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|----|--------------|---|--|--|
| 1. | Ming Lee     | Guy's and St<br>Thomas<br>Hospital NHS<br>Trust | Thank you for the updated guidelines, which provide much needed clarity and updates on window periods and recommendations on frequency in testing.  For ease of reading, perhaps the following points could be addressed:  Executive summary - could provide a table summary of changes in recommendations since previous guidelines:  1. 4th gen tests reliably exclude HIV by 45 days post-exposure, this should be the window period applied.  2. HIV opt out testing now recommended in the following settings: Specialist sexual health services, addiction and substance misuse services, antenatal services, TOP services, healthcare services for HBV, HCV, TB, Lymphoma.  3. Routine HIV testing is recommended for all individuals who have not previously tested in: accessing healthcare in areas of extremely high prevalence (>5 per 1000)  4. Annual test recommended for: Heterosexuals who have changed partners, PWID, Sex workers, sexually active MSM (other than those with one long term mutually exclusive partner)  5. MSM reporting any of the following should be tested every 3 months: - condomless AI with partners of unknown or serodifferent HIV status etc  Summary table of indicator conditions is very helpful, but could be reformatted and classified based on systems as in the previous guidelines for readability.  Many thanks again for the guidelines. | The executive summary has been updated. The main changes that are important to highlight are: (i) change from not recommending to recommending ED testing in high seroprevalence area (ii) change to the window period to 45 days (iii) now have evidence-based indicator condition testing (iv) high and extremely high areas of seroprevalence as two categories. Testing in ED; evidence is for only when prevalence is high and extremely high. Used same terminology as NICE, i.e. 'high' and 'extremely high' (not very high), defined using same definitions used by NICE |
| 2. | Carlos Smith | Patients  | For those patients, that wish to opt-out on a permanent basis. Why are you not incorporating, a National Opt-Out register? As an example, if a   | We have written back to Mr Smith thanking him for his comments.  |

| patient is unconscious in an I.C.U, and does not wish to, of been tested. |  |
|---|--|
| Trust!!!  |  |

No further action required

This, can then lead to a patient, not giveng any recognition to a positve diagnosis! Trust!!!

Acute, testing in an E.D.

All Patients, have an absolute right, when being asked about opting out, and to have total privacy. And that goes well beyond, curtains drawn in a E.D setting. Reference to NICE [NG60]. And you also now have contend with the updated privacy data personal data (2018) And, your local E.D it very common, to be in niegbouring cubicles to local people you know, so if you are being questioned by a health professional, about an HIV test, and you are pressurised into giving a reason why you are opting out, this could be overheard in an acute environment, as stated in NICE [NG60] And could be, a breach of data Protection!

What, processes are in place for a positive test result, that has not been consented to, by the patient. Being deleteted from all, recorded systems? Including PHE.

With, hospitals & G.P Surgeries, linking up, with databases. What safeguards, are in place. To stop other hospital departments and G.P's accessing the hiv positive blood test result? in an Opt-Out test. (Reference to HIV Confidentially 2015 Policy)

You then push, patients down the path of deceiving the system. By having to give false details, for example, age, so to make sure you full out of the age range of testing. Give no contact details, so the test result cannot be delivered.

Maybe give a false name in the E.D acute setting, so to protect your privacy as a patient, if a test maybe carried out without your consent.

To protect, patients & health professionals, why not have a box on the patients records so the patient signs for consent, that why both sides are protected, if there is a dispute of a hiv test being valid.

And, if you use the excuse of low uptake.

| Sameena               |                                   |   |  |
|-----------------------|-----------------------------------|---|--|
| Ahmad                 | Manchester<br>Foundation<br>Trust | Reference 8 does not actually seem to provide country specific prevalence re HIV, unless I am overlooking it.   | We have checked and it does provide country-specific prevalence  |
| John Watson           | University of<br>Birmingham       | I am very disappointed regarding the sentance on page 6 and that individuals should be aware that they will be tested for hiv.  If it remains in there it will be a massive mistake. That will stay with us for the 20y. Like Brexit  HIV testing must be like any other blood testing eg for kidney failure diabetes or hepatitis. By stipulating people need to be aware they are being tested it means it will continue to be forgotten or missed. Even in very high prevalence areas like king's college ED its between one in 500 and one in a thousand. To say you need to tell everyone they are being tested when it's that rare is insane. Most people when they have blood taken are not aware what they are being tested for that is the reality of the NHs. Most people expect you diagnose what's going on.  Many places are already not informing people when they test them bhiva needs to be brave and lead from the front.  Labs need to automatically test for hiv. Eg when anyone does a coeliac ab test or requests help serology or a Ana. These are good example where hiv education has been a disaster in the uk. Symptom overlap with these testing conditions but 95 percent or more of people being tested for these are not hiv tested is my guess. | We agree that people should know they are being tested for HIV, or anything else, in line with GMC recommendations, but this should not be a barrier to testing.  We have written to thank Dr Watson for his comments but no further action  |
| Jonathan<br>Cartledge | Mortimer<br>Market Centre         | 1. I think that the grouping of indicators by system and presentation as per the previous guidelines is more useful to our no HIV/GU colleagues, than basing the framework around the type of organism which is not a very clinically friendly approach, and requires the clinician to have sent the relevant micro etc which they may not consider if the presentation isn't highlighted as a potential reason to consider HIV  2. I think the recent EACS guidelines recommended HIV testing to any   | Agreed: we have kept the current evidence-based table (used to develop the recommendations) in the appendix but have also included a more accessible system- or specialty-based table, as in the European guidelines  Agreed: this group has been included but as a GPP (not evidence-based recommendation for HIV testing)  |
|                       | Jonathan                          | John Watson University of Birmingham  Jonathan Mortimer   | University of Birmingham  I am very disappointed regarding the sentance on page 6 and that individuals should be aware that they will be tested for hiv.  If it remains in there it will be a massive mistake. That will stay with us for the 20y. Like Brexit  HIV testing must be like any other blood testing eg for kidney failure diabetes or hepatitis. By stipulating people need to be aware they are being tested it means it will continue to be forgotten or missed. Even in very high prevalence areas like king's college ED its between one in 500 and one in a thousand. To say you need to tell everyone they are being tested when it's that rare is insane. Most people when they have blood taken are not aware what they are being tested for that is the reality of the NHs. Most people expect you diagnose what's going on .  Many places are already not informing people when they test them bhiva needs to be brave and lead from the front.  Labs need to automatically test for hiv. Eg when anyone does a coeliac ab test or requests help serology or a Ana. These are good example where hiv education has been a disaster in the uk . Symptom overlap with these testing conditions but 95 percent or more of people being tested for these are not hiv tested is my guess.  Jonathan  Cartledge  Mortimer  Market Centre  Market Centre  Market Centre  Market Centre  Alt hit hat the grouping of indicators by system and presentation as per the previous guidelines is more useful to our no HIV/GU colleagues , than basing the framework around the type of organism which is not a very clinically friendly approach, and requires the clinician to have sent the relevant micro etc which they may not consider if the presentation isn't highlighted as a potential reason to consider if the presentation isn't highlighted as a potential reason to consider HIV |

|    |              |   | I wondered what they based that decision upon and why BHIVA had not included this group  There are some other categories of individual who are universally screened for HIV not mentioned - health care workers and medical students - blood or organ donors  Apologies if I missed it , but is there a recommendation that a patient with any other STI should be tested for HIV - couldn't see that in the table but may have missed it .  | that it is included in separate specialty guidelines for HIV testing  We have stated not cover healthcare workers in the guidelines (covered by government policy and practice)  This is already included  A sentence has been added; also added link to CHIVA |
|----|--------------|---|--|--|
| 6. | Rak Nandwani | Joint Chair,<br>Scottish Health<br>Protection<br>Network Sexual<br>Health &<br>Bloodborne<br>Viruses<br>Strategic Leads | Do you discuss children of positive parents?  The Health & Social Care Secretary for England set out a commitment to end HIV transmission by 2030 in England only (not the entire UK) to be supported by £600k from Public Health England's HIV Prevention Innovation Fund.  Please could the guideline document provide greater clarity about what specifically applies to NHS England and what might be considered in the other UK devolved nations.   | Agreed: will make clear that England only  No further action   |
| 7. | Ray Fox      | Greater<br>Glasgow &<br>Clyde Health<br>Board   | I don't understand why you have changed the format of the table. The previous guideline had all the AIDS-defining conditions and Other conditions on a single page listed under body system, in addition to Oncology and Other. The new guideline has a seemingly endless list of conditions stretching over 3 pages (although presumably without the double spacing that will reduce to a page and a half?), and do you really need the strength of recommendation and grade of evidence for testing for every condition listed? We just need to know whether BHIVA recommend testing, yes or no.  I'm also concerned by the lack of awareness of the HIV testing guidelines by other specialists. I have been involved in local audits of late diagnoses over the last couple of years and when we bring to the attention of other specialists that there have been missed opportunities for earlier | Have tried to get recommendations for HIV testing included in other society treatment guidelines; however it is up to them what is included.   |
|    |              |   | other specialists that there have been missed opportunities for earlier diagnosis as per the BHIVA 2008 testing guidelines, it is often brought to our attention that recommendations for HIV testing in their own   | There is an opportunity to push this when replying RCP – AS: a recent paper in HIV Medicine about N recommendation of HIV testing for indicator  |

|    |             |                           | specialist society treatment guidelines cannot be found. Examples include: British Society for Gastroenterology guidelines make no mention of HIV testing in patients with unexplained chronic diarrhoea; I could not find mention of HIV testing in NICE or BTS guidelines for the management of patients with community acquired pneumonia or primary lung cancer; there is no mention of HIV testing in the NICE guidelines for the management of women with CIN-2, nor in the guidelines of the British Society for Colposcopy and Cervical Pathology.  I don't know if the writing group has cross referenced these guidelines | conditions could be appended                         |
|----|-------------|---------------------------|---|--|
|    |             |                           | with other societies guidelines, or have requested feedback from them but without doing so we will continue to struggle to raise awareness of   |  |
|    |             |                           | the need to test these patients.  |  |
| 8. | Nadia Ahmed | Mortimer<br>Market Centre | The guidelines are very well written, logical and easy to read. They are clear and I particularly like the subheadings of the key points, general information and then evidence.  |  |
|    |             |                           | Some minor suggestions:   |  |
|    |             |                           | 1) In the second paragraph of the executive summary - is there an extra   |  |
|    |             |                           | testing in the last sentence?   |  |
|    |             |                           | 2) Consistent use or ART or antiretroviral treatment  |  |
|    |             |                           | 3) Under 2.3 basic information of benefits of HIV testing - include   |  |
|    |             |                           | prognosis; I did wander whether this could be more specific and detailed  |  |
|    |             |                           | including U=U as this would be educational for non HIV/SRH  |  |
|    |             |                           | professionals   | 4. We do not recommend molecular assays (viral RNA   |
|    |             |                           | 4) A note on pro-viral DNA and HIV RNA testing for diagnosis?   | or proviral DNA) as part of routine diagnostic       |
|    |             |                           | 5) Although included generally, would it be ok to include a section on  | algorithms though this may change as evidence and/or |
|    |             |                           | what to do following a positive result? Reassure, re-iterate basic  | assay approvals evolve                               |
|    |             |                           | information, refer to XXX, with the addition of resources the patient could immediately access? Again I mentioned this thinking is a non  | 6. UNAIDS reference added                            |
|    |             |                           | HIV/SRH professional reads it   | o. Olyalos reference added                           |
|    |             |                           | 6) There is a new 95 95 95 goal from UANIDS.  | Other points have been addressed                     |
| 9. | Paul Scott  | Micropathology            | Within these guidelines, although there is mention of the different tests   | We suggest the use of molecular assays in cases of   |
| ٠. |             | Ltd                       | and there has been a specific removal of the advice to not use HIV RNA  | diagnostic uncertainty (e.g. primary HIV,            |
|    |             |                           | ultra sensitive RT-PCR assays as part of the diagnostic arsenal of tests, it  | indeterminate serology on PrEP) via locally          |
|    |             |                           | is not clear if this advice still stands. Are the new guidelines stating that   | determined pathways in liaison with local Virology   |
|    |             |                           | we can use sensitive HIV-1 RNA tests as a front-line diagnostic test in   | teams  |
|    |             |                           | cases where seroconversion has not occurred? In cases where a donor   |  |
|    |             |                           | screen is required and molecular testing is performed, should HIV RNA   |  |

|     |                |                              | testing be done along with proviral DNA testing (to catch donors who do not have detectable RNA or immune response).  Clarification on these factors to take into account evolving testing  |  |
|-----|----------------|------------------------------|---|--|
|     |                |                              | strategies would aid health care providers in selecting appropriate tests   |  |
|     |                |                              | in different circumstances. For example, inclusion of a clear stance on   |  |
|     |                |                              | when to use sensitive (   |  |
| 10. | Alvaro         | Health Services Laboratories | Dear Sir/Madam  |  |
|     | Guerrero-      |                              | I am writing to you in order to suggest the removal of the term "fifth  | Agreed: the term fifth generation is confusing and has |
|     | Ramos          |                              | generation" from appendix 2 as this nomenclature is confusing. As explained in appendix 2, a fourth generation HIV assay has the capacity to detect HIV-1&2 IgM and IgG antibodies and HIV-1 p24 antigen. However, fourth generation assays may be classified in three types according to the ability to distinguish the nature of the reactivity: 1) those that produce a single result regardless of the analyte/s present (e.g., combo HIV Architect-Abbott); 2) those that produce two subresults, one for the HIV-1&2 antibodies and another for HIV-1 p24 antigen (e.g., HIV DUO vidas ultra-Biomerieux or Elecsys HIV DUO-Roche) and 3) those that produce three sub-results, one for the HIV-1 antibodies, one for HIV-2 antibodies and another for HIV-1 p24 antigen (i.e., Bioplex 2200 HIV Ag-Ab-Biorad). The latter one is the so called fifth generation assay (a name proposed by the manufacturer to sell better the product). Importantly, window period testing recommendations are equivalent for all types of fourth generation assays. Although, fourth generation assays that produce two or three sub-results are more informative (Ab vs Ag) as they may aid in the confimation process, they are not designed to be supplemental/confirmatory assays, which still relies on HIV 1&2 differentiation assays and/or molecular techniques. | been removed   |
|     |                |                              | Thank you very much in anticipation for your attention.   |  |
|     |                |                              | Kind regards Alvaro Guerrero-Ramos  |  |
|     | Laura Hilton   | Southend<br>Hospital         | Clear, well written guidelines. I am delighted to see new window period classification for the 4th generation tests. I fully support these draft guidelines.  | No action required                                     |
| 12. | Tristan Barber | Royal Free                   | Many thanks for these. My own personal view, particularly in light of the   | Agreed: much of this has been addressed in the         |
|     |                | London NHS                   | recent PHE report, is that they remain very somewhat cautious, and  | executive summary; included primary care and the       |
|     |                | Hospital  Royal Free         | Clear, well written guidelines. I am delighted to see new window period classification for the 4th generation tests. I fully support these draft guidelines.  Many thanks for these. My own personal view, particularly in light of the   | Agreed: much of this has been addressed in the         |

## Foundation Trust

avoid more generalised testing on the basis of cost effectiveness, but favour targeted testing on the whole.

I'm worried that, as we know, this approach continues to miss people, leading to late diagnosis, and that the emphasis on assessing those at risk and needing testing means that we may end up with the same problems of old, hampering our attempts to improve on 'the first 90'.

Whilst celebrating the successes described by PHE in falling diagnoses we have to consider that achieving rapid drops in white gay men in London whilst less is achieved in other groups (even if there's some progress) is a health inequity that requires urgent attention

We have the tools as evidenced by these data to achieve much better results

These should not be taken as 'success'

The testing continue to shy away from more universal testing and indicate targeted testing which we know has and is failing heterosexuals and BAME GBM who do not see/feel responsive to testing and prevention messages.

These people come late and are diagnosed often with AIDS which is a significant failure in 2020

- TWICE as many with undiagnosed infection are outside London
- The proportion of late diagnoses is 43% especially in white hetero, black African men, PWHID and those >50 urgent public health campaigns and more generalised testing needed for these groups we can see HOW to win to stop late diagnoses and onward transmission but we are NOT DOING IT
- Tiny testing rates in primary care

Targeted testing and testing in sexual health settings is not reaching all groups; I feel the guideline needs a stronger recommendation to test more people, in more settings, with less reliance on understanding risk background.

need to adapt recommendations to local setting with regard to prevalence (high/extremely high vs low prevalence where indicator condition/risk more important).

Reiterated writing guidelines not standards document

| 13. | Andrew<br>Freedman | Cardiff<br>University<br>School of<br>Medicine       | This is a very comprehensive review of the topic, but I wonder whether it would be useful to include a summary table of who should be tested (rather than just a section in the text of the executive summary & the two tables in appendix 1).   | Summary included   |
|-----|--------------------|--|--|--|
|     |                    |  | A few minor suggestions/typos:  Section 2 (page 7) first para, 3rs sentence - might be better to say "reduce their risk of acquiring HIV infection.", rather than"becoming HIV positive"  Section 2.1, first sentence - should say"98% of those were on ART"  Section 2.4, page 9, para 3 - should read situations (not situation) & next sentence? "how", not "who"   | These comments have been addressed   |
|     |                    |  | Appendix 1, table 1 - Is this list up to date? Not sure all Non-Hodgkin's Lymphom, as are AIDS-defining. Penicilliosis has been renamed Talaromycosis. Should HIV encephalopathy be included?  | Appendix 1, Table 1 has been updated   |
|     |                    |  | Unexpalined raised serum globulins & low level monoclonal gammopathy are common findings - is there not enough evidence to include these in table 2?   | This did not come up in literature review  |
| 14. | Durba Raha         | iCaSH Norfolk,<br>Cambridge<br>Community<br>Services | A summary of the changes from the previous guidelines would be helpful.  | Discussed above  |
| 15. | Kaveh Manavi       | University<br>Hospitals<br>Birmingham                | I would skip commenting on positive points of the draft guidelines. I am sorry to say that in my view the document fails to address a significant gap in clinical practice.  The document provides updated information on how the issue of late HIV diagnosis continues to remain, and yet offers no solution. It fails to point out that most cases of the late HIV diagnoses should have been diagnosed in primary and secondary care settings at an earlier stage of infection (several BHIVA audits have shown this). It fails to state that 'opt-out' HIV testing should become a routine practice everywhere, and irrespective of background prevalence, and it does not spell out the care referral pathways that non GU/ HIV physicians, surgeons and GP colleagues require to feel supported and enabled to offer the test to their patients. | This is suggesting everyone should be tested, but not what recommending in guidelines.  This has been covered in the executive summary; stated need to take part of guidance that is relevant to your setting, i.e. risk/indicator condition-based testing important in some cases  Already mention in overarching principles section that should have pathway to care (NB importance of clear pathway for follow-up outside ED etc) |
|     |                    |  | referral pathways that non GU/ HIV physicians, surgeons and GP colleagues require to feel supported and enabled to offer the test to   |  |

the background population prevalence is flawed. As the result of such argument, areas with 'low prevalence' of HIV will continue to experience disproportionately high proportion of patients diagnosed late. The authors are aware that the proportion of late HIV diagnosis is already significantly less in London compared to the rest of the country. Why should we not expect the same improvement across the UK? The document misses on significant evidence on the best method of HIV testing; e.g. BMJ 2016; 352 doi: <a href="https://doi.org/10.1136/bmj.h6895">https://doi.org/10.1136/bmj.h6895</a>, a prospective RCT with clear conclusion that opt out testing is associated with superior uptake of the test in non-traditional settings. Rather than trying to justify the cost effectiveness of HIV testing in antenatal care, we should promote 'opt out' HIV testing in all ED, AMU and GP practices across the UK. There are mathematical modelling studies that have shown such plans would significantly reduce the incidence of HIV and the rate of late HIV diagnoses within a decade.

The document's recommendation on clinical indications is significantly flawed. I would have thought that we should at least keep in line with NICE guidelines on HIV testing. For example, NICE recommends anyone starting chemotherapy, or immunosuupressive/ modulatory treatment must be tested for HIV before the start of those treatments. The document completely misses this point.

The document fails to discuss and address non GU/ SH/ HIV clinicians' barriers to HIV testing. This in my experience is colleagues' justified concern about tracking and informing someone with positive result of their HIV test particularly in settings with high turn over of patients (e.g. ED/ CDUs). There would have been a great opportunity to spell out the 'closed loop' referral pathway where in addition to the 'consultant in charge', the local GU/ SH clinicians would be informed of the result of anyone testing positive for HIV by the laboratory colleagues. In this arrangement, HIV/ SH health advisors will assist the 'consultant in charge' of those patients to recall the patients and inform them of their results. This arrangement has significantly enabled my physician and surgeon colleagues to carry out the testing without the fear of missing to act on positive results.

In summary, I am deeply disappointed that the new draft of the guideline is essentially a 'toned down' version of the previous document issued over a decade ago. I strongly doubt if this document will be followed by many non GU/ SH clinicians or would impact on the issue of late HIV diagnosis particularly outside London.

BMJ paper discussed efficacy of opt-out testing in ED but in San Francisco (where presumably high prevalence)

Only one modelling study in France, suggested test everyone in population once (but not managed very successfully). Must consider practicality

Already discussed above; included as GPP

| 16. | lain Reeves   | Homerton        | Hi - sorry should have mentioned this in my initial comments and             | Agreed, but it is an issue for standards. No further  |
|-----|---------------|-----------------|--|---|
|     |               | Hospital        | apologies if I have missed it, but should the guidelines specify a           | action  |
|     |               |                 | maximum turnaround time for HIV serology - negative and positive?            |   |
|     |               |                 | The BASSH standards are not that clear with respect to HIV testing as far    |   |
|     |               |                 | as I can see.  |   |
| 17. | Danna Millett | HIV Spec nurse, | P8: For those testing negative who remain at risk there should be clear      | Reviewed and amended for clarity                      |
|     |               | Homerton        | pathways to prevention services.   |   |
|     |               | Sexual Health   | There is a disconnect between testing in non-traditional settings and        |   |
|     |               | Service         | what is being asked for. There are not resources available for this          |   |
|     |               |                 | anywhere in the nhs, apart from sexual health.                               |   |
|     |               |                 | I did run a community testing programme & agree with the issues              |   |
|     |               |                 | raised, that though acceptable, linkage into care is problematic.            |   |
|     |               |                 | Self-testing: the guidelines seem to be written by people living in a        |   |
|     |               |                 | urban setting, they do not consider that self testing may be the only        |   |
|     |               |                 | accessible form of testing for those in a more rural areas, at a time when   |   |
|     |               |                 | access sexual health services has been reduced.                              |   |
|     |               |                 | I am disappointed how little they have mentioned about testing within        |   |
|     |               |                 | the 'acute settings'. A&E testing has been tremendously successful;          |   |
|     |               |                 | Homerton tested 11 out of the 84 diagnosis made in the UK. ED isn't          |   |
|     |               |                 | mentioned specifically. Again, linkage into care, as with GP testing is      |   |
|     |               |                 | much higher.   |   |
|     |               |                 | I would also question the age criteria in high prevalence areas, in light of | This has been changed. No longer age criterion in     |
|     |               |                 | the 2 oldest diagnosis within the hospital were 2 x 72 year old men, one     | these guidelines                                      |
|     |               |                 | of whom was seroconverting. We have have had similar presentations           |   |
|     |               |                 | recently from GP testing. Providing limits makes universal testing more      |   |
|     |               |                 | complicated & electronic order sets, used to increase opt out testing        |   |
|     |               |                 | cannot be applied.   |   |
| 18. | Anne Glew     | The Brunswick   | Hi, All looks good to me I just have one comment to add.                     | Fear of a positive test included already, and ways of |
|     |               | Centre          | The last paragraph on page 6, Barriers to testing - It's been my             | taking blood other than venepuncture                  |
|     |               |                 | experience that quite a few people have identified barriers around being     |   |
|     |               |                 | frightened of the results of the test, and some even frightened of the       |   |
|     |               |                 | test itself, especially in older MSMs that haven't tested until 50+          |   |
|     |               |                 | because of these barriers. Hope this helps.                                  |   |
|     |               |                 | Kind Regards   |   |

|     |                             |                             | Anne  |  |
|-----|-----------------------------|-----------------------------|---|--|
| 19  | Sophie<br>Meagher           | LGBT<br>Foundation          | In general this is a comprehensive and clear set of guidelines.  It needs to be ensured that there is a clear strategy alongside these guidelines so that they can be effectively implemented.  Page 13 recommends that sex workers have an HIV test every year, it should instead be recommended that sex workers have an HIV test every three months.  Page 15 recognises that 'People report significant barriers associated with healthcare facility-based testing', it should be stated here that it is higher risk and/ or marginalised groups who are more likely to face barriers.  | Evidence does not support every 3 months; amended to sex workers should have an HIV test every year but those who fall into other risk categories (e.g. MSM and trans women) should be tested more frequently Agree with this; wording amended |
|     |                             |                             | It is very positive that the guideline recognises trans communities throughout. However there does need to be more recognition of the fact that education around trans communities needs to be drastically improved among clinicians. LGBT Foundation's sexual health team supports a number of trans people who have had poor experiences at sexual health clinics due to clinicians asking inappropriate questions and having a general lack of knowledge on trans communities. This needs to be recognised and addressed. Additionally a lack of trans awareness is a barrier to ensuring trans status is being accurately recorded by clinicians. | Referenced BASHH guidelines special interest group for trans communities   |
|     |                             |                             | It needs to be recognised that there is a difference between gay and bisexual men and other MSM. MSM who don't identify as gay or bisexual are higher risk group for being diagnosed late and therefore recommendations must include targeted outreach and support for this group.  | This is about implementation; referenced guideline on sexual healthcare in MSM   |
| 20. | HIV Pharmacy<br>Association | HIV Pharmacy<br>Association | HIVPA support the guidelines which we feel are well written and researched. We note that our community pharmacy colleagues are mentioned as a means of purchasing HIV self-test kits, however wonder whether community testing initiatives including community pharmacies aren't outlined in enough detail for high prevalence areas. We are keen to involve our community colleagues effectively and encourage NHSE to support funding in this setting of HIV testing to achieve zero  | A couple of sentences highlighting community pharmacy have been added  |

|     | т.             |             |   | ,   |
|-----|----------------|-------------|---|---|
|     |                |             | transmissions by 2030. 2020 will see an increase use of the community     |   |
|     |                |             | pharmacist consultation service for urgent supplies of medication or      |   |
|     |                |             | advice from NHS 111 and a further referral pathway from general           |   |
|     |                |             | practice to community pharmacy is currently being piloted, with the aim   |   |
|     |                |             | of an April 2020 rollout, further increasing utilisation of community     |   |
|     |                |             | pharmacy services. We feel this increased throughput and elevated         |   |
|     |                |             | profile of community pharmacy will help support this                      |   |
| 21. | Sarah Allstaff | NHS Tayside | Thank you for this revised guideline. I wonder if you would consider      | This is a BHIVA standard of care                  |
|     |                |             | adding a recommendation around the investigation and reporting of         |   |
|     |                |             | missed opportunities for testing. A recommendation in a national          |   |
|     |                |             | guideline would help to support the local implementation of critical case |   |
|     |                |             | reviews particularly in cases of late diagnoses and AIDS-related deaths.  |   |
| 22  | Roger Pebody   | NAM         | One general thought. The previous guidelines were admirable for their     | Helpful comments about wording. Have reviewed and |
| 22. | Noger Febour   | INAIVI      | succinctness and clear sense of purpose. This draft feels less focused,   | amended   |
|     |                |             | with the risk of key messages getting lost. Compare, for example, the     | amended   |
|     |                |             | executive summary of the 2008 document with that of this draft. We        |   |
|     |                |             |   |   |
|     |                |             | feel that the message of HIV testing being a responsibility for all       |   |
|     |                |             | healthcare workers should be communicated more clearly.                   |   |
|     |                |             | 1: Executive summary  |   |
|     |                |             | Para 1: The point about knowing you are HIV negative is broader than      |   |
|     |                |             | relating just to PrEP. We suggest "Similarly, those who test negative can |   |
|     |                |             | == :  |   |
|     |                |             | make more informed choices about HIV prevention."                         |   |
|     |                |             | Para 2: opt out needs to be defined at this stage.                        |   |
|     |                |             | Last bullet point: we suggest "People accessing any healthcare service"   |   |
|     |                |             | 2.1 UK epidemiology   |   |
|     |                |             | Why is there not a clearer description of the profile of people who are   |   |
|     |                |             | diagnosed late? This is the crucial epidemiological information to get    |   |
|     |                |             | across – particularly the point that it is often individuals who do not   |   |
|     |                |             | correspond to the most obvious risk profiles (older, heterosexual, etc).  |   |
|     |                |             | The guidelines need to convey that our (subconscious) assumptions         |   |
|     |                |             | about who is at risk of HIV can result in missed diagnoses.               |   |
|     |                |             |   |   |
|     |                |             | 2.2 Cost-effective threshold  | Section has been replaced                         |

How is the reader meant to make sense of this information? It states that HIV screening would be cost effective with an undiagnosed prevalence over 0.1% but gives no indication of the undiagnosed prevalence in different populations and geographical areas. This section does not state that undiagnosed prevalence in key populations is in excess of this or refer reader to page 11, where those figures are given. There is some information on geographical areas on page 12, but it is extremely hard to interpret.

The only clear message that comes across in this section is, "Universal HIV testing is not recommended in the UK". However, the guidelines do recommend universal HIV testing in healthcare services in areas of high prevalence. Shouldn't this section begin to prepare the ground for that recommendation, rather than contradict it?

2.3 Overarching principles

The first paragraph was clearly written by a committee. What is it saying? What are the practical implications that follow on from this?

3 Who should test

Line on heterosexuals would be clearer as "Heterosexuals who have changed sexual partner(s) since their last test."

The line introducing the bullet pointed list of specific health services would be clearer as "HIV opt-out testing is recommended for all patients in the following settings"

Line on high prevalence areas would be clearer as "All patients accessing any primary or secondary healthcare service in areas...."

Line on repeat testing should give examples of ongoing risk, including change of partner and travel in a high prevalence country.

Page 12, data on undiagnosed prevalence in different geographical areas. There should be consistency in the guidelines in how figures are reported (0.1% or 1 per 1000).

We have rewritten for clarity

4 Frequency of testing

Bullet points on MSM every 3 months: behaviours "over the last 6 months" would be clearer as "in the last six months". 'Over' suggests repetition.

Bullet points on MSM every 3 months: "drug use during sex". Any drug? Cannabis?

5 Community and self-testing/sampling

This section should state that public health commissioners should seek to provide a mix of approaches, to allow user choice. The evidence paragraph on community testing states that most community projects are MSM focused. Should there not be more effort to provide community testing services which reflect local epidemiology?

Self-sampling and self-testing are defined, but not community testing. While it's usually assumed to involve POCT in an outreach or non-medical setting, self-sampling or self-testing kits could be offered within community testing.

Evidence section on self-testing should state that as approved devices are second or third generation, the window period is longer than for lab tests. This information is important for people with recent risk and should be shared with people testing.

"Oral fluid self-tests are preferred". By whom? There's limited evidence on this that is relevant to the UK. And how relevant is this when oral self-testing is not available in the UK?

The term 'reactive' could do with a clearer explanation, perhaps something along these lines <a href="http://www.aidsmap.com/about-hiv/fag/what-does-reactive-mean-when-testing-hiv">http://www.aidsmap.com/about-hiv/fag/what-does-reactive-mean-when-testing-hiv</a>

6 Testing approach

First recommendation: for clarity, specify the prevalence threshold.

7 Testing technology

Terms reactive and optout have been defined

This section needs to specify the recommended algorithm and assays for confirmatory testing, especially after a reactive result on POCT, self-sampling or self-testing.

It should make it clear that a fourth-generation POCT is available.

In the recommendations, "this should be the window period described when using these tests" would be clearer.

First paragraph after recommendations states "There are two methods for routine HIV testing" before describing four (venepuncture lab tests, self-sampling, self-testing and POCT). The latter three are distinct from each other.

Last paragraph before the evidence review could be clearer. "Consensus guidelines recommend fourth-generation laboratory tests with venous sampling as the first line choice, with POCTs also available."

Taylor's window period study. Would be clearer as "the probability of a false-negative test result". Also, specify third-generation laboratory tests.

The Delaney table will be confusing for many readers if the types of test are not explained in the same terms as used elsewhere in the guideline. Antibody/antigen laboratory = 4th generation laboratory; IgG/IgM-sensitive laboratory = 3rd generation laboratory; IgG-sensitive rapid screening = 2nd generation rapid POCT.

An important caveat to Delaney's figures for POCT. The analyses were based on testing plasma samples, but window periods are likely to be several days longer when testing samples of fingerprick blood or of oral fluid, which is usual practice for POCT.

Section on atypical results on ART. Need to explain that older generation testing technologies, as often used in POCT and self-testing, are more vulnerable to this problem. Practical advice or recommendations would be helpful, especially given self-testing and the possibility of confusion about the meaning of undetectable viral load – individuals wanting to check that "they are still positive".

Link has been inserted to new WHO algorithm for testing

Section has been revised

|     |             |  | 8 Barriers  |  |
|-----|-------------|--|---|--|
|     |             |  | We wonder whether this section should go towards the beginning of the guideline as it is of fundamental importance.   |  |
|     |             |  | The sentence about individuals being concerned about their immigration status or prosecutions would sit better in section on individual barriers/fear of positive result, than under 'access to services'.  |  |
|     |             |  | The cost barrier (page 21), mentioning a lack of reimbursement, should specify that this is especially relevant in non-specialist services. Also, the paragraph at the top of page 23 which states that opt-out testing requires no additional resources does not acknowledge this issue.   |  |
| 23. | S Cavilla   | Brighton &<br>Sussex<br>University<br>Hospitals NHS<br>Trust | Thank you for a thorough and well evidenced guideline.  1. In section 8 "Barriers to testing at the individual level", needle phobia is not mentioned, this is a common reason for declining an HIV test in GUM clinics in practise. Should there be advice on discussing oral fluid tests and how to access them online when a POCT and venepuncture are refused on these grounds with high risk individuals? I surmise their cost may be beyond sexual health clinic's declining budgets to stock them routinely! | This has been covered  |
|     |             |  | 2. Did the writing group consider commenting on HIV testing practises in patients lacking capacity or in an unconscious state, when the question arises following a needlestick/exposure incident? This is a common query to our specialty and when advising it should only be done if in the patient's best interests, you could argue it is of benefit to everyone to know their status. This is a vulnerable group of patients   | This is outside the scope of this guideline  |
|     |             |  | 3. Has there been any discussion with NICE over HIV testing advice in indicator diseases to embed it in their relevant guidelines to reach our medical colleagues?  | This has been covered  |
|     |             |  | Thank you   |  |
| 24. | David Asboe | HIV Clinical<br>Reference                                    | The HIV CRG welcomes the guidance. Overall it outlines mostly workable recommendations for managing the diagnosis of individuals  | Good point but not for these guidelines (i.e. need to be evidence based and this is government policy) |

| 2, 2. | Asim, bia Addie invites | 8                                     |   |
|-------|-------------------------|---|---|
|       | Group                   | with HIV. However we think there should be an increased focus on how        |   |
|       |                         | testing needs to evolve to address the new public health objective of       |   |
|       |                         | eliminating HIV transmissions within 10 years. Will this require us just to |   |
|       |                         | be better at delivering the longstanding interventions or do we in          |   |
|       |                         | addition need novel strategies. It's hard to get a sense from these         |   |
|       |                         | guidelines how the gap will be addressed.                                   |   |
|       |                         | Specifically  |   |
|       |                         | 2. The recommendations for HIV testing based on geographical                | Cost-effective threshold discussed above              |
|       |                         | indications are based on a single cost effectiveness study from the US      |   |
|       |                         | published 15 years ago. The extreme limitations of this evidence should     |   |
|       |                         | be described, especially as it drives the entire testing strategy.          |   |
|       |                         | 3. It's not really clear what this statement on page 8 means "Thus,         |   |
|       |                         | universal HIV testing is not recommended in the UK. It is worth noting      |   |
|       |                         | that since this evidence was published, the cost of HIV treatment has       |   |
|       |                         | decreased and life expectancy has increased leading to a likely             |   |
|       |                         | downward revision of the cost-effective threshold."                         |   |
|       |                         | 4. What is the accepted cost- effectiveness threshold and where is the      |   |
|       |                         | evidence that this has reduced? The threshold should be a consensus         |   |
|       |                         | view of the level at which a health intervention is worth undertaking. A    |   |
|       |                         | substantial revision upwards of this threshold to take account of the       |   |
|       |                         | population objective of eliminating transmissions should be debated. If     |   |
|       |                         | accepted this would potentially unlock a whole raft of interventions        |   |
|       |                         | especially those aimed at lower prevalence areas.                           |   |
|       |                         | 5. There is no reference to the CHIVA guidelines on testing and "Don't      | Already amended, including these three points         |
|       |                         | Forget the Children" - chiva.org.uk/guidelines/testing/. New guidelines     | Alleady amended, including these three points         |
|       |                         | are being developed.  |   |
|       |                         | Although this is a guideline for adults there are recommendations in the    |   |
|       |                         | Don't forget the Children document which are relevant                       |   |
|       |                         | - if an individual presenting to adult services is known to have an HIV     |   |
|       |                         | infected mother and:  |   |
|       |                         | - the mother has no documented HIV negative result after the date of        |   |
|       |                         | birth of the individual   |   |
|       |                         |   |   |
|       |                         | - and the individual does not have documented negative screening test       |   |
|       |                         | for HIV previously  |   |
|       |                         | They should be tested.  |   |
|       |                         | Similarly if a women is known to adult HIV services and has a child who     |   |
|       |                         | is over 18 years old who is known to be at risk of perinatal HIV (for the   |   |
|       |                         | same reasons stated above) efforts should be made to test the adult         |   |
|       |                         | child,  | Additional tout an adoption to local cotting book     |
|       |                         | 6. We believe there needs to be a more focussed discussion within the       | Additional text on adapting to local setting has been |

| 1 |   |   |
|---|---|---|
|   | guidelines of low prevalence areas, to outline importance of having a very robust testing policy, I wonder about ensuring in all areas where venepuncture is carried out suggesting having information posters/leaflets about having a HIV test and it is OK to ask for one. I think at the very least there should be a statement that if a patient requests a test they should be tested.  7. Where the recommendation is based on whether individuals are having a blood test should there be the offer of other methods such as | included  We are not recommending this. |
|   | saliva testing, or even point-of-care testing for those not having a blood test 8. Section 3 should be titled "Who should be tested" not "Who should  | Title has been changed                  |
|   | test"  9. Page 10 2) People attending certain health services  • HIV opt-out testing is recommended in the following settings  While many people understand what the term "opt-out " means, many do not. We would add "for all attenders" to this statement;  • HIV opt-out testing is recommended for all attenders in the following settings  | This has been addressed                 |
|   | <ul> <li>10. Page 13: We think there is a huge overlap between the following two categories with different recommendations regarding frequency of testing and hence believe this will be confusing.</li> <li>An annual test is recommended for (Grade 1C):</li> <li>Sexually active MSM (other than those with one long-term mutually exclusive partner).</li> </ul>  |   |
|   | MSM reporting any of the following should test every 3 months:  • Multiple or anonymous partners since the last HIV test (Grade 1C);  | This has been clarified                 |
|   | 11. Page 11: We believe ALL sexual partners of those with diagnosed HIV should be recommended a test irrespective of a history of sexual contact protected by TASP. We know from the Partner study that partners are at increased risk of incident HIV infection from other partners and as a group they are almost certainly at higher risk of prevalent infection also.   |   |

| 25. | Patrick French        | BASHH Public<br>Panel | As Chair of the BASHH Public panel I circulated this guideline to panel and two lay members responded. Their responses are below. Patrick French  1.  Two comments both on page 14.  Pg 14 line 2 is it possible to change "transgender women" to "trans women", for consistency in language throughout the document?  Pg 14 Paragraph 5 of Evidence Review: when sex worker is mentioned  | Changed throughout document  Agreed not needed; covered by changing sex worker |
|-----|-----------------------|-----------------------|--|--|
|     |                       |                       | here, can there be a definition of sex worker, or somewhere else throughout the document. I'm mainly thinking in terms of clients: does this only encompass male sex workers exclusively with women and female sex workers exclusively with men, or also MSM sex workers – or would they just be classed under MSM? Clarification on this would be helpful.  2.  I have read the document and am probably not suitably qualified to comment on most of it with the exception of 9. Capacity to Consent. I am curious to know if either a social worker or care support | recommendation  Agreed no change needed  |
|     |                       |                       | worker/advocate associated with the patient's mental health is involved in helping the patient to make the choice to consent? I have noticed that this is an issue that arises with Dementia patients, where spouses and family can 'force' treatment on patients while they are vulnerable When the NHS says the patient is at the centre of everything, it needs to show this.   |  |
| 26. | Rochelle<br>Keenaghan | RCP                   | The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with our Joint Specialty Committee for Genitourinary Medicine and would like to make the following comments.  The document provides updated information on how the issue of late HIV diagnosis continues which was commended. Numerous concerns and suggestions were made. Please see below.   |  |

# Concerns Operational Concerns regarding implementation in services where there is no re-imbursement, and where there are perceived or real barriers to providing results to patients not followed-up by the service doing the test eg. A&E. We know colleagues outside of sexual health (SH) can't / don't Seroprevalence/indicator condition based means not want / have time to risk assess have to assess risk Does not discuss and address non-SH/ HIV clinicians' barriers to HIV testing. E.g. colleagues' justified concern about tracking Have addressed concerns about follow-up of results in and informing someone with positive result of their HIV test particularly in settings with high turnover of patients (e.g. ED/ CDUs). Issues with targeted testing Focusses heavily on targeted (opt out) testing which we know (as evidenced by recent PHE report) favours GBM/white/London populations The proportion of late HIV diagnosis is already significantly less in London compared to the rest of the country. Some believe that the concept of pitching routine HIV testing according to the background population prevalence is flawed. As a result, areas with 'low prevalence' of HIV may continue to experience disproportionately high proportion of patients diagnosed late. The problem of late diagnoses especially in low risk low Amended: adapting recommendations to local setting prevalence areas may be overlooked and the importance of is key look back exercises to learn should be emphasised More opt out/normalised testing needed to meet first 90 This is a crucial time for stronger recommendations with no one missed or left behind Training/ education gaps There is still some misapprehensions about offering the test A clear statement about U=U has been included in the and widespread lack of understanding that someone executive summary

| established on effective HIV treatment is not-infective.   |                 |
|--|-----------------|
| <ul> <li>Overall</li> <li>The document's recommendation on clinical indications could be at least kept in line with NICE guidelines on HIV testing. For example, NICE recommends anyone starting chemotherapy, or immunosuppressive/ modulatory treatment must be tested for HIV before the start of those treatments.</li> <li>Concerns that the document will not be followed by many non-GU/SH clinicians or impact on the issue of late HIV diagnosis particularly outside London.</li> <li>Currently there is a significant gap in clinical practice and this guideline may fail to help effect change needed and the timing is crucial as the last guideline was 12 years ago</li> </ul> | Discussed above |
| Suggestions: - Highlight the evidence on the best method of HIV testing; e.g.  | Discussed above |
| Recommend that 'opt-out' HIV testing should become a routine practice everywhere, and irrespective of background   |                 |

|  | prevalence, and clarify the care referral pathways that non-SH/HIV physicians, surgeons and GP colleagues require to feel supported and enabled to offer the test to their patients.  - Could discuss 'closed loop' referral pathway where in addition to the 'consultant in charge', the local SH/HIV clinicians would be informed of the result of anyone testing positive for HIV by the laboratory colleagues. In this arrangement, HIV/SH health advisors will assist the 'consultant in charge' of those patients to recall the patients and inform them of their results. This arrangement can significantly enable physician and surgeon colleagues to carry out the testing without the fear of missing to act on positive results. |  |
|--|--|--|
|  |  |  |

| 27. | Amanda Ely   | CHIVA  | Please see below a few comments from Amanda Williams Testing guidance is good.  2 comments:  1. It is quite wordy and a summary document or flowchart would be easier for people to use in clinics/GP practices 2. There are documented diagnoses of perinatally acquired HIV in children >15 years and young adults made where they have remained well until late childhood or late teens. These young people may not identified as at risk from sexual contact or iv drug use and may not be aware of parental HIV diagnosis. ie. Perinatally acquired HIV should be considered as a route of transmission in young people included in this guidance ( although a rare occurrence).  | Discussed above   |
|-----|--------------|--------|--|---|
| 28. | Leena Sathia | Gilead | Introduction Gilead Sciences appreciate the opportunity to provide feedback during this consultation on the BHIVA/BASHH/BIA Adult HIV Testing guidelines 2020. A robust evidence base (to Jan 2017) has been included as part of the literature review, and the writing committee should be commended on the production of clear testing guidance, which we fully support in its aims.  As feedback has been requested, we suggest the writing committee consider the incorporation of more recently (since Jan 17) published salient data, that could serve as best practice examples, and some guidance around current commissioning accountability for HIV testing and combination prevention initiatives.  Whilst this may not directly be the remit of this testing guidance, perhaps a considered approach to this could be incorporated as an appendix, to facilitate pragmatic implementation of this important guidance.  National Policy background This 2020 guidance is timely given;  The Government's commitment to eliminating HIV transmission by 2030  The anticipated outputs of the Independent HIV Commission (recommendations due to read out Spring/summer 2020)  many UK and Ireland cities committed to achieving Fast Track City goals  and the DHSC commitment to developing a National Sexual Health Strategy (expected Autumn 2020). | Would be useful for implementation document rather than guidelines. No further action |

The separation of commissioning powers in the 2012 Health and Social Care Act weakened the relationship between HIV clinics and sexual health clinics in England. There is fragmentation within HIV testing responsibility which falls within local authorities (as part of their broad responsibilities for prevention), CCGs (through GPs), and NHSE (through secondary care clinical services). With the NHS Long Term Plan signalling the roll-out of ICSs and a potential change to the commissioning of sexual health services, local health economies should be instructed to re-bridge this gap and set out clearly how their footprints will ensure seamless cooperation between different components of the HIV pathway, specifically (within the remit of this guidance) regarding HIV testing and combination prevention.

Whilst Gilead are aware that defining accountability for implementation of testing strategies across a local health economy is likely outside the scope of this document, consideration should be given to the addition of an appendix outlining current commissioning responsibilities, with recent best practice examples shared.

The Testing Guidelines are essential component of good clinical care and will help support efforts to reduce new infections to zero, however the absence of an England wide, mandated national strategy for HIV, including testing guidelines, means HIV care will remain fragmented. We would urge the writing committee to support efforts for such a national HIV strategy.

## Suggestions for consideration:

1. Systematic implementation of NICE HIV testing guidance (best practice sharing):

### 1.1 Systematic screening for indicator conditions

Whilst there is currently little systematic HIV testing outside specialist settings (e.g GUM, antenatal, and variable in TB services etc) there is emerging evidence on the effectiveness and sustainability of electronically requested pathology order sets for HIV indicator conditions in primary care. A 20141 joint working initiative between NHSE, PHE and Gilead (i) aimed to systematically implement NICE guideline NG60 recommendation 'HIV indicator condition testing' through electronic inclusion of opt-out HIV tests in glandular fever screens and has the lowest 'number needed to test' for any service type in comparison to those stated in the PHE 2017 HIV report.

the Data Protection Act 2018 came into force. Implementation and feasibility of such a testing programme would require consideration by each hospital, centre etc to ensure that all applicable Data Protection considerations are addressed

- ii (ii) Gilead has not been involved in the roll out of these initiatives
- iii (iii) Please note that implementation and feasibility of such a testing programme would require consideration by each hospital, centre etc to ensure that all applicable data protection considerations are addressed
- iv (iv) Halve It was funded by a grant from Gilead

Since initiation in 2014 the intervention has become operational standard of care in Lambeth and Southwark (ii); an estimated additional 5,000 HIV tests in Lambeth have been conducted resulting in an estimated 30 new HIV diagnoses of which nearly half were recent infections. The initiative is now being rolled out in 2020 through Barts Health across East London (ii)

### 1.2 A&E testing in high prevalence localities\*

There is increasing evidence for implementing HIV opt-out testing in A&E departments through electronic medical record (EMR) modification in high prevalence areas as recommended in NICE Guidance (NG60), particularly for identifying late diagnoses in patients otherwise untested. Health authorities should consider rolling this out more widely2 This updated BHIVA guideline suggests that successful application of the NICE testing guidance could potentially impact on 2/3 late diagnoses nationally – We recommend easy implementation guide and best practice sharing to assist the common goal (iii)

# 2. Incorporate the 'Halve it' Coalition recommendations to reduce late diagnosis4

Late diagnosis remains high, at over 40% of all new diagnosis. (PHE Jan 2020). Since late diagnosis is associated with an increased likelihood of HIV transmission, progress against this metric will likely accelerate the realisation of wider elimination goals. As such, the recommendations of the Halve It Coalition report3 should be explicitly highlighted in this guidance (iv).

The recommendations focus on up-scaling proactive testing methods, to increase the reach of sexual health services. Recommendations include:

- Supporting local health systems to commission a GP HIV testing champion to drive awareness in primary care of the need to focus on certain groups.
- Introducing a key performance indicator on GP practice dashboards that relates to the number of HIV tests offered, particularly for surgeries in high prevalence areas.
- Involving community pharmacy in providing HIV testing, either on site or through the provision of self-sampling and self-testing kits.

#### 3. Health Economics and Outcomes Research

The changing face of the HIV epidemic in the UK means that enhanced data (surveillance to more accurately target specific localities and demographics for enhanced testing and educational initiatives) is vital. If ~15,000 individuals remain detectable nationally, we need to hone in on additional data sources, where available, to help identify those who remain unaware of their diagnosis or are not engaged in care. A range of initiatives in other countries that have targeted extremely high prevalence localities for HIV with a community-centric approach to ownership of knowing one's status (e.g 'Bronx knows')5 could act as useful best practice resources. Recent work carried out by Brogan et al

Given the 'likely downward revision of the cost effectiveness [of HIV testing] threshold', this 2020 guidance should consider providing explicit advice on the importance of capturing cost effectiveness data for each of testing methodologies proposed.

(2019) in partnership with Gilead explores the cost effectiveness of

### 4. Specific at-risk communities

increasing screening and treatment6.

Our comments here are not highlighting all at risk communities. Consideration should be given to flagging specific initiatives that also address the testing/ late diagnosis inequalities that exist amongst (for example): Women, BME communities (heterosexual men and women and BME MSM), older people, young people.

### 4.1 Trans and non-binary people

Surveillance data is poor for trans and non-binary people, and PHE's, the LGBTQ+, the sexual health and HIV communities' efforts to address this are important and necessary.

Globally, we are aware that trans people face higher rates of HIV infection than the general population, as such measures are required to target this group for prevention, testing and linkage care. Perhaps the writing committee could highlight the pivotal role that sexual health and HIV services will need to take in spearheading the call for trans and non-binary individuals to be (at a minimum), accurately

### 4.2 People who inject drugs

registered during public sector interactions.

As part of NHSE's HCV elimination tender, Care UK and Gilead have partnered to improve BBV diagnosis and patient linkage to care work in 43 prisons where healthcare is provided by Care UK on BBV testing. The HIV testing on admission was 28% in Jan 2019 and, through the collaboration partnership with Gilead, it had reached 46% by late October 2019. (NHS England Health and Justice Indicators of Performance; Care UK unpublished data).

Furthermore, as part of the NHSE HCV Elimination programme, HCV Intensive Test and Treat events are to be rolled out in across the entire English prison estate to test for HCV, enabling testing of those not tested during admission and those with longer sentences. NHSE specialised commissioning has turned down all requests to fund HIV and HBV testing at these events, representing a significant missed opportunity for HIV testing in this vulnerable population. Cities and PHE should explore expansion of drug user health services and harm reduction programs, promote expanded access to clean syringes for injection drug users and substance use treatment services,

### **To Summarise**

Gilead Sciences appreciate the opportunity to comment on this important guidance.

and ensure that HIV testing is integrated into drug services.

For 30 years, Gilead has focused on the development of antiretroviral therapy to treat HIV, helping transform HIV infection from a fatal and debilitating disease into a chronic, manageable condition with a normal life expectancy. We are now keen to play our part in responding to new challenges, including working to end new infections by 2030. As it stands, the consultation document will be a robust evidence-based

As it stands, the consultation document will be a robust evidence-based guideline. We have incorporated suggestions for your consideration that we hope could provide a more useful, practical working document, and have largely only incorporated best practice suggestions in which we have direct involvement.

We hope the writing committee give due consideration to our

|    |     |     | suggestions for considering this be a guideline that assists meaningful implementation of testing strategies that can get us to zero new infections by 2030.  Reference list  1. Hsu et al. LIGHT initiative Phase 1, Fast Track City conference, Oral #9122 https://www.iapac.org/conferences/fast-track-cities-2019/  2. Page E, 'Get Tested LeEDs': (Re)-diagnosing and (re)-engaging PWID with blood borne viruses (BBV) in an urban emergency department. INHSU 2019  3. https://www.readkong.com/page/a-roadmap-for-eliminating-late-diagnosis-of-hiv-in-england-294  4. https://www.gov.uk/government/collections/hiv-surveillance-data-and-management 9164  5. https://www1.nyc.gov/site/doh/about/press/pr2018/pr057-18.page  6. Brogan A, Talbid SE, Davis E. Wild C, Flanagan D (2019) Is increased screening and early antiretroviral treatment forHIV-1 worth the investment? An analysis of the public health and economic impact of improvement in the UK, HIV Medicine  |   |
|----|-----|-----|---|---|
| 29 | PHE | PHE | I can see several significant points of difference between these draft recommendations and the recommendations within our PHE HIV testing report and previous BASHH/BHIVA and NICE recommendations.  General – I think the document should clearly set out the recommendations which have changed since the previous version. I also think it would be good if every recommendation referenced the supporting evidence – rather than just the grade of recommendation.  Specific points:  1 This document recommends annual HIV tests for heterosexuals who have changed sexual partners. This is new and we do not recommend this. BTW this document is aimed at all health care providers/commissioners including GPs, hospitals and community services as well as specialist SHS. Given the other recommendations for 100% coverage in specialist SHS, and high prevalence areas, this recommendation would only have any effect on patients attending other services in low prevalence areas. Is this what anyone wants/intends?  2 While this document recommends HIV tests for people born in a | Have clarified points raised (i) groups who may be at risk of HIV (i.e. anyone who has had sex); 1D recommendation for testing when change partner if attending a sexual health clinic/in the context of a sexual health screen (ii) frequency of testing: evidence in sexual health settings of no benefit if screening heterosexuals more frequently than annually. This has been deleted from the frequency section  This has been amended |

country with high diagnosed seroprevalence, it does not mention testing people with **black African ethnicity**. We include this recommendation in our report at their numbers tested and test positivity % are similar to those born in high prevalence countries.

3 High and extremely high prevalence areas.

were in London.

This document recommends HIV testing for **all patients accessing healthcare** in high (if they are having a blood test) and extremely high prevalence areas (all patients).

This is an expansion of the current NICE recommendations which apply to patients on admission to hospital, including emergency departments) and GP registrants and attendees having a blood test (and opportunistic testing in EH prev areas), as this will now include outpatients.

This is a big change - I had a quick look at NHS digital – there were 93.5 million OPD appointments attended in 2017/18, 17.7 million of which

For comparison there were— 20.8 million FCE (hospital in patient episodes) in 2018/19, 3.1 million of which were in London. The document doesn't supply any data to support the new recommendation. It would be good to see and comment on that data.

4. The document emphasises **opt out testing in specialist sexual health services**. Helpfully it defines opt out testing and discusses it in some detail. The document does not mention testing **those with sexual health needs**. This is different from the BASHH standards of care and the STI management guide. 2019 BASHH STI management guide says that 'people with needs relating to STIs' should be tested for HIV . It defines 'People with needs relating to STIs' as those who have needs or concerns about STIs which are either expressed spontaneously; or on a triage form; or elicited verbally during a consultation; or on a self completed history pro forma either in person or via an online portal. The term is analogous with, and includes, the term 'people contacting a sexual health service about an STI', which is used in the NICE Sexual Health Quality Standard).

This is what we want -universal testing in specialist SHS. Previously we have been criticised for including women receiving contraceptive care in the denominator of our HIV testing coverage data for specialist SHS. Does this new recommendation include those attending for contraception only? If so, it should explicitly state this to remove

No change required (in line with evidence)

We agree that those with sexual health needs (e.g. contraception) should be offered an HIV test if considered at risk; in high-risk areas will have a test anyway, in low-risk area will have a test if part of a sexual health screen but otherwise if only presenting for contraceptive services and not changed partner not need a test.

Should be captured by place-based recommendation which includes specialist sexual health services

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|   |  | ambiguity.  |   |
|   |  | The other recommendation about testing all healthcare attendees in  |   |
|   |  | high and extremely high prevalence areas implies that people attending  |   |
|   |  | L2 services for contraception in those areas should also be tested.   |   |
|   |  | 5 I am pleased that this document has picked up the need for repeat   |   |
|   |  | testing in MSM with bacterial STI , but would like it to cite our data on   |   |
|   |  | this published in the HIV report data.  |   |
|   |  |   |   |
|   |  | 6 I am pleased that this document talks about community testing, but  |   |
|   |  | would like it to cite our data on this published in the HIV report, and   |   |
|   |  | Sophie's presentation at BASHH.   |   |
|   |  | Decrees and the second |   |
|   |  | Recommendation for community testing – this seems vague and for me  |   |
|   |  | it's unclear how commissioners are expected to consider and apply this  |   |
|   |  | recommendation.   |   |
|   |  | 7 This report doesn't mention HIV testing in <b>prisons</b> . It should, and I  |   |
|   |  | would like it to cite our data on this published in the HIV report.   | Amended to include should be offered in prisons |
| 1 |  | would like it to cite our data on this published in the rily report.  | Amended to include should be offered in prisons |