

PrEPared

Prosiect PrEP Cymru Wales PrEP Project

A Project Scope and Study Protocol for the Implementation of Pre-Exposure Prophylaxis (PrEP) in Wales

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July 2017

Version 2

Overview

Project Background and Description

On Friday 28th April 2017, Cabinet Secretary for Health, Well-being and Sport, Vaughan Gething AM, announced an all-Wales study to provide the drug Truvada[®] as Pre-Exposure Prophylaxis (PrEP) to all those who would benefit from the preventative treatment [1]. The study was intended to last three years, and commence no later than Summer 2017. Public Health Wales and the Independent HIV Expert Group were asked to work together to deliver the study.

This decision followed work undertaken by Public Health Wales and the Independent HIV Expert Group in November 2016 in assessing the public health effectiveness of PrEP, 'Preparing for PrEP?' [2], and a Health Technology Assessment (HTA) of the treatment by the All Wales Medicines Strategy Group (AWMSG) in April 2017 [3]. The AWMSG recommendation to the Cabinet Secretary for Health, Well-being and Sport was that Truvada[®] should not be recommended for provision within NHS Wales, due to concerns around cost-effectiveness. However the Cabinet Secretary, whilst acknowledging the AWMSG recommendation, chose on the basis of the evidence for clinical effectiveness, to make PrEP available to all of those for whom the medicine is clinically appropriate. Subsequent discussions have confirmed that this includes those outlined within the 'Preparing for PrEP?' report's eligibility criteria [2, p.38].

The announcement also stated that the study 'will help us to learn how best to provide the preventative treatment to reduce risks of HIV transmission in Wales and answer some of the questions raised by the All Wales Medicines Strategy Group around incidence rates'.

Project Scope

The PrEPared project will see potential recipients of PrEP - as defined in the [eligibility criteria](#) outlined by the Independent HIV Expert Group - offered PrEP within Integrated Sexual Health Clinics or HIV Treatment Clinics within Wales. Patients taking up the offer of PrEP will be closely monitored as per the [PrEP Management Guidelines](#) [4], with data collated and analysed by Public Health Wales on a quarterly basis. Reasons for those declining the offer of PrEP will also be collected and analysed to understand these decisions.

This is **neither a clinical trial nor a feasibility study**. Rather, this project focuses on monitoring the acceptability of PrEP to the relevant population, HIV/STI acquisition and the health outcomes of those who accept or reject it. An evaluation of the project will be undertaken at its conclusion (An Evaluation Plan is being prepared).

Methodology

In the PrEPared project, eligible recipients of PrEP will be identified in the first instance through access to Integrated Sexual Health Services, and subsequent consultation with an appropriately-trained clinician. Other community-based settings (e.g. sexual health charities, Primary Care clinics) should refer prospective recipients to an Integrated Sexual Health Service for an appropriate consultation.

During the consultation with the prospective recipient, the clinician will follow the processes outlined within the Public Health Wales [PrEP Management Guidelines](#) [4] to ascertain if the potential recipient is eligible to access PrEP through the NHS. This consultation will include discussion of all available HIV prevention options, and will emphasise the importance of condom use, with the provision of free condoms, to prevent the transmission of other sexually transmitted infections (STIs). There will also be discussion regarding the regimen that should be followed when using PrEP. During the consultation, and if the prospective recipient is eligible, the clinician should offer the

option of being prescribed PrEP through the NHS. If the recipient accepts, this will be coded using codes from the National Dataset for Wales and follow-up appointments will be scheduled. If, following discussion, the potential recipient declines the option of PrEP, this should also be noted along with any reasons for the decline, since it is as important for the project to consider the health outcomes of this population group over the study period..

For patients using PrEP, at each clinic visit, they should be offered PrEP alongside free condoms, behaviour change interventions, other treatment options as appropriate, testing for STIs/HIV, renal function and bone profile monitoring.

For patients who are not eligible to receive PrEP through the NHS but who choose to access privately, at each clinic visit, they should be offered free condoms, advice on risk minimisation, other treatment options as appropriate, testing for STIs/HIV, renal function and bone profile monitoring.

Patients who are eligible but refuse PrEP should be screened for HIV and STIs, offered free condoms, advice on risk minimisation, other treatment options as appropriate and advised to return for STI/HIV screening every three months,

All patients commencing PrEP require initial follow up at the clinic after one month, followed by quarterly clinical assessments.

All notes and subsequent referrals are to be noted on a patient record and coded on the National Dataset for Wales. Notes should include reference to any risk behaviours identified, clinical assessments, prescribing information and other relevant details as outlined in the PrEP Management Guidelines and this protocol.

Project Governance

The PrEPared Project will be overseen by the Independent HIV Expert Group, managed and administered by Public Health Wales and will report to the Welsh Government Steering Group which, in turn, reports to the CMO's Sexual Health Oversight Group. The PrEPared Project Group will include the following representation:

- Clinicians from the six Health Boards currently providing sexual health care who will offer PrEP at the outset (Cardiff and Vale University Health Board, Abertawe Bro Morgannwg University Health Board, Hywel Dda University Health Board, Betsi Cadwaladr University Health Board, Aneurin Bevan University Health Board, Cwm Taf University Health Board)
- NHS Direct Wales
- Public Health Wales – Policy, Health Protection, Communications and Epidemiology Representation
- Other Independent HIV Expert Group Patient Group representatives

Terms of Reference for this Group are being prepared.

The Independent HIV Expert Group will be tasked to:

- Ratify the requirements of the project;
- Consider options for promoting the project;
- Identify, and take steps to address, risks of the project;
- Oversee the monitoring of the project;
- Report on project developments in their setting.

Eligibility Criteria

The criteria should be taken as a minimum, and should not substitute clinical judgement. It relates to someone who is already engaged in care.

Inclusion Criteria

Populations	MSM, transgender people
Necessary Aspects	<ul style="list-style-type: none"> • A documented confirmed 4th generation HIV negative test at initiation of PrEP • Reporting condomless anal intercourse in the previous three months • Considered likely to engage in repeated condomless intercourse in the next three months • Proof of Welsh residency provided*
Further Guidance	Where available, use point of care testing (fourth generation test).
Population	HIV negative partner of a HIV positive person
Necessary Aspects	<ul style="list-style-type: none"> • HIV positive partner's viral suppression is unknown • Condomless intercourse is anticipated or has occurred within the past three months • Proof of Welsh residency provided*
Further guidance	PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion) Treatment as prevention for the HIV positive partner should be considered.
Population	HIV negative heterosexuals
Necessary Aspects	<ul style="list-style-type: none"> • Known to have had condomless sex with a person with HIV within unknown viral suppression within the past three months • Anticipated to have condomless sex with person, or person of similar status, again • Proof of Welsh residency provided*
Further guidance	PrEP should be recommended where the treating clinician recommends and monitors treatment as part of wider risk reduction (e.g. health education, safer sex promotion)

If it is deemed clinically appropriate that Truvada[®] is prescribed to an individual between 16-18 years of age or prescribed for event-based dosing rather than a daily regime this would be outside of the licence and, therefore, subject to health board policy for off label prescribing. Each health board will have its own policy, for example Aneurin Bevan Health Board [5].

*PrEP is outwith the normal sexual health and HIV provision so treatment costs cannot be cross – charged with other nations.

Exclusion Criteria

This includes individuals in monogamous relationships with HIV positive partners with an undetectable viral load, individuals without a current confirmed HIV negative test, those who are already HIV positive and individuals under 16 years of age. [6, p.22]

Parameters

In order to evaluate the use of PrEP a number of data items will be collected for each individual seen in the services for whom PrEP is deemed appropriate. The data will provide information on the following:

- Number of new diagnoses of HIV (specifically from those who were tested as a result of wishing to use PrEP)
- High risk behaviour group (reason for eligibility for PrEP)
- Number of individuals offered PrEP as judged clinically appropriate
- Number of individuals who accept PrEP

- Number of individuals who refuse PrEP when offered as judged clinically appropriate
- Length of time using PrEP
- Adherence to PrEP

The data collected will provide trend data for the use of PrEP which will be reported to Welsh Government in an Annual report.

The following data items will be collected to help with the monitoring and evaluation of use and uptake of PrEP in the PrEPared project:

Data Item	Collected Via	Frequency
Service Type	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Service Name	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Patient ID	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Date of Birth	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Gender	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Sexuality	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Date of attendance	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
Postcode of residence	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
HIV status	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
PrEP offered but not started at current attendance. (This code should be used for any patients offered a new course of PrEP at the current attendance but deciding not to take up PrEP)	National Dataset (via Blithe or Mill submission)	First contact
PrEP from another source (eligible for NHS provision)	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
PrEP from another source (not eligible for NHS provision)	National Dataset (via Blithe or Mill submission)	First contact, month one follow up, three monthly ongoing
PrEP started at current attendance	National Dataset (via Blithe or Mill submission)	First contact
PrEP continued at current attendance	National Dataset (via Blithe or Mill submission)	month one follow up, three monthly ongoing
PrEP stopped since last or at current attendance	National Dataset (via Blithe or Mill submission)	month one follow up, three monthly ongoing

N.B further codes are being discussed, therefore there will be updates introduced to allow the detailed monitoring of PrEP uptake, regimen and duration of use which will address questions around the impact of PrEP and inform future service planning.

Data collection form

(adapted from CRI for use in clinical interaction)

Service Name:

Patient ID:

First Visit

Is patient eligible for PrEP from NHS? Yes/No

Does patient want PrEP from NHS?

Yes/No **Is patient already on PrEP? Yes/No**

If yes and sourced online check information about source on www.iwantprepnw.co.uk

Reason for recommending/wanting PrEP?

PMH (any bone/renal disease)

DH

HIV/STI screen last 12 months? Yes/No
If yes details....

Previous hepatitis B vaccine? Yes/No
If no offer hepatitis B vaccine

Sexual history last 3 months

If already on PrEP which regime are they using? Daily/Event based

If not on PrEP discuss regime: For MSM daily and event based
All others daily

Regime chosen: Daily/Event based

Discussed

Adherence is important before and after exposure risk

Risks and benefits of PrEP and consideration of online purchase www.iwantprepnw.co.uk

Importance of 3 monthly HIV/STI screen

Risk reduction including information and support with chemsex as appropriate

Adherence (if already on PrEP)

Adverse events (if already on PrEP)

Urinalysis

STI screen (use male proforma)

	Requested	Result
Oral CT/GC NAAT		
Rectal CT/GC NAAT		
Urine CT/GC NAAT		
HIV		
STS		
HBV		
HCV		
Creatinine and eGFR		

Follow up

	Appointment date
1 month (if just starting PrEP)	
3 months	

Refer to SHA

1 month follow up

Adherence (including reasons for non-adherence)

Adverse events

**Do patients require EOWP STI/HIV screen? Yes/No
If yes make appointment**

3 monthly follow up

Reason for continuing PrEP?

Regimen: Daily/Event based

Adherence (including reasons for non-adherence)

Adverse events

Urinalysis

STI screen (use male proforma

	Requested	Result
Oral CT/GC NAAT		
Rectal CT/GC NAAT		
Urine CT/GC NAAT		
HIV		
STS		
HBV		
HCV		
Creatinine and eGFR*		

* Serum creatinine if protein > 1+ on urinalysis

Serum creatinine and eGFR annually (more frequent if abnormal at baseline or proteinuria or >50 or on concomitant medications that are relevant to renal function)

Communications Plan

Prospective recipients will of course need to be aware of the opportunity to receive PrEP. This will require a series of promotional materials, for example posters, patient information leaflets, and an internet presence.

Costs

In addition to the drug provision there will be a requirement for funding for provision of point-of-care testing (POCT) in clinics, along with the provision of information for clients, this will include design, translation, web presence and printing costs. A clearer estimation of projected costs for information provision will be available prior to the commencement of the project, after consultation on the requirements with service users and the Independent HIV Expert Group

Risks

A full risk log is being prepared and will be available at commencement of the project, pending final consideration of the Independent HIV Expert Group.

Timeline/Schedule

The aim is to provide PrEP across Wales from July 2017. Welsh Government has requested an Implementation Plan by 26th May. Given this timescale we propose the following approach:

- we will produce a draft implementation plan and circulate this by 15th May
- comments back to us by midday 19th May, amendments made and re-circulated for final comment □
- Final document to Welsh Government on 26th May

Beyond this we will prepare for implementation with a proposed date, at this time, of 17th July. Given this we propose that we have a face to face meeting of the Independent HIV Expert Group on 12th July, and have proposed a series of service user engagement opportunities, to be delivered with Terrence Higgins Trust Cymru, in June 2017, to ascertain service users information provision needs.

Once the provision of PrEP commences, the Independent HIV Expert Group will meet quarterly to oversee the reporting to Welsh Government.

Approval and Authority to Proceed

We approve the project as described above, and authorize the team to proceed.

Name	Title	Date

Approved By _____ Date _____

Approved By _____ Date _____

References

1. Welsh Government Health Secretary Vaughan Gething announces all-Wales PrEP trial. 2017. Available at: <http://gov.wales/newsroom/health-and-social-services/2017/170428trial/?lang=en> (Accessed: 28 April 2017)
2. Public Health Wales NHS Trust 'Preparing for PrEP?' A Review of the Current Evidence for Pre-Exposure Prophylaxis (PrEP) to prevent HIV infection in Wales. Cardiff, Wales: Public Health Wales NHS Trust; March 2017. Available at: <http://www.wales.nhs.uk/sitesplus/888/opendoc/304708> (Accessed: 15 March 2017)
3. All Wales Medicines Strategy Group (AWMSG) All Wales Medicines Strategy Group (AWMSG) - emtricitabine/tenofovir disoproxil fumarate (Truvada). All Wales Medicines Strategy Group (AWMSG). 2017. Available at: <http://www.awmsg.org/awmsgonline/app/appraisalinfo/1625> (Accessed: 6 May 2017)
4. Public Health Wales Pre-Exposure Prophylaxis (PrEP) Management Guidelines. Public Health Wales NHS Trust; 2017. Available at: http://www.publichealthnetwork.cymru/files/3814/9458/8248/PrEP_Management_Guidelines_2017_12_05_17.docx (Accessed: 12 May 2017)
5. Aneurin Bevan Health Board Policy for the use of Unlicensed Medicines and Medicines used outside their Market Authorisation. 2010. Available at: <http://www.wales.nhs.uk/sites3/Documents/814/ABHB0159%20Unlicensed%20Medicines%20Policy%20-%20Issue%202.pdf> (Accessed: 23 May 2017)
6. NHS England Specialised Services Clinical Reference Group for HIV Clinical Commissioning Policy Proposition: Pre-exposure prophylaxis (PrEP) to prevent the acquisition of HIV in adults. NHS England; Available at: https://www.engage.england.nhs.uk/consultation/specialised-services/user_uploads/f03x06-policy-proposition.pdf (Accessed: 4 November 2016)