



Good immune restitution but unsatisfactory viral suppression in children on ART in a remote Western Kenyan area

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BACKGROUND

In the context of scaling-up of antiretroviral treatment (ART), WHO recommends simplifying the follow-up of children living in areas with restricted access to laboratory facilities. However, little information is available on the long-term outcomes of such strategy.

MSF-F program in Homa-Bay

Homa-Bay district
 - 350,000 inhabitants
 - 35% of HIV prevalence in district hospital (Sentinel surveillance, MoH 2003)

In March 28th, 2007
 - 5138 patients had initiated ART
 - 3755 patients still followed on ART



ART prescription in MSF program

- Every day in Homa-Bay district hospital
- Once per week in mobile clinics located in 3 peripheral Health Centers (HC)

Strategy of care in children

1. Criteria for initiating ART

- WHO stage 3 or 4 and/or
- Children with a severe immune suppression such as :
 From 2001, children aged 0-18 months CD4 < 20%
 18-59 months < 15%
 5-14 years CD4 < 200 cells / mm³
 From February 2006 : 0-11 months CD4 < 25%
 12-35 months < 20%
 36-59 months < 15%
 5-14 years CD4 < 200 cells / mm³

2. First line regimens recommended by WHO

3. d4t-3TC-NEV as generic Fixed Dose Combination (FDC) with drug formulation according to child weight :

- >25kg : Adult Triviro tablet
- 10-25kg : Half adult Triviro tablet
- < 10kg : Syrup formulation

4. Clinic attendance :

- Visit once per month during the first 6 months by a clinical officer
- Visit every 2-3 months as stabilized on ART

5. Adherence support :

- Designation of a care giver
- 2 counseling sessions pre-ART initiation
- 4 adherence sessions during the first 6 months then every 6 months

6. Biological monitoring : CD4 count every 12 months

7. Daily cotrimoxazole prophylaxis

8. Nutritional support : Ready to Use Therapeutic Food for acute malnutrition Weight-Height <80% of the reference median

OBJECTIVE

Main objective :

Assessment of long term outcomes in children followed in a remote area

Specific objectives :

Outcomes at 24 and 36 months on ART in children followed in Homa-Bay program in terms of : survival, viral failure, immuno-restitution, drugs toxicities

METHODS

1. Retrospective analyses of surveillance data

- Recall period: 19 Dec 2001- 28 Mar 2007
- Target population : All children under 15 years starting ART in the Homa-Bay program
- Data collected in the Fuchia software (Epicentre, Paris, France)
- Probabilities of remaining in care [Confidence Interval (CI) 95%] using Kaplan Meier analysis with death and lost to follow-up as combined endpoint.

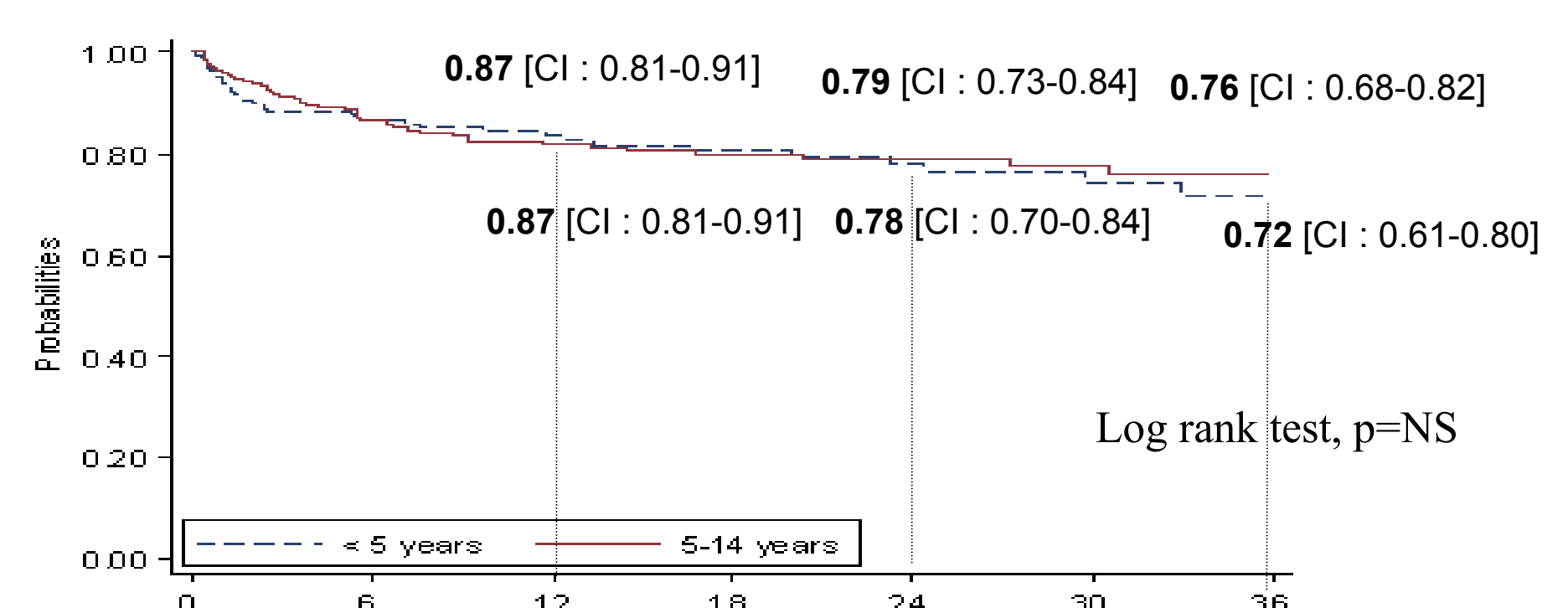
2. Cross sectional evaluation of viral load and toxicities at 24 and 36 months on ART

- Study period : 01 Oct 2006 – 30 April 2007
- Target population : All children under 15 years receiving ART for 24 or 36 months +/- 2 months
- Clinical and biological evaluation including HIV viral load (VL) measurement (detection threshold : 300 copies/mm³)
- Factors associated with a VL ≥ 10 000 copies/mm³ (virological failure) studied by logistic regression

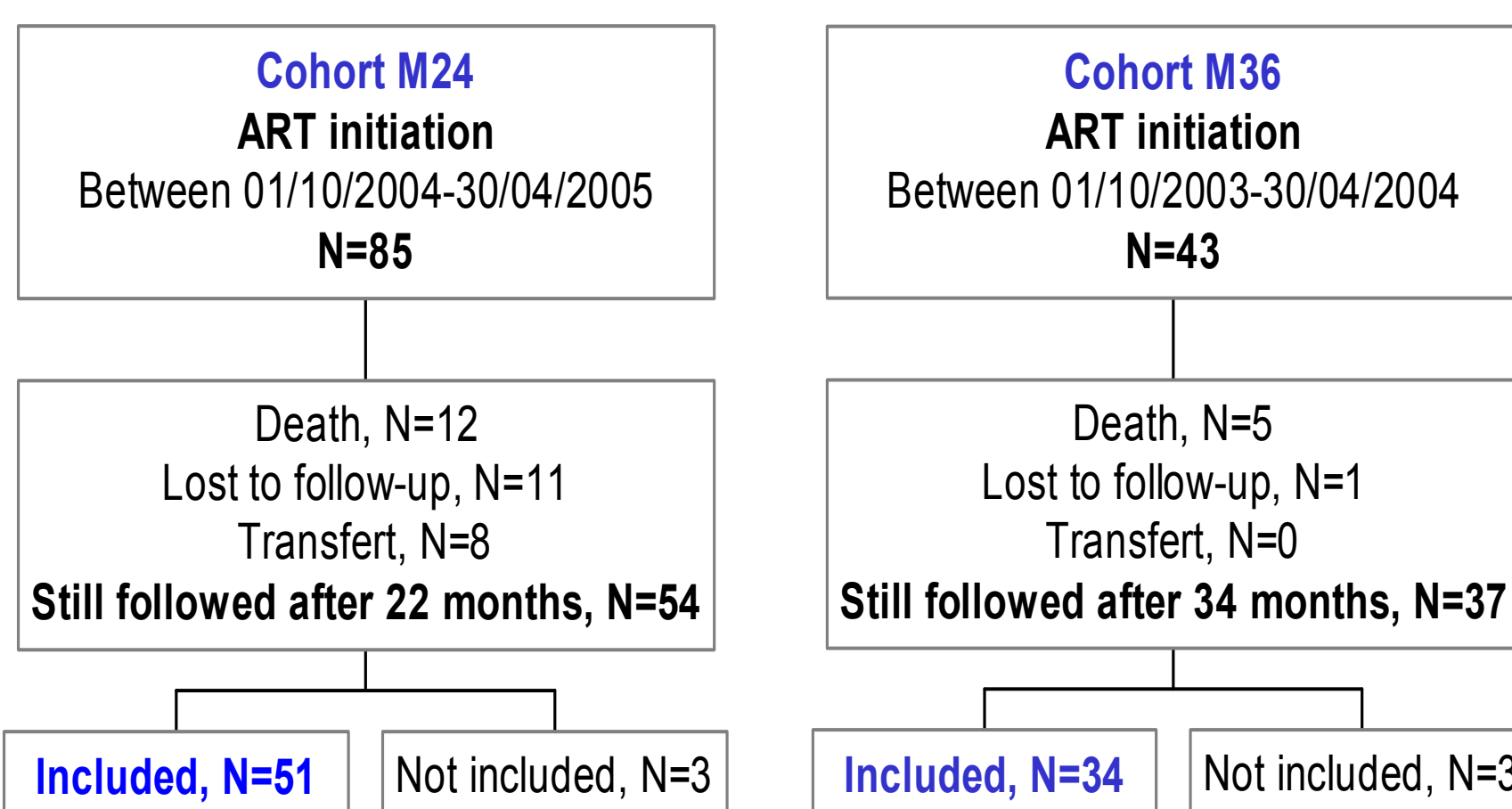
RESULTS

Retrospective analysis- Baseline characteristics and probability of remaining in care among children on ART

ART initiation period	19 Dec 2001- 28 Mar 2007	
Total < 15 years	432 children	
Female	204	47.2 %
WHO Stage 3	173	40.0 %
Stage 4	89	20.6 %
ART regimens		
d4T-3TC-NVP	213	49.3 %
AZT-3TC-NVP	120	27.8 %



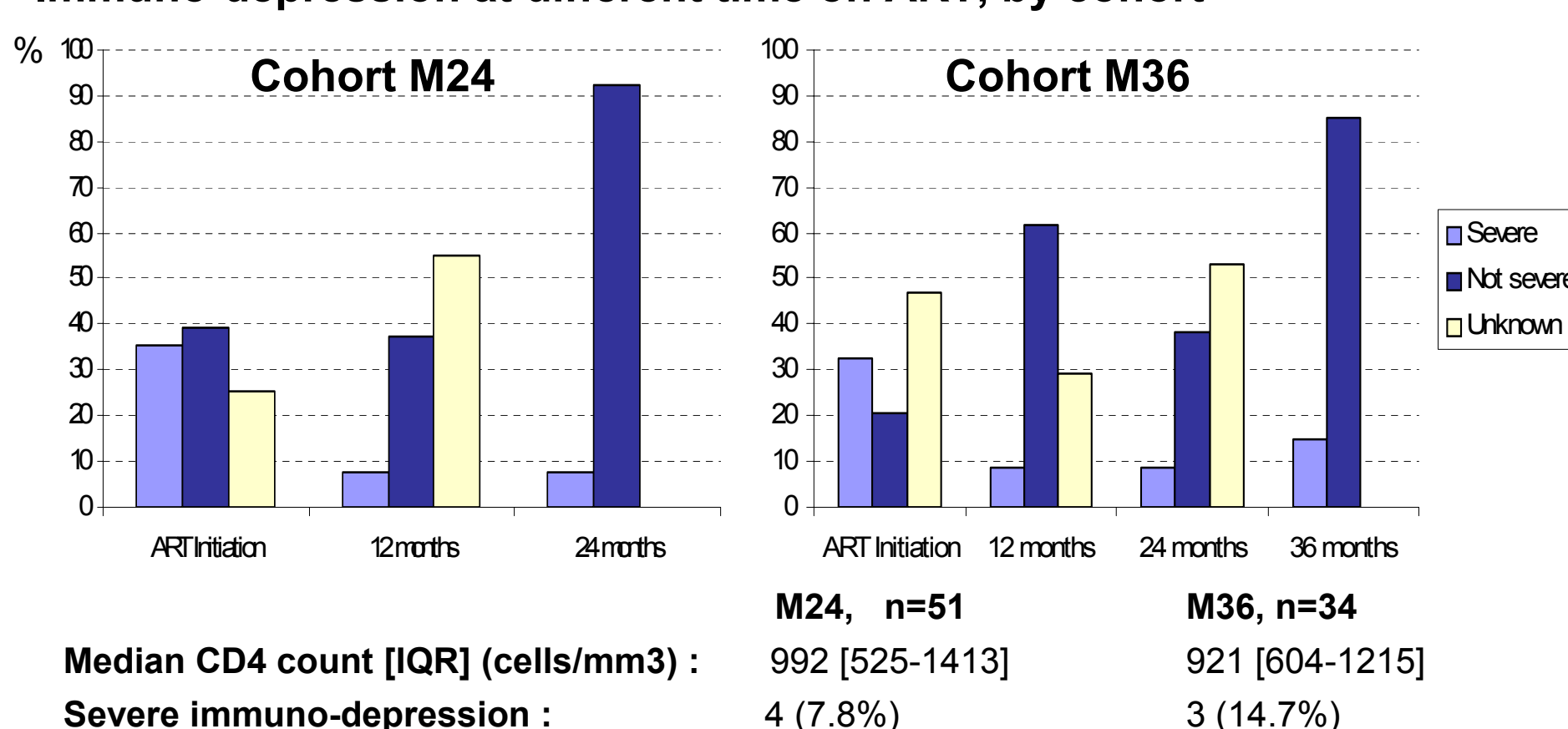
Cross-sectional evaluation in children after 24 and 36 months on ART



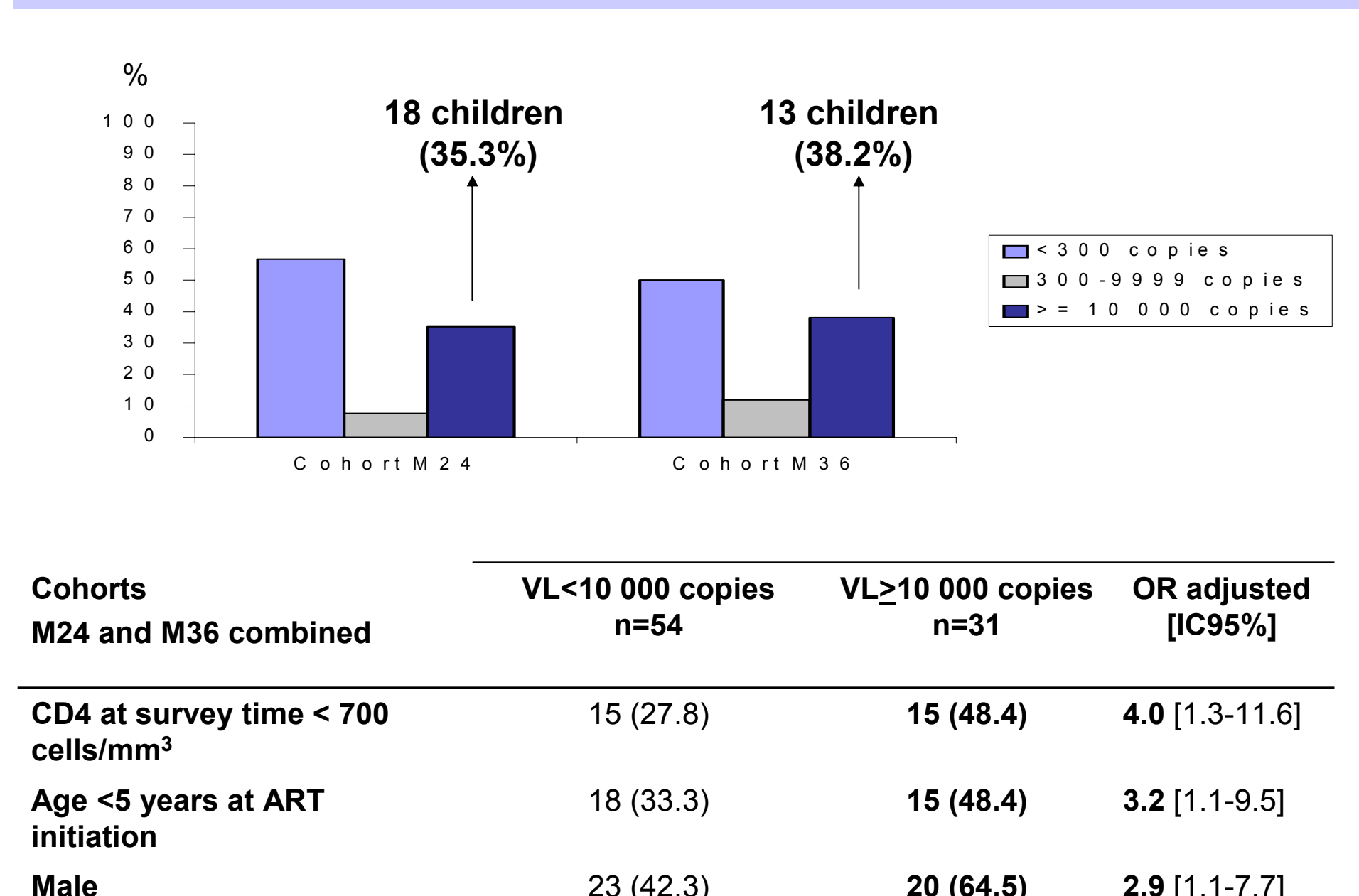
	Cohort M24 n=51	Cohort M36 n=34
Median age at ART initiation [IQR]	4 years [3-4]	4 years [3-4]
Male, n (%)	26 (51.0)	17 (50.0)
Orphans, n (%)	17 (33.3)	9 (26.5)
d4T-3TC-NVP at initiation, n (%)	36 (70.6)	20 (58.8)
Change at least one ARV drug, n (%)	8 (15.7)	15 (44.1)
Median follow-up time [IQR]	25.4 months [23-27]	36.6 months [35-40]
ART compliance in last 4 days, n (%)	50 (98.0)	31 (91.2)

Immune restitution

Immuno-depression at different time on ART, by cohort



Viral failure



Toxicity

A total of 36 (42%) children had WHO grade 1 hypersensitivity and 3 (4%) grade 1 abdominal distension.

CONCLUSION

Survival of children after 2 and 3 years of ART was similar to that reported in adults living in remote areas. Immune restitution was good but, despite an apparently well tolerated treatment, the absence of viral suppression in 50% of children is worrying. Efforts to provide more adapted ARV paediatric formulations and develop new long-term adherence strategies for children should be re-enforced.