

# ALL SET FOR PREP

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

Ann Nolan, Gay Health Forum, 30<sup>th</sup> June 2017

# Objectives

- Scope the evidence for PrEP efficacy (Fonner *et al*, 2016; WHO; CDC; NICE; NHS Scotland & Wales; BHIVA);
- Scope the evidence for PrEP in Ireland (Garvey *et al*, 2016; David *et al*, 2016; Glynn, 2016; *Flash! PrEP in Europe*. 2017; *PrEP in Europe Initiative*, 2016; O'Donnell *et al*, 2015);
- Establish the views of key populations affected by HIV;
- Establish the views of stakeholders directly and indirectly involved in the provision of HIV services throughout Ireland;
- Assess real & perceived barriers to PrEP implementation;
- **To enable informed policy dialogue and an advocacy platform for PrEP**

# Methodology

- 2 pathways:
  - i) scoping the evidence-base for PrEP efficacy;
  - ii) small qualitative study of health personnel & potential end-user perspectives (focus of presentation)**
- (Time-limited) scoping guided by Fonner *et al* (2016) systematic review of the evidence for PrEP;
- PubMed; Science Direct, and the Cochrane Databases;
- Desk review supported by 17 semi-structured key-informant interviews & two FGDs;
- Generic purposive sample included HCPs; pharmaco-economists, a health researcher, an epidemiologist, civil society activists, and international actors.

# Limitations of the Research

- Not an unbiased sample;
- Poor participation of stakeholders from outside Dublin;
- Poor participation of senior policy makers;
- Paucity of Irish-specific documentary data precluded cross-validation of interview data;
- Capacity & time-limited.

# Findings Overview

- 94% in support of PrEP implementation in Ireland;
- PrEP should be seen as an additional prevention intervention that should not replace existing emphasis on condom use to prevent HIV and STIs (100%);
- 88% favoured an implementation/demonstration study as a first step.

# Findings: Cost Effectiveness

- Context & epidemic-specific - sensitive to key variables such as HIV incidence, levels of adherence, willingness to use PrEP, risk behaviours, the cost of drugs and other clinical interventions required to support PrEP programmes;
- Cost effectiveness of PrEP - not yet established by the NCPE - is a *perceived* threat to PrEP implementation;
- 2 studies in UK (Ong *et al* 2015; Cambiano *et al*, 2015) PrEP not cost-effective unless the price of Truvada® is cut substantially;
- Perceived barrier to implementation in Ireland (Garvey *et al*, 2016);
- Gilead's application for SPC for Truvada® reinforcing that perception;
- Recommended *Return on Investment* (RoI) analysis – accepts initial budget impact which is potentially offset by prevention gains in future years.

# Findings: MSM FGD

- Preferred to access PrEP in a specialist clinic/hospital where staff are sensitive to and understand MSM lifestyles (aligned with *Flash* study);
- Lack of clinical support for PrEP cause for concern among men buying PrEP online;
- Potential interactions with performance enhancing & prescribed drugs was a particular worry for participants, especially those with life-threatening or chronic conditions;
- “The biggest concern for me as a PrEP user is that I am breaking the law by buying PrEP online.”;
- Outreach to MSM reported increasing demand for education and information on PrEP;
- Some men entirely rejected ‘eligibility criteria’ favouring self-assessment of risk – not supported by HCPs;
- No consensus on risk compensation (aligned with evidence-base);
- Majority of men recommended that PrEP be free at point of access.

# Findings: Health Worker Perspectives

- Questioned capacity of the health care system to respond to HIV-negative people (Garvey *et al*, 2016);
- One specialist centre providing clinical support on an informal basis as a gesture of goodwill to MSM buying PrEP online without budgetary support;
- Over half of all health workers interviewed reported initial doubts about PrEP which they had reversed given the weight of the evidence for PrEP efficacy;
- HCP's more likely to doubt claims that PrEP does not prompt risk compensation;
- All HCPs interviewed favoured the introduction of PrEP: *Increasingly seen as a preventive intervention like any other.*

# Findings: HIV+ FGD (MSM & women from SSA)

- Drug resistance was most significant concern raised by HIV+ FGD participants;
- Did not agree with view that PrEP should be free-of-charge at point of access (short term intervention rather than chronic condition);
- Welcomed PrEP but highlighted a paucity of information and knowledge among non-MSM key populations;
- Eligibility assessment should be available to anyone who perceives themselves to be at risk;
- Highlighted concerns around the PEP to PrEP nexus: reported anecdotal evidence suggesting that some people are clinic-hopping to acquire PEP in order to use it as PrEP without medical supervision (aligned with *PrEP In Europe* study).

# Findings : Who should get PrEP?

- Contested: “*PrEP should be available to anyone who wishes to take it.*” vs. “Strict eligibility criteria needs to be applied.”;
- WHO - offered to all population groups at substantial risk of HIV infection;
- Eligibility criteria based on risk exposure rather than risk group but target population MSM in practice;
- 6% of the sample suggested that PrEP should not be extended to non-citizens of Ireland – offset prevention gains;
- The Bangkok Tenofovir Study is the only large-scale study conducted with PWID and its findings not transferable to an Irish context;
- Low level engagement with PrEP in the drugs sector.

# Findings: Policy Framework for PrEP

## Macro, Meso & Micro Level Engagement

- *all-of-government* approach;
- PrEP is governed – directly and indirectly - by international policy instruments that have been ratified by Ireland;
- United Nations Political Declaration on HIV and AIDS: On the Fast-Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030 (June 2016);
- *Action plan for the health sector response to HIV in the WHO European Region 2017-2022* emphasises the need for member states to optimise prevention efforts through the prioritisation of evidence-based HIV prevention urging a particular focus on key populations, ‘with inclusion of novel approaches such as pre-exposure prophylaxis (PrEP) for populations at substantial risk of HIV acquisition’;
- Dublin Declaration, 2004 – Special Report, 2016 emphasises the need to reduce HIV infections in Europe as “Coverage of key prevention interventions, including condom promotion and distribution, behaviour change interventions, pre-exposure prophylaxis (PrEP) and harm reduction for people who inject drugs remains too low in many countries to make a real impact.”
- National Sexual Health Strategy 2015-2020

# Conclusion

- Strong basis for the immediate implementation of PrEP to key populations at substantial risk of HIV, as part of a comprehensive package of HIV prevention measures;
- At an absolute minimum, the failure to provide HIV testing and clinical monitoring to MSM who are self-purchasing and administering PrEP is a risk to the individual and broader public health.

Thank you!