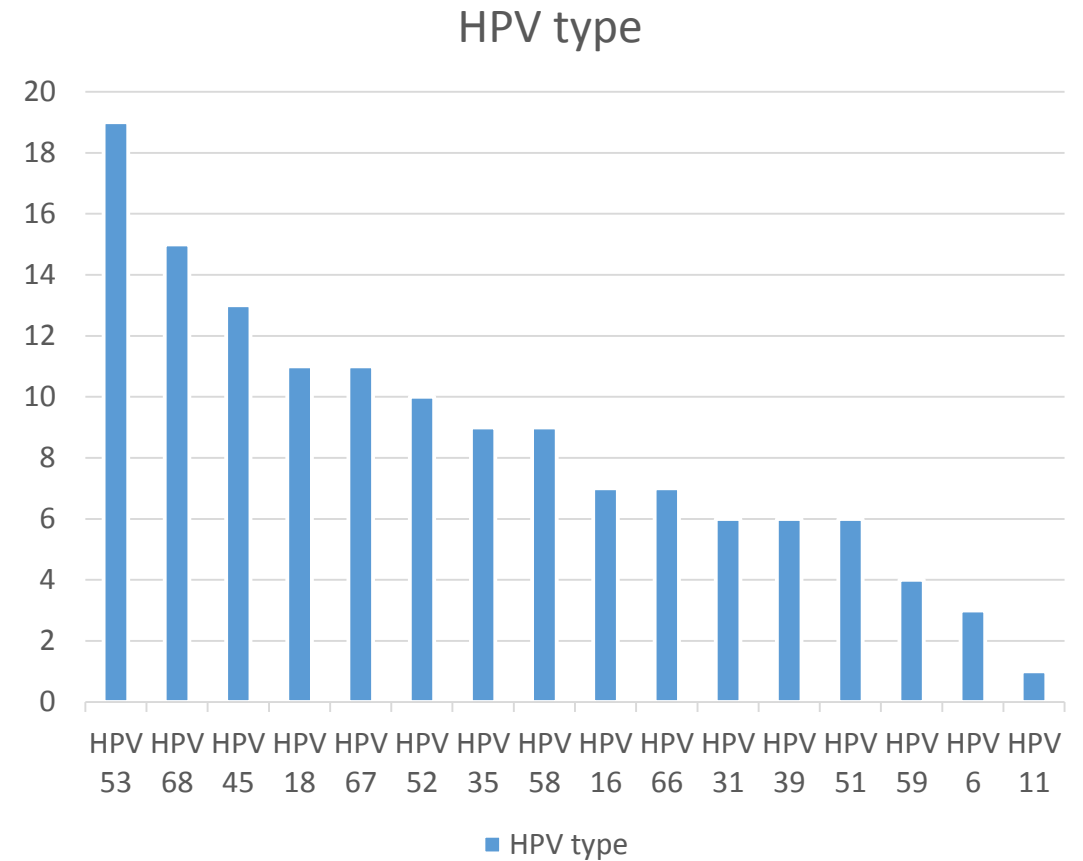
| | | |
|----------|-----|-------|
| positive | 55 | 16,9 |
| HPV Pos | 33 | 10,2 |
| negative | 237 | 72,9 |
| Total | 325 | 100,0 |

HPV Prevalence

| HPV Testing | N | % |
|-------------|-----|------|
| Positive | 115 | 22,5 |
| Negative | 396 | 77,5 |
| Total | 511 | 100 |

HPV Genotypes found in 88 HPV positive Specimen

| | HPV Strains | N Specimen |
|----|-------------|------------|
| 1 | HPV 53 | 19 |
| 2 | HPV 68 | 15 |
| 3 | HPV 45 | 13 |
| 4 | HPV 18 | 11 |
| 5 | HPV 67 | 11 |
| 6 | HPV 52 | 10 |
| 7 | HPV 35 | 9 |
| 8 | HPV 58 | 9 |
| 9 | HPV 16 | 7 |
| 10 | HPV 66 | 7 |
| 11 | HPV 31 | 6 |
| 12 | HPV 39 | 6 |
| 13 | HPV 51 | 6 |
| 14 | HPV 59 | 4 |
| 15 | HPV 6 | 3 |
| 16 | HPV 11 | 1 |



- **HPV 53 and 68 are the most prevalent HR-HPV types found and this situation may compromise the effect of vaccination with current vaccine targeting HPV 16 and 18.**

Questions to work out

Which VIA were
HPV positive?

Which VIA were
ASCUS, LSIL, HSIL...

Missed ASCUS,
LSIL, HSIL by VIA

Correlations
between Cytology
vs HPV testing

HPV genotype and
cytology/ VIA

After unblinding

Changes in
viral load

Differences in
VIA regression

THANK YOU