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The Paulista HIV / AIDS Cohort Study (PHACS) – Organization and selected characteristics of the participants

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RATIONALE

The clinical and laboratorial data from a population at a STD/AIDS Referral and Training Center (CRT) in Sao Paulo, Brazil, with 7,853 HIV infected individuals present:

- a well documented follow-up of clinical data,
- a range from 1988 to 2005, (including the pre and post HAART periods),
- patients with different duration of HIV infection, with and without AIDS,

So, this is a chance to study the natural history of HIV infection in our setting.

OBJECTIVES:

- To describe the study design, selection criteria and data collecting method,
- To describe baseline characteristics of patients infected with HIV, with and without AIDS,
- To discuss the limitations and strongest aspects of the study, appointing to expected results.

METHODS:

- **TYPE OF STUDY:** Retrospective cohort study.
- **STUDY SITE:** CRT outpatient clinic in Sao Paulo, Brazil.

  This clinic has 57,298 patients enrolled until 2005, 46% of which have HIV and AIDS.

- **STUDY POPULATION: 7,853 patients** seen at the outpatient clinic.

METHODS:

INCLUSION CRITERIA

- Patients 13 years old or more,
- HIV infected patients with and without AIDS,
- Entry into the clinic between Jan/01/**1988** and Dec/31/**2003**,
- Patients with effective follow-up period **above 90 days** and at least **two** outpatient visits.

EXCLUSION CRITERIA

- Mother-to-child transmission cases,
- Blood-transfusion related transmission cases
- Deaths that occurred on the date or within seven days of AIDS diagnosis.

METHODS:

LOST TO FOLLOW-UP CRITERIA:

RIGHT CENSOR OCCURED IN 4 SITUATIONS:

- For patients alive at the end of follow-up (Dec/31/**2005**),
- On the death date, for patients who died before becoming AIDS cases,
- On the death date, for patients who died of causes other than AIDS,
- On the date of the last visit for patients who abandoned follow-up for one year.

METHODS:

DATA SOURCES

- Epidemiology Surveillance Data Base (FAA),
- Laboratory Tests Control System (SISCEL) and
- State Data Analysis System Foundation (SEADE).

DATA COLLECTING

- The inclusion date into the cohorts was the date of the first HIV positive test.

- The **final entry date into the study was** Dec/31/**2003**, with a follow-up until the **end of the study on** Dec/31/**2005**, with censor to the right.

METHODS:

The population was divided into four groups according to therapies available in Brazil, at the beginning of treatment:

1. Monotherapy from 1988 to 1991,
2. Combined therapy from 1992 to 1994,
3. Non-HAART triple therapy from 1995 to 1996,
4. HAART from 1997 to 2003.

The most complex therapy among those taken by each patient was used.

Separate analyses will be performed for:

1. patients with HIV positive serology who did not develop AIDS during the follow-up period (first end-point – **AIDS-free time**).

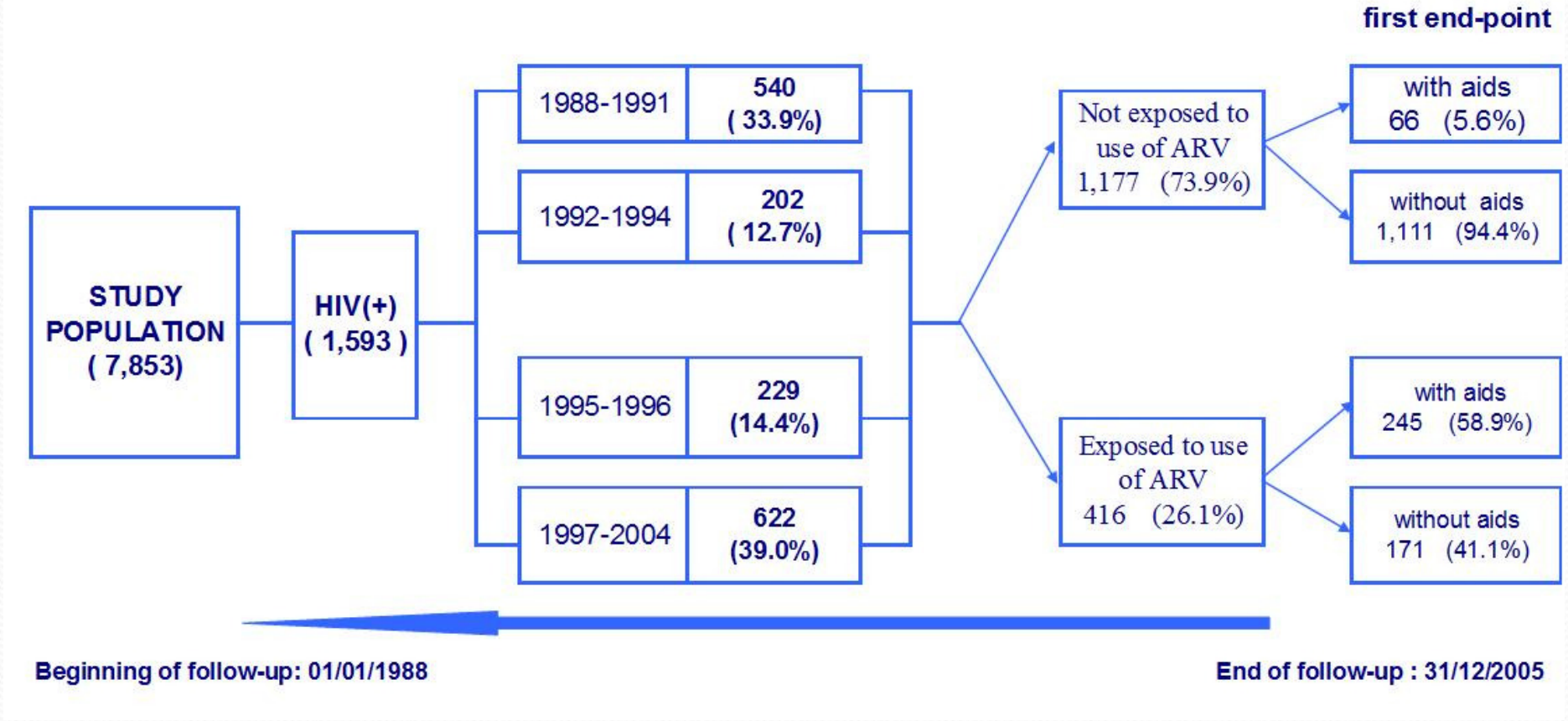
2. patients who developed aids (second end-point – **survival with AIDS**).

METHODS:

For the first end-point (becoming AIDS case):

- The AIDS incidence rate will be calculated based on the **number of new aids cases** in the numerator and the **total persons-year at risk for the event** in the denominator, that is, patients who entered the cohort infected by the HIV, but without AIDS.

Study design until first end-point (AIDS-free time)



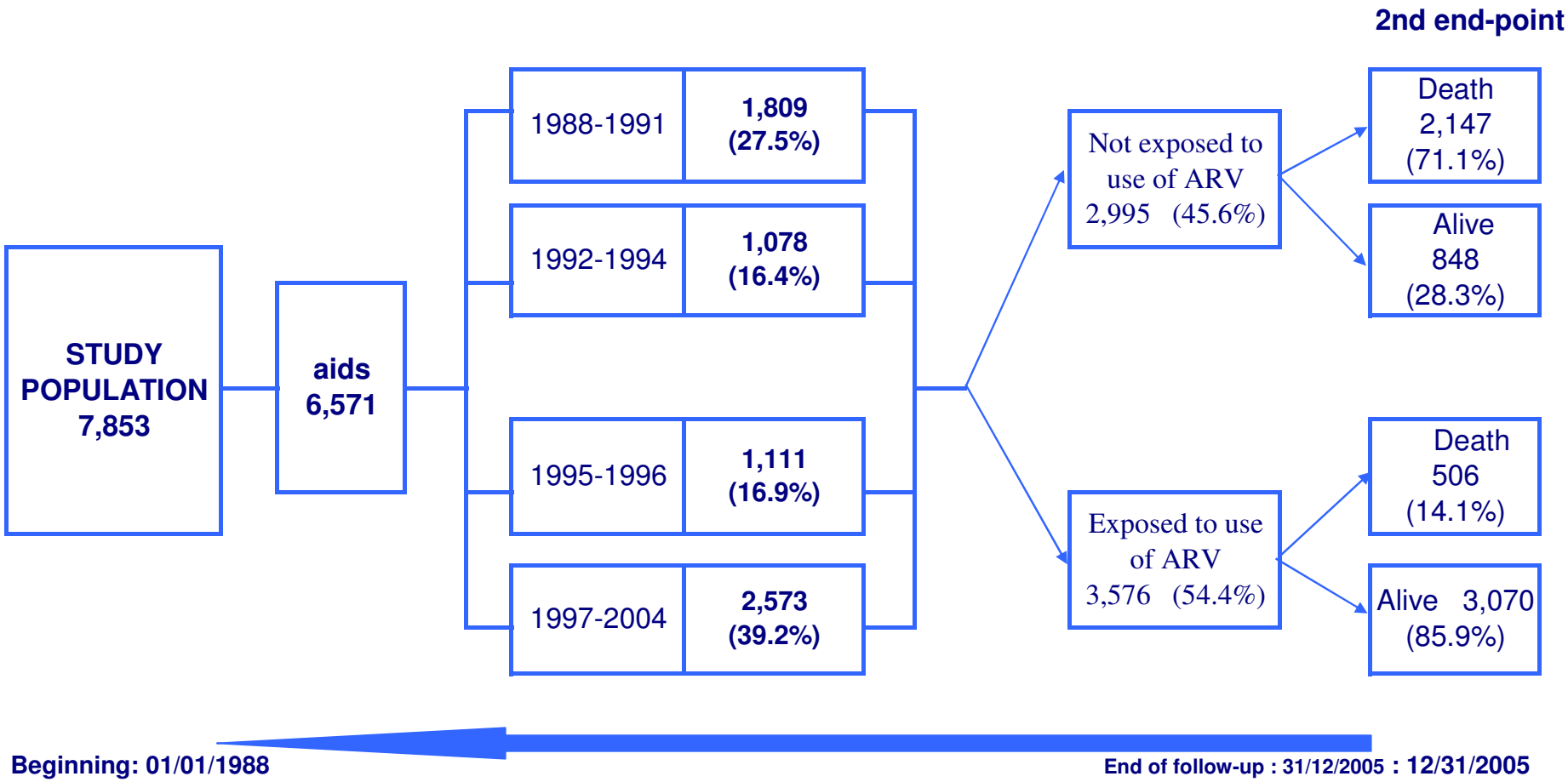
METHODS:

For the second end-point (death or censoring):

Include patients who entered in the study with AIDS and those who developed AIDS during follow-up.

- Survival analysis will be performed using the Kaplan-Meier estimator and the Cox model.
- To estimate the *hazard ratio* (HR), with 95% confidence intervals (95% CI), adjusted for deaths due to aids, the Cox proportional hazards models will be used.
- To identify factors associated with outcomes of interest: sociodemographic, transmission, development of clinical, treatment and laboratory characteristics will be analyzed.

Study design until second end-point (AIDS survival)



METHODS:

DATA QUALITY CONTROL:

- **Consistency and completeness of data analysis,**
- **Reproducibility test** of the Epidemiology Surveillance Data Base (FAA), comparing the following variables: gender, schooling and exposure category with a random sample of 100 medical records,
- **Data manager training** to collect unknown data from medical records,
- **Pre-test** using standardized data collection forms.

PRELIMINARY RESULTS:

- **7,853** individuals with HIV positive serology were included in the study.

- At the beginning of the study:

  6,260 (**80%**) individuals were AIDS cases;

  1,593 (**20%**) were HIV infected without Aids, among which 311 developed Aids.

- Characteristics of patients:

  75% were men,

  41% were 30 to 39 years,

  32% had an elementary school degree,

  43% characterized themselves as men who have sex with men, 35% as heterosexuals and 19% as injecting drug users.

- Cases were confirmed by the CDC case definition in 62%, by the RJ/Caracas criterion in 18%, and by CD4 in 9%.

PRELIMINARY RESULTS:

Clinical development:

- **51%** of all patients received ART or HAART.
- **26%** patients without aids received ART or HAART (during the AIDS incubation period).
- **40%** of patients died during the study period.

Baseline socio-demographic features of patients with HIV/AIDS, CRT, 1988 to 2003.

Characteristics of patients	Total	
	N	%
Total	7853	100
Gender		
Female	1930	25
Male	5923	75
Highest level of schooling		
None	66	1
Elementary School	2552	32
High School	1628	21
College	1604	20
Unknown	2003	26
Exposure category		
Heterosexual	2714	35
MSM	3350	43
IDU	1513	19
IGN	276	4

Baseline socio-demographic features of patients with HIV/AIDS, CRT, 1988 to 2003.

Characteristics of patients	Total	
	N	%
Total	7853	100
Age (years)		
13 - 29	181	2
20 - 29	2567	33
30 - 39	3252	41
40 - 49	1396	18
50 - 59	357	5
60 +	100	1
Case definition criteria*		
CD4	570	9
CDC	4074	62
RJ-CARACAS	1159	18
Unknown	768	12

Study Limitations

- The utilization of the date of the first HIV positive serology can under-estimate the duration of the incubation period because the infection and seroconversion dates are unknown.

- The classification of the study periods by available treatment regimens, in each calendar periods, reflects the mean estimated **use by populations** and **not by individuals**, and neither adherence to prescriptions.

- Changes in case-definitions → more sensitive case definitions increase the number of cases diagnosed **earlier** and may overestimate of survival.

Expected Results:

- The construction of this cohort, after the validation of clinical data, will allow the assessment of the effectiveness of public health interventions, and
- offer valuable information for clinical decisions and public health policies.

Thank you very much.