BIC/FTC/TAF for PEP: Completion, Tolerability, and Transition to PrEP in a Real-World Cohort

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BACKGROUND

Post exposure prophylaxis (PEP) is a cornerstone of HIV prevention. The associations TDF/FTC + DTG or RAL is the most used in clinical practice, but the single-drug-regimen BIC/FTC/TAF is increasingly adopted due to its efficacy, resistance barrier and tolerability. Real-world data on its use as PEP are still limited. Furthermore, PEP represents a key strategy for engaging key population for HIV and STI in a prevention continuum, including vaccinations and PrEP.

We present characteristics of people referred for PEP to "D. Cotugno" hospital in Naples, South Italy, describe outcome, tolerability, treatment completion rates and linkage to PrEP using BIC/FTC/TAF as PEP.

METHODS

At "D. Cotugno" an Emergency Department (ED) is available 24/24h for initial PEP dispensation and "Time 0" serology assessment, then indication for PEP is systematically reassessed in a dedicated infectious diseases service, operating 2 days a week, allowing refined risk stratification and optimization of PEP use.

We retrospectively analyzed all individuals presenting at "D. Cotugno" Hospital, Naples, after HIV at-risk exposure (March 2023–August 2025). Data included demographics, type of exposure, baseline HIV/STI serologies, PEP prescription and completion, adverse events (AEs), HIV outcomes, PrEP transition, and preventive vaccinations.

RESULTS

A total of 405 individuals referred to ED in the study period, and PEP with BIC/FTC/TAF was started in 381. Among them, PEP was confirmed in 273 persons after reassessment in the dedicated service. Demographic and clinical characteristics are presented in table 1.

Individuals in whom PEP was confirmed after reassessment differed significantly from those in whom PEP was discontinued. Participants who continued PEP more frequently reported high-risk sexual exposures, including receptive anal intercourse and were more often referred following sexual exposure rather than occupational or other low-risk contacts. Conversely, individuals who discontinued PEP after reassessment more commonly presented with exposures subsequently classified as low or negligible risk.

The association BIC/FTC/TAF has been used in all 273 confirmed PEP. The 28-day course has been completed in 262 (96%). Among the not 11 completed, 3 were lost-to-follow-up, 3 suspended for HIV-negative test from the source, and 5 for side effects, mainly gastrointestinal symptoms. Among those who completed, 24 (9%) reported self-limited side effects (nausea, gastralgia, diarrhoea, headache, insomnia). A 3-month follow-up was completed in 261: no HIV seroconversion was documented. New syphilis infections emerged in 15 clients.

PEP-to-PrEP continuum was proposed to 161 clients, and 102 (63%) started PrEP. Vaccinations for HAV, HBV, HPV, Mpox were recommended if indicated, though uptake rates are under evaluation.

Table - Demographic, clinical and exposure characteristics of 405 people referring to "D. Cotugno" Emergency Department referring a at-risk exposure for HIV, March 2023 – August 2025

Sexual exposures				
	Confirmed PEP (n 273)	Not confirmed PEP (n 55)	Total (n 328)	P*
Gender at birth:				<0.000
Male (n,%)	269, 88	37, 12	306	
Female (n,%)	4, 18	18, 82	22	
Age (median, SD)	33, 13	37, 16	36, 15	0.086
Origin:				<0.000
Italian (n, %)	265, 87	40, 13	305	
Not Italian (n, %)	8, 35	15, 65	23	
Sexual orientation:				<0.000
Men who have Sex with Men (n, %)	149, 98	3, 2	152	
Transgender M to F (n, %)	10, 91	1, 9	11	
Male, heterosexual (n, %)	110, 77	33, 23	143	
Women, heterosexual (n, %)	4, 18	18, 82	22	
Type of exposure:				<0.000
Receptive anal sex (n, %)	110, 99	1, 1	111	
Insertive anal sex (n,%)	71, 99	1, 1	72	
Insertive vaginal sex (n,%)	82, 92	7, 8	89	
Receptive vaginal sex (n,%)	4, 36	7, 64	11	
Fellatio (n,%)	4, 21	15, 79	19	
Receiving fellatio (n,%)	0, 0	13, 100	13	
Semen splash into eye (n,%)	2, 15	11, 85	13	
Use of condom (for anal and vaginal exposures only, n. 283):				<0.000
Yes (n, %)				
Yes, with breaking or slipping (n, %)	1, 7	13, 93	14	
No (n, %)	154, 99	2, 1	156	
	112, 99	1, 1	113	
Serologies at Time 0:				0.004
HIV-Ab positive (n, %)	0	0	0	
HAV-IgG positive (n,%)	53, 71	22, 29	75	
HCV-Ab positive (n, %)	1, 20	4, 80	5	
HBsAg positive (n, %)	2, 50	2, 50	4	
HBsAb positive (n, %)	161, 80	40, 20	201	
HBcAb positive (n, %)	49, 86	8, 14	57	
TPHA positive (n, %)	57, 84	11, 16	68	
VDRL positive (n, %)	19, 90	2, 10	21	
Occupational or other non-sexual exposures				
	Confirmed PEP (n 12)	Not confirmed PEP (n 65)	Total (n 77)	P
Gender:				0.184
Male (n, %)	9, 22	32, 78	41	
Female (n, %)	3, 8	33, 92	36	
Age (median, SD)	50, 25	56, 28	54, 26	0.464
Origin:				0.710
Italian (n, %)	11, 15	64, 85	75	
Not Italian (n, %)	1, 50	1, 50	2	
Type of exposure:				0.053
Needle/Sharp injury in HCS** (n, %)	9, 27	24, 73	33	
Splash in mucosae in HCS** (n, %)	3, 14	18, 86	21	
Other occupational exposure in community setting (n, %)	0, 0	12, 100	12	
Needlestick from a needle discarded in community setting (n, %)	0, 0	11, 100	11	
Serologies:				0.020
HIV-Ab positive (n, %)	0	0	0	
HAV-IgG positive (n,%)	5, 14	32, 86	37	
HCV-Ab positive (n, %)	0, 0	2, 100	2	
HBsAg positive (n, %)	1, 100	0, 0	1	
HBsAb positive (n, %)	10, 16	54, 84	64	
HBcAb positive (n, %)	1, 4	27, 96	28	
TPHA positive (n, %)	1, 50	1, 50	2	
VDRL positive (n, %)	0	0	0	

* p with chi square test OR Mann–Whitney U test, significance level <0.05; ** HCS: Health Care Setting

CONCLUSIONS

As expected in a real-world setting, PEP reassessment allowed identification of individuals with lower-risk exposures, in whom PEP could be safely discontinued, while maintaining high completion rates among those with confirmed indications.

In this large real-world cohort, BIC/FTC/TAF was highly effective and well tolerated as PEP, with very high completion rate and no HIV infections. Importantly, most among eligible individuals transitioned from PEP to PrEP, highlighting the role of PEP as an entry point into the HIV prevention continuum.

IMPLICATIONS

- A structured reassessment pathway allowed appropriate discontinuation of PEP in low-risk exposures, while maintaining excellent completion and safety outcomes among individuals with confirmed indications;
- BIC/FTC/TAF is a valuable and effective option for PEP, combining high efficacy with excellent tolerability;
- PEP represents a key intervention in HIV prevention and an opportunity to initiate an integrated HIV and STI prevention pathway.

CONTACT INFORMATION

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