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Short report

High uptake of pre-exposure prophylaxis (PrEP) during early roll-out in Belgium: results from surveillance reports

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Abstract. ***Background*:** Since 1 June 2017, oral pre-exposure prophylaxis (PrEP) could be prescribed and reimbursed in Belgium as prophylactic medication for people who are at increased risk of HIV acquisition. The aim of this study was to determine the uptake of daily and event-driven PrEP in Belgium during the first 9 months of roll-out. ***Methods*:** Routine aggregated data on the number of reimbursement requests and the number of boxes of Truvada (Gilead Sciences, Cambridge, UK) delivered for PrEP through the Belgian pharmacies were obtained from the National Institute for Health and Disability Insurance. We also collected aggregated data from seven Aids Reference Centres (ARCs) currently providing most of the PrEP care in Belgium. ***Results*:** From 1 June 2017 to 28 February 2018, 1352 requests for reimbursement were approved by the National Institute for Health and Disability Insurance. Almost 98% of those who bought at least one box of 30 tablets of emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (FTC/TDF) in a Belgian pharmacy were male, and most (67%) were between 30 and 50 years of age. According to data obtained from ARCs, the proportion of those choosing event-driven PrEP initially ranged between 29% and 73%. ***Conclusions*:** The uptake of PrEP in Belgium since the start of the roll-out in June 2017 has been high, and almost entirely limited to men who have sex with men, of whom 43% initially prefer a non-daily regimen. A better understanding is needed as to why other populations, such as sub-Saharan African migrants, are not accessing PrEP, as well as the development of a more sustainable PrEP delivery model.

Additional keywords: HIV prevention, implementation.

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Introduction

Belgium remains one of the countries in the European Union–European Economic Area reporting the highest HIV incidence, with 8.1 new HIV infections per 100 000 inhabitants in 2016.[1,2] The epidemic mainly affects two populations: men who have sex with men (MSM) and sub-Saharan African migrants (SAM), most of whom have acquired HIV through unprotected heterosexual contacts.[2] A recent study suggests that ongoing clustered transmission in Belgium is almost exclusively MSM driven.[3]

Pre-exposure prophylaxis (PrEP) is an efficacious tool to prevent HIV, as evidenced by several trials.[4,5] Hence, the European Medicines Agency (EMA) approved Truvada (Gilead Sciences, Cambridge, UK) (emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg; FTC/TDF) as daily PrEP in August 2016.

In 2013, Belgium launched a national HIV Plan that included the development of a framework for pilot PrEP projects and operational research on PrEP feasibility.[6] A PrEP demonstration study 'Be-PrEP-ared' was set up to evaluate uptake, acceptability and feasibility of using and adhering to two regimens of PrEP (i.e. choosing between daily or event driven).[7] The latter involves taking PrEP before, during and after a sexually active episode.[5] Starting in September 2015, the study enrolled 197 MSM and three transgender women at high risk of HIV. Data collection was completed in June 2018.

In 2016, a Belgian PrEP task force was set up to advise policy makers on PrEP roll-out and discuss provider-related issues about PrEP. The task force includes community organisations, academic institutions and Aids Reference Centres (ARCs), which are specialised clinics that provide multidisciplinary HIV care geographically distributed across Belgium.

Since 1 June 2017, Truvada could be prescribed and reimbursed as prophylactic medication for people who are at increased risk of HIV acquisition. Belgium has been one of the first European countries, next to France, Norway and Scotland, to roll-out PrEP.

Current reimbursement procedures stipulate that candidates for PrEP make an appointment in one of the 11 ARCs. During the first visit, HIV and renal function tests are performed to confirm HIV-negative status and to assess exclusion criteria for the use of FTC/TDF. In case of eligibility, physicians fill out a request for reimbursement to be submitted to the social health insurance company of the future user (see Box 1). The approval is attributed for 1 year, renewable and sent to the candidate by post. During the first or second visit, the physician or a counsellor assists the candidate in choosing between daily and event-driven PrEP on the basis of individual needs and risk behaviour. The medical prescription together, with the authorisation of reimbursement, entitles the user to buy Truvada at a maximum price of €11.90 for 30 tablets. The PrEP user needs to attend the ARC every 3 months for check-ups.

This paper reports on the uptake of daily and event-driven PrEP in Belgium during the first 9 months of roll-out.

Methods

Routine aggregated data were obtained from three independent data sources. The National Institute for Health and Disability Insurance provided data on the monthly number of reimbursement requests authorised from June 2017 to February 2018 and the monthly number of boxes of Truvada delivered for PrEP through Belgian pharmacies from June to November 2017. Finally, we sent a simple data collection tool to early adopting ARCs in order to obtain the number and main characteristics of people initiating PrEP in their centres up to February 2018. Data collected during the PrEP demonstration project were not included in this analysis.

Results

From 1 June 2017 to 28 February 2018, 1352 requests for reimbursement were approved by the National Institute for Health and Disability Insurance (Fig. 1). During the first 9 months of roll-out, approximately 150 patients per month have been enrolled in the program. The number of boxes of Truvada (30 tablets per box) sold in Belgian pharmacies on PrEP prescription increased gradually from 105 in June to 607 after 5 months.

Among the 698 people who bought at least one box of 30 FTC/TDF tablets in Belgian pharmacies between 1 June and 30 November 2017, 683 (97.9%) were male, 4 (0.6%) were female and sex was not known for 11 (1.6%). Users' median age was 38 years, with a minimum of 19 years and a maximum of 70 years. Most (67%) were between 30 and 50 years of age.

By 28 February 2018, seven ARCs providing most of the PrEP care in Belgium reported a total number of 1050 people

Box 1. Criteria for reimbursement of pre-exposure prophylaxis (PrEP) in Belgium[A]

Criteria allowing re-imbursement in Belgium:

- For men who have sex with men
  - Having had unprotected anal intercourse with at least two partners in the past 6 months
  - Having had multiple sexually transmissible infections in the past year
  - Having taken post-exposure prophylaxis in the past year
  - Using psychoactive substances during sexual activities
- Other people at high risk of HIV
  - People who inject drugs and share needles
  - Sex workers who are exposed to unprotected sex
  - Partners of HIV-positive people without viral suppression

[A]From Rijksinstituut voor ziekte – en invaliditeitsverzekering (http://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/geneesmiddel-gezondheidsproduct/terugbetalen/specialiteiten/wijzigingen/Paginas/geneesmiddelen-PrEp-HIV.aspx#.WqErna0zU3E, accessed 5 September 2018).

who started PrEP, almost all MSM. Forty-three per cent preferred the event-driven regimen at their first visit, but there was wide variation across the centres, ranging from 29% to 73% (see Table 1).

Discussion

The uptake of PrEP in Belgium since the start of the roll-out in June 2017 has been high, and almost entirely limited to MSM, of whom 43% initially prefer a non-daily regimen.

Triangulation of data from the National Institute for Health and Disability and from seven ARCs shows a steady increase in new PrEP users since June 2017, with an estimated number of 1352 PrEP users after 9 months of roll-out. These figures do not include people who do not have a health insurance or who buy PrEP through other channels, indicating that the total number of PrEP users in Belgium may even be higher. In comparison, 1077 PrEP users were registered during the first 27 weeks of PrEP roll-out in France (November 2015–May 2016), a country with an almost sixfold greater population than Belgium.[8] Increasing awareness about PrEP in Belgium as a result of the demonstration project and a strong coalition between community organisations, HIV clinical centres and prevention organisations may have contributed to this high uptake.

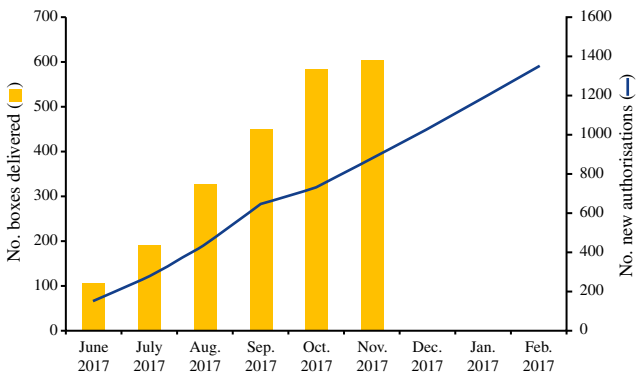

Fig. 1. Cumulative number of new authorisations for reimbursement issued and the number of boxes of Truvada (Gilead Sciences, Cambridge, UK) (30 tablets in each box) delivered in Belgian pharmacies for pre-exposure prophylaxis (PrEP) indication.

Interestingly, almost half (43%) the Belgian PrEP users preferred event-driven PrEP at the start, which is higher than the 23% found in our Belgian demonstration project.[9] In the demonstration project, men choosing a non-daily regimen had a lower risk profile and reported to be better able to anticipate their risk of HIV. It is likely that compared with a study, the roll-out of PrEP attracts more users with a lower risk of HIV. This may explain the higher preference for event-driven regimens, which may better suit the prevention needs of MSM with less frequent sexual risk taking. In France, where both daily and event-driven PrEP have been provided since 2015, approximately 6 of 10 PrEP users take event-driven PrEP.[8] However, MSM in France may be more familiar with this dosing regimen as a result of the Ipergay study design, which offered only event-driven PrEP to participants.[5] The high proportion of event-driven users in Belgium may explain the differences observed between the cumulative number of authorisations for reimbursement and the monthly number of boxes of Truvada delivered, which is lagging behind. We hypothesise that because event-driven users need less Truvada than daily users, they may delay refilling prescriptions.

Our report shows that SAM are heavily underrepresented among early PrEP users in Belgium. This is also the case in France, where PrEP has been available since November 2015 to any person with substantial HIV risk and, thus far, over 95% of people using PrEP are MSM.[10] Based on our experience with implementing HIV prevention among migrants communities from sub-Saharan Africa in Flanders, we assume that PrEP use may face specific barriers (i.e. overall low HIV prevention demand and cultural challenges).[11] Further research is needed to explore knowledge gaps and potential cultural barriers (e.g.

Table 1. Number and characteristics of pre-exposure prophylaxis (PrEP) users in seven Aids Reference Centres (ARCs) in Belgium (up to 28 February 2018)

ITM, Institute of Tropical Medicine; CHU, Centre Hospitalier Universitaire (university hospital); UZ, Universitair Ziekenhuis (university hospital); SAM, sub-Saharan African migrants; MSM, men who have sex with men

	No. PrEP users							
	Antwerp ITM	Brussels CHU St Pierre	Brussels Hospital Erasme	Brussels UZ	Charleroi CHU	Gent UZ	Liège CHU	Total
No. started PrEP (at end Feb. 2018)	345	187	152	66	31	157	112	1050
Started before 1 June 2017	0	3	31	0	0	0	10	44
Started after 1 June 2017	345	184	121	66	31	157	102	1006
Risk category								
MSM	345	186	152	66	31	146	105	1031
SAM	0	0	0	0	0	0	2	2
MSM+SAM	0	6	0	0	0	0	1	7
Other	0	1	0	0	0	0	4	5
Unknown	0	0	0	0	0	11	0	0
Regimen chosen at start						[A]		
Daily	221	103	86	32	22	95	25	584
Event driven	124	82	66	34	9	52	68	435

[A] $n = 147$ for UZ Ghent (for 10 people, the starting regimen was not known).

sexual norms and HIV stigma) that may impede PrEP uptake within this community.

There is currently no national registration system for PrEP users in Belgium. Each ARC set up its own registration system, which is not standardised and may have resulted in underreporting of the number of PrEP users. This could contribute to the difference between the number of people starting PrEP in the seven ARCs (1050) and the number of authorisations for reimbursement (1352) at the end of February. It also draws the attention to the need for a standardised PrEP registration system.

At the moment, PrEP in Belgium is only provided through specialised HIV clinics. Given the diversity of tasks in providing PrEP care, it remains unclear how and by whom PrEP, as part of comprehensive sexual health care, will best be provided in the Belgian healthcare system. Results of an online survey among Belgian healthcare providers show that primary care physicians assess their own knowledge about PrEP as insufficient.[12] In contrast, in an online survey among MSM in Belgium, 56% of potential PrEP users indicated that they would prefer PrEP prescriptions from primary care physicians compared with 28% who would prefer PrEP prescriptions from ARCs.[13] Clearly, raising PrEP awareness and providing knowledge and skills on comprehensive sexual health counselling among Belgian primary care physicians will be crucial from a health systems perspective. Sustainable delivery models will have to be developed allowing for the provision of PrEP as part of a true HIV prevention combination package, with sufficient resources to ensure comprehensive counselling at the individual level, if needed.[14] This could increase quality of care and uptake in the long run.

The ultimate goal of rolling out PrEP is to decrease HIV incidence in Belgium. Monitoring and surveillance systems should be improved to monitor the effect of PrEP on new HIV diagnoses and to keep track of indicators of risk compensation as a result of PrEP, such as the incidence of sexually transmissible infections.[15]

Conflicts of interest

Gilead Sciences funded author attendance at international AIDS conferences.

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