

All set for PrEP: A review of policy options for the introduction of Pre-exposure Prophylaxis (PrEP) in the Republic of Ireland

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Introduction

In August 2016, the European Commission granted marketing authorisation for once-daily Truvada® (emtricitabine 200 mg/tenofovir disoproxil 245 mg; FTC/TDF) in combination with safer-sex practices to reduce the risk of sexually acquired HIV-1 infection among uninfected adults at high risk. Consequently, once-daily Truvada® is licensed for Pre-Exposure Prophylaxis (PrEP) in Ireland. However, while PrEP is currently available to buy on prescription it is not available through the Health Service Executive's general medical scheme (GMS). This policy options review was commissioned by *HIV Ireland Ltd* (HIVI) and the *Gay Health Network* (GHN) to provide evidence-based guidance to inform policy dialogue for PrEP in the Republic of Ireland (RoI).

Methodology

This study applied qualitative research methods in the social sciences. A review of the evidence base for PrEP efficacy relied in part on the systematic review of the evidence undertaken on behalf of the World Health Organisation (WHO) by Fonner *et al* (2016). The desk review further included a scoping of databases including *PubMed*; *Science Direct*, and the *Cochrane Database*, and recognisable journals known to provide high-quality evidence for HIV-specific interventions. Desk review was supported by 17 semi-structured key-informant interviews; two focus group discussions (FGDs) and four email submissions. The generic purposive sample included health care providers (HCPs), pharmaco-economists, a health researcher, an epidemiologist, civil society activists, and international actors. The first FGD included 11 men who have sex with men (MSM) who were potential end-users of PrEP and the second FGD was held with 6 people living with HIV including women from sub-Saharan Africa and MSM.

The research is limited by the poor participation of stakeholders from outside Dublin while stakeholder bias must be factored into the interpretation of findings as the purposive sample were sector insiders and consequently more likely to support the introduction of PrEP.

References

Fonner, Virginia A.; Dalglish, Sarah L.; Kennedy, Caitlin E.; Baggaley, Rachel; O'Reilly, Kevin R.; Koechlin, Florence M.; Rodolph, Michelle; Hodges-Mameletzis, Ioannis; Grant, Robert M. *Effectiveness and safety of oral HIV preexposure prophylaxis for all populations*, AIDS: 31 July 2016 - Volume 30 - Issue 12 - p 1973–1983 doi: 10.1097/QAD.0000000000001145.

Stuart, D. Nneka Nwokolo, Alan McOwan, Margherita Bracchi, Marta Boffito, *ChemSex: Data on Recreational Drug Use and Sexual Behaviour in Men Who Have Sex with Men (MSM) from a Busy Sexual Health Clinic in London, UK*, Chelsea and Westminster Hospital Trust, 2016.

Trend indications provided by Siobhán O'Dea, GMHS, on 15th March 2017 by email.

Results

- Some study participants expressed reservations or concerns around *how* PrEP should be implemented but 94% supported the implementation of PrEP into the RoI on public health grounds;
- All participants (100%) expressed the view that PrEP should be seen as one prevention intervention among an arsenal of measures that are targeted and appropriate to the needs of the individual, but should not replace the emphasis on condom use to prevent HIV and STIs;
- Data in the initial stages of collection by the Gay Men's Health Service (GMHS) in Dublin points to a "significantly higher" rate of recreational drug use and condomless anal intercourse (CAI) among men attending the service compared to the Dean Street, London study into recreational drug use and sexual behaviour among MSM (Stuart *et al* 2016);
- The most significant barrier to PrEP implementation in the RoI is Gilead Science's application for a Supplementary Protection Certificate (SPC) for Truvada® as the cost effectiveness of PrEP, while not yet established by the National Centre for Pharmacoeconomics (NCPe) Ireland, is a perceived threat to PrEP administration through the GMS;
- Ambiguity and a general lack of consensus on risk compensation was reported by MSM FGD participants reflecting the lack of definitive consensus in the evidence base;
- Both FGDs raised fears and concerns around the lack of clinical monitoring and support for people using generic PrEP purchased online. These concerns were shared by HCPs highlighting the need to prioritise the establishment of information, advice and clinical monitoring services;
- That PrEP should be provided free-of-charge at the point of delivery was contested in this study;
- There is insufficient evidence to support routine commissioning of PrEP for people who inject drugs (PWIDs) in the RoI;
- The vast majority of contributors to this research argued for an implementation/demonstration study as a first step before national implementation is considered;
- The policy architecture for PrEP is well established at national, regional and international levels.

Conclusion

The global, regional and national policy context actively advocates PrEP implementation, which coupled with rising rates of sexually acquired HIV must render PrEP a policy priority in Ireland. PrEP efficacy is well established and the high level of support for PrEP implementation among key stakeholders and potential end-users who participated in this study, points to the need for immediate steps to be taken to make PrEP available to key populations at substantial risk of HIV as part of a comprehensive package of HIV prevention measures.