Response ID ANON-TGZF-U31F-T

Submitted to **Consultation on Specialised Services clinical commissioning policies and service specifications**
Submitted on **2016-09-23 16:57:35**

Clinical Commissioning Policies

1 What is your name?

Name:
David Asboe

2 Who are you responding on behalf of?

Who are you responding on behalf of?:
British HIV Association

3 Job title?

Job title:
Consultant Physician and Chair, British HIV Association (BHIVA)

4 What is your email address?

Email:
bhiva@bhiva.org

Clinical Commissioning Policies

5 Has all the relevant evidence been taken into account?

Yes

Comments::
We believe the policy proposal fairly reflects the evidence available. There is some evidence that tenofovir related toxicity is greater in older adults. Consideration should be given to additional monitoring according to risk algorithms.

6 Does the impact assessment fairly reflect the likely activity, budget and service impact?

No

If you have selected 'No', what is accurate? :
The service delivery model is based on “piggy-backing” a PrEP programme onto recommended 3-monthly STI screening of MSM in level 3 sexual health services. There has been fairly limited discussion about the additional resources required to support delivery of this. This discussion has focussed on issues related to toxicity screening (eg U+Es testing). It is important that the impact on staff time is also considered especially bearing in mind the need to consider, at each visit, whether the PrEP recipient is to remain on PrEP or not. For this to be done effectively, it is critical that sufficient staff resource is available. This may be more of an issue for clinics with high numbers of attending MSM. It may be that development of an appropriate tariff is indicated.

7 Does the proposed policy accurately described the groups for whom PrEP should be routinely commissioned?

Yes

Comments::
Yes but see below regarding potential impact on inequalities. Additionally, we support the indications for people 16 years or over.

8 Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?

Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?:
We believe the policy proposal as it relates to MSM is appropriate, evidenced based and deliverable. It represents an intervention with the potential to significantly and positively impact HIV incidence in this group. We also agree with the additional criteria to give PrEP access to heterosexuals at high risk. However, it is unclear how such individuals will be identified and offered PrEP. This raises the issue of inequity not in policy development but in delivery. In spite of this, we strongly support the consideration of the policy as it stands as we are not aware of any evidence that would support modification of the criteria or the delivery service model. While it is out-with the scope of this consultation, we believe in order to reduce future health inequalities, further service delivery research is required focussed on PrEP offer and delivery to heterosexuals at higher HIV risk.

9 Are there any changes or additions you think need to made to this document, and why?

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Yes

In view of the price of Truvada and the impact that drug price has on the financial modelling we believe that full consideration of the use of generics should be considered. The World Health Organisation are going to recommend that PrEP consist of either TDF/FTC or TDF/3TC. They convened an expert group, which reviewed the evidence on the clinical efficacy of 3TC versus FTC as a treatment for HIV, and showed no difference between the two. They have reviewed the clinical pharmacology of the two drugs and do not see any conclusive evidence why FTC should perform differently as a preventative drug than 3TC. Most importantly, they have conducted a meta-analysis of the clinical trials of TDF versus TDF/FTC as PrEP. In this analysis, there was no clear trend for TDF/FTC to perform better than TDF, across a wide range of studies. This is the main basis for their recommendation to use either TDF/3TC or TDF/FTC - their assessment is that TDF is responsible for most of the preventative effects of PrEP.

In Australia, generic TDF/FTC is being imported from India as part of a programme of clinical trials. It should be possible to do the same for the UK. There are suppliers of generic TDF/FTC or TDF/3TC which have products pre-approved by the US FDA and the World Health Organisation's pre-qualification process, so there should be no concerns over drug quality. A large observational study could be established to monitor the efficacy and PK of generic TDF/3TC and/or TDF/FTC imported into the UK. This could be conducted as a collaboration with the Australian research programme on PrEP.

Clinical Commissioning Policies

10 Before completing the survey you must declare any financial or other interests in any specialised services. For example, if you are responding on behalf of a voluntary organisation and your organisation received any funding within the last two years (including sponsorship or grants) from companies that manufacture drugs or treatments used in the treatment of specialised services, you must declare this. If you are a commercial supplier to the NHS of specialised services this should also be specified.

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The British HIV Association (BHIVA) receives funding support from the pharmaceutical industry. Please see the BHIVA Annual Report and Accounts for the year ended 31 December 2014, which are available on the Charity Commission website at:
http://apps.charitycommission.gov.uk/Showcharity/RegisterOfCharities/CharityWithPartB.aspx?RegisteredCharityNumber=1056354&SubsidiaryNumber=0.

The account for the year ended 31 December 2015 will be filed with the Charity Commission by the deadline of 31 October 2016.