

# Cohort audit of patients starting ART from naïve

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## Description

To audit outcomes in adult patients starting ART from naïve:

- ☞ Primary outcome: VL measured closest to 6 months after starting
- ☞ Prospective design: where relevant, analyses include patients who stopped ART and/or ceased attending for care.

# Participation

Patients over 15 starting ART from naïve during April-September 2006 were eligible for inclusion.

Set up phase:

- ☞ 133 clinical centres submitted data for 1319 patients, of which 18 were ineligible and excluded.

Follow up phase:

- ☞ 11 centres did not take part, accounting for 86 patients.
- ☞ 1215 patients from 122 centres were included in analyses.

## Participation, continued

Among these 1215 patients:

- ☞ 45 had major discrepancies\* between set-up and follow-up forms. These were excluded from analyses involving matching of data between these forms.
- ☞ 1170 were eligible for inclusion in all analyses.
- ☞ Some data points were incomplete for many patients. Missing data has been omitted from slides for clarity.

\*eg wrong sex, wrong ethnicity, date of starting (prescribing) ART differing by 30 or more days.

## Patient characteristics

		Number (%)
Sex:	Male	629 (53.8)
	Female	508 (43.4)
	Not stated	33 (2.8)
Ethnicity:	Black-African	570 (48.7)
	White	452 (38.6)
	Black-Caribbean	43 (3.7)
	Other	79 (6.8)
	Not stated	26 (2.2)
Known to be pregnant at outset:		193 (16.5)

## Patient characteristics, cont.

Baseline CD4	Number (%)	Baseline VL	Number (%)
0-50	222 (19.1)	0-1000	40 (3.5)
51-200	478 (41.1)	1001-10,000	152 (13.2)
201-350	350 (30.1)	10,001-50,000	272 (23.7)
351-500	61 (5.3)	50,001-100,000	189 (16.4)
>500	52 (4.5)	>100,000	496 (43.2)

## Pre-ART resistance testing

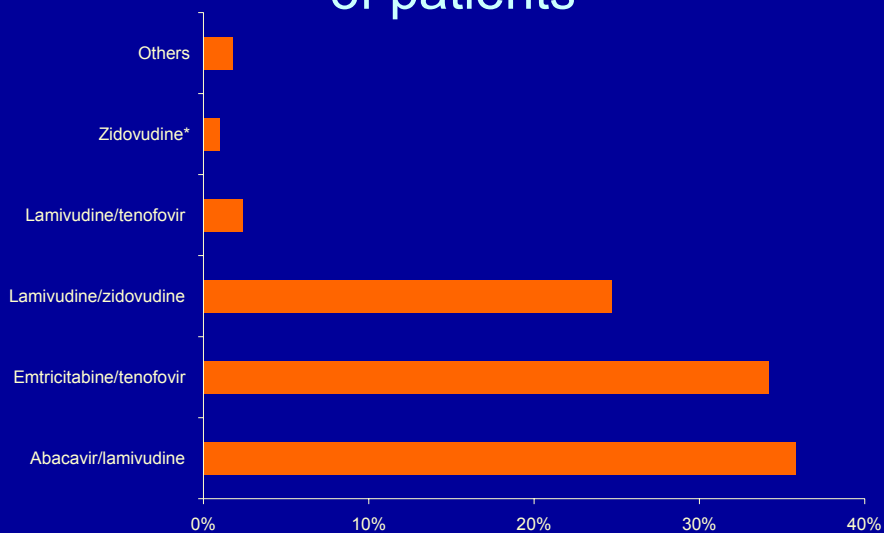
- ☞ 843 (72.1%) had a resistance result available when starting ART
- ☞ 77 (6.6%) had been tested but the result was not available
- ☞ 192 (16.4%) had not been tested
- ☞ 41 (3.5%) were reported as not known whether tested
- ☞ 17 (1.5%) no answer.

## Resistance at baseline

Of those for whom a resistance result was available when starting ART:

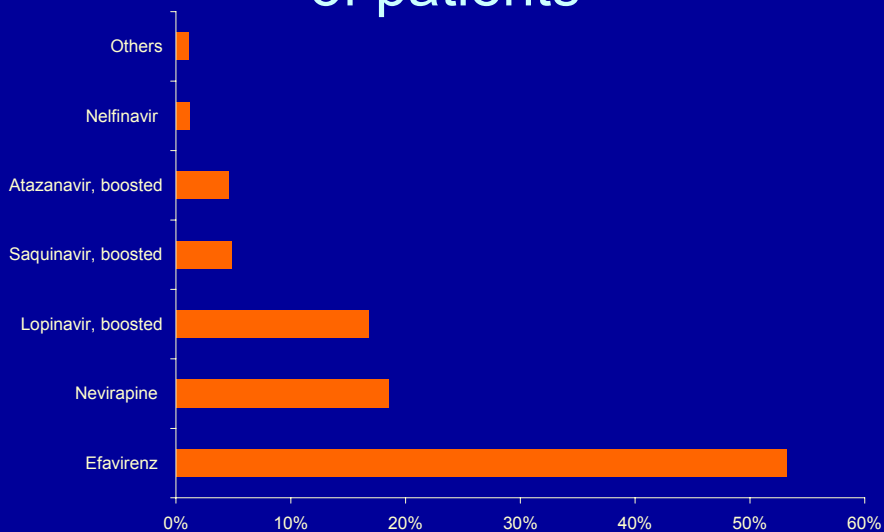
- ☞ 787 (93.5%) reportedly showed no resistance
- ☞ 47 (5.6%) showed single class resistance
- ☞ 8 (0.95%) showed multi-class resistance
- ☞ 1 (0.12%) showed resistance, classes not stated.

## Initial drug “backbones” – percentage of patients



\*All pregnant.

## Initial PIs/NNRTIs – percentage of patients



## Primary outcome: viral load at follow-up

VL outcomes for the 1215 patients were:

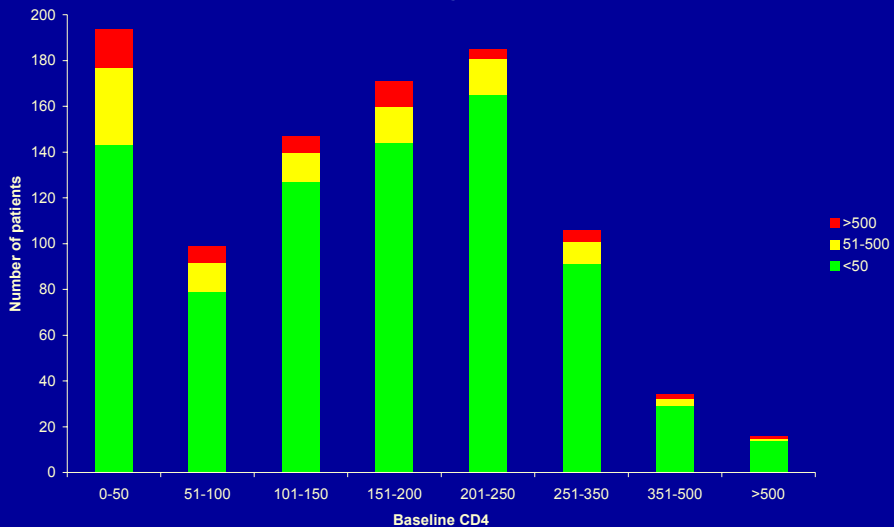
- ☞ 826 (68.0%) undetectable
- ☞ 170 (14.0%) detectable, not accounted for by stopping ART at end of pregnancy
- ☞ 68 (5.6%) stopped ART after pregnancy, including 2 with baseline CD4 <200
- ☞ 151 (12.4%) no outcome data reported.

## Primary outcome: viral load at follow-up, cont.

801 patients were still on HAART and had VL measured at least 150 days after starting. Among this sub-group:

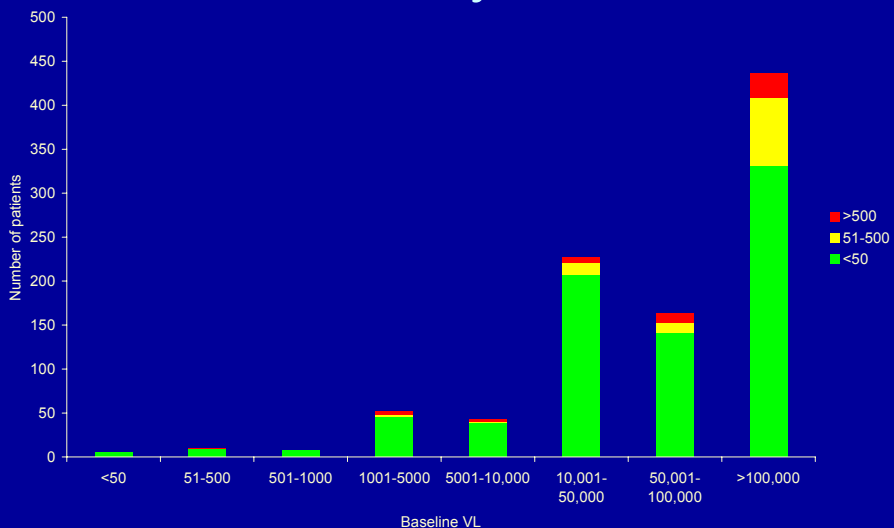
- ☞ 670 (83.6%) had undetectable VL
- ☞ 131 (16.4%) had detectable VL.

# VL outcomes by baseline CD4



NB this over-estimates "success" rates as it excludes patients with no reported outcome data. Patients who stopped short-term ART for pregnancy or Spartac and those with poor data matching between set-up and follow-up forms are also excluded.

# VL outcomes by baseline VL



NB this over-estimates "success" rates as it excludes patients with no reported outcome data. Patients who stopped short-term ART for pregnancy or Spartac and those with poor data matching between set-up and follow-up forms are also excluded.

## VL outcomes by centre caseload

Centre caseload (number of HIV patients):	VL outcome: number (%) of patients		
	<50	51-500	>500
1-50	21 (87.5)	2 (8.3)	1 (4.2)
51-100	74 (79.6)	11(11.8)	8 (8.6)
101-200	114 (87.0)	13 (9.9)	4 (3.1)
201-500	246 (81.5)	37 (12.3)	19 (6.3)
>500	277 (83.9)	34 (10.3)	19 (5.8)

NB this over-estimates "success" rates as it excludes patients with no reported outcome data. Patients who stopped short-term ART for pregnancy or Spartac and those with poor data matching between set-up and follow-up forms are also excluded.

## Patients without outcome data

Of the 151 patients for whom no primary VL outcome was reported:

- ☞ 66 were known to have transferred care to another clinical centre
- ☞ 51 had stopped attending and were not known to be receiving care elsewhere
- ☞ 11 had died
- ☞ 14 could not be traced by the reporting centre
- ☞ No reason was given for 9.

## Patients who stopped attending

Patients who stopped attending and were not known to be receiving care elsewhere were:

- ☞ 72.6% black-African compared with 48.7% of the cohort as a whole
- ☞ 60.8% female compared with 43.4% of the cohort as a whole.

## Outcome quality ratings

Ratings were designed to summarise outcome qualities across as many patients as possible including those lacking primary VL outcomes or having valid reasons for stopping ART.

## “Good” outcome ratings

894 (73.6%) of patients were judged to have “good” outcomes:

- ☞ VL undetectable OR
- ☞ Stopped ART at end of pregnancy plus baseline CD4 >200 OR
- ☞ Stopped ART in Spartac OR
- ☞ Detectable VL described as a blip with previous and following VL <50.

## “Poor” outcome ratings

214 (17.6%) were judged to have “poor” outcomes:

- ☞ Died (12 patients) OR
- ☞ VL not reported because stopped attending
  - not known to be receiving care elsewhere, unless known to have left UK or been imprisoned OR
- ☞ VL detectable without a valid reason
  - i.e. stopped short-term ART for Spartac or pregnancy or measured less than 150 days from starting ART.

# Unrated outcomes

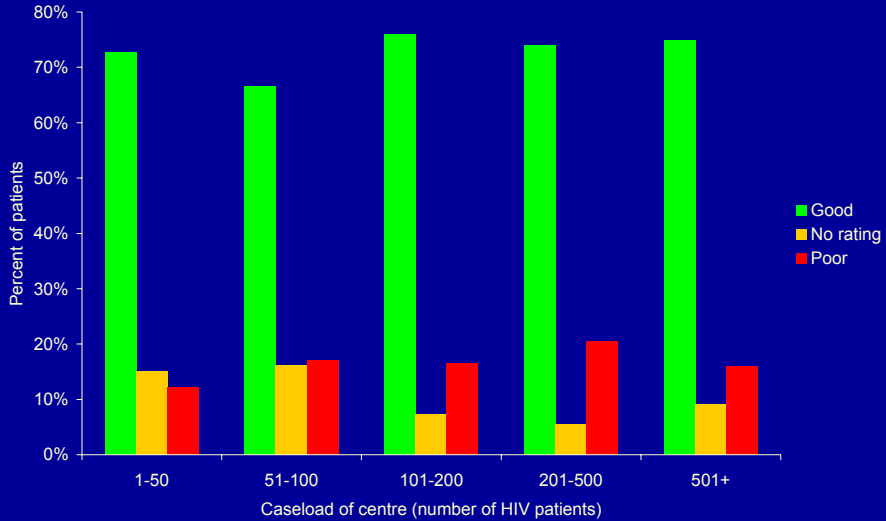
107 (8.8%) of patients were given “no rating”:

- ☞ VL not reported because transferred care, untraceable or reasons unknown OR
- ☞ VL not reported because stopped attending, not known to be receiving care elsewhere, but known to have left UK or been imprisoned (4 patients) OR
- ☞ VL detectable but reportedly measured at less than 150 days from starting ART (14 patients).

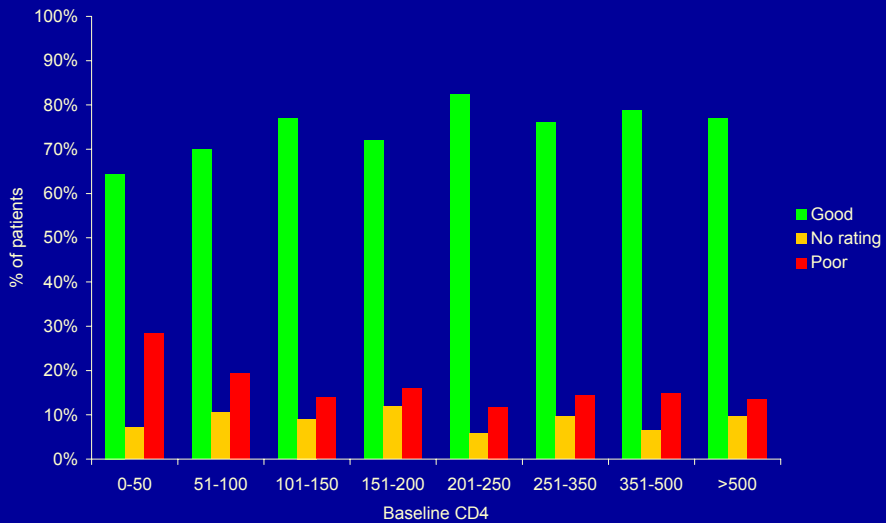
# Relationship of baseline factors with outcome quality

	Outcome ratings for number (%) of patients		
	“Good”	“No rating”	“Poor”
Male	463 (73.6)	52 (8.2)	114 (18.1)
Female	377 (74.2)	46 (9.1)	85 (16.7)
Black-African	416 (74.7)	51 (8.9)	93 (16.3)
White	332 (73.5)	37 (8.2)	83 (18.4)
With baseline resistance	42 (75.0)	8 (14.3)	6 (10.7)
No baseline resistance	592 (75.2)	66 (8.4)	129 (16.4)
Not tested	139 (72.4)	15 (7.8)	38 (19.8)

# Outcome ratings by centre size



# Outcome ratings by baseline CD4



Patients with poor data matching between set-up and follow-up forms are excluded.

## Other findings

## Adherence

For patients followed up, adherence was:

- ☞ 905 (85.1%) “no known issues”
- ☞ 111 (10.6%) “some issues or problems”
- ☞ 35 (3.3%) “substantial problems”.

## HBV and HCV coinfection

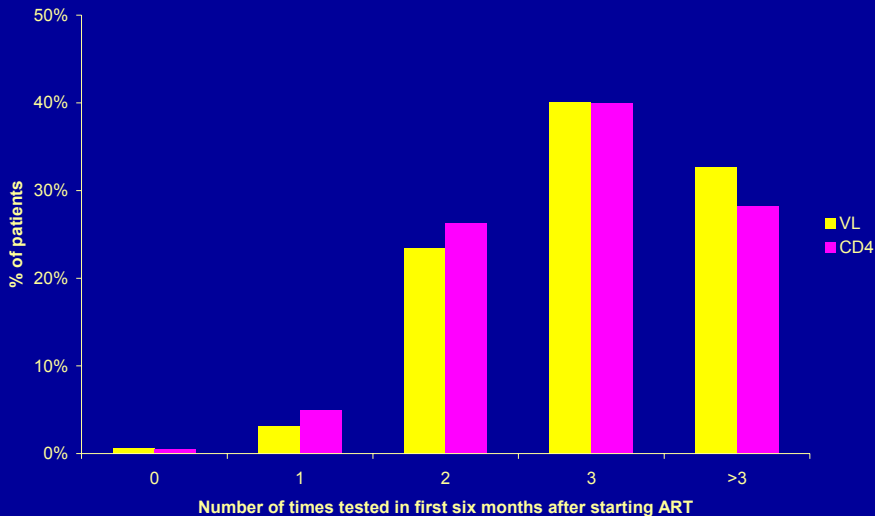
- ☞ 53 (4.5%) of patients were HbsAg positive at baseline and 75 (6.4%) were untested.
- ☞ Among those positive, 13 (25%) had reportedly started on lamivudine without tenofovir.
- ☞ 32 (2.7%) of patients were hepatitis C Ab positive at baseline and 56 (4.8%) were untested.

## Time to first VL test after starting ART

Cumulative number (%) of patients having had a VL test

By 28 days	361 (46.3)
By 42 days	577 (74.0)
By 56 days	665 (85.3)

# Frequency of VL and CD4 tests



## Conclusions

- Overall, outcomes were good across all centre sizes.
- It is of concern that 51 (4.2%) patients stopped attending during the year or so after starting ART, and were not known to be receiving care elsewhere.
- Starting ART at low CD4 was associated with poorer outcomes.
- About 1 in 6 patients still on ART and with measured VL had detectable VL at 5-12 months after commencing.

## Conclusions, cont.

- ⌘ 26% of patients did not have a VL estimation within the first 6 weeks of commencing ART.
- ⌘ 1 in 4 patients with Hep B/HIV coinfection were started on lamivudine without tenofovir.
- ⌘ CD4 may have been monitored unnecessarily frequently soon after starting ART.