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Characteristics of women living with HIV in the RESPOND cohort.

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RESPOND International Cohort Consortium of Infectious Diseases

Introduction:

We describe women living with HIV in the RESPOND consortium, a large multinational collaboration of 17 pre-existing observational cohorts of people living with HIV from Europe and Australia.

Methods:

- Characteristics of women recruited to RESPOND are compared to men and presented at RESPOND baseline: the date of starting an integrase inhibitor (INSTI) after 01-Jan-2012, or for those who did not start an INSTI at enrolment, the latest of 01-Jan-2012 or enrolment into the local cohort.
- Viral load (VL, copies/mL), CD4 cell count (cells/µl), antiretroviral (ARV) regimens and the number of comorbidities are presented for the treatment naïve at first ART initiation ≥01-Jan-2012. For VL + CD4, the closest measurements to ART initiation were captured within a window period of 12-months prior + 7-days post.
- Percentages are presented excluding missing data and P-values are based on difference in binomial proportions.
- Burden of comorbidity at ART initiation, was assessed by counting the number of comorbidities: hypertension, dyslipidemia, diabetes, Non-Aids Defining Malignancies, Cardiovascular disease (myocardial infarction, stroke or invasive cardiovascular procedure), renal disease (CKD and/or end-stage renal disease), and end-stage liver disease.
- Comorbidities from cohorts with rates at <50% of total RESPOND cohort were set to missing, and only sites with complete data on 4/7 comorbidities were included in the index, with unknown in included cohorts set to zero for relevant conditions.

Figure 1: Number of comorbidities at first ART initiation among treatment naive

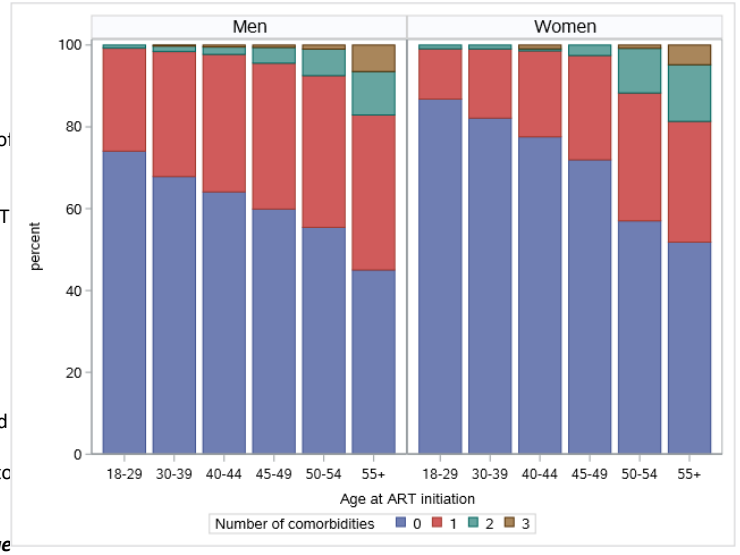

Table 1: Clinical characteristics at first ART initiation ≥ 01-Jan-2012 among naïve by age

at first ART initiation	Total	18-29 years	30-39 years	40-44 years	45-49 years	50-54 years	55+ years
Women (n) **Men (n)**	**2003** **7883**	**479** **1760**	**707** **2595**	**250** **1177**	**230** **974**	**152** **670**	**185** **707**
Women on INSTI Men on INSTI	580 (29.0) 2835 (36.0)	132 (27.6) 698 (39.7)	182 (25.7) 862 (33.2)	71 (28.4) 371 (31.5)	65 (28.3) 347 (35.6)	61 (40.1) 270 (40.3)	69 (37.3) 287 (40.6)
Women on PI Men on PI	436 (21.8) 1349 (17.1)	135 (28.2) 266 (15.1)	171 (24.2) 451 (17.4)	43 (17.2) 217 (18.4)	42 (18.3) 171 (17.6)	27 (17.8) 126 (18.8)	18 (9.7) 118 (16.7)
Women on NNRTI Men on NNRTI	557 (27.8) 2322 (29.5)	97 (20.3) 522 (29.7)	190 (26.9) 844 (32.5)	89 (35.6) 383 (32.5)	76 (33.0) 253 (26.0)	44 (29.0) 158 (23.6)	61 (33.0) 162 (22.9)
CD4 <350 cells/µL (n, %) Women Men	 914 (53.4) 3191 (46.4)	 196 (48.0) 543 (35.3)	 303 (51.8) 1004 (45.1)	 123 (57.2) 542 (52.7)	 118 (58.1) 424 (49.4)	 82 (61.7) 312 (52.9)	 92 (55.1) 366 (58.0)
VL>100,000 copies/mL (n, %) Women Men	 499 (29.3) 2562 (37.3)	 83 (20.7) 501 (32.7)	 173 (29.7) 789 (35.2)	 74 (34.7) 396 (38.5)	 64 (32.0) 337 (39.6)	 52 (38.2) 265 (45.5)	 53 (31.6) 274 (43.2)
≥1 comorbidity (n, %) Women Men	 406 (20.3) 2507 (31.8)	 57 (11.9) 421 (23.9)	 111 (15.7) 764 (29.4)	 48 (19.2) 378 (32.1)	 55 (23.9) 345 (35.4)	 55 (36.2) 268 (40.0)	 80 (43.2) 331 (46.8)

Results:

- Of 33, 087 recruited to RESPOND up to 2019, 25% (n=8348) were women and among these most are white (59.5%) or black (25.4%), among men 83.6% are White and 6.0% Black.

At baseline:

- median age (years) [IQR] among women was 43.2 [36, 51] and 45.8 [37, 53] in men; 74.6% of women acquired HIV heterosexually, and 15.1% through injecting drug use: 20.8% and 12.5%, respectively among men.
- median [IQR] CD4 cells/µL for women was 540 [355, 744] and 539 [363, 737] for men; of those with data, 27.3% of women and 29.2% of men had VL≥200 copies/mL. Prior AIDS diagnosis was reported in 20.4% of women, and 19.5% of men. Similar rates of Hepatitis C for women and men (23.9% and 20.0%); Hepatitis B: (5.9% and 7.5%) and current smoking reported in (18.6% and 24.9%) respectively.
- the most common comorbidities in women were dyslipidemia (51.0%) and hypertension (27.0%), less than that reported in men: 61.4% and 34.0% respectively; 4.3% of women and 4.9% of men had diabetes; 7.5% of women and 4.3% of men were classified as obese.
- 24.0% (n=2003) of women and 31.9% (n=7883) of men initiated first ART ≥01-Jan-2012.

Among treatment naïve at first ART initiation [Table 1] compared to men, women:

- were less likely to initiate INSTI (P<0.001), more likely to initiate PI (P<0.001), while rates of NNRTI were comparable(P=0.45).
- Had a lower proportion with high VL (at 100,00 copies/mL) at all ages, a higher proportion with CD4<350 cells/µL and lower median CD4 cell count at all age-groups except for 55+ years.
- had a lower proportion with ≥ 1 comorbidity (P<0.001) except among those aged 55+ years, where proportions were comparable (Figure 1).

Limitations:

- Key factors such as socio-economic and immigrant status, alcohol use, osteoporosis, pregnancy outcomes, contraception and menopause are currently not collected in RESPOND (collected poorly or not collected across all cohorts) and likely to be important confounders for women.
- RESPOND'S focus was initially on INSTI and so for those not on INSTI, baseline is more arbitrary. The treatment naïve subset may have potential for bias among women of reproductive age given treatment guidelines changed for pregnant women in 2011-12 with recommendations dependent on CD4.

Conclusion: Women in RESPOND are diverse in age, treatment stage and clinical history. Compared to men, women were more likely to be black, less likely to smoke and were more treatment experienced at baseline. Women differed in terms of ART regimen initiated, CD4 and viral load at first ART initiation. There is a need for more sex-stratified analyses on comorbidities and ageing. Further investigation of sex differences in RESPOND may help inform screening and management approaches specific for women of all ages with HIV. Addressing the data gap is critical in improving clinical outcomes for women and driving future research questions specifically addressing the complex inter-relationships between menopause, ART and age in women.

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The RESPOND Study Group https://www.chip.dk/Studies/RESPOND/Study-Group
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