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Evaluation of injectable long acting cabotegravir as response to oral PrEP-related medical issues

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Introduction/Summary

- Long-acting injectable cabotegravir (ICAB) has been recently approved by FDA and EMA as pre-exposure prophylaxis (PrEP). RCTs have been prematurely concluded by DSMB for ICAB superiority compared to oral PrEP either in men who have sex with men (MSM), transgender women (TGW), and cis women.
- Despite the greater efficacy, ICAB represents an issue for PrEP management given the higher economic cost and the relevant burden on clinics workload.
- Aims of the present study are: (i) to describe the proportion of PrEP users requiring ICAB for medical or adherence issues; (ii) to evaluate factors associated to clinical need of injectable over the oral drug.

Study Design

- Retrospective evaluation of all individuals who started oral PrEP attending a community-based, peer run service that provides medical assistance to a large cohort of PrEP users in Milan.
- Clinical and behavioral data routinely collected have been used to measure the proportion of individuals who might benefit the most of ICAB for medical reasons.

Methods

- Milano Checkpoint (MCP) in an NGO that provides medical assistance for sexual health issues in Milan.
- All individuals who attended at least two visits in MCP were included in the analysis. Users were considered in need of ICAB if they presented **toxicity**, **adherence**, or **efficacy** issues.
- **Toxicity** was defined as:
  - two consecutive eGFR values below 60 mL/min;
  - gastrointestinal side effects complaints after the third visit;
  - discontinuation due to any adverse event.
- **Poor adherence** was defined as:
  - post-exposure prophylaxis (PEP) prescription;
  - sexual encounters without PrEP or condom reported more than twice;
  - chemsex use for more than 8 months consecutively.
- Being cis woman was considered as an indication for ICAB given oral strategies poor **efficacy** in this population.
- Descriptive and non-parametric statistics were used to describe study population. Bivariate logistic regression analysis was employed to test factors associated to ICAB clinical need.

Results

- The analysis included 1,056 individuals, mainly cis men (1,036, 98.1%), MSM (1,018, 97.0%), born in Italy (838, 79.4%), with a median age of 38 (IQR 33-47) years. Of them, 294 (**27.8%**) showed at least one criterion according to study definitions to be eligible to ICAB: 241 (82.0%) had only one condition, 46 (25.6%) two conditions, and 7 (2.4%) three conditions. **Table 1** depicts demographic, clinical, and behavioral features of study population.

Table 1.		Total (N=1.056)	Not eligible (N=762)	Eligible (N=294)	p
Age (years), median (IQR)		38.0 (33.0-47.0)	38.0 (33.0-46.0)	40.0 (34.0-48.0)	0.060
Gender, n (%)	Female	14 (1.3%)	0 (0.0%)	14 (4.8%)	**<0.001**
	Male	1,036 (98.1%)	758 (99.5%)	278 (94.6%)	
	TGW	6 (0.6%)	4 (0.5%)	2 (0.7%)	
Sexual behavior, n (%)	Bisex	106 (10.0%)	68 (8.9%)	38 (12.9%)	**<0.001**
	Hetero	31 (2.9%)	12 (1.6%)	19 (6.5%)	
	MSM	912 (86.4%)	677 (88.8%)	235 (79.9%)	
	Unknown	7 (0.7%)	5 (0.7%)	2 (0.7%)	
Italian born, n (%)		838 (79.4%)	600 (78.7%)	238 (81.0%)	0.426
Marital status, n (%)	Steady relationship	277 (26.2%)	194 (25.5%)	83 (28.2%)	0.455
	Single/divorced	777 (73.6%)	566 (74.3%)	211 (71.8%)	
	Unknown	2 (0.2%)	2 (0.3%)	0 (0.0%)	
Level of education, n (%)	Lower	35 (3.3%)	22 (2.9%)	13 (4.4%)	0.157
	Secondary	286 (27.1%)	196 (25.7%)	90 (30.6%)	
	Degree	733 (69.4%)	543 (71.3%)	190 (64.6%)	
	Unknown	2 (0.2%)	1 (0.1%)	1 (0.3%)	
Employed, n (%)		918 (87.0%)	665 (87.4%)	253 (86.1%)	0.564
Months_on_prep, median (IQR)		17.0 (6.8-31.8)	13.8 (6.0-26.8)	26.0 (14.3-38.2)	**<0.001**
Health status according to the VAS scale (0-100), median (IQR)		86.0 (77.0-95.0)	87.0 (80.0-95.0)	85.0 (73.0-94.0)	**0.002**
Number of casual partners in the previous 3 months, median (IQR)		6.0 (3.0-15.0)	6.0 (3.0-15.0)	6.0 (3.0-15.0)	0.631
Use of antidepressants, n (%)		117 (11.1%)	71 (9.3%)	46 (15.6%)	**0.003**
Use of (any) concomitant therapy, n (%)		260 (24.6%)	171 (22.4%)	89 (30.3%)	**0.008**

Figure 1. Multivariable bivariate logistic regression analysis to test factors associated to ICAB medical need (forest plot).

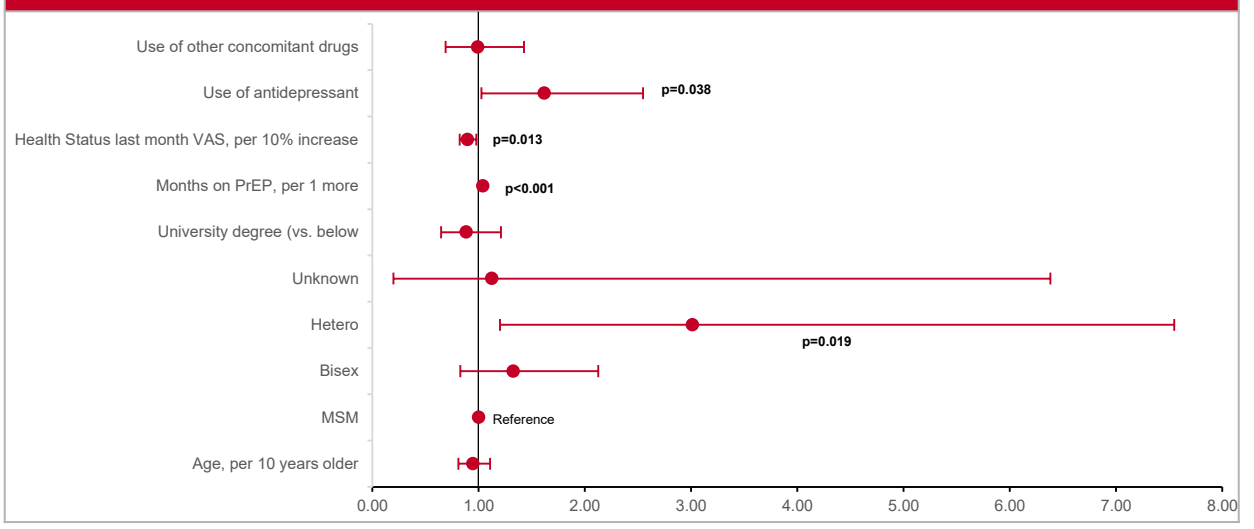
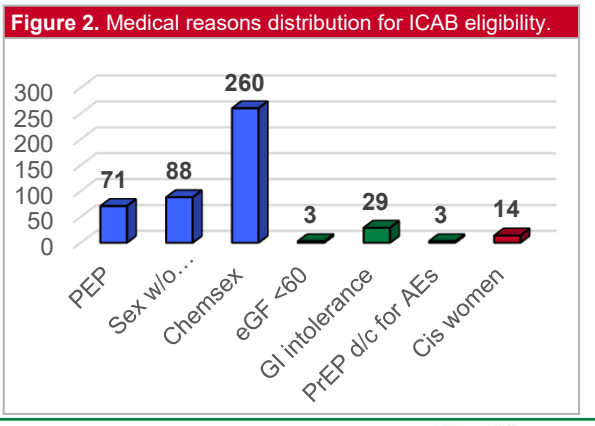


Figure 2. Medical reasons distribution for ICAB eligibility.



Conclusions

- Around one forth of PrEP users attending a community-based service showed a medical issue that would benefit from ICAB. These data suggest that ICAB would respond to common problems in PrEP management.
- Nevertheless, clinical centers might be overwhelmed by economic costs and increasing workload. Thus, health system needs to be implemented to face the issues that this novel approach would pose.

References

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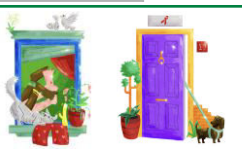

Milano CHECKPOINT