Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Report on the results of the public consultation on the draft health technology assessment (HTA) of a PrEP programme for populations at substantial risk of sexual acquisition of HIV

14 June 2019

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services —** Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health services, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

- **National Care Experience Services** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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Particular thanks are due to the Expert Advisory Group (EAG) and the individuals within the organisations listed below who provided advice.

The membership of the EAG was as follows:

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Dr Patricia Harrington	Health Information and Quality Authority
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Members of the Evaluation Team

Members of HIQA's Evaluation Team were Dr Éamon Ó Murchú (project lead), Dr Patricia Harrington, Mr Liam Marshall, Ms Debra Spillane, Dr Conor Teljeur and Dr Máirín Ryan

Conflicts of interest

None

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1. Introduction

In August 2018, the Health Information and Quality Authority (HIQA) commenced work on a health technology assessment (HTA) on a pre-exposure prophylaxis (PrEP) programme for populations at substantial risk of sexual acquisition of HIV. The HTA was requested by the Clinical Lead in Sexual Health at the Health Service Executive (HSE), with the endorsement of the Department of Health. The aim of the assessment was to examine the clinical and cost-effectiveness of introducing a PrEP programme in Ireland.

This report summarises the feedback received from the public consultation process and details HIQA's responses to the issues raised, including any changes that were made to the report as a result.

2. The consultation process

The aim of the consultation process was to obtain feedback on any issues that may not have been adequately addressed in the report and, based on the feedback, to expand coverage of material requiring further clarification.

The draft HTA was published on the HIQA website on 23 April 2019. The public consultation period closed on 28 May 2019. The public were provided with an opportunity to give feedback through a variety of means (postal, email or online) to ensure the consultation process was widely accessible. The consultation webpage contained a link to the draft report, a link to the Crowdsignal website for online submission of feedback, and a consultation feedback form that could be downloaded.

A press release was issued at the beginning of the consultation period, and the findings of the draft HTA were widely reported in the media. Individuals and organisations with expertise in the area and those who are likely to be affected by the introduction of the programme were targeted directly and requested to provide feedback. This included relevant stakeholders within the HSE, national and international experts in the field of HIV prevention, and organisations that represent individuals, families or healthcare professionals who may be affected by the proposed introduction of a PrEP programme in Ireland.

3. Methods

All comments received were saved in an online database. Submissions from individuals were anonymised before being transferred to Microsoft Excel for analysis.

The template for submission consisted of five questions. Character or word limits were not applied to submissions. A copy of the submission template is provided in Appendix A. The following questions were asked:

Question 1

The report contains evidence regarding the clinical and cost-effectiveness of pre-exposure prophylaxis (PrEP). Do you think any changes should be made to the scientific evidence included in the report?

Question 2

The report includes background information regarding the organisational and resource implications of introducing a PrEP programme. Do you think any changes should be made to the background information included in the report?

Question 3

Do you think our interpretation of the evidence should be changed?

Question 4

Did you have any issues with the clarity or presentation of the report? Please specify the sections that require improvement.

Question 5

Do you have any general comments you would like to make about this report?

4. Results

A total of 69 separate submissions were received, 57 from individual respondents and 12 on behalf of organisations or institutions. 65 submissions were received via online feedback through the consultation webpage and four submissions were received by e-mail. Appendix B provides a full list of all the organisations that made a submission.

Each submission was read in its entirety, broken down into individual comments, and recorded to create a database of comments. In cases where a question was skipped by the respondent, HIQA assumed that there were no issues of concern.

Most submissions were from Irish respondents; however, submissions were also received from Australia, Denmark, France, Greece and the United Kingdom.

As a general comment on submissions received, all were in favour (or very strongly in favour) of introducing a national PrEP programme in Ireland. However, many submissions highlighted the need for adequate investment in sexually transmitted infection (STI) services to provide a safe and sustainable service.

Table 1, below, outlines specific points raised during the consultation process and provides a brief summary of HIQA's response. General comments in favour of programme implementation and submissions commending the work by HIQA are not included. Comments are listed in Table 1 in the order in which they were received.

Table 1 Specific comments received and responses

Number	Comment	Response
1	"Table 2.3 indicates that the HPV vaccine is available to MSM under 26. Since July 2018 its available to MSM 45 years and under"	Table 2.3 has been amended.
2	"Will eligibility criteria be enforced or is there prescriber discretion?"	There may be provider discretion as prospective PrEP users will be enrolled on a case-by-case basis in line with national clinical guidelines. In this assessment, however, it was assumed that individuals enrolled in the PrEP programme were at substantial risk of HIV infection. Therefore, the magnitude of clinical effect and the measure of cost-effectiveness and budget impact associated with PrEP reported in this HTA assumes that the eligibility criteria are met.
3	"Is there a risk of patients not meeting criteria falsely reporting condomless sex thus affecting future data collection or will they buy it online and not have any monitoring appointments?"	The proposed PrEP programme is a holisitic programme that includes patient education and counselling to improve education and awareness of safer sex practices. It is not possible to assess the likelihood of whether or not individuals would falsify information to obtain PrEP. It is reasonable to assume that this would have an impact on the quality of future data collection. Consistent with the advice of the HPRA[(1)], the purchase of PrEP online is not recommended. All individuals taking PrEP, regardless of how they obtain PrEP, will continue to have access to sexual health service clinics including appropriate STI

		testing and counselling services.
4	"You should make summary available for download separate, as it's a 244 page document that makes for heavy reading with its detailed scientific and economic analysis"	In the final report, an Executive Summary and a section on the Advice to the Minister will be included, which summarise the information contained in the HTA. Additionally, a Plain English summary will be included which should prove useful to non-scientific readers.
5	"A simple breakdown on what the final cost and procedure for access of PrEP is likely to be for an individual accessing it on the HSE would also be welcomed as this is the key piece of info end service users are most interested in, particularly those already taking PrEP via current means"	A core tenet of the proposed national PrEP programme is that there would be equitable access to PrEP services, with PrEP medication provided free of charge. This would ensure consistency with current public health policy to limit onward transmission of infectious diseases. It was, therefore, assumed in this assessment that PrEP would be made available at no cost to the patient.
6	"The font was not to my liking"	The font is specified in the HIQA House Style and was selected on the basis of its readability.
7	"In the background information, it would be wise to acknowledge the historical context of PrEP and its significance within the LGBT community, even briefly, especially considering the trojan work by activist groups such as ACT UP (including their awareness raising regarding the legal situation regarding Gilead) and the Gay Health Network"	The historical context of PrEP is discussed briefly in Chapter 2, Section 2.4. Additional information on the historical context of PrEP is available in a publication by HIV Ireland in 2017, entitled *Pre-exposure Prophylaxis (PrEP): Scoping and Policy Options Review*.[2]
8	"It is important to consider the nature of the public information campaign suggested in Chapter 7, especially consdiering the phenomena of PrEP stigma and PrEP sorting. We support the suggestion to engage with advocacy groups on this. Chapter 7 also highlights the importance of adherence and funding - strong recomendations for intiatives to support both of these should be included in the report if possible.	If a decision is made to fund a PrEP programme, clear consideration should be given in the HSE implementation plan to the nature of the public information campaign and initiatives to improve adherence. This may include engagement with patient and community advocacy organisations. The role of advocacy organisations is highlighted in Chapter 7 (Organisational issues).

	In general, an excellent report which the National LGBT Federation supports."	
9	"Very difficult to read for non-specialists"	The document is necessarily technical in nature. However, we have added sections to the final report to improve readability for a general audience. The following sections of the final report should improve readability for non-scientific readers: • Executive summary • Advice to the Minister for Health and the HSE • Plain English summary
10	"A gross budget impact should be provided to enable decision makers to fully understand what steps they would need to put a programme in place. In the absence of the detail of a gross budget impact the suggestion that significant investments need to be made doesn't align well with the relatively modest proportion of the budget impact (29%) associated with same. In the absence of a gross BI, 29% could reasonably be applied to incremental costs."	A new section has been added to Chapter 6 (Section 6.5.2.3) which provides an itemised budget impact for the whole population by year, which includes medication-only costs and programme-only costs. Yearly medication and programme costs are detailed in Tables 6.27 and 6.28. Additionally, Figure 6.18 provides the 5-year budget impact for the five cost items (medications, programme, STI treatment, post-exposure prophylaxis after sexual exposure [PEPSE] and HIV treatment costs).
11	"I think additional details should be provided for decision makers to assist them around understanding what "significant investments" mean. If those investments involve appropriately trained staff recruitment could become a RDS for implemetation of a PrEP programme in compliance with appropriate standards. Not calling that out clearly may lead to a lack of understanding that a recruitment campaign may be necessary (assuming additinoal staff are part of the deficit)"	This assessment only included the additional cost associated with the provision of PrEP and did not take into consideration the current gaps in service delivery and the lack of investment in public sexual health services to date. Allocation of any additional resources will also need to take consideration of expected demand at a clinic and regional level and the existing capacity and resourcing of the STI clinics serving that area. A recruitment campaign may be needed in some areas to address staff shortages. Additionally, as previously noted, HIV notifications in HSE East are almost twice the national average. Geographical differences in the need for PrEP as well as the requirement to provide equitable access should, therefore, be taken into consideration

		when allocating resources.
12	"Minor observatino on the order of the sections, would CE and BI sections be more appropriately placed after the sections on organisational issues chapter. Decision makers might expect that organisational issues (changes / costs) are captured in the modelling exercises. Could placing this section post modelling raise doubts as to whether all known costs are captured in models?"	The sequencing reflects the fact that potential organisational issues are often identified through the economic modelling exercise and then elaborated on in the chapter on organisational issues.
13	"The PSI welcomes the recognition of the potential role of the hospital and community pharmacist in the supply of medication to ensure the delivery of safe and effective delivery of PrEP. The PSI would recommend that under Section 7: Access to PrEP Medication, specific reference be made that the prescription needs to be written in a manner that complies with the legislative requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended in order to be dispensed in a retail pharmacy business"	This recommendation has been incorporated into Chapter 7, Section 7.5.
14	"HIV Ireland notes the report clearly states PrEP is safe and highly effective at preventing HIV infection in MSM and in HIV-uninfected partners of serodifferent couples. HIV Ireland recommends the report should also state that PrEP is an important and efficacious prevention option for other populations vulnerable to HIV infection via sexual exposure such as women (particularly trans women), sex workers, and migrants. We advocate for full and free access to all those vulnerable to acquiring HIV."	The biological mode of transmission, as opposed to demographic factors, was used to distinguish efficacy in different groups. HIQA reports that PrEP is highly effective at preventing HIV infection in trials where the mode of transmission was MSM (which included trials with a combination of gay/bisexual men and trans women) and in HIV-negative partners of serodifferent couples. Trials were not identified that specifically enrolled sex workers or migrants, leading to the inability to report efficacy separately in these groups. Additionally, while recommended in trans women who have sex with men, very few participants were trans women in the identified trials. However, all populations will still fall under one of the following groups:

		MSM/trans women who have sex with men, heterosexual transmission or people who inject drugs. Possibly due to poor adherence, evidence of efficacy was inconsistent in heterosexuals. Efficacy was noted in people who inject drugs in one trial where the route of transmission may have been sexual or parenteral; the results of the study may not be directly applicable to Ireland. It was noted in Scotland's programme that over 99% of participants in the first year of their national programme were MSM. Ireland's proposed programme will assess all populations at risk of HIV for PrEP eligibility in line with national clinical standards. In cases where the individual is not MSM/trans woman who has sex with men or a HIV-uninfected partner of a serodifferent couple, these individuals will be assessed for eligibility on a case-by-case basis. In the budget impact assessment, it was assumed that up to 5% of participants in the programme will not belong to the MSM group, acknowledging the potential uptake in others identified to be at substantial risk of sexual acquisition of HIV. It is noteworthy also that 'on demand' PrEP has only demonstrated efficacy in the MSM group.
15	"HIV Ireland believes that without a well-resourced and culturally competent clinical staff, a PrEP programme will be unable to function properly. In order to access a critical mass of those vulnerable to HIV, clinics must be accessible and welcoming to the populations who will benefit from the intervention. We recommend a significant investment in staff and infrastructural needs."	A significant investment in STI services is required for a national PrEP programme to ensure a safe and sustainable service, as outlined in Chapter 7: Organisational issues. Without investment in STI services, sub-optimal delivery of a PrEP programme could result in inequitable access to care and poor medication adherence and monitoring. Without the allocation of additional resources, the delivery of PrEP could result in disruption of core STI clinic services, with increased wait time for non-PrEP attendees.
16	"HIV Ireland supports the trial evidence. If sexual behaviour or	The proposed PrEP programme is a holistic and supportive programme that

	STI incidence subsequently rise, users of PrEP must continue to be supported and encouraged as to do differently will increase stigma and discourage their engagement with health services, increasing vulnerability to HIV acquisition."	includes testing, education and counselling in addition to access to medications.
17	"HIV Ireland supports PrEP as a biomedical prevention approach which holds the greatest promise in achieving an end to new HIV transmissions. Investment in sexual health services is a priority as it can remove geographical and capacity based access barriers."	PrEP is the newest development in the field of HIV prevention, and is highly effective when used correctly. Significant investment in STI services will be required to ensure a safe and sustainable service, however. The allocation of any additional resources will also need to take consideration of expected demand at a clinic and regional level and the existing capacity and resourcing of the STI clinics serving that area.
18	"The title of the Health Technology Assessment and subsequent background information outline the need for a holistic PrEP Programme in Ireland which includes "assessment, preventive PrEP treatment, education and advice". The organisation has some comments in relation to same: 1. Page 11 Paragraph 3 should also detail outreach and support programmes if the programme is to be holistic. 2. Table 2.1 does not display the 95% CI lower limit. This would be useful for the reader when interpreting findings. 3. Chapter one, two and three provide a clear overview of the technology and epidemiology of PrEP. However, there is no overview of a holistic PrEP programme, elements of education, advice and support and how these are incorporated into programme delivery. 4. Page 54, paragraph 4 – In relation to highest reported cases by region it would be interesting to know if these individuals all reported a home address in HSE East"	The HSE Sexual Health and Crisis Pregnancy Programme (SHCPP) has responsibility for implementing the National Sexual Health Strategy, which contains policy provision for PrEP. To inform its work, SHCPP convened a multisectoral working group to develop recommendations in relation to the use of HIV PrEP in Ireland (the PrEP Working Group). This group, with community representation, developed clinical guidance documents and national standards in relation to the use of PrEP in Ireland. In response to specific points raised: 1. Outreach workers fall under the general remit of public sexual health services in Ireland and are not specifically included as part of a PrEP intervention. 2. Table 2.1 provides the number of HIV infections observed in the HIV PARTNER observational study – there were zero HIV transmissions (therefore, the lower limit is also zero). 3. A holistic PrEP programme would include elements of education, advice and support. This holistic service is described in Chapter 1, Section 1.1. How these are incorporated into programme delivery will be a matter for the HSE and the

		implementation of a PrEP programme was outside the scope of this assessment. 4. Indeed, the notification rate by HSE region does not necessarily reflect the area of residence of individuals attending services.
19	"There is a very clear overview of evidence presented. In chapter 4, the span of included years of publication of the included trials would be interesting to be included under key points. Chapter 4 speaks about a low risk of bias but does not mention which Critical Appraisal tool it utilised or if one was utilised? Chapter 8 outlines the need to information on PrEP to be available and alludes to the benefits of motivational interventions, education programmes, professional training and one-to-one supports but a plan or format for same is not clear."	Chapter 4, Section 4.2.5 outlines the methods for assessing the risk of bias in included studies. The Cochrane Risk of Bias tool was employed. This included information on the sequence generation, allocation concealment, blinding (participants, personnel and outcome assessor), incomplete outcome data, selective outcome reporting and other sources of bias. The methodological components of the studies were assessed and classified as adequate, inadequate or unclear as per the Cochrane Handbook of Systematic Reviews of Interventions. Additionally, an overall assessment of the quality of the evidence was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. In terms of the benefits of motivational interventions, education programmes, professional training and one-to-one supports, the implementation plan will be a matter for the HSE and while these measures may be considered, they were outside the scope of this HTA.
20	"The Health Technology Assessment of a PrEP programme for populations at substantial risk of sexual acquisition of HIV provides a clear overview of the clinical aspects of the introduction of such a programme in Ireland. The evidence is clearly stated and deliberated, framed by a discussion of ethical considerations. The title and introduction propose a PrEP programme and the overall HTA would benefit from greater information on the education, outreach and support parameters required to fulfil the	The primary purpose of the HTA was to assess the clinical and cost-effectiveness of a national PrEP programme and to provide evidence-based advice and recommendations to the Minister for Health. The implementation of a PrEP programme, including outreach and support services, will be a matter for the HSE and were outside the scope of this HTA.

	implementation of such a programme in Ireland."	
21	"The evidence regarding the clinical and cost-effectiveness of PrEP is fully comprehensive from global studies. It is detailed and includes all at-risk populations, including MSM, serodifferent couples, PWID and heterosexuals. The summary of findings tables for efficacy and safety are similarly comprehensive. Forest plots clearly favour PrEP in all populations. It was good to see that PrEP was found to be cost-saving in the first cost-effectiveness analysis of a targeted PrEP programme tailored to the Irish HIV epidemic"	The forest plots favour PrEP in all populations with the exception of heterosexuals at substantial risk (here, the relative risk [RR] was 0.77 across all trials, 95% confidence interval [CI] 0.46 to 1.29). However, in the only trial that recruited heterosexuals where the adherence was high (>80%), a significant effect was observed (RR 0.39, 95% CI: 0.18 to 0.83).
22	"HIV i-Base strongly agree with the final conclusion "9.3 The successful implementation of a national PrEP programme would be safe, effective and cost-saving over the medium to long term." We therefore urge rapid access to this programme as soon as possible." =.	This HTA concluded that PrEP is a safe, effective and cost-saving intervention. It is important to note that the purpose of the HTA is provide advice to inform the decision, but that any decision around the programme including its implementation rests with the Minister forf Health and the HSE.
23	"We would have liked to see the language for…"sex work" as government bodies and the legislation usually refer to it as prostitution. From our experience women are involved in this trade for a wide range and often complex reasons and we regularly work with women who are exploited by this trade and wouldn't see it as a form of work so "women/men in prostitution" is the language we recommend to use so that all experiences are included."	In the report, an explanation of the terms 'sex worker' and 'prostitution' was included in Chapter 3 Section 3.3.4.3. In terms of reporting trial data that enrolled sex workers/individuals involved in prostitution, the terminology used in the primary study will be used (studies typically used the term 'sex worker').
24	"The evidence provided in the clinical and cost effectiveness of PrEP appears robust. However, it would be important to ensure that appropriate reviewing of the	The evidence was systematically reviewed up until 31 July 2018. An updated search on 29 May 2019 did not identify any additional RCTs. Due to the strength of the evidence, it is unlikely that

	research and/or update to the systematIc review are completed to ensure that any new research on PrEP or other preventative programmes which may produce better outcomes are recognised."	subsequent trials will significantly change the findings of the assessment. Clinical audit of a prospective PrEP programme will be important, which should include monitoring adherence, persistence on PrEP/PREP discontinuation rate and any changes in STI rates pre- and post-implementation. This ongoing monitoring and surveillance will require data collection at a national level (as discussed in Chapter 8: Organisational issues and Chapter 9: Discussion).
25	"The organisational and resource implications of introducing PrEP will have a huge impact on the roll out of the programme and its ability to reach patients. The current incoherent nature of how patients access the programme needs to be addressed before it can be rolled out. Sexual health services in Ireland are, at present, inadequately resourced. Rates of STIs and HIV increase yearly with no corresponding increase in the staff compliment in the services. Patients on PrEP need three monthly monitoring visits and STI screens and may need assessment in between times if they become symptomatic of an STI. It is essential that appropriate levels of staffing, skill mix and suitably qualified staff are identified and in situ before the programme is rolled out. The current staffing problems within sexual health clinics cannot continue and will have an adverse effect on how the PrEP programme will work. When funding is in place and PreP is being provided it will be necessary to monitor the effect on the services and ensure the resources are being fairly provided to services impacted by the initiative. There is little evidence as to what is the best approach in terms of the rollout of the programme. In Australia many PrEP clinics are nurse-led and the	The organisational and resource implications of introducing a PrEP programme were assessed in Chapter 7 and formed the key recommendation that significant investment in STI services is required to ensure a safe and sustainable service. If a decision is made to fund PrEP, the implementation of the programme will be the remit of the HSE. It will be necesary to consider the additional resource requirements at a clinic/regional level. It is proposed that a national PrEP programme would be delivered at any site that has the expertise and capacity to deliver PrEP in line with the national standards. It is anticipated that, conditional on there being adequate resources, this would include delivery through established public STI services. In this assessment, HIQA conservatively costed the delivery of a PrEP programme based on a consultant-led service at public STI clinics. However, delivery of the programme may take place in other settings, such as in primary care. As highlighted by the Pharmaceutical Society of Ireland (and noted in Chapter 7, Section 7.7 of the report), prescriptions need to be written in a manner that complies with the legislative requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003. Anyone who fulfils the legal requirements will therefore be entitiled to prescribe

	medication is being prescribed by nurses. A study completed in 2018, suggest this model could be a viable option and should be considered to ensure that the programme can reach as many patients in a timely and cost effective manner (Schmidt et al. 2018). The inclusion of specialists in the field of sexual health will be vital for the success of the programme. It would be essential to ensure that advanced nurse practitioners and clinical nurse specialists are members of the team. There must also be in place, suitable educational and administrative support for the programme and again, this must be in place before the programme can commence. It is essential in delivering quality care to PrEP patients, that investment in appropriate specialists is require. How this programme affects others in primary care must also be considered. Primary care nurses are likely to be impacted by this also and may need additional education to identify those in need of PrEP (to prevent new HIV diagnoses in the future) and to properly monitor those taking it."	PrEP.
26	"Again, the current evidence available appears sound, however, it would be important that the programme has in place appropriate measures and evaluations as well as inclusion of any new evidence that may come to light in the future to ensure quality care to patients."	The ongoing monitoring and surveillance of a prospective programme will require data collection at a national level. Programme performance may be evaluated in this way, including metrics such as the number of PrEP users (uptake rate), adherence (in terms of redeemed prescriptions), discontinuation/drop-out rate and PrEP interruptions, and geographical distribution of prescriptions dispensed. Ongoing monitoring and surveillance is discussed in Chapter 8: Organisational issues and Chapter 9: Discussion).
27	"The use of condoms in addition to the use of PrEP is strongly recommended by sexual health	Of particular concern to sexual and public health professionals is the potential occurrence of 'risk compensation' in

	service staff. However, the provision of PrEP is anticipated to result in a significant increase in bacterial STIs in populations such as men who have sex with men. This has been the experience in countries that have been providing PrEP for the last three to four years. The provision of PrEP to those who meet the criteria is a very welcome development and forward thinking by the DoH."	individuals who take PrEP (risk compensation is an increase in unsafe sex due to the knowledge that PrEP prevents HIV) resulting in an increase in STIs. Trial data have not demonstrated this phenomenon to date, however observational data have suggested otherwise. Unfortunately, observational studies (such as those that report on STI rates before and after PrEP implementation) are frequently subject to significant confounding, including differences in STI testing frequency pre- and post-PrEP initiation. As outlined in Chapter 7, Section 7.6, the potential rise in STIs (other than HIV) reinforces the need for frequent (3-monthly) STI testing and the need for education and counselling regarding safer sex.

5. Changes to the report from the consultation process

The following changes were made to the draft report in response to comments and feedback received through the consultation process:

1. Table 2.3 has been amended to reflect the age at which HPV vaccination can be provided (up to 45 years).

2. A new section has been added to Chapter 6 (Section 6.5.2.3) which provides an annual itemised budget impact for the whole population over five years.

3. The additional investment that would be associated with a staff recruitment campaign has been highlighted in Chapter 7.

4. Specific reference has been made in Chapter 7, Section 7.5, that the prescription needs to be written in a manner that complies with the legislative requirements of the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

5. The importance of an information and awareness campaign and the role of advocacy groups is highlighted in Chapter 7, Section 7.7.

6. The terms ‘sex workers’ and ‘individuals involved in prostitution’ have been explained further in Chapter 3, Section 3.3.4.3. In terms of reporting trial data that enrolled individuals involved in prostitution, the terminology used in the primary study was used (studies typically used the term ‘sex worker’).

In addition to the changes made above, the Advice to the Minister, an Executive Summary and a plain English summary have been provided in the final report. Every attempt has been made in the plain English summary, the Executive Summary and the Advice to the Minister to further emphasise issues of importance that were highlighted during the consultation process.

5. References

1. Health Products Regulatory Authority (HPRA). The dangers of buying prescription medicines online. Available at: http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/dangers-bpmo_web.pdf?sfvrsn=2. Accessed 31/5/2019.

2. HIV Ireland. Pre-exposure Prophylaxis (PrEP): Scoping and Policy Options Review. 15th June 2017. Available at: http://gayhealthnetwork.ie/wp-content/uploads/2017/06/PrEp-Scoping-and-Policy-Options-Review.pdf. Accessed June 2019.

Appendix A — Copy of submission feedback form

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment of a PrEP programme for populations at substantial risk of sexual acquisition of HIV

For public consultation

Consultation Feedback Form

Your feedback is very important to us. We welcome responses to all questions as well as any additional comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The closing date for consultation is 5pm on Tuesday, 28 May 2019.

You may email or post a completed form to us. You may also complete and submit your feedback online at www.hiqa.ie.

About you

Name	
Address	
Contact details	
Date	

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

Are you replying in a personal capacity or on behalf of an institution or organisation?

☐ Personal capacity

☐ On behalf of an institution

☐ On behalf of an organisation

Part 2

Please outline any general or specific feedback on the documents. In your response, where applicable, please specify the section to which you are referring.

Question 1
The report contains evidence regarding the clinical and cost-effectiveness of pre-exposure prophylaxis (PrEP). Do you think any changes should be made to the scientific evidence included in the report?

Please comment

Question 2
The report includes background information regarding the organisational and resource implications of introducing a PrEP programme. Do you think any changes should be made to the background information included in the report?

Please comment

Question 3

Do you think our interpretation of the evidence should be changed?

Please comment

Question 4

Did you have any issues with the clarity or presentation of the report? Please specify the sections that require improvement.

Please comment

Question 5

Do you have any general comments you would like to make about this report?

Please comment

Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on http://www.hiqa.ie.

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email or post:

consultation@hiqa.ie

Health Information and Quality Authority
HTA on a PrEP programme
George's Court
George's Lane
Dublin 7

If you have any questions you can contact the consultation team by calling (01) 814 7463.

Please return your form to us either by email or post before 5pm on Tuesday, 28 May 2019.

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Appendix B — List of organisations and institutions that made submissions

1. HIV Ireland
2. HIV i-base (UK)
3. Irish Nurses & Midwives Organisation (INMO)
4. Irish Pharmacy Union
5. Merchants Quay Ireland
6. National LGBT Federation
7. Northern Uganda environmental protection and prevention of HIV/AIDS (Nuepha)
8. NUI Galway Health Promotion Research Centre
9. Ruhama
10. The Pharmaceutical Society of Ireland
11. The Sexual Health Centre (Cork)
12. Youth Health Service (YHS) Cork

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