HIV testing: Increasing the uptake of HIV testing among people at higher risk of exposure

Consultation on draft guideline
Stakeholder comments table

03/05/16 to 15/06/16

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1	[office use only]	Alere Ltd	Full	7	22	Alere welcomes the inclusion of point of care testing (POCT) of HIV in the guideline as an enabler in facilitating increased access to testing, rapid results and active case finding in a community setting. However, with respect to the statement that point-of-care tests have relatively poor sensitivity and specificity, we feel it is incorrect to position all point of care tests in this way. There are a number of point-of-care tests available for detecting HIV infection, and these have been mainly 2nd and 3rd generation tests that detect the presence of HIV antibodies post seroconversion. The earlier versions of 4th generation tests that were evaluated were found to have lower sensitivity for detection of the p24 antigen in the acute phase of the infection than the laboratory 4th generation tests. The new 4th generation point-of-care test, Alere HIV Combo, has very good sensitivity and specificity (88% sensitivity and 100% specificity) compared to the laboratory serological tests, as evidenced in the recent study by Fitzgerald *et a*l (accepted for publication). This confirmed previously published data by Ottiger & Huber (Ann Clin Lab Res 2015 3:1-4) which showed significantly improved detection of the p24 antigen by this test. Additional data is also presented in the pack insert for the Alere HIV Combo test, where over 2000 samples were evaluated. The use of new 4th generation POCT can increase case finding particularly in high risk communities at a time when individuals are at their most infectious (Livant et al, 2016 poster presented at CROI). It is important that healthcare professionals understand the differences in the POCT that are available and recent advances in point of care technology. The current statement presents the tests as though they all use the same technology and have similar performance, which is incorrect.	Thank you for this comment. Comparison of the effectiveness and accuracy of different tests is specifically excluded in the scope for this guideline. However we have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing.
2	[office use	Alere Ltd		12	24	As outlined in the comment above, the statement that point of care tests lack specificity is not correct for all tests. The new 4th	Thank you for this comment. Comparison of the effectiveness and accuracy of different

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	only]					generation Alere HIV Combo test has very good specificity in published evaluation (Fitzgerald, accepted for publication).	tests is specifically excluded in the scope for this guideline. However, we have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing.
3	[office use only]	Alere Ltd		62	9	The section entitled 'Point of Care testing' does not explain the differences in the point of care tests available. The sensitivity and specificity is very different for the different types of tests available on the market and should be explained here such as outlining 2nd/3rd and 4th generation point of care tests and the high sensitivity and specificity of the new 4th generation Alere HIV Combo test. It is important that healthcare professionals understand the differences in the point of care tests available.	Thank you for this comment. Comparison of the effectiveness and accuracy of different tests is specifically excluded in the scope for this guideline
4	[office use only]	Association of Directors of Public Health	Full	5	5-25	First bullet - high prevalence needs to be defined. It is suggested that in this bullet we are talking about high prevalence in the UK. However, the third bullet is then confusing "Is known to be from a country or community with a high prevalence of HIV" – this bullet needs to be clearer – which countries/communities? Also in bullet regarding high risk sexual practices, it is important to define these. The bullet that suggests anyone disclosing they have changed a sexual partner, is there evidence to support this? Men who have sex with men – PHE recommend testing every 3 months – but this guidance suggests only testing if a test has not been done in the last year. Missing groups = sex workers? Female contacts of men who have sex with men (these are in the UK National HIV testing guidelines) We particularly appreciate the updated and new recommendations on repeat testing for HIV; and the recommendation of an HIV test for all hospital admissions in high prevalence areas. However, there are reservations about testing everyone who attends hospital and is having blood tests and who lives in a high prevalence area. This isn't practical at the level of the catchment population of a hospital.	Thank you for this comment. A new definition of high prevalence has been formulated by Public Health England (PHE) and we have used this definition. Also, see the committee discussion section of the guideline for more detail. Chemsex has been given as an example of a high-risk sexual practice within the guideline recommendations. However, the committee did not want to define this further as they felt that defining high risk sexual practices is not always clear cut and would be dependent on the information a person discloses regarding a particular situation. The bullet referring to partner change has been removed. The committee discussed the PHE recommendation to test every 3 months among MSM who have new or different

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						This was looked into in Watford, and huge variation was found in prevalence across the hospital's catchment despite prevalence looking high on average. This could do with some qualification – based on age, or something more specific. Do we really want to test every elderly person going into hospital? This isn't much of an issue at the GP practice level where the catchments are smaller, but it is the same issue.	partners. They decided to align the recommendation with that from PHE. We have updated the list of groups in the relevant recommendations to include female contacts of MSM. Sex workers would normally fall within the definition of high risk groups. Thank you for highlighting the possible resource impact of additional HIV testing. We hope the new criteria for high prevalence developed by PHE will help to focus resources. People who use NICE guidelines in their work should always use them in conjunction with professional judgement and discussion with people using services. This issue is also included in the committee discussion section of the guideline.
5	[office use only]	Association of Directors of Public Health	Full	6	28-29	What evidence is there for the effectiveness/cost effectiveness of community testing services at PSE sites, in third sector provider premises etc. A PHE evidence briefing suggested that community testing of this nature tended to exceed cost effectiveness thresholds, although it may have been more effective in some circumstances.	Thank you for this comment. Public sex environments (PSE) are given as an example of the kind of place that services may be set up. The recommendation is not that testing services should be specifically set up in PSE sites.
6	[office use only]	Association of Directors of Public Health	Full	7	22-24	"about the relatively poor specificity and sensitivity of POCT and the 24 need for confirmatory serological testing." This needs rephrasing, as many of the POCTs these days are quite sensitive and specific 3 months after exposure. What is more important is explaining the window period and getting individuals to test again (as per 1.2.7) Self-sampling provision – what evidence supports this?	Thank you for this comment. We have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing. All of the evidence used to make the recommendation on self-sampling is described in the 'evidence reviews' section under the Committee Discussion. To note that the phrasing of the recommendation (i.e. 'consider providing self-sampling kits'….) denotes that the strength of

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							the evidence base did not enable a stronger recommendation to be made (please see NICE manual re strength of wording for recommendations).
7	[office use only]	Association of Directors of Public Health	Full	8	14-17	An expansion of the offer of a HIV test to more people in more settings is welcome, but it is important to be really clear about the frequency of testing and for which groups.	Thank you for this comment. Examination of the frequency of re-testing was outside of the scope of this guideline. In the guideline recommendations (section 1.1.), specific criteria is given to indicate when testing should be offered to people in secondary. Emergency care and GP practice settings. The need for re-testing in many cases will be based on professional judgement although a recommendation is made on annual testing for people in groups or communities with a high rate of HIV or at higher risk of exposure.
8	[office use only]	Association of Directors of Public Health	Full	9	16-18	"detail how and where to access local HIV testing services, including 17 services offering POCT and self-sampling, and sexual health clinics (where people do not have to give their real name)" It isn't helpful to tell people that they don't have to give their real name in GUM clinics – this is likely to reinforce stigma associated with HIV and STIs. Talking about privacy and confidentiality is fine.	Thank you for this comment. Only evidence that some people value anonymity was found in the evidence reviews, which the committee considered and decided to include in the recommendations. For more information, the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion within the guideline.
9	[office use only]	Association of Directors of Public Health	Full	11	1-21	Previous comments. Also – people with negative tests need to know where they can get a full STI screen.	Thank you for this comment. This is made clear within section 1.4 of the guideline recommendations.
10	[office use	Association of Directors of	Full	15	General	According to the HIV in UK report 2015, 17% overall not 24% of people with HIV are estimated to be unaware of their diagnosis.	Thank you for this comment. We have corrected this, in line with your comment.

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	only]	Public Health					
11	[office use only]	Association of Directors of Public Health	Full	16	General	It is noted that the Committee notes that the BHIVA testing guidelines still stand (with the exception of some of the HIV clinical indicator conditions), but this is not consistent with the risk groups identified in this guidance earlier (1.1.4 and 1.1.5). It may be that NICE evidence has suggested changes to the risk groups? If not then they should be the same?	Thank you for this comment. We have updated the risk groups to more closely match the BHIVA guidelines.
12	[office use only]	Association of Directors of Public Health	Full	17	General	The change of definition of high prevalence is interesting (which needs to be higher in the guidance) 4/1000 population. How was this arrived at? Also – although it is noted that GPs may not have time to offer tests in their appointments - Warwickshire are doing testing in practices, where nurses and HCAs do during registration checks. Haringey GPs do opportunistic testing	Thank you for this comment. A new definition of high prevalence has been formulated by PHE and we have used this definition. Also, please see the committee discussion section of the guideline for more detail.
13	[office use only]	Association of Directors of Public Health	Full	General		The inclusion of the latest information and evidence of new HIV testing technologies and platforms, enabling more people to be tested by clinical staff, allied professionals, outreach workers, and by people themselves; through self-sampling testing kits is well-timed. However, there are multiple references to self-testing in the document. It isn't clear whether this means postal requested tests as opposed to taking your own sample face to face with a	Thank you for this comment. Self-testing is not recommended in the guideline as there was insufficient evidence. The guideline does recommend self-sampling and this can be delivered in various ways, including postal and face to face. All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.

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						practitioner.	
14	[office use only]	Association of Directors of Public Health	Full	1		The guidance states it is focused on people who live in areas or communities with a high prevalence – however, even in areas of relatively low prevalence elements of this guidance is very helpful and applicable and colleagues could certainly be implementing some of the recommendations.	Thank you for this comment.
15	[office use only]	Association of Directors of Public Health	Full	General		We welcome the new NICE guidance on increasing the uptake of HIV testing, which combines and updates PH33 (AFC) and PH34 (MSM) – there was duplication across these two guidelines previously, so bringing them together streamlines the action needed to increase HIV testing within these and other communities. The recommendations are themselves very clear and the new updates provide that extra clarity. We value the inclusion of digital platforms not only to promote HIV testing but also to encourage health seeking behaviour and system wide and individual behaviour change. However, the ones around secondary and emergency care and GPs may be quite hard to implement – and I wonder whether CCGs and NHS England (as Commissioners of these services) will see that they have a major role to play in ensuring implementation of these recommendations. The Commissioners will need to write it into contracts with KPI's. Perhaps their role could be highlighted, and joint working with LA public health and local sexual health services recommended. Examples of good practice would also be useful.	Thank you for this comment. We will pass this information on to our implementation colleagues. We would welcome any examples of good practice being submitted to the NICE shared learning database.
16	[office use only]	Association of Directors of Public Health	Full	7	20-27	The consultation asks specifically about whether there will be significant resource impact for implementing recommendations 1.2.1 (POCT), and 1.2.3 (self-sampling). From a low prevalence area point of view (North Yorkshire), these services are already provided as per the recommendations as part of a contract with the integrated sexual health service; therefore, there wouldn't be a significant resource impact within North Yorkshire.	Thank you for this comment. Resource impact tools will be published alongside the guideline and these will look at the resource impact of implementing the guideline.

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						However, we would welcome a cost-calculator that would provide Local Authorities with the means to plan for implementation and provide crucial information on the cost implications of fully implementing these guidelines.	
17	[office use only]	Association of Directors of Public Health	Full	6 7	28-29 22-24	It is important to consider extending access to HIV testing in rural areas and populations and in particular reaching at risk MSM groups who do not identify openly as "gay" men in their often small communities. Testing models in public sex environments are important in this case (6:28-29) as are access to online HIV home testing and sampling models (7: 22-24).	Thank you for raising this issue. Both access to self-sampling and testing in public sex environments are included in the guideline – see recommendations in section 1.1 and section 1.2.
18	[office use only]	BioSure (UK) Limited	Full	General	General	The objective of the guidance is to provide guidance on options for increasing the uptake of HIV testing. There has been clear evidence of the impact of HIV testing uptake in the MSM group in post publication of PH33 (GUM tests performed 2011 = 90,926, 2014 = 120,925, *HIV in the UK – Situation Report 2015: data to end 2014. November 2015. Public Health England, London. Public Health England*). However, most of this increase can actually be explained by increases in new STI attendances. HIV testing services and facilities aimed at MSM are already highly developed. However, there is evidence that this cohort are still not testing with sufficient frequency. There is also a level of bias in this data: sexual preference is self-reported. There is still considerable stigma (both external and internal) with regard to male homosexual preference. Not all MSM are openly gay, and as such are considered as difficult to reach. There is a reluctance (reported across the world) for MSM to fail to engage with healthcare and particularly with regard to accessing testing services for HIV. This is just as true now of black African women, as it was in 2009 (Barriers to HIV testing – Final full report, NICE 2009). Stigma and fear of being "outed" are very significant barriers to accessing HIV testing services. "Self" (or more commonly referred to as "Home") sampling does nothing to address these issues. The	Thank you for this comment. There was insufficient evidence to make recommendations on self-testing. We hope that when this guideline is reviewed for update there will be more evidence. A research recommendation on self-sampling has also been made in the guideline, which could increase the likelihood of research in this area being undertaken. For further information, the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.

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						results are transmitted from a healthcare provider in a similar manner to traditional testing. The self-sampler does not have control of their result and its dissemination.	
19	[office use only]	BioSure (UK) Limited	Full	17	20	"No evidence was found for self-testing". This is unfortunate. There is considerable evidence of the acceptance and uptake of HIV self-TESTING where available. This is particularly true when the test is offered for free as part of a funded programme. The literature review ignores all studies that are not UK based. HIV does not discriminate geographically, by gender, race or age. Whilst the UK is more liberal with regard to attitudes to HIV than many of the places where large scale self-testing research has been conducted, there is still a uniformity of reported barriers to testing and by implication to equivalence of potential uptake in the UK. It is unfortunate that some excellent research on acceptability has been ignored on the basis of its geographical starting point. (ER1). The WHO guidelines on HIV testing services make specific reference to the need to include HIV self testing as a part of HIV testing development. (*Consolidated guidelines on HIV testing services, WHO. July 2015*) There is evidence of acceptance and accuracy of HIV self-testing. More than 30,000 people have purchased and probably used the BioSURE HIV Self Test. The vast majority of those tests have been funded by the tester. There has been a considerable body of feedback evidence collected on false positive results, at a rate of 0.03% of all tests sold and whole system failures (including invalid tests) at a rate of 0.13%. It is accepted that these results may be understated. But even a 5 fold increase in either would not take the performance of the test outside of the parameters expected at regulatory approval. At least half of those who reported had tested for HIV for the first time. Most (75%) are male and most (78% are from non-metropolitan addresses). The very nature of a self-test makes it difficult to collate data on results accurately. We have anecdotal feedback that at least 8 people have accessed care in the UK following a positive BioSURE HIV Self Test result. There is evidence from outside of the UK (again not captured by ER1) that shows that HIV self testers do alter behaviour at the very least and do access care (for example http://www.thelancet.com/journals/lanhiv/article/PIIS2352-	Thank you for this comment. All of the reviews included the available evidence from most OECD (Organisation for Economic Co-operation and Development) countries except the qualitative review which was UK based to reflect the contextual nature of qualitative evidence. The criteria to use evidence from OECD countries was agreed with the guideline committee. Please see the review protocol for the inclusion criteria for the evidence reviews for this guideline. All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion. To note, the study highlighted would not have met the inclusion criteria for the evidence reviews for this guideline development as it is based in Kenya, a non OECD country.

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						3018(16)00041-2/fulltext).	
20	[office use only]	BioSure (UK) Limited	Full	1	18	The guidelines begin with a statement "People who want to use self-testing or self-sampling kits to test for HIV", however the document does not address self-testing as an option in its own right. Home sampling is an effective testing option. However, it has been around and publicly funded for a number of years with limited effect. PHE have an aspiration to provide 50,000 such tests per annum. The BioSURE HIV self test was accessed by 30,000 self-funding users in its first year on the market with very limited marketing spend. Self-sampling is not innovative nor really dismantle most of the barriers to accessing HIV testing facilities.	Thank you for this comment. There was insufficient evidence to make recommendations on self-testing. We hope that when this guideline is reviewed for update there will be more evidence. A research recommendation on self-sampling has also been made in the guideline, which could increase the likelihood of research in this area being undertaken. For further information, the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.
21	[office use only]	BioSure (UK) Limited	Full	53	1.1.2	This seems to indicate that 4th generation rapid tests would be recommended as point-of-care tests. There is considerable published, as well as anecdotal evidence, that 4th generation rapid tests are unreliable (the p24 antigen detection line generates a very high rate of false positive results). They are also extremely expensive and do not represent value for money. 3rd (or 2nd) generation HIV tests currently provide the most robust platforms for rapid, point-of-care testing.	Thank you for this comment. Comparison of the effectiveness and accuracy of different tests is specifically excluded in the scope for this guideline.
22	[office use only]	British Association for Sexual Health & HIV (BASHH)	1.2.1			Offer POCT in situations where follow-up may be difficult so that people do not need to return to get their results. [new 2016] This would suggest that A+E should offer POCT which might be a barrier for implementing. Given the low positivity rate it would be better to have strategy of being able to contact those who are positive on testing. As in GU clinics, people should not have to return in person for results, instead they can be when they can be texted their results.	Thank you for this comment. We have changed the wording of the recommendation to clarify that POCT may be beneficial in situations where it would be difficult to give people their results, for example if the person is unwilling to leave contact details.
23	[office use only]	British Association for Sexual	1.3.7			Use or modify existing resources, for example TV screens in GP 14 surgeries, to help raise awareness that HIV testing is available locally (for 15 content see recommendations 1.3.1 and 1.3.2). [new 2016]	Thank you for this comment. We have added a reference to self-sampling in this recommendation. However, there was insufficient evidence to make

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		Health & HIV (BASHH)				We suggest that TV screens should advertise self testing websites that are funded such as SH24, the new pan London home testing and other NHS/LA supported home testing sites.	recommendations on self-testing. We hope that when this guideline is reviewed for update there will be more evidence. A research recommendation on self-sampling and self-testing has also been made in the guideline, which could increase the likelihood of research in this area being undertaken. For further information, the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.
24	[office use only]	[British Dental Association]	Full	General	General	The BDA is content that the suggestions with implications for secondary care dentistry are sensible and practical.	Thank you for this comment.
25	[office use only]	[British HIV Association (BHIVA)]	Full	General	General	We would like to check the final agreed title is HIV testing: increasing uptake among people who may have undiagnosed HIV" not "Increasing the uptake of HIV testing among people at higher risk of exposure" as this is still appearing in most communication cover notes	Thank you for this comment. We will address this with our internal colleagues. The title of the guideline is "HIV testing: increasing uptake among people who may have undiagnosed HIV".
26	[office use only]	[British HIV Association (BHIVA)]	Full	General	General	We would like to request inclusion specifically of ensuring effective Partner notification, emphasising its importance in all settings where diagnoses are given	Thank you for this comment. The committee agreed that partner notification was an important issue and have added a recommendation to the guideline on this.

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27	[office use only]	[British HIV Association (BHIVA)]	Full	General	General	The indicator condition infectious mono-nucleosis-like illness should be specifically mentioned as a strong recommendation – high level of undiagnosed HIV, indicates recent infection and so highly infectious and allows earliest possible diagnosis.	Thank you for this comment. The post-consultation guideline now mentions mononucleosis like illness as an example indicator condition at various points in the recommendations.
28	[office use only]	[British HIV Association (BHIVA)]	Full	16	16	Need to reword recommendations about sex abroad - it is where partner is from not where they have sex that is the point	Thank you for this comment. The committee were asked to check this sentence within the guideline and agreed that the original wording on this was clear.
29	[office use only]	[British HIV Association (BHIVA)]	Full	16	10-12	We believe a stronger word than 'useful' should be used, we would like to suggest 'essential'	Thank you for this comment. This text has been amended to note that 'it is important for national guidelines to recommend HIV testing when diagnosing or treating conditions that may indicate HIV infection'.
30	[office use only]	[British HIV Association (BHIVA)]	Full	General	General	The high prevalence terminology needs to be clearer – there are definitions for high prevalence. BHIVA uses 1/1000 for countries of HP to recommend an HIV test in GU. The 4/1000 in this guideline is	Thank you for this comment. A new definition of high prevalence has been formulated by PHE and we have used that definition. Also,

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						to indicate where there may be an undiagnosed rate of 1/1000, i.e. cost effective, which is clearly very different. The problem is that one cannot get local undiagnosed rate, only the national rate, so this surrogate is probably the only way to do it, but a different term should be employed.	see the committee discussion section of the guideline for more detail.
31	[office use only]	Department of Health	Full	General	General	Department of Health has no substantive comments to make, regarding this consultation	Thank you for this comment.
32	[office use only]	Halve It	Full	General	General	To support the target stakeholders that are identified in the NICE guidance, Halve It recommends that the guidance includes a link to the National AIDS Trust's *Commissioning HIV testing services in England: A practical guide for Commissioners* to ensure that planned services are suitable and acceptable to different communities	Thank you for this comment. Issues related to implementation and service delivery are beyond the scope of this guideline. However, we have flagged this to the NICE implementation team and we would also encourage you to provide feedback via the Into practice section of the NICE website.
33	[office use only]	Halve It	Full	General	General	There is little information on self-tests for HIV. Whilst we understand that NICE guidelines are developed from the evidence and that there is limited evidence on self-testing as of yet, the guidance should clearly reflect the current circumstances in that self-tests are legal and available on the market. There may be circumstances where a person might ask about a self-test or where making people aware that they are available is appropriate	Thank you for this comment. We have reflected this in the context section, but since there is insufficient evidence on which to base a recommendation we are unable to highlight it further. We have made a research recommendation about self-testing kits and hope this will encourage further research.

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34	[office use only]	Halve It	Full	General	General	The updated scope of the guidelines confirms that they should consider testing in places of detention and other custodial settings such as Initial Accommodation Centres (IACs). This is not something which is explicitly mentioned within the guidance and we feel it should be incorporated in sections on settings for testing and as places where information and materials on testing should be provided. NICE should recommend that people in IACs and Immigration Removal Centres (IRCs) are all offered a test if from high prevalence countries or who are otherwise at risk according to other NICE criteria. NICE should also reinforce current NHS England and PHE policy to test everyone in custody for HIV as well as hepatitis B and C	Thank you for this comment. This was part of the scope but we did not identify any evidence for custodial settings other than timing of HIV testing in prisons. Following guideline consultation, the committee reconsidered the importance of encouraging HIV testing in custodial settings and based on the evidence, have made a recommendation on HIV testing in prisons.
35	[office use only]	Halve It	Full	1	7	The paragraph starts 'This guideline covers…' There is a missing 'or' in the second sentence which we believe should read, 'The guidance focuses on people who live in areas or communities with a high prevalence of HIV, or whose lifestyle or sexual behaviour puts them at risk, or who have an illness that may indicate HIV infection.' Without this additional 'or' the guidance could be limited in scope to covering only those in high prevalence areas whose lifestyle or sexual behaviour puts them at risk	Thank you for this comment. That was not our intention and we can see the ambiguity of this sentence. We have amended it for clarity.
36	[office use only]	Halve It	Full	5	15	Add 'or at significant risk'. This will encourage healthcare practitioners to consider the offer of an HIV test in the circumstances that someone testing discloses that they have engaged in sexual practices that are highly risky but not covered by other more specific guidance in this document	Thank you for this comment. This is covered in section 1.1 of the guideline recommendations.
37	[office use only]	Halve It	Full	5	16	Consider rewording to: 'reports sexual contact, in the UK or abroad, with someone from a country of high HIV prevalence'. This will prevent confusion, since the current wording suggests that anyone who has sex abroad (even with a long-term partner) is at high risk of contracting HIV	Thank you for this comment. We have reworded this text in line with your comment.

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38	[office use only]	Halve It	Full	5	24	Consider clarifying 'chemsex' as part of drug use that is likely to put people at higher risk of acquiring HIV. Recent quantitative and anecdotal evidence suggests that so-called 'chemsex' or the use of recreational drugs to heighten or improve sex is on the rise and people engaging in 'chemsex' are less likely to be able to take precautions to prevent themselves contracting HIV	Thank you for this comment. We have added chemsex as an example.
39	[office use only]	Halve It	Full	5	25	NICE should consider including 'female sexual contacts of men who have sex with men' in line with the *2008 UK National Guidelines for HIV testing*	Thank you for this comment. We have added this group to the relevant recommendations in section 1.1 of the guideline.
40	[office use only]	Halve It	Full	6	3	Halve It recognises that the time pressures on primary care may make routine offering of a test implausible but encourages NICE to think about how the adaptation of this guideline will impact on high prevalence areas which are still recommended to routinely offer tests to new registrants in areas of high HIV prevalence	Thank you for this comment. A new definition of high prevalence has been formulated by PHE and we have used that definition. Also, see the committee discussion section of the guideline for more detail. Resource impact tools will also be published alongside the guideline to support local areas in considering resource issues.
41	[office	Halve It	Full	6	4	While the Halve It campaign recognises the advantages of	Thank you for this comment. While NICE is

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	use only]					broadening the definition of 'at risk' communities beyond the 'black African communities' focus of PH33 2011, NICE should support those organisations that work with communities of high HIV prevalence to ensure that people are aware of the high prevalence within their community and are encouraged to test in appropriate settings	not able to directly support implementation of guidelines, tools will be published alongside the guideline to support local area in considering resource issues. We would also encourage feedback and best practice examples to be shared via the Into Practice section of the NICE website.
42	[office use only]	Halve It	Full	6	15	Halve It would also recommend the inclusion of guidance around the need to contact known sexual partners of people that have recently been diagnosed with HIV so that they can test for HIV in a setting appropriate to them. Pilot studies 2008-2011 on 'partner notification' have returned positivity rates of between 10–34%	Thank you for this comment. The committee has added a recommendation on partner notification.
43	[office use only]	Halve It	Full	6	18	NICE should consider including 'female sexual contacts of men who have sex with men' in line with the *UK National Guidelines for HIV testing* Halve It would also recommend the inclusion of guidance around the need to contact known sexual partners of people that have recently been diagnosed with HIV	Thank you for this comment. We have added this group to the relevant recommendations in section 1.1 of the guideline and a new recommendation on partner notification has also been added in section 1.2.
44	[office use only]	Halve It	Full	6	30	Given the time pressures on primary care which limits the ability of general practitioners to perform HIV tests, there is an opportunity for primary care to work in partnership with voluntary sector organisations to provide onsite testing which will 'endorse' community testing within a clinical setting	Thank you for this comment. This is beyond the remit of NICE and would be reliant on local arrangements.

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45	[office use only]	Halve It	Full	7	2	Given the non-specific nature of 'venues where people at high risk may gather', the Halve It campaign suggests that NICE clarify some of the venues that have shown high levels of undiagnosed HIV through pilot studies and anecdotal evidence. These include nightclubs, saunas and festivals	Thank you for this comment. This recommendation has been reworded for clarity and to give examples of venues where people at high risk may gather such as nightclubs, saunas and festivals.
46	[office use only]	Halve It	Full	7	6	Replace 'British HIV Association guidelines' with 'current UK national guidelines on HIV testing'. This wording allows the guidelines to adapt and grow with changes to the *UK National Guidelines for HIV testing* which were originally drafted by the British HIV Association, the British Association of Sexual Health and HIV and the British Infection Society. The Halve It coalition supports the deliberately generic wording in this instance so that the guidelines reflect changes in best practice where necessary	Thank you for this suggestion. This change has been made to the guideline.
47	[office use only]	Halve It	Full	7	15	NICE should consider reinforcing that results should be communicated in an appropriate and sensitive manner - it may not be appropriate to give test result in situ in certain circumstances. In these instances, NICE should clarify to lay testers that they should make it clear to the test recipient that they are offering tests in conjunction with a clinic and give an expected timeframe for disseminating results relevant to the setting and type of test. It would also be helpful for NICE to recommend that lay testers in the community are trained sufficiently to feel comfortable referring people to appropriate primary and secondary care services	Thank you for this comment. The committee discussed these issues but felt that in the absence of specific evidence, they were not able to make a recommendation on this and that this would be subject to local arrangements.
48	[office use only]	Halve It	Full	7	15	We welcome the addition in 1.1.11 referring to lay testers. We are aware that some local authorities insist that tests are carried out by clinical staff. This addition will increase confidence in commissioners that with the right support other individuals may be	Thank you for this comment.

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						able to deliver HIV testing	
49	[office use only]	Halve It	Full	7	21	Halve It recommends the inclusion of some of the potential benefits of POCT and clarification over when a confirmatory serological test is required	Thank you for this comment. We have changed the wording here to confirm the need for serological testing, but the various kinds of POCT and their relative accuracy is beyond the remit of this guideline and is excluded in the scope.
50	[office use only]	Halve It	Full	8	7	Add clarity on the variety of stakeholders required to ensure that self-sampling services are culturally sensitive and sustainably commissioned. Different pilot projects have shown the breadth of stakeholders that can be mobilised to advocate for people to test for HIV including commercial venues, faith leaders, local PHE epidemiological data, sexual health commissioners, sports clubs and places of work.	Thank you for providing this information. While local implementation issues are outside the remit of the guideline, if Halve It have examples of shared learning related to self-sampling services, these may be suitable to be submitted inclusion on the NICE shared learning database. Please see the NICE website for further information.
51	[office use only]	Halve It	Full	8	15	Consider adding 'in line with PHE guidance' to section on more frequent testing for those who have a high risk of exposure	Thank you for this comment. This has been amended to reflect PHE's Situation report 2015 as suggested.

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52	[office use only]	Halve It	Full	8	23	Consider adding 'electronic reminders for people who test positive for STIs' to ensure that people testing regularly for STIs are receiving a joined-up sexual health service	Thank you for this comment. We did not identify any evidence related to electronic reminders for people who test positive for sexually transmitted infections (STIs). All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.
53	[office use only]	Halve It	Full	9	24	Consider adding 'and migrant populations' to sentence addressing the needs of non-English speaking communities for example through translated information. The scope of the consultation specifically qualifies that custodial settings and places of detention should be considered by stakeholders in their response. Materials should be made available to people in places of detention and more should be done to ensure that materials communicating the benefits of HIV testing are focused to specific high risk communities in a culturally sensitive manner that recognises the cultural nuances between groups that are categorised as 'at risk'	Thank you for this comment. We have changed the wording slightly so that it more explicitly includes migrant populations. Custodial settings were part of the scope but we did not identify any evidence for custodial settings other than timing of HIV testing in prisons. Following guideline consultation, the committee reconsidered the importance of this encouraging HIV testing in custodial settings and based on the evidence, have made a recommendation about on HIV testing in prisons.
54	[office use only]	Halve It	Full	11	28 / 29	Remove 'British HIV Association' from title of *UK National Guidelines for HIV testing 2008* reference	Thank you for this comment. This is the standard referencing format for NICE since the guidelines were published by BHIVA and the copyright is assigned to BHIVA.
55	[office use only]	Halve It	Full	12	18	Consider adding 'the benefits of early diagnosis to the health system and local authorities in the form of lower care costs associated to improved outcomes for people diagnosed early as living with HIV'. This will ensure that local authorities recognise that every new HIV infection costs £250,000–360,000 in lifetime treatment costs alone and that each early diagnosis saves the health system £63,000. If	Thank you for this comment. This section of the guideline is intended to be succinct and include key information on the context for the guideline. Links to more detailed sources of information are provided within the text of the context section.

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						every new infection in 2011 had been prevented, the UK taxpayer would have saved £1.9 billion and local authorities should be supported in the view that testing improves not only individual and public health but also represents a return on their investment in public health	
56	[office use only]	Halve It	Full	12	23	Guidance should include reference to stakeholder involvement in determining testing solutions that are sensitive to local need. This will ensure that commissioned services are accessible to all their residents, particularly those communities that are most at risk of acquiring HIV	Thank you for this comment. This section of the guideline is intended to be succinct and include key information on the context for the guideline. Links to more detailed sources of information are provided within the text of the context section.
57	[office use only]	Halve It	Full	13	11	Consider adding partner notification protocol as a means of effective implementation of the NICE guidance under 'things staff can include in their own practice straight away'	Thank you for this comment. The committee agreed that partner notification is an important issue and a recommendation about this has been added to the guideline following stakeholder consultation.
58	[office use only]	Halve It	Full	16	10	The Halve It campaign is pleased to see NICE advocating for HIV testing in other NICE guidance especially in conditions that may indicate HIV infection. Differential diagnosis is an excellent opportunity to deploy the offer of an HIV test and alleviates concerns that have been raised about the fear from healthcare professionals that an offer of a test based on those most at risk of infection, will cause offence. Making other specialities aware of the symptoms of HIV will also improve healthcare professionals' ability to diagnose earlier. A 2008 study referenced by the National AIDS Trust, found that among newly diagnosed black Africans in 15 London treatment centres (49.8% of whom had been diagnosed very late with a CD4 count of <200 mm^3), 76.4% (181/237) had seen their GP in the previous year, 38.3% (98/256) had attended outpatient services,	Thank you for this comment.

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						and 15.2% (39/257) inpatient services, representing missed opportunities for earlier HIV diagnosis. The authors also noted that; 'medical attention was sought for wide-ranging reasons, often not obviously connected to underlying HIV status'	
59	[office use only]	Halve It	Full	17	9	NICE guidance should consider advocating for practice nurses to offer POCT with a particular focus on practices in high prevalence areas	Thank you for this comment. This section reflects the committee's discussions and it does not contain recommendations. However, this point was discussed with the guideline committee and we have amended the text here to reflect your comment.
60	[office use only]	Halve It	Full	17	18	Clarify the definition of high prevalence of 4 per 1,000 compared to PHE definition of 2 per 1,000 particularly given the potential impacts of this on the prioritisation of sexual health for commissioners in areas of prevalence between 2-4 per 1,000. The Halve It campaign is concerned that this change will need to be communicated clearly to local authorities to prevent disinvestment from sexual health commissioners and a 'domino' effect by neighbouring local authorities. It should also be noted that late diagnosis brings with it serious health and cost implications that are currently not covered by the high prevalence threshold	Thank you for this comment. A new definition of high prevalence has been formulated by PHE and we have used that definition. Also, please see the committee discussion section of the guideline for more detail.
61	[office use only]	Halve It	Full	17	24	The Halve It campaign welcomes the NICE committee's recognition of the time constraints on general practitioners and the impact that this can have on the likelihood of test being offered. Time constraints was one of the top two leading challenges facing those GPs surveyed as part of the Halve It RCGP conference survey from both 2014 and 2015	Thank you for this comment.
62	[office use only]	Halve It	Full	61	2	Include clarification that 'high-risk sexual behaviour' includes 'chemsex' in this section	Thank you for this comment. Chemsex has been given as an example of a high-risk sexual practice within the guideline

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							recommendations. However, the committee did not want to define this further as they felt that defining high risk sexual practices is not always clear cut and would be dependent on the information a person discloses regarding a particular situation.
63	[office use only]	[Homerton University Hospital NHS Foundation Trust]	FULL	GENERAL	GENERAL	In today's multi - commissioner and multi – service provider landscape it is important to minimise confusion between expert bodies and to simplify the guidance that is published. It would be very nice to see this guidance somehow co badged with BHIVA and PHE rather than having several different sources of guidance on this matter.	Thank you for this comment. The BHIVA guideline is accredited by NICE and is linked to in the guideline document. As part of arrangements for further collaboration with PHE, this guideline and future public health guidelines will be co-badged with PHE.
64	[office use only]	[Homerton University Hospital NHS Foundation Trust]	FULL	GENERAL	GENERAL	Very pleased to see PH33 and PH34 replaced by a single document and to have moved away from simply looking at two identified populations. However I don't see enough clarity about what you mean by "high risk" a term that you use throughout the document. Suggest that there is a clearer risk based narrative running through the document.	Thank you for this comment. In most places the guideline gives examples of high risk, and in recommendations in section 1.1 it is very specific about high risk populations and high risk behaviours. In places where the term is not defined it is because to the committee wanted to enable some flexibility for local interpretation.
65	[office use only]	[Homerton University Hospital NHS Foundation Trust]		FULL	GENERAL	The document doesn't give enough emphasis to the fact that the offer of a test is still not being made in many clinical setting where it ought to be. The document has a major focus on the UPTAKE of a test rather than the OFFER of a test. Despite the 2011 guidance there is still in 2016 clear evidence that clinicians are not considering or offering HIV tests in line with existing NICE guidance. We suggest this point is highlighted in the preamble and more weight given to getting clinicians on board and	Thank you for this comment. The committee considered that the guideline was clear about the offer and recommendation of a test. Therefore further changes have not been made to the guideline.

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						explaining where THEY can get additional support and / or training.	
66	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P1	L5	What do you mean by specialist sexual health services (including genitourinary medicine)? Do you mean this term to include reproductive health services, abortion providers, psychosexual health services etc.? This distinction matters as the commissioning of HIV testing differs depending on where and under what circumstances HIV testing is being advocated, See PHE "Making it Work" page 56	Thank you for this comment. The term was kept inclusive so that decisions can be made on a case by case basis using local information and needs assessment as to which specialist sexual health services HIV testing should be commissioned.
67	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P5 and 62		We note that you define high prevalence as greater than 4 diagnosed cases per 1000 population. This is different from the current definition of 2 per 1000 population. Please explain your reasons for changing the definition.	Thank you for this comment. A new definition of high prevalence has been formulated by PHE and we have used that definition. Also, see the committee discussion section of the guideline for more detail.
68	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P5	L5	1.1.4 We recommend that this point is strengthened and that routine HIV testing, with an opt-out policy for all patients admitted to hospital or attending emergency departments, should be the standard of care in high prevalence settings. This approach has been shown to feasible and acceptable (HINTS study and Department of Health Pilot HIV testing projects ("Time to Test" HPA).	Thank you for this comment. The committee discussed routine testing with an opt-out policy for all patients. They agreed that it would have an excessive resource impact and therefore could not recommend it.
69	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P5	L 14	We are concerned that the wording here places the responsibility for identifying as a man who has sex with other men (and thus the possibility of a test being offered) sits with the patient. Most healthcare practitioners outside sexual health services probably	Thank you for this comment. We did not identify any evidence about interventions to improve disclosure and their effects on HIV testing. All of the evidence used to make a particular recommendation is listed in the

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						don't routinely ask (and there is already some evidence for this, particularly in primary care). If a clinician in a lower prevalence area fails to identify that a man is MSM then that man will probably only be offered a test when he is sick. We feel this document could say more about identifying core groups in areas of low prevalence.	'evidence reviews' section under the Committee Discussion.
70	[office use only]	[Homerton University Hospital NHS Foundation Trust]		Ps 4,5 and 6	113/114/115	No mention of Trans people who should all be offered a test in all these settings No mention of women who have sex with MSM	Thank you for this comment. Trans people have been added as an at risk group to the relevant recommendations and female contacts of men who have sex with men have also been given as an example within recommendations in section 1.1.
71	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P6	119	Suggest that settings where linkage to care is problematic would also be considered unsuitable and cross reference with your later section on care.	Thank you for this comment. The committee were of the view that the existing phrasing was clear.
72	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P7	122	This is harsh on the reliability of a POCT test. We suggest rewording along the lines "Practitioners delivering POCT should explain to people at the time of their test the limitations of this method of HIV testing and that there may be a need for additional serological testing to clarify the POCT result" This further flags the point that whoever is offering whatever test in whatever setting should be competent to explain the limitations of any test that they are performing. We believe this should be included in the document as a generic point	Thank you for this comment. We have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing.
73	[office	[Homerton		P7	123		Thank you for raising this issue. The

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	use only]	University Hospital NHS Foundation Trust]				We have concerns that self-sampling is becoming seen as a cheaper approach to HIV testing. Suggest add something that reinforces self-sampling as an additional testing modality not simply a cheap substitute for clinician – delivered tests.	committee were of the view that the updated guideline does not imply that self-sampling should be a substitute for other forms of testing. The committee discussion section highlights that self-sampling is likely to cost about the same as other tests.
74	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P8	1.2.10	Tell them about all alternative testing possibilities as well as nearby ones.	Thank you for this comment. The committee were of the view that the existing phrasing of the recommendation was sufficient in terms of what information should be provided to people who decline a test. .
75	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P9	1.3 And 1.41 And Page 24	The section "Promoting awareness and uptake of HIV testing" should include something about promoting the awareness and understanding of importance of HIV testing for CLINICAL PROVIDERS and their role in making the offer. Its awareness on both sides of the equation and you do not adequately deal with clinician inertia. Clinician inertia/ignorance needs to be tackled particularly in emergency departments, acute admissions and ITU. Section 141 paints a far too rosy picture – if only staff DID welcome the opportunity we wouldn't be where we are now……. Glad to see something on Page 24 but needs to be upfront in the document	Thank you for raising this issue. The committee agreed that the role of clinical provider's in making the offer and recommendation of a test was key, and that the evidence suggested that in many cases it could be improved. In view of the limited evidence, the committee made a research recommendation to address this.
76	[office use only]	[Homerton University Hospital NHS			1.4.3	Suggest minor amend here for clarity as the commissioning of sexual health services is not the same as HIV services – the two	Thank you for this comment. We have added HIV services in line with your comment.

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		Foundation Trust]				services are increasingly becoming separated from one another. "Ensure practitioners delivering HIV tests (including those delivering outreach POCT) have clear referral pathways available for people with both positive and negative test results, including to sexual health services, HIV services and confirmatory serological testing. These pathways should ensure the following: .."	
77	[office use only]	[Homerton University Hospital NHS Foundation Trust]		P25		The RHIVA 2 study of HIV testing in general practice in Hackney which Homerton was a part is undertaking a cost effectiveness analysis of the intervention. This can be shared once submitted for publication.	Thank you for providing this information.
78	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	4	13	You've talked about 'emergency care' but have not defined it.	Thank you for this comment. Emergency care refers to emergency departments, accident and emergency units and similar departments.
79	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	5	14	States if discloses/known to have sex with men & has not had a test in the last year. This is a high risk population and a year is too long, espeiclaly with the increasing no.'s of seroconversion in this population. If MSM, just retest.	Thank you for this comment. Men who have Sex with Men (MSM) who are sexually active with different people would fall under the partner change criteria for more frequent testing. The committee discussed the Public Health England (PHE) recommendation to test every 3 months among MSM who have new or different partners. The committee decided to align the recommendation with that from PHE.

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80	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	6	21	The offer of point of care POCT is very difficult in the real world, apart from in sexual health. Serology gives you guaranteed follow up, is far cheaper and does not have the issues with seroconversion.	Thank you for raising this issue.
81	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	7	20-24	POCT is not feasible in an A&E dept and I say this as an ex A&E Sr.	Thank you for this comment. The Committee were of the view that the guideline does not suggest that Emergency departments should routinely offer POCT and that it is down to local areas to decide which types of testing will best meet the needs of the local population.
82	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	9	23-29	Sadly the realities of this are that though this is a great recommendation, this is a very expensive intervention, screening on admission, brings about far more diagnosis.	Thank you for this comment. This recommendation is for statutory and voluntary sector organisations who offer or promote HIV testing. For example, these could be community organisations who work with the majority of people who are not admitted to hospital.
83	[office use only]	[Homerton University Hospital NHS Foundation Trust]	Full	General	General	I am very concerned at the guidelines reliance on POCT. I understand that this is a very useful tool in self sampling, but having worked on the RHIVA study I can say that the quality assurance of POCT is a nightmare. The co-ordination of POCT over multiple sites needs a great deal of co-ordination and who is going to do this? The quality assurance is expensive costing several hundreds of pounds	Thank you for this comment. The guideline only recommends POCT in two main situations; these are in specialist sexual health services and situations where follow up may be difficult. A recommendation is also included on the need for confirmatory

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						per surgery, who will pay for this at each centre? What happens if the results for this are poor, who follows this up. There are also EU rules about any form of point of care test, that if the individual does not undertake the test on a 'regular basis', regular is not defined, then they are not qualifies to undertake testing. Who trains and updates the people delivering the testing and the cost of the tests; even in London where we buy the INSTI test in bulk and cut a deal with Pasante, it's 3x the cost of serology. It does not pick up seroconversion, which currently accounts for 10-155 of all our new diagnosis. My biggest concern, there is no safety net. Serology produces a positive list month monthly which is followed up like all other standard sexual health tests. I have seen examples, even when the GP systems were in place, of patients being missed. Also as an HIV Liaison nurse who has very good links in A&E, they are happy to test, but POCT will not work as they do not want, with increasing numbers and a 4 hour target to deal with giving a result. They have a point. POCT is not difficult procedure, it's the skills required in breaking bad news and a patients reaction s where the skills lie.	serological testing following POCT, if the test is reactive. .
84	[office use only]	Abacus Sexual Health Clinics Liverpool Community Health NHS Trust	Full	11	12	Our outreach team who work specifically with the LGBT community would like an example of cultural guidance for MSM to be included i.e. some MSM may be fearful of the impact of disclosure of their sexual identity or behaviour to others on diagnosis with HIV.	Thank you for this comment. This is an implementation issue and beyond the remit of this guideline. However, recommendations in section 1.4 of the guideline do highlight the issue of confidentiality.
85	[office use only]	Abacus Sexual Health Clinics Liverpool Community Health NHS	Full	7	25	We are very pleased that self-testing is being recommended as part of this guideline. Will NICE recommend specific tests for this?	Thank you for this comment. Self-testing is not being recommended as part of this guideline because there is insufficient evidence to support it. However, the committee were able to make recommendations on self-sampling in section

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		Trust					1.2 of the guideline recommendations. All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.
86	[office use only]	Abacus Sexual Health Clinics Liverpool Community Health NHS Trust	Full	General	General	Overall we think this is a useful document to take to commissioners when planning our HIV testing programme. Question 2. Funding is a challenge because resources for our outreach services have been significantly cut in the last 12 months as part of wider cuts in our funding. Self sampling and more targeted outreach would have significant cost implications in terms of tests and staff.	Thank you for responding to these questions and providing this information.
87	[office use only]	Abacus Sexual Health Clinics Liverpool Community Health NHS Trust	Full	General	General	Question 4 – yes. 4a: currently we offer venous blood sample HIV testing to all patients in our service. POCT is available at a once weekly clinic in our Armistead service for the LGBT community. Self sampling is not available. We would like to expand POCT testing and introduce access to self sampling. The expansion of the POCT service is already underway. 4b. we don't know how popular this option would be so cannot predict the number of tests.	Thank you for responding to these questions and providing this information.
88	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	General	General	MEDFASH is a member of Halve It and has contributed to the Halve It response. We will not duplicate that but wish to add the points below.	Thank you for this comment.
89	[office use	MEDFASH (Medical	Full	5	8, 12, 17	The term 'high prevalence' is used in the recommendations, sometimes to refer to areas of England and sometimes to areas of	Thank you for this comment. A new definition of high prevalence has been formulated by

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	only]	Foundation for HIV & Sexual Health)		6	3, 4, 8, 13, 28	the world, although the common understanding of what constitutes 'high prevalence' in the latter is likely to be very different. It is also used in relation to communities. There is no definition within the recommendations themselves of 'high prevalence', and the definition proposed on page 17 (lines 17-18) refers to the UK context, implying (though not stating explicitly) that it refers to prevalence in geographical areas within the UK. The lack of clarity is compounded by the statement, on p 17, that the definition of 'high prevalence' has been changed for the purposes of this guideline from 2/1000 to 4/1000. While the rationale for when to offer routine testing may be correct (but see comment re page 17 below), it is not clear why the same diagnosed prevalence was deemed 'high' before but no longer is. Concepts seem to have become mixed up, with the potential to cause confusion arising from the terminology. In fact, the previous NICE guidance made explicit in the wording of its actual recommendations that the threshold for testing was 2/1000 - this was unambiguous.	Public Health England (PHE) and we have used that definition. Terminology on prevalence has therefore been made consistent throughout the guideline. Also, see the committee discussion section of the guideline for more detail.
90	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	6	5	We suggest adding 'or have had' sex with another man, and perhaps specifying 'within the last x years'.	Thank you for this comment. The committee were of the view that this change was not necessary and that the existing wording was clear.
91	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	6	21-23	As correctly stated on page 17, lines 8-9, a GP would not be able to perform point-of-care testing (POCT) during a 10-minute appointment in addition to the main consultation. In addition to fitting in more easily to standard general practice routines, a further advantage of a venous sample sent to the lab for a 4th generation test is the possibly higher sensitivity and specificity than a POCT and the ability to pick up infection at an earlier stage. Therefore, except where the patient refuses to provide a venous sample, it is not clear why NICE recommends in 1.1.7 that a mouth swab or finger prick (ie a POCT) should be offered if a venous sample is not already being taken for another reason. Offering a test to people who have disclosed significant risk of exposure to HIV, as in 1.1.5, is	Thank you for this comment. The wording of the recommendation has been changed to indicate that if a venous blood sample is declined, then a less invasive form of testing should be offered.

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						surely a good enough reason in itself to take or arrange the most appropriate test, regardless of whether blood is already being taken. In general practice, this would most often be the most appropriate and practicable option. Unlike in some other settings where the rationale for use of a POCT includes reducing the risk of patients not returning for the result and being lost to follow-up, GPs have their patients' contact details and usually have an ongoing relationship with them, so this risk is very low.	
92	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	15	3	The national undiagnosed proportion is now lower than the 24% quoted.	Thank you for this comment. This was an error which has been corrected in the updated guideline.
93	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	17	17-18	The rationale for moving the threshold for a test offer from 2/1000 to 4/1000 may appear sound. However, the cost effectiveness threshold was calculated many years ago and was based on US data. It was adopted for the *UK national guidelines on HIV testing 2008* as no better evidence existed. It has since proved a sensible threshold, been incorporated into standard monitoring data (see PHE SRH profiles) and is widely recognised by LA sexual health commissioners around the country. While the threshold of 1/1000 undiagnosed may still be based on the best evidence available for cost effectiveness, its robustness needs to be weighed against the likely impact of changing the recommended test offer threshold to 4/1000 diagnosed. In the current context of extreme financial challenges for local government, falling out of the 'high prevalence' category, as many LAs will do if the new definition is adopted, could provide a reason (or an easy excuse) to abandon or scale down investment in local testing initiatives. This would have the opposite effect to what the NICE guideline is designed to achieve. '>2/1000 diagnosed' provides a useful rule of thumb to drive the necessary public health interventions, and in the absence of up-to-date, UK-based evidence for changing it, we fear the 'baby may be thrown out with the bathwater' if this change is made. If, on the other hand,	Thank you for this comment. A new definition of high prevalence has been formulated by Public Health England (PHE) and we have used that definition. Terminology on prevalence has therefore been made consistent throughout the guideline. Also, see the committee discussion section of the guideline for more detail.

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						NICE wishes to argue that in light of the latest evidence, areas with between 2 and 4/1000 diagnosed should no longer prioritise opportunistic HIV testing based on geography, and should instead prioritise investment in interventions with communities at higher risk and people with indicator conditions, it would be good to state this very explicitly in the guidance, explaining the rationale. More clarity is needed on this issue to minimise the risk of inadvertently prompting reductions in investment where it would still be beneficial. (See also our comment above re use of the term 'high prevalence' which could exacerbate the risk.)	
94	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	18	16	The term 'routine' is vague here, as opportunistic testing could also be deemed routine. 'Universal' would be more accurate.	Thank you for this comment. Screening is beyond the remit of NICE, so we could not make a recommendation about universal testing.
95	[office use only]	MEDFASH (Medical Foundation for HIV & Sexual Health)	Full	25	21	Again, 'routine' is not a very helpful term here to describe an alternative to indicator condition-guided testing. In fact, one way to increase indicator condition-guided would be to make it more routine. As above, 'universal' would be more accurate.	Thank you for this comment. Screening is beyond the remit of NICE, so we could not make a recommendation about universal testing.
96	[office use only]	[NAT (National AIDS Trust)]	Full	5 and 6	12 and 4	'High prevalence' is used in two different contexts within 1.1.4 and 1.1.5. These are when referring to areas of high prevalence (which are re-defined in this document to be areas where more than four people are diagnosed with HIV per 1000) and when referring to countries and communities of high prevalence which may be subject to a different definition. It would be useful to define what is meant by countries or communities with a high prevalence of HIV. Whilst we note that MSM and black African men and women are referred to	Thank you for this comment. A new definition of high prevalence has been formulated by Public Health England (PHE) and we have used that definition. Terminology on prevalence has therefore been made consistent throughout the guideline. Also, see the committee discussion section of the guideline for more detail.

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						in the 'context' section of the guidance, we think that these could be clarified as high prevalence communities and that high prevalence countries should be defined.	
97	[office use only]	[NAT (National AIDS Trust)]	Full	7	14	We welcome the addition in 1.1.11 referring to lay testers. We are aware that some local authorities insist that tests are carried out by clinical staff. This addition will increase confidence in commissioners that with the right support other individuals may be able to deliver HIV testing. This is something which may support the reach of testing services in, for example, community settings, and may increase the capacity of organisations to deliver testing services.	Thank you for this comment. The committee shared this view.
98	[office use only]	[NAT (National AIDS Trust)]	Full	7	22	We are concerned that this over-emphasises the issues with specificity and sensitivity of POCT. There is also no mention of the window period, which should be explained to a person when taking the test. We suggest changing this to read, 'Practitioners delivering POCT should explain to people at the time of their test the window period for the test being used, and that the specificity and sensitivity of the test is not as high as a serological test. Reactive results should be followed up with a confirmatory serological test.'	Thank you for this comment. We have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing.
99	[office use only]	[NAT (National AIDS Trust)]	Full	8	17	There could also be a recommendation to call someone for repeat tests sooner should they have been diagnosed with an STI as this may indicate higher risk of seroconversion.	Thank you for this comment. Testing following diagnosis of an STI is covered in the guideline.
100	[office use only]	[NAT (National AIDS Trust)]	Full	13	7 onwards	This section providers 'pointers to help organisations put NICE guidelines into practice'. A helpful addition to this section would be to identify local communities or areas which are higher prevalence as this will support '3. Carry out a baseline assessment against the	Thank you for this comment. Recommendation 1.1.1 points people to information on how local communities can identify HIV prevalence in their area.

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						recommendations to find out any significant issues locally.'	
101	[office use only]	[NAT (National AIDS Trust)]	Full	14	General on Context	This section provides useful background to the guidance and helps define the scope of the guidance by providing explanation of high prevalence groups. Given that the scope of the guidance also covers people who have injected drugs, we think that the context should provide some information on how this population is affected by HIV. We would also note that in our previous comments to NICE on the scope of this document we opposed the exclusion of people at risk because they have injected drugs on the basis that such exclusion assumes readily separable categories of risk. However, recent discussion in the UK and internationally of the 'chemsex' phenomenon amongst MSM shows that this is not appropriate. The context should therefore also acknowledge some of the changing patterns of drug use and how this might impact on HIV.	Thank you for this comment. This section of the guideline is intended to be succinct and include key information on the context for the guideline. It is not intended to cover all potential issues. Links to more detailed sources of information are provided.
102	[office use only]	[NAT (National AIDS Trust)]	Full	15	3	The estimated numbers of people who are unaware they are living with HIV in the guidance are from 2013. This should be updated to the 2014 figure of 17%.	Thank you for this comment. This was an error that has now been corrected.
103	[office use only]	[NAT (National AIDS Trust)]	Full	General	General	There is little information on self-tests for HIV. Whilst we understand that NICE guidelines are developed from the evidence and that there is limited evidence on self-testing as of yet, the guidance should clearly reflect the current circumstances in that self-tests are legal and available on the market. There may be circumstances where a person might ask about a self-test or where making people aware that they are available is appropriate. In these circumstances it is important that a person is informed of necessary information such as the window period and the need for a	Thank you for this comment. The purpose of the guideline is to reflect the evidence on the effectiveness of interventions to increase HIV testing. There was no evidence to support the use of self-tests. The committee made a research recommendation that we hope will be picked up and inform future updates of the guideline. All of the evidence used to make a particular recommendation is listed in the

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						confirmatory test/ entry into care, should the result be reactive.	'evidence reviews' section under the Committee Discussion.
104	[office use only]	[NAT (National AIDS Trust)]	Full	General	General	We are concerned that there is no mention of partner notification in the guidance. Whilst we understand that this may have been considered outside of the terms of reference for this guidance, it is a key testing strategy which is extremely effective in timely diagnosis of STIs. There is also a recently published standards document from BHIVA, BASHH, NAT (National AIDS Trust) and SSHA.[1] We recommend that the NICE guidance refers to this standard and makes a recommendation to implement partner notification standards as a key diagnostic strategy.	Thank you for this comment. The committee agreed that partner notification was important and a recommendation in section 1.2 has been added to the updated guideline.
105	[office use only]	[NAT (National AIDS Trust)]	Full	General	General	The updated scope of the guidelines confirms that they should consider testing in places of detention, other custodial settings and Initial Accommodation Centres (IACs). This is not something which is explicitly mentioned within the guidance and we feel it should be incorporated in sections on settings for testing and as places where information and materials on testing should be provided. NICE should recommend that people in IACs and Immigration Removal Centres are all offered a test if from high prevalence countries or who are otherwise at risk according to other NICE criteria.[2] NICE should also reinforce current NHS England and PHE policy to test everyone in custody for BBVs.[3]	Thank you for this comment. Custodial settings were part of the scope but we did not identify any evidence for custodial settings other than timing of HIV testing in prisons. Following guideline consultation, the committee reconsidered the importance of this encouraging HIV testing in custodial settings and based on the evidence, have made a recommendation about on HIV testing in prisons.
106	[office use only]	NHS England	Full	General	General	I wish to confirm that NHS England have no substantive comments to make regarding this consultation.	Thank you for this comment.

[1] HIV partner notification for adults: definitions, outcomes and standards: http://www.bhiva.org/documents/Publications/HIV_Partner_Notification_Standards_2015.pdf
[2] Sidebottom M and Street E. (2014) 'HIV Testing in an Initial Accommodation Centre', HIV Medicine, 15(3):252 http://www.bhiva.org/documents/Conferences/2014Liverpool/Presentations/Posters/commended-poster-presentations/P252.pdf
[3] https://www.gov.uk/government/publications/improving-testing-rates-for-blood-borne-viruses-in-prisons-and-other-secure-settings

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107	[office use only]	[Public Health England]	Full	4	10	The 'UK Standards for Microbiological Investigations (SMI) V 11: HIV screening and confirmation' has also been out for consultation recently. It is important to ensure that this NICE guidance is consistent with the final SMI document.	Thank you for this comment. Both this document and the guideline are consistent with one another.
108	[office use only]	[Public Health England]	Full	5	5	We are aware that existing guidance is not always followed. We have analysed the distribution of diagnosed HIV prevalence (see comment 11), and suggest recommending different levels of interventions for areas with different levels of prevalence. We suggest changing this recommendation as follows: For **high prevalence local authorities** (see comment 11), offer and recommend HIV testing for all general medical admissions (consistent with BHIVA guidance). For **extremely high prevalence local authorities** (see comment 11), offer and recommend HIV testing on admission to hospital, including emergency departments, to everyone who has not previously been diagnosed with HIV, and is undergoing blood tests for another reason (guidance under consultation).	Thank you for this comment. The committee discussed these proposed definitions in detail. They agreed that these definitions are helpful and have used them in the updated guideline.
109	[office use only]	[Public Health England]	Full	5	8	We question the practicality of offering tests to patients on basis of the HIV prevalence in their local authority of residence? Would implementation be easier if the recommendation was for patients in hospitals in high prevalence areas?	Thank you for this comment. The recommendations in section 1.1 of the guideline have been restructured based on the new definitions of high prevalence and extremely high prevalence formulated by PHE. They now set out the activity around HIV testing required in different settings based on the updated definitions of HIV prevalence.
110	[office use	[Public Health England]	Full	5	12	Similarly, we question the practicality of offering tests to patients on the basis of their country of birth.	Thank you for this comment. This recommendation was from the previous

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	only]						guideline (PH33) and is consistent with the British HIV Association guidelines from 2008, which is a NICE accredited guideline.
111	[office use only]	[Public Health England]	Full	5	18	As currently worded, the guidance recommends testing all patients (regardless of sexual orientation) who have had a new sexual partner (not defined, since when). PHE does not have evidence to support this recommendation.	Thank you for this comment. The recommendations have been updated so that it no longer refers to testing all people regardless of sexual orientation who have a new sexual partner. However, the committee discussed the PHE recommendation to test every 3 months among MSM who have new or different partners. They decided to align the recommendation with that from PHE.
112	[office use only]	[Public Health England]	Full	6	3	We are aware that existing guidance is not always followed. We have analysed the distribution of diagnosed HIV prevalence (see comment 11), and suggest recommending different levels of interventions for areas with different levels of prevalence. We suggest changing this recommendation as follows: For **high prevalence local authorities** (see comment 11) offer and recommend HIV testing to all men and women registering in general practice who have not previously been diagnosed with HIV (consistent with BHIVA guidance). For **extremely high prevalence local authorities** (see comment 11), offer and recommend HIV testing to all patients who have not previously been diagnosed with HIV, and are undergoing blood tests for another reason. (guidance under consultation).	Thank you for this comment. The committee discussed these proposed definitions in detail. They agreed that these definitions are helpful and have used them in the updated guideline.
113	[office use only]	[Public Health England]	Full	6	4	Please see comment 4	Thank you for this comment. The committee discussed these proposed definitions in detail. They agreed that these definitions are helpful and have used them in the updated guideline.

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114	[office use only]	[Public Health England]	Full	6	9	Please see comment 5	Thank you for this comment. The committee discussed these proposed definitions in detail. They agreed that these definitions are helpful and have used them in the updated guideline.
115	[office use only]	[Public Health England]	Full	6	13	This recommendation to test by area of residence appears to overlap with the recommendation in page 6, line 3 'practice in area with a high prevalence'?	Thank you for this comment. One of the bullets refers to new registrants at a practice, while the other refers to opportunistic testing when bloods are being taken. There has been rewording to parts of this recommendation to match new definitions of high and extremely high prevalence. We hope that that the recommendations are now clearer.
116	[office use only]	[Public Health England]	Full	6	21	Please see comment 1	Thank you for this comment. The recommendations have been updated so that it no longer refers to testing all people regardless of sexual orientation who have a new sexual partner. However, the committee discussed the PHE recommendation to test every 3 months among MSM who have new or different partners. They decided to align the recommendation with that from PHE. .
117	[office use only]	[Public Health England]	Full	general	general	PHE is working with the National Offender Management Service and NHSE to roll out a national programme of opt-out HIV testing in prisons and other detention centres.	Thank you for providing this information.

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						We note that you do not accept attachments with this consultation, and are happy to send you this information on this separately.	
118	[office use only]	[Public Health England]	Full	7	25	PHE works with local authorities to run a national self-sampling service that is available to the public on-line. Over 28,000 people obtained self-sampling HIV testing kits in the first 6 months of setting up this service. As currently worded, the only form of self-sampling recognised or recommended are kits distributed in community settings. PHE recommends that all local authorities should commission on-line self-sampling HIV testing to be made available for people at increased risk of HIV. We note that you do not accept attachments with this consultation, and are happy to send you this information on this service separately.	Thank you for this comment. The text has been amended in line with your comment.
119	[office use only]	[Public Health England]	Full	8	14	In 2008, BHIVA recommended that HIV testing should be expanded in areas where the diagnosed prevalence is greater than 2/1000 population aged 15-59 years. This was based on modelling data that indicated that expanded HIV testing was cost effective if the undiagnosed prevalence was greater than 1/1000 population. Since at the time, one third of people living with HIV were estimated to be unaware of their HIV, the 2/1000 threshold was chosen as a proxy for areas where at least 1/1000 were living with an undiagnosed infection. This threshold requires updating since the ratio of diagnosed to undiagnosed HIV infection has changed as increasing numbers of people are living with diagnosed HIV infection due to effective treatment. The threshold also needs to more accurately tailored to target late HIV diagnoses. To this end, PHE has carried out a k-median cluster analysis to model diagnosed HIV prevalence distribution in local authorities in England. We recommend using 2016 data to redefine 'groups and	Thank you for this comment. The committee discussed these proposed definitions in detail. They agreed that these definitions are helpful and have used them in the updated guideline.

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						communities at high diagnosed prevalence of HIV' as follows: **High prevalence** local authorities which have a diagnosed HIV prevalence of 2-5/1,000 (n= 50) **Extremely high prevalence** local authorities which have a diagnosed HIV prevalence of at least 5/1,000 (n= 20) When this model is applied to national late HIV diagnosis data, it is shown that two-thirds of late HIV diagnoses occur in high prevalence and extremely high HIV prevalence local authorities. This means that if these guidelines are successfully applied, we could potentially impact on two-thirds of late diagnoses nationally. The k-median cluster analysis could be repeated at three yearly intervals, to review the thresholds prevalence levels. LAs are able to access their diagnosed HIV prevalence levels on the PHE website.	
120	[office use only]	[Public Health England]	Full	8	15	We would recommend using the wording on testing frequency used in the PHE annual report on HIV, 2015: Recommend that MSM have an HIV and STI screen at least annually, and every three months if having unprotected sex with new or casual partners. Black African men and women are advised to have an HIV test and a regular HIV and STI screen if having unprotected sex with new or casual partners [HIV in the UK – Situation Report 2015].	Thank you for this comment. The recommendations in the guideline have been updated in line with your comment. .
121	[office use only]	[Public Health England]	Full	17	18	Please see comment 11	Thank you for providing this information.
122	[office use only]	[Public Health England]	Full	62	5	Please see comment 11	Thank you for providing this information.

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123	[office use only]	[Public Health England]	Full	general	General	We would like to see the recommendations accompanied by a table that clearly sets out what should be provided in areas of different prevalence levels. i.e. Specialist sexual health services – all areas Secondary care – risk condition services & risk behaviours – all areas Secondary care –general medical admissions – high prevalence areas Secondary care – all admissions (including emergency) –extremely high prevalence areas GP –risk behaviours – all areas GP –new registrants– high prevalence areas GP – all patients having blood tests for other reasons –extremely high prevalence areas Self –sampling – on-line service– all areas Community settings, including self-sampling- depending on local needs (diagnosed HIV prevalence, local populations at increased risk)	Thank you for this comment. Unfortunately we cannot publish tables within our guidelines. We hope that the layout of the recommendations now will be easier to follow.
124	[office use only]	[Renaissance at Drugline Lancashire]	Full	General	General	The draft guidance seems well thought out and we do not foresee any problems implementing the approaches. We do have experience of implementing the some of the approaches and would be willing to submit our experiences to the NICE shared learning database.	Thank you for this comment. We would encourage you to submit any relevant work to the NICE shared learning database.
125	[office use	[Renaissance at Drugline	Full	General	General	Whilst there is mention of people with a history of injecting drug use, there is no mention of those injecting steroids, image and	Thank you for this comment. The committee discussed steroid and image enhancing drug

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	only]	Lancashire]				performance enhancing drugs and we wonder whether this group of people should be specifically mentioned, as some members of this group do share needles etc and anecdotally are known to have unprotected sex with multiple partners. Maybe the wording could be altered to read 'history of injecting drug or SIPED (Steroid Image and Performance Enhancing Drug) use.' The guidance refers to POCT and intravenous testing, however dry blood spot testing is also used, particularly with injecting drug and SIPED users, so Hep C and Hep B can be screened for at the same time.	users at some length but they did not consider it would be helpful to make specific reference to this group. NICE guidelines on Needle and Syringe Programmes make specific recommendations for all injecting steroid, image and performance enhancing drug users, including the need for HIV testing.
126	[office use only]	[Renaissance at Drugline Lancashire]	Full	General	General	With regards to Men who have sex with Men and injecting drug use, we wonder if Chemsex and slamming need to be mentioned within the document as non-traditional injecting drug users.	Thank you for this comment. Chemsex has been added as an example, in line with your comment.
127	[office use only]	Roche Diagnostics Limited	Guidelines (full)	7	22-24	As with the comment above, we believe this section is currently worded in a way that discourages use of point of care tests (POCT). Although POCT are not as sensitive and specific as laboratory tests, most POCT are now 4th generation and have good performance. The 2014 UK Standards for Microbiology Investigations: Anti-HIV Screening, recommend both 4th generation tests, and that all results, regardless of test used, need confirmatory testing - Standards Unit, Public Health England. Virology ; V 11 (Issue no: 3.2), April 14. A suggested re-word is: "Practitioners delivering POCT should explain to people at the time of their test about the differences in specificity and sensitivity of POCT compared to the higher specification laboratory test and the need for confirmatory serological testing."	Thank you for this comment. We have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT at the time of testing.
128	[office use only]	Roche Diagnostics Limited	Guidelines (full)	37 53	Table Table	Both the Guidelines and Economic report state "1.1.2 Ensure both fourth generation serological testing and point-of-care testing (POCT) are available." Most POCT are now also fourth generation, which are recommended by the 2014 UK Standards for Microbiology Investigations: Anti-HIV Screening (referenced above). We would suggest the following edit "Ensure laboratory-based or	Thank you for this comment. Comparison of the effectiveness and accuracy of different tests is specifically excluded in the scope for this guideline.

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						POCT HIV testing is available. A fourth generation test is recommended for highest sensitivity."	
129	[office use only]	Roche Diagnostics Limited	Guidelines (full)	62	General and lines 15-16.	Again, we would reiterate that all test results, regardless of assay used, require a confirmatory test, (as per the standards referenced above). Currently, this is only highlighted for POCT.	Thank you for this comment. We would expect anyone using serological testing to be aware of this so the committee did not feel the need to highlight it.
130	[office use only]	Royal College of General Practitioners	Short	General	General	It is very good news for the primary care (generalist) setting that these guidelines integrate the previous black African [PH33] and men who have sex with men [PH34] guidelines. Primary care can take integrated and holistic approaches to good effect, particularly in relation to country of origin and also sexual health; HIV testing is only one aspect of this and it is good that further 'atomisation' of the topic is being avoided this time. It is also good to loosen the association with risk group when an individual is presenting to the GP with an HIV-associated condition: which should be considered as potentially significant in anyone (whether they are 'visibly' in a risk group - or not). (PM)	Thank you for this comment.
131	[office use only]	Royal College of General Practitioners		General	General	There are benefits to testing and finding a negative result (as well as identifying positives): a negative result is constructive for patients and can present an opportunity to change behaviour and reduce risk. Negative results present particular opportunities to intervene in the care of those at highest risk (not least this may in the future include PreP).	Thank you for raising this issue.
132	[office	Royal College	Short	4	15	Routine HIV testing in pregnancy needs consideration.	Thank you for this comment. Routine HIV

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	use only]	of General Practitioners				(PS)	screening in pregnancy is already in place in the UK and has a very high uptake. For that reason, antenatal screening is specifically excluded in the scope for this guideline. It is not within the remit of NICE to make recommendations about screening.
133	[office use only]	Royal College of General Practitioners	Short	6	line 5-16	*'If a male discloses that they have sex with men'* *'if they disclose that they have changed sexual partner'* *'if they disclose they are the partner of a man or woman known to be HIV positive'* *'if they report a history of injecting drug use'* In many settings (eg a sexual health clinic) all attendees are all asked about these aspects of their history as a matter of routine. This is unfeasible in the general practice setting. There is a coyness about using the words 'disclose' or 'report' when considered from the general practice perspective: 'disclosure' and 'reporting' rates will be much higher if a GP or practice nurse has good sexual history-taking skills. Sexual history taking in the GP setting is particularly difficult, and risk assessment is particularly meaningful – we see a lot of people at NO risk, some of who are in a 'risk group' (eg see Sonnenberg and other NATSAL papers: eg on numbers of under-25s who have never had sex). Suggested wording: **Nurses and doctors in primary care should be confident and able to:** • conduct a consultation and take a sexual history in a way that avoids being judgmental or making assumptions • practice in a way that is responsive to fears of stigma and judgment, particularly in the groups most affected by HIV • introduce the topic of sexual health, HIV, and drug use into consultations when appropriate • take a partner history and assess risk in a way that will be time-efficient (brief) in the majority of cases [See Comment 8 for fuller list of relevant knowledge and skills]	Thank you for this comment. The committee discussed that there are particular challenges for GPs that mean that the offer of an HIV test is not as common as it could be. It is hoped that these guidelines will support professional bodies in developing continuing professional development tools to support people offering HIV testing. Implementation issues such as training or staff competencies are outside the scope of this guideline.

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						The NICE guidelines should state that time-efficient sexual history taking and risk assessment skills, appropriate to the general practice setting, should be taught and learned. This teaching is not widely available. It is probably best taught at a postgraduate level, by peers, – and when doctors and nurses are working in general practice (when the challenges and barriers of the setting are clearer). (PM)	
134	[office use only]	Royal College of General Practitioners	Short	7	17-22	It is being suggested that general practice should offer POCT in some situations '*where follow up may be difficult'*. It may be worth, somewhere in the guideline, recommending that local diagnostic laboratories supply HIV POCTs for use in practices to support this. It can be made clear this would be for relatively occasional use (i.e. not to implement systematic screening). Labs would then be able to manage quality control and advise re storage etc (individual practices are not so likely to order small numbers of POCT kits for themselves in any case). ALTERNATIVELY – exclude general practice from this statement. (PM)	Thank you for this comment. POCT is recommended in two main situations; these are in specialist sexual health services and in circumstances where follow-up may be difficult. We anticipate that POCT would not be routinely offered in general practice as follow-up practices are well established.
135	[office use only]	Royal College of General Practitioners	Short	9-10	1 on p9 to 22 on p10	Although general practice appears to be included in the title 'Promoting awareness and uptake of HIV testing' as it is for 'statutory…organisations who offer HIV testing' much of this section does not apply to the general practice setting. For example it is not realistic or practicable for each practice to 'produce promotional material tailored to the needs of local communities'. It would be helpful to distinguish what practices might be expected to do (e.g. use their patient information screens to promote testing). But also, given practices use electronic patient information leaflets, to specify which organisations might produce these and/or other relevant resources such as posters – especially if local population needs are to be considered. I.e. who should have responsibility to ensure practices in their area have the locally tailored patient resources that are required? (PM)	Thank you for this comment. The text has been amended to say 'provide promotional material' rather than 'produce'.
136	[office use	Royal College of General	Short	10 11	23-25 1 to 20	It is not made explicit in the heading that the barriers being addressed are the barriers that prevent people seeking or obtaining	Thank you for this comment. The barriers listed in this recommendation all relate to

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	only]	Practitioners				a test for themselves. Whilst 1.4.2 lists how staff can help patients overcome barriers, it is a bit of a 'rag bag' of points (see below). This section would be better structured as patient barriers and, separately, clinician barriers (this is particularly an issue for clinicians working in a generalist setting i.e. GPs and practice nurses, but perhaps also A&E). A patient who does not know they are at risk; or who does not know that their rash is an indicator condition for HIV, will be dependent on the clinician overcoming clinician barriers before a test will be offered. The list of clinician barriers given here is derived from i) 15 years of teaching, systematically asking GPs and practice nurses what the barriers to HIV testing are, listing them, and devising strategies to overcome them – and ii) Yeung 2015 – on barriers to chlamydia testing, which have strong parallels. **Clinician:** Lack of knowledge Lack of skills* Lack of confidence* Assume patient will raise the topic* 'Not a GP job' **Clinician and patient shared:** Stigma and embarrassment* Wrong assumptions about risk* Fear of a positive result* **Patient** Confidentiality concerns* Fear of being judged* Assume clinician will raise the topic* **System factors** Limited time* Many patients at risk do not present to GUM / do not get tested (e.g. see NATSAL) Scale of use of general practice, including by those at risk, not appreciated –huge footfall. Resource constraints *All those marked with an asterisk can be modified by good communication and sexual history skills teaching* – i.e. some 'patient' barriers can be overcome by a good clinician. See Pillay, 2012 (this commentator is an author) on HIV testing in Haringey. Impacts on testing were mediated through clinician training only (not	staff. They are based on the evidence considered by the committee. All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.

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						service users/patients). See also Mullineux 2008 re time efficiency and confidence. HIV TIPs is a website, funded by DH and hosted by MEDFASH that aims to help practices overcome a range of barriers to HIV testing. (PM)	
137	[office use only]	Royal College of General Practitioners	Short	11	1 to 21	**Section 1.4.2 can be restructured.** (see also barriers list above): **Staff knowledge – general** **Nurses and doctors in primary care should be able to:** • list the benefits of early diagnosis of HIV (primary HIV infection; asymptomatic HIV) • describe the positive impact of treatment, including cost-benefit, at all stages of HIV diagnosis • explain that evidence shows the uptake of HIV testing is high and most patients value the offer ***[this moved from page 17 line 23-26]*** • give the approximate HIV prevalence in their area, and, if their practice population should differ substantially, able to outline how this might make their practice population prevalence differ***.*** ***[from page 17]*** • recognise when primary HIV infection is a possible differential diagnosis • list the majority of those conditions that are associated with, but in general not diagnostic of, HIV infection • list the initial management and referral implications of a positive HIV test, • give the opportunities presented when a test is negative in a person identified as at high risk • describe when when re-testing is indicated**.** **[Latter from page 18 4-5]** **Staff skills and attitudes** **Nurses and doctors in primary care should be confident and able to:** • conduct a consultation and take a sexual history in a way that avoids being judgmental or making assumptions • practice in a way that is responsive to fears of stigma and judgment, particularly in the groups most affected by HIV • introduce the topic of sexual health, HIV, and drug use into consultations when appropriate:	Thank you for this comment. Implementation issues such as training or staff competencies are outside the scope of this guideline.

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						○ Able to introduce the topic of HIV into a consultation with the symptomatic patient, even when HIV remains an unlikely cause ○ Able to introduce the topic of HIV into consultations with asymptomatic patients • take a partner history and assess risk in a way that will be time-efficient (brief) in the majority of cases • promote the benefits of HIV testing • assess and respond appropriately to the psychological and social implications of a positive HIV test **Staff knowledge of local services / availability** • Able to list alternative sites for testing • Able to describe local HIV services and referral pathways • Able to list local sources of free condoms • Able to give at least one local service where sexual health promotion / behavioural interventions are available for those at highest risk **Infrastructure needed:** • Referral pathways should be in place, with clear information available • Free condoms should be available • Services for behavioural interventions should be available • Appropriate resources for patient information NICE endorsment of these – ie a revised section 1.4.2 - would be extremely helpful in strengthening the quality of existing and future education as these represent learning / other outcomes that can be assessed or measured. Further improvements to this content would be welcome. (PM)	
138	[office use only]	Royal College of General Practitioners	Short	11	22-31	***Ensuring clear referral pathways:*** Guidance should reflect that positive HIV test results are comparatively rare for individual practitioners, even in high prevalence areas and when testing a lot: the clearest referral pathway will be a normal – ie usual - referral pathway. *Ensuring timely referral for those who test positive 'preferably within 48 hours, certainly within 2 weeks'.* 1) HIV referral has become exceptionalised, and is, at least in some areas, excluded from Choose and Book – which is where GPs will turn to plan a referral for the majority of patients,	Thank you for this comment. Referral pathways and their implementation are beyond the scope of this guideline. The focus of this guideline is on increasing the uptake of HIV testing, and while the committee agreed that it was important to mention timely referral for people with positive results, they did not examine the evidence for specific referral mechanisms and so did not take a view on how this should work.

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						including for a cancer 2 week wait referral, with electronic uploading of referral letters. There is inbuilt 'safety netting' in such a system to flag up, for example, when a patient has not attended. Clearly some suspected cancer patients will end up being referred within 2 weeks, which will sometimes be outside the C&B system, based on the clinical judgment of the GP and the availability of appointments on line. Is it the best and most appropriate choice for NICE to continue the exceptionalisation of HIV referrals? (and what does that say about stigma reduction?). **The clearest and most robust referral pathway for a GP to use for HIV will be a normalised referral pathway.** 2) If NICE guidance chooses not to recommend normalised referral within existing NHS systems, then it needs to be regularised and normalised across all HIV services. HIV specialist services should provide 1) phone numbers for clinical advice; 2) a phone number for appointments that will accept GP referrals; 3) secure email addresses for referral letters (that will remain 'in date' and continuously monitored for ever more!); and 4) clear and up to date information on their website re 1,2 and 3. In addition clinics should write after clinic attendances, including giving GPs the results of investigations. HIV specialist services should encourage use of GP referral letters, not discourage them 3) Communication from clinics to GPs also remains anomalous for some HIV clinics. Following referral, high quality clinic letters updating GPs on patient care (and from which they may gain crucial clinical information and from which they may learn) should be sent electronically, for each attendance, using standard systems. Results of clinic investigations should also be shared with the GP in a timely fashion to ensure patient safety. Recommending the website hiv-druginteractions.org at the foot of the letter would be good practice. (PM)	
139	[office use only]	Royal College of General Practitioners	Short	12	9	The link to tools and resources not live, we would very much like to review these before they are finalised. (PM)	Thank you for this comment. In line with our usual processes, any supporting tools or resources will be published after the publication of the guideline and have not yet been agreed.

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140	[office use only]	Royal College of General Practitioners	Short	16	10-12	*It would be useful for other NICE guidelines to recommend offering HIV testing, especially when diagnosing or treating conditions that may indicate HIV infection.* From a generalist perspective **there is a quid pro quo here.** Associated risks: sexual risks of HIV overlap with risks of Hepatitis B & C (if thinking of blood tests only – STI testing can also be added here). Country of origin risks for HIV overlap with risks for Hepatitis B & C, lack of immunity to rubella and risk of sickle cell trait (or disease) – the latter two relevant for women of child bearing age born overseas. Injecting risk for HIV is similar for Hepatitis B &C. See, for example, Hepatitis C in the UK PHW 2015 report. NICE guidelines should point out these basic 'good clinical care' associations. It is advantageous to highlight the huge potential value of opportunistic discussions about sexual history / needle use / country of origin as well as then the offers of (a single needle) blood test where relevant (undiagnosed viral hepatitis is far commoner than HIV). In other words, where opportunistic approaches are being encouraged, it is valuable to highlight just how much important, treatable, disease can be found (or, in the case of rubella immunity or sickle trait – prevented, in offspring). This is time-efficient in a highly time-constrained service. It also starts to normalise HIV testing within the context of many important, treatable or preventable conditions. The RCGP would welcome an integrated approach (ie the bringing together risks of, and benefits of diagnosis for, a range of conditions that could be opportunistically tested for in a blood sample). Such integrated guidelines would be of great relevance to general practice.. [Of course HIV POCTs preclude such integration, so it is good the guidelines do not overly emphasise these for the GP context]. (PM)	Thank you for this comment. The committee discussed that reference to HIV testing in other NICE guidelines is important and reflected this in the Committee Discussion section of the guideline. NICE pathways are also used to link related NICE guidelines, which will highlight the need for HIV testing as part of the differential diagnosis for conditions associated with HIV, for example Tuberculosis . A pathway for the HIV testing guideline will be published at the same time as the guideline itself.
141	[office	Royal College	Short	18	17-19	Here adding an HIV test for anyone having a blood test in a high	Thank you for this comment. The

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	use only]	of General Practitioners				prevalence area is proposed. This may be worthwhile but NICE should note that: 1) A huge proportion of blood tests relate to routine chronic disease management; might bloods for initial investigation of symptomatic patients provide a more targeted approach? (along the lines of testing for medical admissions, but before the patient is so unwell). 2) If the existing recommendation goes ahead, older patients undergoing chronic disease management should only have one HIV test by this means, unless on-going risk is identified, or the patient requests further HIV tests (opt in). 3) Also please note that, as per comment 11 above, initiating testing of asymptomatic patients (following discussion of risks) may feel much more worthwhile when additional/alternative valuable diagnoses (eg viral hepatitis) are even more likely to be made: pooling relevant tests. (PM)	recommendations have been modified to reflect a new definition of high prevalence and very high prevalence of HIV, and this has had an impact on this guideline (see recommendations, terms used and committee discussion for more information). NICE guidelines are intended to be used alongside clinical judgement.
142	[office use only]	Royal College of General Practitioners	Short	22	21-23	There is no point, in our view, of trying to 'increase awareness of HIV indicators and the benefits of testing' in isolation from all the other skills and knowledge needed, but given a little later in the guidance. See the integrated list we developed in comment 8, above. Splitting up the topic is not the right approach for general practice. On the basis of what is known about both effective education and successful implementation: ALL the barriers to testing should be addressed by an educational intervention. This will also be more time efficient. Informally, in Islington, HIV testing rates increased fastest when viral hepatitis testing was added to holistic sexual health and HIV teaching tailored to general practice (manuscript in preparation). The RCGP feels that there is at least a little learning to gain from the Pillay 2012 audit of the impact of training, excluded by NICE because it was not an RCT and did not fulfil the criteria – but this was a 'real life' evaluation and statistically highly significant. Islington will be happy to share updated data from the same setting (Haringey; manuscript in preparation) if needed - where a 500% in testing has now been achieved, highly significantly correlated with attendance at training (evaluated by using practice fixed-effects panel regressions). (PM)	Thank you for this comment. Training and education are outside of the scope of this guideline but the implementation section recognises their importance.
143	[office	Royal College	Short	Question		**1. Which areas will have the biggest impact on practice and be**	Thank you for responding to these questions

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	use only]	of General Practitioners		1		**challenging to implement? Please say for whom and why.** HIV testing in general practice encompasses: a) **Diagnostic testing**: the use of the HIV test in the differential diagnosis of symptoms and conditions (glandular fever like presentations; shingles etc) b) **Opportunistic testing of those at risk:** i) Asymptomatic people found to be at risk through routine use of sexual history-taking and risk assessment. ii) Those diagnosed with a sexually transmitted infection. c) **'Add-in' HIV tests:** NICE draft guideline recommendation to offer an HIV test when blood is taken for other reasons in a high prevalence area. d) **Patient request** e) **Screening of sub-populations:** Whilst pregnant women are offered HIV tests, guidance is awaited for other screening (eg new registrants in high prevalence areas; women undergoing an abortion etc). [f) **Home sampling or testing** – could be supported by practices through patient information and/or on line links.] We note that NICE does not intend to make recommendations on population screening in these guidelines (e). The implementation of HIV screening (particularly if using rapid tests) – such as happened in the RHIVA study in Hackney – would require public health leadership and new funding for full implementation. We do not address screening further here. We think a, b and c have the most potential for impact on practice (increased testing and diagnosis). It is not possible (or sensible) to tease apart the implementation of a, b, c and d in practices. 'Add-in' HIV tests (c), given the scale of chronic disease monitoring bloods, might be better focussed these HIV test offers on the initial investigation of new symptoms (and in this instance, might even be extended geographically, ie even for lower prevalence areas for HIV, where late diagnosis is a larger proportion of all diagnoses). Patient request tests (d) are small scale (even in the most pro-active practice) in comparison with a, b and, potentially, c. Changing a, b and c represents changing complex clinical behaviours. Whilst this might be described as a challenge, it is is achievable with the right	and providing this information.

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						educational intervention, even without incentives to test (Pillay 2012, and subsequent unpublished data from Haringey and Islington, although 'add-in' HIV test offers are not taught in this intervention). Resources (video material, posters, leaflets) to support patient request tests and also self testing and sampling should be made available to general practice. However it is the RCGP view that these should also give information on viral hepatitis. (PM) (MH)	
144	[office use only]	Royal College of General Practitioners	Short	Question 2		**2. Would implementation of any of the draft recommendations have significant cost implications?** Costs in general practice are often time costs – and in a service that is already highly time constrained. Even in high prevalence areas, HIV remains a comparatively rare condition. To keep relevance for primary care, a holistic approach (ie encompassing other STIs and viral hepatitis, and drawing meaningful links to contraceptive care) is important. Skill mix and staff roles need to be considered too. Such integrated, primary care 'tailored' interventions are time efficient: time efficient to teach – but, more importantly, practitioners find them time-efficient to apply (Mullineux 2008). GPs can hugely increase their HIV testing rates without financial incentives (Pillay, 2012, and updated data from Haringey and Islington). Diagnostic testing (a, above): does not have substantial time or cost implications, aside from the costs of education. Opportunistic testing of those found to be at risk (b, above): has implication for time (through its teaching, and also its application). Time-efficient (tailored to general practice) strategies should be taught by peers within the context of a broader educational intervention (so that the benefits of risk assessment are clear, including the benefits of, for example, identifying those who also need to be offered a chlamydia test). The NATSAL paper (Sonnenberg 2013) demonstrated that the HIV found in this population-based study correlated entirely with reported risk. It also confirmed, for example, that many young people are at no risk of STI: risk assessment is much more meaningful in the general practice setting than in specialist sexual health settings. If someone has been found to have no risk, or no risk since last test, these are	Thank you responding to this question and for the comprehensive answer.

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						meaningful healthcare interactions: *"From what you tell me, you are currently protecting your sexual health very well".* It does not help to give mixed messages about what constitutes risk when working in a setting where quite a few people are at no risk. 'Add-in' HIV tests on blood taken for other reasons (c, above), if fully applied, would have enormous cost implications for laboratories and pathology service contracts. Even in high prevalence areas, it is not clear that offering 'add-in' HIV tests as a part of chronic disease monitoring bloods would be effective, given the older average age group (whilst the College does understand that late diagnosis is an issue in older age groups: undiagnosed HIV prevalence is still low in this age group). It would add quite a bit of time to routine chronic disease monitoring to discuss and explain the HIV test. How to prevent unnecessary repeated tests, at scale, should be also be considered by NICE before making this recommendation. NICE should be able to gain estimates from laboratories as to how many routine samples are currently received from general practice (although NB different labs may of course receive different samples from the same patient); a consent rate would then have to be estimated (it may be hard to do this). We believe the recommendation of the offer of an HIV test when any blood test is being used for the investigation of new symptoms might not be more practicable. This would be smaller scale. It would lead to increased time spent in the relevant consultations. It is not possible to quantify how many additional HIV tests this would lead to - either assuming perfect implementation or in real life. It is not possible to quantify how many new diagnoses would ensue: although it is clear that for many patients with a new HIV diagnosis opportunities had been missed in general practice in the past, and led to delay. Implementation of this would have costs for time and education, but if integrated along with a broad educational intervention, these would greatly reduce. Some slight change might be achieved simply with a clear NICE recommendation, although we fear that if NICE chose to stay with this plan for ALL blood tests, there may be greater resistance to the idea than should it recommend doing this with new presentations. In Islington the new diagnosis of viral hepatitis and also important,	

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						treatable STIs (including HIV) by practices is substantially financially rewarded by the Locally Enhanced Service contract. Patient request tests (d, above), and support of home sampling or testing (e, above), would not have great cost implications for general practice, but relevant resources should be supplied. Testing technology: Use of rapid (point of care) HIV tests We agree with the draft guidance that currently GP consultations are too time-constrained to advocate the widespread adoption of rapid testing for HIV, and this also loses the opportunity to offer tests for other conditions with overlapping risks such as viral hepatitis. They may be valuable with the occasional patient. (PM) (MH)	
145	[office use only]	Royal College of General Practitioners	Short	Question 3		**3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.** What is being attempted is a change of complex clinical behaviours. An appropriate educational intervention to achieve this should draw on the relevant generic evidence (eg MRC complex interventions guidelines) and be highly targeted to the general practice setting (tailored, peer-led, integrated, identify and overcome barriers etc). PM is currently working with the Faculty of Sexual and Reproductive Healthcare to transform basic national educational qualifications for GPs and practice nurses based on knowledge and experience of SHIP (Sexual Health in Practice) training (Pillay 2012). In addition the MEDFASH HIV TIPS website attempts to support practices to increase HIV testing through a variety of means http://www.medfash.org.uk/welcome-to-hiv-tips - as with most educational interventions, proper evaluation of impact is impossible as it is unfunded. If the impact of this website on primary care teams could be formally evaluated by someone with expertise in e-learning interventions (eg Prof Elizabeth Murray) this would be helpful. (PM) (MH)	Thank you for responding to this question and for the comprehensive answer.
146	[office use	Royal College of General	Short	Question 4		**4.Do you think there will be a significant resource impact when implementing recommendations 1.2.1 (POCT) and 1.2.3 (Self-**	Thank you for responding to this question and for the comprehensive answer.

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	only]	Practitioners				**sampling)?:** 1.2.1 Re POCT is pragmatic, and will likely rarely be used in the GP setting. For this occasional use of POCT, reliable and 'in date' testing kits should be made available and replaced, probably by local labs. One member of staff from each primary care team could be trained in the use of POCTs (including giving statement 1.2.2), but, for what will probably account for a tiny proportion of tests, this may be overkill (a doctor who has seen a short training video should be able to use such a test). Therefore we see time and resource costs above all for laboratories, and some small time costs for primary care teams. 1.2.3 The RCGP supports the use of self-sampling (and self-testing). Practices could promote this with relevant materials, but these should be supplied and so this will incur costs for the organisation(s) commissioned to develop and provide these. (PM) (MH)	
147	[office use only]	Royal College of General Practitioners	Short	Question 4a – 4e		**4a. What is current practice (i.e. traditional testing via healthcare workers in clinics) and what will change by implementing the recommendations** For the reasons given above, we feel that, in the absence of a screening programme, the increases in testing through POCT use will be very small in comparison with the range of opportunities to increase use of venous sample HIV tests. Promotion of home sampling or testing would be an innovation in general practice. Resources should be made available, and there is potential for practice websites to host links to relevant services (including, for example, for patients newly registering, or booking appointments, on line). **4b. How this will increase numbers of tests offered including how many self-sampling kits may be taken and returned** POCT: it is likely this would be small scale, especially given the further normalisation of venous sampling for HIV tests. Self-sampling: General practice would not 'host' this service and it is	Thank you for responding to this question and for the comprehensive answer.

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						not possible to estimate the impact of the promotion of self sampling by practices. **4c. Unit costs of tests (both) or equipment/healthcare worker who would deliver/time to deliver test (POCT)** POCT: Small scale Self-sampling: general practice would not host this service. **4d. Results i.e. proportion diagnosed with HIV, or increases in early diagnosis** POCT: Small scale, but might be the occasional very high risk person (difficult to engage, clinicians concern re risk, opportunity seized). Self-sampling: general practice would not host this service and we could not estimate this. **4e. Estimated treatment costs and potential savings from early diagnosis.** It is not possible to give these estimates for either small scale POCT or the general practice signposting of self-sampling. (PM) (MH)	
148	[office use only]	[Royal College of Nursing]	General	General	General	The Royal College of Nursing welcomes proposals to develop these guidelines. The RCN invited members who work in sexual health and public health to review the documents on its behalf. The comments reflect the views of our members.	Thank you for this comment.
149	[office use only]	[Royal College of Nursing]	General	General	General	The draft guidance seems comprehensive. There are no further comments to add.	Thank you for this comment.

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150	[office use only]	Royal College of Physicians	Full	7	20 -21	**Offer POCT in situations where follow-up may be difficult so that people 20 do not need to return to get their results. [new 2016]** Our experts note that this would suggest that A+E should offer POCT which might be a barrier for implementing. Given the low positivity rate it would be better to have strategy of being able to contact those who are positive on testing. As in GU clinics, people should not have to return in person for results, instead they can be texted their results.	Thank you for this comment. The recommendation has been amended to include an example, that if people are unwilling to leave contact details, POCT may be the most pragmatic option for testing.
151	[office use only]	Royal College of Physicians	Full	10	14 - 16	**Use or modify existing resources, for example TV screens in GP 14 surgeries, to help raise awareness that HIV testing is available locally (for 15 content see recommendations 1.3.1 and 1.3.2). [new 2016]** We suggest that TV screens should advertise self-testing websites that are funded such as SH24, the new pan London home testing and other NHS/LA supported home testing sites.	Thank you for this suggestion. No evidence was identified on self-testing, therefore the committee were unable to make a recommendation on this.
152	[office use only]	Royal Pharmaceutical Society		General	General	The Royal Pharmaceutical Society welcomes the draft guideline HIV testing: increasing uptake among people who may have may have undiagnosed HIV. We would like to highlight the role of community pharmacies, some of whom provide locally commissioned services as highlighted below.	Thank you for this comment. In section 1.1 of the guideline, we have added pharmacies as an example of where testing might be offered.
153	[office	Royal	1.1 Offering	4	3	There are several locally commissioned HIV Point of Care	Thank you for this comment. We would

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	use only]	Pharmaceutical Society	and recommending HIV testing in different settings			Testing Pharmacy pilots around the country. Examples of some of these services are provided by the Pharmaceutical Services Negotiating Committee on their website: http://psnc.org.uk/dudley-lpc/services/commissionedservices/hiv-poct-testing/ http://psnc.org.uk/?our-services=hiv-testing-pilot-inpharmacy-coventry-city-centre-area http://www.haringey.gov.uk/social-care-andhealth/health/public-health/healthy-living-pharmacy	encourage you to submit any relevant work to the NICE shared learning database.
154	[office use only]	Royal Pharmaceutical Society	1.1 GP surgeries	5	27	We would like to highlight the role of pharmacists working in GP surgeries who would also be well placed to provide this advice. Further information on the RPS campaign Pharmacists and GP Surgeries is available on our website at http://www.rpharms.com/our-campaigns/pharmacistsand-gp-surgeries.asp	Thank you for this comment. Pharmacists would be included under the heading of healthcare professionals in the recommendations for GP surgeries in section 1.1.
155	[office use only]	Royal Pharmaceutical Society	1.3 Promoting awareness and uptake of HIV testing	9	general	Many community pharmacies provide locally commissioned services such as needle exchange and supervised administration, providing an opportunity for community pharmacists to promote HIV testing to at risk groups: http://psnc.org.uk/services-commissioning/locallycommissioned-services/en2-needle-syringe-exchange/ http://psnc.org.uk/services-commissioning/locallycommissioned-services/en1-supervised-administration/	Thank you for raising this issue.
156	[office use only]	Society of Sexual Health Advisers	Full	08	14	Does not match BASHH recommendation for MSM with significant risk which is 3 monthly.	Thank you for this comment. Men who have Sex with Men (MSM) who are sexually active with different people would fall under the partner change criteria for more frequent testing. The committee discussed the Public Health England (PHE) recommendation to test every 3 months among MSM who have new or different partners. They decided to

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							align the recommendation with that from PHE.
157	[office use only]	Society of Sexual Health Advisers	Full	04	10	May need clarification should venous sampling and POCT be available for all? Or does rest of document clarify appropriate use?	Thank you for this comment. The committee did not consider any evidence relating to choice of test since this was out of scope for this guideline. The committee were of the view that if both options are available then professional judgment should prevail.
158	[office use only]	Society of Sexual Health Advisers	Full	05	14	Again rather than MSM without a test in last year should match BASHH 3 monthly testing guidance.	Thank you for this comment. Men who have Sex with Men (MSM) who are sexually active with different people would fall under the partner change criteria for more frequent testing. The committee discussed the Public Health England (PHE) recommendation to test every 3 months among MSM who have new or different partners. They decided to align the recommendation with that from PHE.
159	[office use only]	Society of Sexual Health Advisers	Full	06	05	AS comment 3.	Thank you for this comment. Men who have Sex with Men (MSM) who are sexually active with different people would fall under the partner change criteria for more frequent testing. The committee discussed the Public Health England (PHE) recommendation to test every 3 months among MSM who have new or different partners. They decided to align the recommendation with that from PHE.
160	[office use only]	Society of Sexual Health Advisers	Full	07	22	Important point but wording may increase clients anxiety could "poor" be replaced by "low" or similar.	Thank you for this comment. We have modified the wording in the guideline to reflect that people offering POCT should explain the variation in specificity and sensitivity of POCT

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							at the time of testing.
161	[office use only]	Society of Sexual Health Advisers	Full	08	11	Window period needs to clarified in Glossary for all tests, e.g venous samples p24 antigen 4 weeks and antibiody element 8 weeks as per BASHH. POCT tests usually 12 weeks.	Thank you for this comment. The committee chose not to define the window period because of the rapid changes in testing technology and the variability among tests.
162	[office use only]	Society of Sexual Health Advisers	Full	11	02	Confidentiality needs better explanation, re-assuring regards confidentiality is important but there are limitations, transparency/honest to this more effective with clients. For example explaining how rare it is to break a clients confidentiality. The referral to specialist service would better to be sold as the use of a unique identifier to test under rather than encourage false names. So for example Encourage specialist sexual health service attendance explaining that tests can be sent under a unique clinic identifier rather than their name.	Thank you for this comment. Information on confidentiality practices was outside of the scope for this guideline. However, the committee did feel that confidentiality is an important issue when trying to encourage the uptake of HIV testing and included this within the recommendations in section 1.4 of the guideline.
163	[office use only]	Society of Sexual Health Advisers	Full	25	5 to 8	Their will be an increase in cost in offering POCT and Self Sampling as these tests currently cost significantly more than a blood sample. It is vital though these tests are available to increase testing and diagnosis as treatment as a prevention vital in reducing onward transmission. But will have cost implications within services. May be worth while having venous samples within services with community settings using POCT or using them with hard to reach community groups.	Thank you for your comment. The committee agreed it was important to make a research recommendation on the cost utility of increasing the offer and uptake of HIV testing using a variety of approaches. It is hoped that further information on this is available when the guideline is reviewed for update.

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164	[office use only]	The National LGB&T Partnership	Full	General	General	The scope of this guidance currently excludes transwomen, who are – alongside Men who have Sex with Men (MSM) – at the highest risk of acquiring HIV in the UK (Public Health England, 2014). HIV prevalence amongst the rest of the trans community, including transmen, trans youth and non-binary people, is less evidenced but estimated to be also significantly high. In addition, preliminary findings of LGBT Foundation's research into trans people living in Greater Manchester showed that over half of trans respondents have never had a sexual health screening or attended a sexual health clinic. Women who have Sex with Women (WSW), which includes lesbian and bisexual women, are potentially at a high risk of acquiring HIV. In 2014, the proportion of lesbian women being diagnosed with HIV (4.4%) at a sexual health clinic was even higher than heterosexual women (3.4%) (Public Health England, 2014). Very few WSW use barrier protection, and many lesbian and bisexual (LB) women who haven't accessed testing do not think they are at risk (Stonewall, 2008). Our concern is that by focusing solely on MSM and Black African communities, the needs of other significantly high-risk groups can be easily ignored, thereby perpetuating the risk within the communities. The lesbian, gay, bisexual and trans (LGBT) communities as a whole should be considered.	Thank you for this comment. This guideline does not exclude transwomen. The only people outside of the scope of this guideline are babies at risk of transmission from an HIV-positive mother and people who cannot provide informed consent to an HIV test. The committee have made this clearer by adding trans women to recommendations in section 1.1 of the guideline. .
165	[office use only]	The National LGB&T Partnership	Full	5	12-13	Although the guidance makes other references to the two high risk groups of MSM and Black African communities, the term 'Black African Communities' is not explicitly referenced within this list.	Thank you for this comment. The intention of the update is to broaden the populations covered by the guideline. However, the guideline does still recognise that MSM and black African communities are the most significant at risk groups.

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166	[office use only]	The National LGB&T Partnership	Full	5	24-25	The reference to a history of injecting drug use is welcome; this could be extended to initiate conversations around Chemsex in discussions around drug use, as this is a high-risk behaviour likely to correlate with HIV prevalence.	Thank you for this comment. Chemsex has been added as an example, in line with your comment.
167	[office use only]	The National LGB&T Partnership	Full	5	Section 1.1.4	As discussed above, evidence suggests that women who disclose themselves as trans (i.e. transwomen) who have not previously been diagnosed with HIV should be offered and recommended HIV testing on admission to hospital. This is because they are one of the groups of people who are at the highest risk of acquiring HIV.	Thank you for this comment. The list has been revised to include transpeople, in line with your comment.
168	[office use only]	The National LGB&T Partnership	Full	6	4	Again, whilst the guidance makes other references to the two high risk groups of MSM and Black African communities, the term 'Black African Communities' is not explicitly referenced within this list.	Thank you for this comment. The intention of the update is to broaden the populations covered by the guideline. However, the guideline does still recognise that MSM and black African communities are the most significant at risk groups.
169	[office use only]	The National LGB&T Partnership	Full	6	Section 1.1.5	Again, evidence suggests that women who disclose themselves as trans (i.e. transwomen) who have not previously been diagnosed with HIV should be offered and recommended HIV testing on admission to hospital. This is because they are one of the groups of people who are at the highest risk of acquiring HIV.	Thank you for this comment. The intention of the update is to broaden the populations covered by the guideline. Transwomen have now been included in section 1.1 of the guideline. However, the guideline does still recognise that MSM and black African communities are the most significant at risk

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							groups.
170	[office use only]	The National LGB&T Partnership	Full	7	14-15	We are extremely encouraged that lay testers are specified within the guidance. This can be a cost effective and community-centred way of increasing access to HIV testing because these testers do not need to be medical professionals. Organisations within The National LGB&T Parntership have had difficulty in securing Clinical Governance from statutory health providers in the past, due to a reluctance to allow POCT delivered by lay testers. The clarification that lay testers have equal access to clinical training, supervision and advice is therefore very important.	Thank you for this comment.
171	[office use only]	The National LGB&T Partnership	Full	7	20-21	This line could be further clarified, potentially with an example/case study, to explain that a rapid POCT is useful in for people/communities who might find it hard to return to get their result.	Thank you for this comment. The recommendation has been amended to include an example, that if people are unwilling to leave contact details, POCT may be the most pragmatic option for testing.
172	[office use only]	The National LGB&T Partnership	Full	8	17	The term 'high-risk sexual practices' rather than 'unsafe sexual practices' is preferred.	Thank you for this comment. The term 'unsafe sexual practices' has been removed from the recommendations and the term 'high-risk sexual behaviours' has been used.
173	[office use only]	The National LGB&T Partnership	Full	9	Sections 1.3.1 and	We agree that the promotional materials around HIV testing should be considered alongside approaches for behaviour change. This is because HIV testing is part of a wider, combined approach to HIV	Thank you for this comment. This guideline is focussed on increasing the uptake of HIV testing and the committee were unable to say

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					1.3.2	prevention which involves condom use and access to treatment. It would be useful to reference the wider role promotion of HIV testing has within HIV prevention because promotional material would often involve messages from across the approach, rather than just to increase the uptake of HIV testing. This is particularly the case for Voluntary Sector Organisations.	anything further on the issue raised, as it did not examine any evidence on broader HIV prevention activities.
174	[office use only]	The National LGB&T Partnership	Full	9	Section 1.3.3	This section encourages HIV testing opportunities which are hosted out in the community, which is very welcome. This section could in addition specify the crucial role of high-risk communities (such as Black Africans and various LGBT communities) in designing and delivering these interventions, thereby recognising that the contribution of community members, organisations, groups and spaces is key.	Thank you for raising this issue. Implementation issues and delivery of services were outside of the scope for the guideline.
175	[office use only]	The National LGB&T Partnership	Full	10-12	Section 1.4 Reducing Barriers to HIV Testing	The Equality Impact Assessment discusses that '…combinations of protected characteristics that may impact on the uptake of HIV testing are excluded from this piece of work'. However, minorities within the high-risk groups – such as BME LGBT people, or trans people with disabilities – face additional barriers to accessing HIV testing services, and as such the needs of people who fall under multiple protected characteristics need to be addressed in this section. Services should ensure they are visibly and genuinely inclusive, and staff should be trained to be proficient and confident in working with a wide range of service users. This is already partly covered in lines 12-17 on page 11 by discussing that there are cultural issues facing different groups and that staff must be sensitive to people's individual needs. For example, in order to be fully trans inclusive, when talking about gender and bodies we must acknowledge that not all people who identify as women will have been born with a vagina, womb and ovaries, and not all those who identify as men have a penis and	Thank you for this comment. This was an error in the equality impact assessment (EIA). Combinations of protected characteristics are not excluded from this piece of work. The EIA has been corrected.

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						testicles. Not all MSM will have a penis, and if practitioners talk exclusively in those terms it will act as an additional barrier to trans people accessing HIV and wider sexual health services.	
176	[office use only]	The National LGB&T Partnership	Full	14	15-17	As discussed earlier, evidence shows that transwomen are at an equal risk in acquiring risk as MSM are. This could be reflected in this paragraph.	Thank you for this comment. This guideline does not exclude transwomen. The committee have made this clearer by adding transwomen to recommendations in section 1.1 of the guideline. The context section is intended to be a brief 'scene-setting' section and is not intended to be exhaustive.
177	[office use only]	The National LGB&T Partnership	Full	16	13-17	This paragraph discusses the proposition to broaden recommendations from MSM and Black Africans to any population at high risk of HIV. The Equality Impact Assessment does not, however, look at the needs of the LGBT community beyond MSM, and doesn't consider the emerging needs of the trans community and transwomen in particular.	Thank you for this comment. The equality impact assessment has been updated following consultation and discussion with the guideline committee to reflect further consideration of the LGBT community and transwomen.
178	[office use only]	The National LGB&T Partnership	Full	17	3-5	As discussed earlier, evidence shows that transwomen are at an equal risk in acquiring risk as MSM are. This could be reflected in this paragraph.	Thank you for this comment. Thank you for this comment. This guideline does not exclude transwomen. The committee have made this clearer by adding transwomen to recommendations in section 1.1 of the guideline. The context section is intended to be a brief 'scene-setting' section and is not intended to be exhaustive.
179	[office use only]	MRC/CSO Social and Public Health	Full	General	General	Although there is reference to men who have sex with men and women, there is no reference to trans people in the draft guidelines. The guidelines do not address issues around trans people's access	Thank you for this comment. The committee have included transwomen within the recommendations in section 1.1 of the

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		Sciences Unit, University of Glasgow				to testing and HIV care and how the complexity around gendered and sexual identities will affect their access to, and experience of, services.	guideline. The equality impact assessment has been updated following consultation and discussion with the guideline committee to reflect further consideration of the LGBT community and transwomen.
180	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	10	5-7	While the guidelines acknowledge the need to reduce stigma (1.3.5), there appears to be less explicit discussion of how to reduce stigma around HIV testing in the 2016 draft guidelines than there had been in the previous 2011 guidelines. This is disappointing since stigma poses a significant challenge to implementation of any guidelines. The evidence suggests that stigma continues to be a significant barrier to testing (Flowers et al 2013, Bolsewicz et al 2015) and stigma and discrimination against MSM continue to shape patient responses to HIV (Altman et al 2012). Flowers, P., Knussen, C., Li, J., & McDaid, L. Has testing been normalized? An analysis of changes in barriers to HIV testing among men who have sex with men between 2000 and 2010 in Scotland, UK. HIV Medicine, 2013 14(2), 92–98. Bolsewicz, K., A. Vallely, J. Debattista, A. Whittaker and L. Fitzgerald Factors impacting HIV testing: a review – perspectives from Australia, Canada, and the UK. AIDS Care 2015 27(5): 570-580. Altman D, Aggleton P, Williams M, Kong T, Reddy V, Harrad D, et al. Men who have sex with men: stigma and discrimination. The Lancet, 2012 380(9839):439-45.	Thank you for this comment. All of the recommendations from the 2011 guidelines (PH33 and PH34) have been reviewed by the committee, the wording refreshed to bring them into current NICE style and incorporated into this guideline. Recommendations in section 1.3 and 1.4 deal with reducing stigma. However, implementation issues such as training or staff competencies are outside the remit of this guideline.
181	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	8	10 - 23	Recommendation 1.2.7 – 1.2.9 on repeat testing will be challenging to implement effectively. Our published research from UK community-based and online surveys has demonstrated that the current UK minimum recommendations for the frequency of HIV testing are not being met. Only half of men who have sex with men surveyed reported at least two HIV tests in the last two years. This is suggestive of annual testing (the minimum recommended in current UK guidelines), and just one quarter of men who have sex with men reporting higher risk UAI also reported the frequent testing recommended (up to every three months for those at high risk of	Thank you for this comment. The committee have highlighted gaps in the evidence base, and have developed research recommendations that they hope will drive the future research agenda. This includes a research recommendation on interventions to improve the acceptability and uptake of HIV testing among people at higher risk, which if taken up, may provide insight on increasing the frequency of uptake of HIV testing.

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						HIV infection) (McDaid LM et al 2016). The call-recall and electronic reminders suggested in the recommendations and other innovative approaches to increasing uptake, such as self-sampling and online testing initiatives have been and are being evaluated. However, we have little evidence on how to increase the frequency of testing or how to routinize this behaviour. Increasing the frequency of HIV testing will be essential to reducing undiagnosed HIV infection in the UK and further research is required to understand how to achieve this. This guideline should acknowledge this evidence gap and recommend further research on specifically increasing the frequency of testing in addition to the guidelines ade on increasing awareness and uptake. Furthermore, our recent, qualitative research on patterns of HIV testing among young men who have sex with men (aged 18-29) (Boydell, Buston and McDaid, under review) found social support and open communication around HIV testing in men's friendship groups served to support the development of a routine of regular (repeat) HIV testing (and STI screening). This suggests that promotion materials could usefully include a focus on supporting positive testing practices within young men's friendship groups. Boydell, N., K. Buston and L. McDaid Patterns of HIV testing practices among young gay and bisexual men living in Scotland: a qualitative study.PloS One (under review). McDaid LM et al Frequency of HIV testing among gay and bisexual men in the UK: implications for HIV prevention HIV Medicine 2016.	
182	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	9-10	9-24	Implementation of effective and relevant promotion material needs to consider the highly varied needs of local communities, and needs to go beyond materials targeted towards specific populations. Our published research on HIV testing among men who have sex with men in the UK has demonstrated strong regional, demographic and behavioural differences, and variations in the risk profiles of	Thank you for this comment. Implementation of promotion materials is beyond the scope of this guideline.

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						testers. The data suggest that interventions to increase the frequency of HIV testing will need to be tailored to the communities in question (McDaid LM et al 2016). In particular, careful consideration is required to ensure that written materials are understandable, address the particular HIV literacy needs of the target group, and have high appeal/acceptability. Our work on literacy in relation to HIV and sexual health (Gilbert, et al 2015) calls attention to this issue. We are concerned that the messages currently presented in the new guidelines fail to sufficiently account for increasingly complex understandings of HIV transmission risks. For instance, suppressed HIV viral loads in HIV-positive sexual partners and the potential use of pre-exposure prophylaxis (PrEP) may complicate risk assessment (Young et al 2014). Information and approaches which are clear and in the appropriate format is needed for people to understand their HIV-related risks and test accordingly. However, the level and nature of HIV and/or sexual health literacy required to do this is unclear and deserves further research. McDaid LM et al Frequency of HIV testing among gay and bisexual men in the UK: implications for HIV prevention HIV Medicine 2016 [in press]. Gilbert, M, Ferlatte, O, Michelow, W, Martin, S, Young I, Donnelle, L, Rootman, I, McDaid, L, Flowers, P. Sexual health literacy – an emerging framework for research and intervention to improve sexual health for gay men. Sexually Transmitted Infections 2015 91 (suppl 2): A85 (Abstract P02). Young I, Flowers P, McDaid LM. Barriers to uptake and use of pre-exposure prophylaxis (PrEP) among communities most affected by HIV in the UK: findings from a qualitative study in Scotland. BMJ Open 2014;4:e005717.	
183	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	9	23-24	In relation to recommendation 1.3.2 and the needs of non-English-speaking communities, we would make the case that the needs of first generation African migrants go beyond the translation of promotional material into different languages. Our ethnographic research on first generation African migrants in Scotland, (PhD, Smith, M) has shown, that discussions of HIV risk	Thank you for this comment. Cultural awareness and sensitivity is covered as part of recommendations in section 1.4 of the guideline. Translation of materials is given as an example only.

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						are not common within the varied African communities in Scotland, and continue to be a highly stigmatised subject. Cultural sensitivity is needed in relation to the norms of sexual health discussions (including the gendered nature of these norms), health promotion practices and high levels of reported community stigma. Smith's research identified specific instances where discussions of HIV testing may be seen as appropriate, such as starting new relationships, marriage and screening during pregnancy. Smith, M. 'Africans in Scotland: Heterogeneity and sensitivities to HIV' PhD Thesis, MRC/CSO Social and Public Health Sciences Unit, 2016 [passed subject to corrections]	
184	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	9	13-15	Information on treatment as a method to prevent onward transmission is an important new inclusion in promotional material around testing. However, our research (Young, et al 2015) highlights mixed responses to treatment as prevention, including potential individual and community ambivalence towards using treatment for prevention and a potential resistance to treatment initiation upon diagnosis. We therefore encourage increased awareness of these potential concerns and sensitivity to the complex issue of treatment initiation and prevention in testing materials. Young, Flowers & McDaid, Key factors in the acceptability of Treatment as Prevention (TasP) in Scotland: a qualitative study with communities affected by HIV. BMJ Sexually Transmitted Infections 2015;91:269-74	Thank you for this comment. This is outside the scope of this guideline. The committee did not examine the evidence for the content of promotional literature and therefore was unable to make a recommendation on this.
185	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	11	1-21	While we welcome the increase in opportunities to test in secondary and emergency care settings and GP surgeries (1.1.3 – 1.1.7), the capacity and skills of non-HIV specialist health workers to offer HIV testing needs critical attention. Experiences of people living with HIV in non-specialist health care continue to be significantly affected by stigma and discrimination by health workers (Waverly Care 2014). A major barrier to offering HIV tests in these settings will be the knowledge and cultural awareness of health staff in relation to those at risk of HIV, as well as pathways	Thank you for raising this issue. Implementation issues and service delivery are beyond the scope of the guideline.

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						to relevant HIV services. While we welcome the recommendation for further research on attitudes towards HIV testing among service providers (Recommendation 9, p.23), it will be imperative to consider the capacity of health workers and their knowledge of and skills in providing HIV information and testing. Our current work around HIV literacy (Young, Developing HIV Literacy, Scottish CSO) points to the complexity of HIV literacy and the need for comprehensive, multi-level interventions to adequately support testing services. Waverly Care, The Healthcare Experiences of People Living with HIV in Scotland, 2014.	
186	[office use only]	MRC/CSO Social and Public Health Sciences Unit, University of Glasgow	Full	17	20-22	While we welcome the inclusion of guidance on POCT and self-sampling, we caution against assuming that these will in and of themselves address issues around lack of engagement with testing and sexual health services. The guidelines need to give greater acknowledgement of the structural drivers of HIV and how these impact on testing practices. It is not surprising that there is a lack of UK evidence for self-testing increasing the uptake of HIV testing, given the recency of the availability of the test kits. However, we are aware of at least one paper that suggests self-testing could increase the frequency of testing among high-risk men who have sex with men (Carballo-Dieguez et al 2012). It is pertinent that the new guidelines recommend further research on the efficacy of self-sampling and self-testing. Our (in press) mixed methods research on preparedness for self-testing with men who have sex with men and those involved in prevention and care in the UK suggests it could increase HIV testing amongst some, but not all, MSM (Flowers P, et al, in press). We found that willingness to use the test was high (89%) among men who have sex with men in bar-based surveys, but again, HIV literacy was important; awareness of self-testing was associated with level of educational attainment and digital literacy was associated with willingness to use the test. Whether test results would be interpreted accurately in relation to the window period and to specific risk events also raised	Thank you for this comment. The recommendations are based on the evidence that was considered by the committee and there was insufficient evidence for the effectiveness of self-testing was found. The papers highlighted did not meet the inclusion criteria for the evidence reviewed that was conducted. We hope that when this guideline is reviewed for update there will be more evidence available. A research recommendation on self-sampling has also been made in the guideline, which could increase the likelihood of research in this area being undertaken. All of the evidence used to make a particular recommendation is listed in the 'evidence reviews' section under the Committee Discussion.

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						concerns. Self-testing was perceived to be convenient and in some cases preferable to going to a clinic, and so could reduce some barriers to testing, but it also presented parallel concerns on loss to follow up testing and treatment, and for opportunities for accessing prevention interventions and partner notification. Carballo-Dieguez A, Frasca T, Balan I, Ibitoye M and Dolezal C. Use of a rapid HIV home test prevents HIV exposure in a high risk sample of men who have sex with men. AIDS Behav. 2012; 16:1753-60. Flowers P, et al Preparedness for the use of the rapid result HIV self-test by gay men and other men who have sex with men (MSM): a mixed methods exploratory study amongst MSM and those involved in HIV prevention and care. HIV Medicine (in press).	