



Guidelines for HIV Testing

Web consultation comments

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1. Comments from Christine Hardwick

Have some renal diseases eg nephrotic syndrome been considered as indicator diseases? Also cardiomyopathy? Perhaps a single sentence somewhere re syphilis serology eg. in those with unexplained neurological symptoms or primary HIV infection symptoms but I'm sure you've thought of this and don't want to confuse issues

2. Comments from Babs Evans

I had a look at the guidelines and my comment is to add: 'Men and women known to be in a sexual relationship with someone diagnosed with HIV' It seems obvious but partners may not always be offered tests, may have been discouraged from taking a test by their partner or may have had a negative test in the past but continued to be at risk. Hope this is helpful

3. Comments from Gus Cairns

Please note these are my own views and not necessarily representative of the views of UK-CAB or any other patient group. On the whole I welcome these new guidelines. I like the specific nature of the list of who should be tested and the list of Indicator Diseases. And I particularly welcome the recommendation that 4th generation assays that include the p24 test should be standard, thus reducing the window period to 15 days. I think they're too cautious about rapid ("point of care") tests. I think the suggested maximum three-day wait for standard test results still won't be good enough to address the problem of people who never return for care; there's a lot of evidence from the USA to show that "while you wait" testing increases the number of people who know they have HIV. I take the point about false-positive results especially in a low-prevalence setting, but most POCTs will be used in high-prevalence populations. At the very least there should have been a short section about the use of POCTs in community settings, specifying exactly what a "community setting" is, rather than just referring to a BASHH document. I'd like to see an expansion in community testing because it may help reduce

what is for me the most shocking statistic in the document, which is the 47% of gay men (and 25% of heterosexuals) who go to GUM clinics with undiagnosed HIV and leave with it still undiagnosed. Community setting testing could encourage these "won't testers" or "anxious avoiders" to test, and I'm afraid these guidelines may be misused as evidence against it. So: more on community testing, please! I also agree with Ben Cromarty of UK-CAB that the crucial next step will be the widespread publicising and dissemination of these guidelines along with education of healthcare workers. It's all very well saying that any doctor, nurse or midwife should be able to suggest, obtain consent for and order an HIV test but if they still have misconceptions about HIV they won't do it.

4. Comments from Hilary Curtis

Response to British Association for Sexual Health and HIV (BASHH), British HIV Association (BHIVA) and British Infection Society (BIS) Guidelines for HIV Testing (Version 3.8 21/5/08)

General

I strongly support these guidelines and have only minor comments, as follows:

Executive summary

The executive summary fails to summarise the key recommendation, which is that HIV testing should be performed on an opt-out basis in a wider range of settings and circumstances than is currently the case, including all patients with indicator diseases.

Background

There is an incorrect statement in the opening paragraph that "A national audit by the British HIV Association (BHIVA) showed that of deaths occurring amongst HIV-positive adults in the UK in 2006, 35% were directly attributable to the diagnosis of HIV being made too late for effective treatment". The correct figure is 24% of ALL deaths amongst HIV-positive adults, or 35% of deaths

considered directly due to HIV-related causes. Because there is uncertainty about the attribution of deaths to HIV-related causes, it would seem wise either to quote only the 24% figure for all deaths, or to quote both figures. However, it would be reasonable to say “at least” 24% of deaths occurring amongst HIV-positive adults were due to late diagnosis, in view of good reasons for likely under-ascertainment.

Definitions

I am not sure that the term “voluntary confidential testing” is helpful. It seems to imply, quite wrongly, that diagnostic testing is not voluntary and confidential. Historically, the term VCT was introduced to distinguish from “anonymous” testing where the person seeking testing identifies him/herself only by a number or pseudonym. That is not relevant here, but the widespread yet often not precisely defined use of this term internationally is liable to cause confusion.

“Self-requested testing” or “self-initiated testing” might be better terms. In any event, I’m not sure why this definition is included since the rest of the guidelines don’t really cover self-requested testing and how it should be provided.

POCT

I wonder whether the recommendation that point of care testing should only be routinely used in limited situations is too strong. I can envisage that this might unduly restrict the development of hospital-based rapid/same-day self-initiated testing services. Although some existing same-day testing services work well with laboratory tests, I imagine this depends on local organisational arrangements and I am not sure that POCT-based services should be precluded. Obviously any such service would need clear protocols for confirmatory testing.

Hilary Curtis

4 June 2008

5. Comments from Alastair Miller

I am very concerned by the paragraph half way down page 11 that says if a patient lacks capacity to consent and it is in their interest to have the test then it needs to be discussed with the appropriate legal advocate - this will be a huge disincentive to testing in the ITU situation. It differs from the GMC position on testing and unless the MCA specifically insists on this then I think that particular paragraph should be removed - it just confuses the situation which has been clearly laid out above. Otherwise I think that this is an excellent document ALASTAIR MILLER Consultant in Infectious Disease. Liverpool

6. Comments from Dr C Mitsides

Clinical indicator for Adult HIV infection- should there be a Urology clinic entry on this list? eg MSM ED Similalry in colorectal surgery indicators could be: abscess/fissures etc

7. Comments from Dr Clive Taylor

Section 4 iv Which test to use? I fully endorse the recommendation that fourth generation HIV tests, rather than 3rd generation tests, should be used as the primary screening assay. We need to use assays which have the shortest window period.

8. Comments from Dr Stephen Dawson

This document is missing a golden opportunity to "normalise" HIV testing. The sponsoring organisations have produced timid recommendations that allow clinicians excuses not to test. If you want more people tested to stop late presentations and onward transmission by carriers ignorant of their status why don't you say so categorically? Other countries can manage it and I don't see why we can't either. A little more courage of your convictions please.

9. Comments from Claire Blackstock

I think these are very wise suggestions. As a nurse who frequently works with HIV positive patients early diagnosis is so much more effective...normalising HIV testing will hopefully reduce the stigma of the disease and help management. Hopefully no particular section of society will feel discriminated or offended by being offered HIV testing if it is "normalised" and therefore people will be more willing to consent.

10. Comments from CHIVA

Dear Writing committee,

We understand the need for the HIV testing guidance to be as short as possible, however in draft 3.8 important paragraphs have been removed from the paediatric section (appendix 4). 1) The introductory statement is necessary to explain the situations which arise for children requiring testing. 2) The paragraph on "what do children need to know" helps to explain that an age appropriate explanation is required. 3) The paragraph on appropriate tests to use, is important as those doing tests need to know that infants require HIV PCR tests. We feel that the guidance would be more practically applicable to children if these paragraphs were replaced. I will send an annotated version of v3.8 directly to mediscript for review.

Yours Hermione Lyall on Behalf of CHIVA 21.6.08

Taken from the annotated version of the HIV Testing Guidelines

Appendix 4. Testing Infants, Children and Young People

Any infant/child/young person thought to be at significant risk of HIV infection, including all those with parents or siblings, who are HIV infected, should be tested. It is in the best interest of the infant/child/young person to be tested in these circumstances although this only needs to be undertaken urgently in infants who are at risk of rapid disease progression.

The family should be referred to local paediatric services for pre-test discussion and testing. If the parents refuse to be referred, then advice should be sought from the local paediatric team who may liaise with their specialist Paediatric HIV colleagues within CHINN (the Children's national HIV Network www.chiva.org) and advise as to how best to proceed.

When an HIV infected adult is in contact with HIV services, it is the responsibility of the HIV team clinicians to enquire as to the existence of any children at risk of vertical transmission from this adult, to document this clearly and to ensure that these children are referred for testing within an appropriate timeframe according to the age of the child.

What Do Children Need to Know about having an HIV Test?

One of the main reasons that parents do not want to test their children for HIV is because they are afraid to share the diagnosis with them. It should be explained to parents that a developmentally and age appropriate explanation of the test should be given to children and that this does not necessarily mean using the term HIV, see below:

- 1) Older and "Fraser Competent" children (usually those > 11-12 years) should be asked to give consent for an HIV test.
- 2) Younger children (usually 5-10 years) can be told they are being tested for a "bug" in the blood,
- 3) Preschool children and infants do not need any formal explanation of why they are having a blood test

Appropriate HIV tests for Infants and Children

Children > 18 months of age: HIV antibody test, as for adults

Infants < 18 months of age: infants born to mothers with HIV receive transplacental maternal HIV antibodies which can usually be detected in the infant blood until about 18 months of age. Infants

are therefore tested for genomic evidence of HIV by PCR (for details see BHIVA guidelines on management of HIV in pregnancy, www.chiva.org).

11. Comments from Professor Jackie Cassell

Dear Writing Committee,

These guidelines are to be welcomed, and will provide an important stimulus to the normalisation of HIV testing in the UK, with a view to earlier diagnosis and reduced transmission. I would like to make two suggestions:

1. The lack of a recommendation of HIV testing for ALL individuals diagnosed with an STI is a strange omission which should be addressed. It is at odds with known principles of STI control, of which HIV is a special case. Individuals diagnosed with an STI should be routinely offered HIV testing, whatever their setting of STI diagnosis. Individuals diagnosed with an STI are on average at increased risk of HIV, on the basis either of their own behaviour or that of a partner.

2. Testing recommendations based on estimates of UNDIAGNOSED prevalence are likely to be vulnerable to many errors in assessment, which will cause confusion in local testing policies. This is likely to increase with the growing use of near patient testing in the private sector. It is TOTAL prevalence which provides the sum of local transmission potential. As an HPA regional epidemiology lead, responsible for co-ordinating strategy in geographically close but contrasting areas, I believe that a policy based on actual prevalence (as in the USA) will be more easily supported and implemented. I hope these comments are helpful, and I will be happy to discuss further if that would be useful.

Yours sincerely,

Jackie Cassell

Brighton and Sussex Medical School Health Protection Agency (South East)

12. Comments from Max Courtney

Email: max.courtney@hpa.org.uk

As a nurse who has undertaken pre test and results giving I feel qualified to raise the point of also refusing to test patients. I have had to do this on several occasions, with high risk taking individuals injecting drug users and men who have sex due to intoxication, suicidal ideation expressed and threats to previous sexual partner. Post test environment is covered by this document. Who under takes the test should give the results. Training, shadowing is beneficial when giving results that have a significant impact on some ones life.

13. Comments from Professor Sebastian Lucas

Email: sebastian.lucas@kcl.ac.uk

I note that nowhere is an "HIV test" actually defined. It should be because there are other approaches to HIV diagnosis than just serology. Low CD4 count evaluation has long been used as a surrogate test; you might wish to comment on that. In the light of histo-pathologists doing HIVp24 immunocytochemistry to diagnose infection in lymphoid tissue, this should also be factored in. Refs: Alarcon et al, oral presentation at Belfast BHIVA AGM 2008; de Paiva et al "Diagnosis of HIV by immunocytochemistry", Am J Surg Pathol 2007, 31:1534-8. I suggest that in the Introduction you add a few sentences such as: Biopsy of lymphoid tissue in HIV-infected persons is often indicative of that infection from the overall morphology. This can be confirmed by positive HIVp24 immunocytochemistry if the viral load is sufficiently high - a test that is very specific. Pathologists presume that consent for the lymphoid tissue biopsy per se includes the expectation that all diagnosable conditions may be evaluated.

14. Comments from Bev Ibbetson

Email: beverly.ibbetson@bradfordhospitals.nhs.uk

Could you clarify what is meant by the tester "other health care worker" and do you think it would be helpful to advise on employment issues if HIV positive?(or is this too vast).
many thanks

15. Comments from Elisabeth Crafer, Positively Women

BHIVA/BASHH/BIS Testing Guidelines CONSULTATION RESPONSE HIV Testing
Introduction It is well documented and recognised that gender inequalities play a serious role in HIV transmission. Positively Women (PW) has tried to ensure that opportunities to address women's vulnerabilities are taken into consideration throughout the Recommendations for Testing. In all testing settings and with all people being tested, those offering the test need to have an awareness of HIV stigma and gender inequalities to maximise the uptake of testing. Investment in training and materials on HIV testing would prove a saving in health economic terms. The guidelines cover testing in healthcare setting and do not refer to testing in voluntary and community settings. It would be an asset to have an equal approach and standards applied in all testing settings. Positively Women (PW) supports the recommendation that testing should result in up to date treatment and care 4. Recommendations for testing: i. Who can test? PW agrees that it may be 'be within the competence of any doctor, midwife, nurse or trained healthcare worker – to obtain consent for an HIV test.' However, the manner in which the test is offered needs to be standardised and non-judgemental. Offering an antenatal test by saying 'you don't need an HIV test do you?' had the consequence of a woman only being diagnosed postnatally. Recommendation: Training and a standardised approach be used in offering the test. ii. Who should be offered a test? PW supports opt out testing, but we would like to see the manner of offering testing to be normalized, that is offer it in a manner that avoids it standing out from any other tests being offered, such as being part of other ante-natal tests. We support opt-out testing in prisons. Providing

prison staff and health care workers are trained and informed and a positive diagnosis does not result in discrimination. It is also important that the health care staff have links to onward referral pathways. Prison can be a safe place and a good place to be diagnosed, health care can be accessed and PW has evidence of women managing to turn their lives around having established stability in prison. Through providing peer support to women with HIV in prisons and training for prison staff, PW is aware of the need for training and provision of a standardised approach to both training and challenging discrimination against HIV positive people in prison. PW recommends more research on the needs of people in prison. Certain clinical presentations should trigger an HIV test but we are aware this is not always the case, it appears there is a case for some cross cutting work to be done to improve this situation. PW recommends that an HIV test be offered when planning a pregnancy. In antenatal settings it would be beneficial to establish whether the woman became pregnant, through unprotected sex, IVF treatment or self insemination, this has a bearing on the partners HIV status/need for a test. iii. How often to test? PW is concerned that testing in the first trimester of pregnancy only, may not be sufficient, as there have been cases of women becoming HIV positive later in the pregnancy. Recommendation: research needs to be done on the potential benefits of testing in the final trimester

5 Pre-test discussion

The discussion needs to include a risk assessment of the result of an HIV+ve diagnosis, such as domestic violence, which is a common result of bringing news of an HIV diagnosis home. There should be a possibility of a partner testing intervention here, and where a woman's partner is tested with the woman, we are aware that the social and psychological outcomes are better. There is an opportunity to initiate a process of behavioral change at this point. If someone couldn't manage safer sex before the test, how will they manage it after the test? Refusing a test: Some reasons that an HIV test is refused include denial, the perceptions that an HIV diagnosis results in disability through reactions to toxic drugs, loss of job, loss of relationship and fear of prosecution for transmission of HIV, never being able to be sexually active again and never becoming a parent. We welcome the recommendation that 'any factual inaccuracies corrected' with regard to insurance and criminal prosecution for transmission of HIV in refusing a test, and recommend that the correction is based on standardised, up to date information

available to everyone involved in HIV testing Recommendation: A standard approach to pre test discussion with a requirement to cover the issues above in the case of a refusal. This requires investment in HIV awareness training and cooperation between the statutory and VCO providers to ensure knowledge of complex issues is shared and acted upon. Post test discussion: Results of an HIV positive test should only be given face to face Negative result Discussion should include a standard intervention, exploring how to make behavioral change as in pre test discussion and for women, an awareness of how gender inequalities impact on practicing safer sex, with appropriate onward referring if necessary. Post Test discussion for Individuals who test HIV positive: As a duty of care PW recommends post test counselling as standard. Receiving an HIV diagnosis is traumatic with special complexities if it is antenatal. We welcome the recommendation of referring to the voluntary sector and believe that access to a PW peer support advocate should be part of the clinical process for HIV+ve newly diagnosed women. The post test discussion should include a risk assessment and exploration of risk reduction, this will help raise issues of domestic violence or fears about immigration status that can impact on adherence and transmission. Appendix 4 PW recommends that infants born to mothers who refused the test must be tested. We suggest that routine testing of children who have been abused be applied rather than according to risk. Testing children of HIV positive parents.: Where parents are accessing support services clinicians should recommend/refer parents to discuss testing and disclosure to older children, with the support service. Disclosure of HIV status is vital if a young person is about to become or has become sexually active. Positively Women June 2008

16. Comments from POZFEM

Thank you for our conversation on the phone just now. As I explained briefly, POZFEM UK is a young network of positive women from across the UK, formed through Positively Women and the International Community of Women living with HIV and AIDS (ICW) working together. We have just published a brief report, attached here, the first of its kind, which contains information on and concerns around women's experiences of many aspects of living with HIV here in the UK, including our experiences of receiving a positive test result and our recommendations for improving testing circumstances for women.

We are sorry that we only learnt of the on-line consultation on testing being run by BHIVA earlier this week and are unable therefore to meet the 30 June deadline. We are glad to hear that UK Cab has already fed into the consultation. We do hope that those reviewing the submissions will also be able to look at the attached pdf, which addresses specifically women's experiences. Pages 4 and 5 are of particular relevance.

I am copying in Fiona Pettitt, from ICW and Silvia Petretti from Positively Women, who are the two coordinators of Pozfem UK.

Kind regards

Alice

Dr Alice Welbourn

ICW Representative

Member, Pozfem UK

17. Comments from George House Trust

BHIVA/BASHH/BIS HIV testing guidelines consultation response

General comments

George House Trust welcomes this initiative to establish new testing guidelines and help reduce the burden of undiagnosed HIV in the population. The Guidelines need to be partnered with a strategy for its adoption by national departments for health as part of developing national HIV strategies, by the range of professionals who will deliver it, and across the diversity of healthcare settings. There will need to be resources to pay for the tests, the administrative burden, research and audit.

We are unsure who will pay for the tests and ancillary costs in the various different settings, but unless these costs are provided for, testing under these Guidelines will make little practical progress. We suspect GPs will have to meet the costs from their current per capita allocation. PCTs providing GP healthcare centres will have additional costs; independent providers (eg in Camden and Derbyshire) will have costs to meet.

Provision probably needs to be made to vary contracts and service specifications (and develop protocols) to specify providing testing under these Guidelines.

Broadly we support the comments, concerns and suggestions of the National Aids Trust. In addition we would make the following comments and suggestions.

The draft Guidelines

1. Introduction

We endorse the need for referral within 48 hours of everyone given a positive diagnosis to appropriate treatment and care. As part of this we believe that the guidelines should include people being given the contact details of appropriate HIV voluntary sector organisations.

We would be explicit and state that testing for the wider public health benefits and individual advantages ethically requires that the NHS extends free STI treatment for all present in the country (under the NHS (Charges to Overseas Visitors) Regulations) to HIV treatment. The department should focus on the public health benefits of removing all barriers to HIV testing and treatment for a transmissible condition such as HIV.

2. Background

In the final paragraph suggesting 4 hour waiting targets at A&E are a barrier to its adoption there, we would seek ways of overcoming the practical difficulties for the benefits of reaching some of those of the hardest to reach among the at risk, particularly when we have evidence that undiagnosed symptomatic HIV and acute infection are often missed in A&E. Screening and testing at A&E is perfectly routine and it must be possible to extend this to providing HIV tests.

3. Recommendations for testing

i. Who can test?

We especially endorse NAT's emphasis on the need for training of all healthcare workers providing testing and results.

We would support this training with appropriate information and advice leaflets being made available for the public to reinforce information discussed and help ensure healthcare workers speak consistently from the same script. This is particularly important in dealing with the complexities of providing

appropriate risk reduction advice, and dealing with medico-legal issues such as prosecution risks.

ii. Who should be offered the test?

We have concerns about opt-out testing in places such as prisons but see public health benefits of testing some who are otherwise hard to reach and at risk. More work needs to be done by PCTs and the prison service to deliver effective and confidential HIV health monitoring and treatment within the prison system, and effective protocols need to be developed first before there is routine testing in the justice system.

Points 9 and 10 refer to people registering in primary care and who are a general medical hospital admission in higher prevalence areas. We would not restrict point 9 to registration – in higher prevalence areas we would like to see all people offered a test perhaps once every 5 years at a regular health review appointment not just at first registration. Potentially this could have a significant impact on the 30% undiagnosed population over a period of a few years.

We think you need to list the high prevalence districts for points 9 and 10 for clarity.

We suggest, Point 7, the high prevalence countries are listed for clarity.

iii. How often to test?

iv. Point 1 (and elsewhere) refers to a 3 month window period. We think this should be 3 weeks, given that the recommended first line assay (see next section, iv *Which test to use?*) has a window period of about 15 days.

Point 5, as above: list the high prevalence districts where this is to apply; also specify the other risk factors for ante-natal women.

4. Which test to use?

We think there is some work and resources needed to bring all laboratories up to speed and to provide the capacity for the increase in testing.

NAT encourage a more radical use of POCT despite their lower specificity and risk of false positives. We suggest that making POCT more widely available in the higher prevalence areas is worth assessing in a trial. We would not at this stage extend POCT more widely into lower prevalence areas.

5. Pre-test discussion

We support NAT's insistence on training.

We would support this training with appropriate information and advice leaflets being made available for the public to reinforce the information discussed and help ensure healthcare workers speak consistently from the same script.

6. Post-test discussion

We support NAT in saying all positive diagnoses must be given face to face. It is not enough to "strongly encourage" this.

Negative results discussions: we have above suggested the appropriate window period be 3 weeks for the recommended assay.

Positive results discussions: we endorse the need for the development of referral pathways, and for protocols for follow-up of people who don't make contact.

We support the need for appropriate training with appropriate information and advice leaflets being made available for the public to reinforce the information discussed and help ensure all healthcare workers speak consistently from the same script.

7. Auditable Standards

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8. Other Issues **Confidentiality in NHS records**

We have a real concern both about how HIV status will be recorded and how this information will be moved within the NHS.

People in rural areas often have no effective choice, especially of primary care provider, with neighbours, acquaintances and relatives potentially part of the health care team. People with HIV have real concerns about protecting the confidentiality of their HIV status within small communities. These concerns need to be addressed with appropriate recording systems.

The recent incident where a courier lost HIV and other test results from Kingston on Thames hospital illustrates just one of the risks of data handling and transfer of such sensitive information. Robust procedures and protocols are essential.

Appendices

Appendix 2 – Detailed Post Test Discussion and Partner Notification

Leaflets dealing with onward transmission risks, appropriate and frank risk reduction information and advice, and with the medico-legal issues of onward transmission and prosecution and PEP are essential to support the consistency and quality of the information provided in post test discussions.

George House Trust

June 2008

18. Comments from Janet Murat and Sascha Auweiler

30th June 2008,

Dear BHIVA,

RE: BASHH, BHIVA and BIS Guidelines for HIV Testing

As a primary care based HIV specialist nursing team we broadly support the guidelines under consultation, and consider they will provide a mechanism, and standards, for increasing the provision and access to HIV testing, particularly in non-GUM settings.

We feel the following points should be highlighted further due to the implications for funding and service development;

- 4. ii. 3. Introduction opt out testing in termination of pregnancy (TOP) services. In London this has implications for the capacity of termination services to introduce testing, and will need to be managed within services that have a high volume of cases (in our service it is approx. 100 per month). This requires appropriate funding to support increased diagnostic costs and increased numbers of referrals to HIV care providers requiring development of pathways to manage positives. This is particularly important when all termination services are measured against the national target for access to TOP before 10 weeks gestation. Additionally this requirement will need to be part of service level agreements with third sector providers
- 4. ii.9 and 10. We support this rationale due to levels of undiagnosed HIV infection in London but this has significant immediate resource implications as the London boroughs exceed this prevalence figure. How will BHIVA work with clinical leads for PCTs and secondary care and commissioners to ensure these recommendations are implemented and services resourced with appropriate staff development, to provide access to testing for all patients fitting these criteria? As independent contractors and increasingly third sector providers deliver a significant part of primary care, this will need to be negotiated and managed within reviewed service specifications.
- Point of care testing (POCT): we feel this provides access for people who would not traditionally access GUM services and therefore would not have access to 4th generation tests. Clearer emphasis from BHIVA as the expert advisory group about the role POCT provides in improving access is likely to influence future commissioning and funding for such testing services outside of GUM services, therefore supporting greater uptake of HIV testing.

We look forward to the publication of the final version of the guidelines and hope its aim of increasing access to HIV testing and diagnoses are achieved. We are happy to be contacted to discuss our perspectives further.

Yours sincerely,

Janet Murat & Sascha Auweiler

Clinical Nurse Specialists HIV

19. Comments from the African HIV Policy Network (AHPN)

The African HIV Policy Network (AHPN) is a national umbrella organisation whose mission is to influence and inform national policies on HIV and sexual health that have implications for African communities. The AHPN is membership-based organisations, which consists of mostly African-led community-based organisations (CBOs). Our members are located across the UK and they provide a range of services, including raising awareness of HIV-related issues within their local communities, providing information on HIV testing and treatment services, and organising support groups for people living with HIV. Some of our members – such as Community Health Action Trust (CHAT) in Brent in London, African Health for Empowerment and Development (AHEAD) in Woolwich in London, and the Crescent Support Group in St. Albans in Hertfordshire - collaborate with their Primary Care Trusts (PCTs) to offer HIV testing services in their premises. These members regularly share with us their experiences of undertaking HIV testing projects in order to inform local and national policy responses.

The AHPN monitors HIV testing strategies and participates in policy discussions on HIV testing because existing research suggests that some people are testing

but there is need to reach people who are living with undiagnosed HIV.¹ Epidemiological data demonstrates late presentation amongst African communities² with the need for more effective HIV testing strategies.

The AHPN's response is based on the experiences of our members that are promoting and undertaking HIV testing within their specific local communities. Many of these CBOs have been disseminating materials about HIV testing developed by the National African HIV Prevention Programme (NAHIP), a project managed by the AHPN to implement prevention initiatives at national level. Our response is also based on a series of meetings organised by the AHPN focused on HIV testing and African communities. The aim of the meetings were to identify who is doing what, to explore different HIV testing models and their effectiveness in reaching those with undiagnosed HIV infection, and to begin to develop some policy priorities for HIV testing amongst African communities in the UK. Thirdly, our response is based on research project led by the AHPN to explore and compare how testing initiatives in the US and several African countries (Ghana, South Africa, Malawi and Ethiopia) were meeting their HIV prevention goals by getting people with undiagnosed HIV infection to come forward for an HIV test³. The research included representatives of the AHPN, a social researcher and clinicians that visited different settings (healthcare and community-based) to learn how they are undertaking HIV testing and how they encourage people with undiagnosed HIV infection to come forward to test.

¹ MAYISHA II Collaborative Group (2005). Mayisha II Main Study Report: Assessing the feasibility and acceptability of community based prevalence surveys of HIV among black Africans in England. Health Protection Agency Centre for Infections: London.

² The UK Collaborative Group for HIV and STI Surveillance. Testing Times. HIV and other Sexually Transmitted Infections in the United Kingdom: 2007. London, Health Protection Agency, Centre for Infections.

³ Elam, G et al HIV testing and African migrant communities in the UK – Exploring policy and practice in the UK, US, Ghana, Malawi, South Africa and Ethiopia African HIV Policy Network – *forthcoming 2008*

General comments

The AHPN welcomes the consultation on the BHIVA/ BASHH/ BIS HIV testing guidelines.

In addition to a well-consulted and evidenced-based set of guidelines, the writing group needs to draft a practical implementation strategy of routine opt-out HIV testing with clear indications of roles and responsibilities and timelines against which we can monitor progress and commitment.

The implementation strategy would require a specific section on the needs of undocumented migrants who have access to free HIV testing but who do not have access to free HIV treatment if they are diagnosed HIV positive and need to take medication.

It is important to secure political and financial support from the Department of Health for the guidelines and the implementation strategy.

The guidelines need to inform and be in line with any updated National strategy for sexual health and HIV⁴ (due to be published in the autumn).

Specific comments

1. Introduction

The guidelines focus on HIV testing within healthcare settings, with minor attention to HIV testing within community-based and other settings. HIV testing in community-based settings presents an additional opportunity to reach people

⁴ Department of Health (2002) National Strategy for Sexual Health and HIV
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006374

with undiagnosed HIV infection, especially migrant populations who do not always use formal health services, so need other ways to gain access to HIV testing⁵. This has been the experience of some AHPN members that are undertaking HIV testing in their local settings in collaboration with their local PCTs. For example, Community Health Action Trust (CHAT) is funded by their PCT to undertake HIV Voluntary Counselling and Testing (VCT) on their premises. This is conducted by a licensed health professional. CHAT testing services include other tests, including diabetes and hypertension, in order to tackle the stigma associated with an HIV test. An interim evaluation undertaken by CHAT found that their strategy enabled them to reach people living with undiagnosed HIV infection.⁶ Additionally, the evaluation by Sigma Research of the Terrence Higgins Trust's 'fasTest' VCT services found that HIV testing within community-based settings offered people more choice about where they could go for an HIV test (other than a GUM setting) and increased overall capacity to provide HIV testing in any specific geographic area.⁷

Initial findings from the AHPN's research on HIV testing demonstrated the value of taking HIV testing initiatives to communities in non-health care settings, and in particular the value of attaching 'readiness to test' programmes to these services⁸. Readiness to test programmes involve community-based programmes delivered over time that address each of the barriers to HIV testing. HIV prevalence among African-born individuals in the settings we visited ranged from levels below that in the UK to levels far in excess of the UK epidemic. In each of

⁵ 'Outcomes if the symposium on HIV testing and Human Rights', Canadian HIV/AIDS Legal Network, Briefing Paper, November 2005.

⁶ Mapara, E. (2007) Community Resource Centre Evaluation Report. Community Health Action Trust.

⁷ Sigma Research (2006) fasTest community HIV testing pilot (DH funded): final evaluation report <http://www.sigmaresearch.org.uk/go.php/reports/report2006/>

⁸ Elam, G et al HIV testing and African migrant communities in the UK – Exploring policy and practice in the UK, US, Ghana, Malawi, South Africa and Ethiopia African HIV Policy Network – *forthcoming 2008*

these very different settings, our research revealed the same pattern of HIV testing. Among GUM and hospital settings, the numbers volunteering for an HIV test at early stage of their HIV infection were very low. In these healthcare settings, the HIV testing population was dominated by people presenting late either with symptoms or via referral from elsewhere within the health service. Services that appear to achieve greater success in earlier diagnosis of HIV included those delivering VCT in non-health care settings (for example community centres, refugee services, educational establishments and workplaces) and services that incorporated readiness to test programmes.

In one example, a workplace readiness to test programme delivered over 10 months achieved 68% participation (ranging from 75% to 53% at different sites) and 12% tested positive. Another achieved high levels of community involvement after four weeks. Core elements of testing preparedness campaigns include:

- Delivered over time to a targeted community
- Address roots of stigma and fear
- Raise awareness of the benefits of knowing your status
- Describe testing and confidentiality procedures
- Use range of techniques, including performance, drama, music, discussions, local champions and leadership
- Local champions lead testing e.g. bosses, church leaders, chiefs
- Peer educators recruited from and trained to work in the community
- Opportunities for questions and discussion in group and one-to-one settings
- Pre-test counselling / group pre-test counselling
- Taken to target population

Delivery of such initiatives in the form of 'Know your status' campaigns aimed at both undiagnosed and HIV negative individuals, overcome barriers to testing rooted in low risk perceptions. Such campaigns encouraged people to know their status as a way of staying HIV negative as well as accessing care and treatment.

CBOs in the UK often look to local PCTs for guidance on HIV testing. It is therefore important that the guidelines recognise the HIV testing services provided by CBOs and that there is clarity about whether and how the guidelines (or certain parts of the guidelines) apply to CBOs and to their collaboration with PCTs.

The guidelines state that it is important that 'following a positive HIV diagnosis, a newly diagnosed individual is immediately linked into appropriate HIV treatment and care.' The AHPN welcomes this statement and believes that irrespective of ones immigration status a person who is newly diagnosed should have access to free HIV treatment and care. This statement is in line with the national plan for action for meeting HIV prevention needs amongst African communities in England.⁹

Results from AHPN's recent consultation with HIV testing providers working with African populations indicate the importance of access to treatment in improving uptake of HIV testing. Nurses, counsellors, doctors and community workers working with African populations in the United States (US), Ghana, South African (SA), Malawi and Ethiopia consistently reported that improvements in access to treatment had been key to increasing the acceptability and uptake of HIV testing in their populations¹⁰. In these settings, treatment availability has underpinned pre-test counselling, community based information campaigns and outreach work. Research in the UK^{11 12} shows that an HIV diagnosis is still equated with a

⁹ Dodds et al The knowledge, the will and the power: A plan of action to meet the HIV prevention needs of Africans living in England. Final report-search, 2008

<http://www.nahip.org.uk/downloads/367.ppt> p53

¹⁰ Elam, G et al HIV testing and African migrant communities in the UK – Exploring policy and practice in the UK, US, Ghana, Malawi, South Africa and Ethiopia African HIV Policy Network – *forthcoming 2008*

¹¹ G Elam, KE Sadler, CA McGarrigle, W Ssanyu-Sseruma, G Othieno, O Davidson, D Mercey, JV Parry and KA Fenton. 'Barriers to voluntary confidential HIV testing among African men and women in England:

'death sentence'. Access to free treatment is vital to efforts to overcome such barriers to uptake of HIV testing.

The guidelines also state that in the UK, HIV testing remains voluntary and confidential. The AHPN welcomes this clear statement, which also impacts on people's willingness to come forward and test.

Recommendations

- Recognise the role of CBOs that are offering HIV testing services;
- Recognise that undiagnosed individuals will not come to services, services need to go to them; to be successful, HIV testing services need to include community-based outreach that embodies the core elements of community readiness to test programmes;
- Clarify whether and how the guidelines apply to CBOs (individually and in their collaborations with PCTs);
- Guidelines to include training and delivery of VCT in non-healthcare settings, including mechanisms for referral for staging and treatment.

3. Background

A strong case has been developed in this section for reducing the numbers of people with undiagnosed HIV infection.

It is useful that the guidelines refer to the experience of implementing HIV testing policies and strategies in the US.

The statement about the feasibility of supporting the use of opt-out testing in certain situations is realistic given the variations in seroprevalence across the

Results from the Mayisha II community-based survey of sexual attitudes and lifestyles among Africans in England.' HIV Medicine; Volume 7, Supplement 1, March 2006

¹² Fakoya et al 'Barriers to HIV testing for migrant black Africans in Western Europe', 2008

UK, however, the guidelines need to specify the settings in which opt-out testing is feasible. Additionally, this section needs to further consider particular populations, such as undocumented migrants, for whom treatment, care, support and other prevention services might not be available, as well as the human rights and ethical questions it raises.

Recommendations

- | |
|--|
| <ul style="list-style-type: none">a. Clarify the settings in which opt-out testing should be supported;b. Include a statement about access to HIV services for particular populations, such as undocumented migrants. |
|--|

4. Confidentiality and HIV testing

The statement 'The outlook for individuals testing positive for HIV is now better than for many other serious illnesses for which clinicians routinely test' is sweeping and not evidenced-based and should be deleted.

As stated in the guidelines, the confidentiality of a patient's information should be well protected. This should remain the case when electronic patient records are introduced.

Recommendation

- | |
|--|
| <ul style="list-style-type: none">a. Remove the sentence beginning 'The outlook for individuals testing positive...' |
|--|

4. Recommendations for testing

v. Who can test?

While any doctor, midwife, nurse or trained healthcare worker can obtain consent for an HIV test, it is important that they receive appropriate training in order to ensure they are obtaining consent appropriately (ie. in a sensitive and

professional manner that takes into account the potential for misunderstandings). If a person is a migrant, they might need access to translation services so they are not misinformed or coerced into testing.

A recent study found that General Practitioners (GPs) are missing valuable opportunities to diagnose HIV in Africans living in the UK¹³. This finding was fully endorsed in one of the expert meetings organised by the AHPN, during which participants discussed at length the potential role that GPs could play in diagnosing HIV. As long as there is appropriate training and as long as care pathways are in place, there is no reason why GPs and nurses within primary care settings cannot test for HIV.

Training on how to do an HIV test should also include information about HIV stigma, confidentiality, and patient/doctor relationships. Training programmes for health workers should involve community representatives.

Recommendations

- The Department of Health should commission the development of training resources on HIV testing within GUM, GP and community-based settings to compliment the new testing guidelines;
- An implementation strategy for the guidelines should include regular training for healthcare professionals on the process of undertaking HIV testing and should include community representatives.

vi. Who should be offered the test?

Bullet points 7 and 8 state that 'All individuals known to be from a high prevalence country and/or men that have disclosed sexual contact with other men' and 'All men and women who report sexual contact with individuals from

¹³ Burns FM et al. 'Missed opportunities for earlier HIV diagnosis within primary and secondary healthcare settings in the UK.' *AIDS* 2008;22(1):107-13.

areas of high HIV prevalence, abroad or in the UK' should be tested for HIV. The AHPN is concerned about *how* this would occur in practice. While it is important to reach those with undiagnosed HIV infection, this needs to be done in an ethical, feasible and non-discriminatory manner. Ethically, it is important that people do not feel targeted or stigmatised. The healthcare professional undertaking the testing needs to be trained to identify whether individuals should be offered an HIV test based on other issues (such as clinical symptoms, high risk activity or higher seroprevalence in certain areas as identified by the Health Protection Agency) other than their country of origin or sexual orientation. This should then be well explained to the individual so they understand why they are being offered an HIV test.

In terms of bullet point 2 'All women attending antenatal services', it is important to consider the partners of women who attend antenatal services. Positive East, in collaboration with Newham PCT, is encouraging pregnant women to bring their partners along for HIV testing during the 20-week scan. The women would have known their HIV status by this time. However, it provides an opportunity for their partners to be tested. Healthcare settings should continue to partner with CBOs to deliver innovative projects, which present an opportunity to diagnose those with HIV undiagnosed infection.

Recommendations

- The statement 'All individuals known to be from a high prevalence country and/or men that have disclosed sexual contact with other men' should be qualified with more information ie. '...that present with clinical symptoms, that have been undertaking high risk activities or that are living in areas of higher seroprevalence';
- Healthcare settings should continue to partner with CBOs to deliver innovative HIV testing projects;
- There should be attempts to test the partners of women attending antenatal services.

vii. How often to test?

The AHPN is not currently able to comment on the regularity of offering or providing an HIV test. Generally, it is important to encourage opportunities that allow for testing after risk of exposure, and the regularity of this testing should be tailored to the individual circumstances and personal risk factors. Individuals must not be coerced or pressured into testing. They must be provided with information and allowed to make an informed choice so they are prepared to receive the results of their test.

viii. Which test to use?

Information in this section about point of care testing is particularly useful for CBOs undertaking HIV testing within community-settings. Any information on testing protocols in the three settings where point of care tests can be used would be helpful.

The Mayisha study identified that testing alone does not provide people with knowledge of their HIV status. Of the survey respondents with a HIV antibody positive oral fluid sample who also reported a previous voluntary HIV test, 32% (28/89) reported their last test result to be negative and 16% did not know their test result or had not collected it.¹⁴ Provision of VCT using rapid tests will overcome such barriers to individuals knowing their status. In all of the settings we visited outside the UK, rapid testing (in the form of two finger prick tests delivering results within 10 minutes) was the norm and regarded as the only effective means of ensuring that service users left the VCT session knowing their HIV status.

¹⁴ MAYISHA II Collaborative Group (2005). Mayisha II Main Study Report: Assessing the feasibility and acceptability of community based prevalence surveys of HIV among black Africans in England. Health Protection Agency Centre for Infections: London.

Recommendation

- Promote the use of rapid tests.

5. Pre-test discussion

The statement 'It is important to establish that the patient understands what a positive and a negative result means in terms of infection with HIV. This can be a particular issue for those for whom English is not a first language.' is very important so that patients are making an informed decision and are prepared for the result.

If a patient refuses to test, it is important to explore the reasons with them. It is important that they are not coerced or pressured to test because this would mean they are unprepared to receive their result.

For example, in terms of women attending antenatal services, it is important that healthcare professionals approach the issue of HIV testing in a manner that does not leave them unprepared for an HIV positive diagnosis (and in some cases, exceptionally vulnerable as a result, including violence, depression, abandonment). This issue was raised prior to the change in government policy on antenatal testing, but it continues to be unaddressed.

One way of addressing this is by providing appropriate training on how to undertake the pre-test discussion so that the patient is genuinely consenting to an HIV test.

The sentence 'If either insurance or implications for criminalisation of transmission are raised by individuals...' is useful. What if the cost of paying for HIV treatment when you are undocumented or fear of being picked up by the

Home Office when you visit a hospital are raised by individuals? How might a healthcare professional respond to those questions?

An issue that has not been addressed, and which may apply more to a community-based setting, is that of group pre-test discussions. The AHPN knows of an organisation that is exploring doing this within a Church setting in London so guidelines on group pre-test discussions would be useful.

Group pre-test discussions were widely used in the different testing settings the AHPN visited in Africa and the US. Group discussions were used as part of readiness to test programmes and mobile community based testing centres. However, these were not a replacement for individual pre-test risk assessment.

Recommendations

- The guidelines need to explicitly state that individuals should not be coerced or pressured into taking an HIV test;
- Appropriate training on pre-test discussions is essential for healthcare professionals;
- The guidelines need to clarify how a healthcare professional would respond to questions about access to treatment for migrants;
- The guidelines need to provide a position on group pre-test discussions.

6. Post-test discussion

In the first paragraph, particular attention should be paid to the means by which negative, as well as positive, results are delivered in order to prevent individuals from thinking they cannot contract HIV in the future.

In the second paragraph, arrangements for communicating results could also be discussed and agreed in a community-based setting, as well as an outpatient or emergency care setting.

In terms of the post-test discussion for individuals who test HIV positive whose first language is not English, it is good that an appropriate confidential translation service will be offered. Another option is to seek the expertise and support of a CBO in the area, if the individual would like this support.

The recommendation for a clear pathway of onward referral for non-GUM/HIV specialists is important. It is absolutely essential that individual's information be protected in this process.

Recommendation

The guidelines need to include the following:

- Attention should be paid to the way in which both negative and positive results are delivered;
- Arrangements for communicating results should also be discussed and agreed in a community-based setting, as well as an outpatient or emergency care settings;
- Individuals can be offered support from local CBOs with expertise in supporting newly diagnosed individuals;
- Patient's information should be protected when it is being transferred.

9. Primary HIV infection

This section demonstrates the potential for HIV to be diagnosed in primary care settings. Training and incentives need to be in place to encourage GPs to recognise symptoms and test their patients for HIV.

Recommendations

- Provide training for GPs in areas of higher seroprevalence;
- Offer incentives for GPs to test their patients for HIV.

10. Auditable Standards

The standards are useful in monitoring progress in providing HIV testing services, however, there needs to be clarity about roles and responsibilities and timelines for achieving specific targets. This can form the basis of an implementation strategy for the guidelines.

Recommendations

- Draft an implementation strategy clearly articulating the roles and responsibilities of different agencies in delivering on HIV testing services.

Appendices:

There needs to be a section on 'Pre-test and post-test discussions for undocumented migrants'. The AHPN has anecdotal evidence of people not wanting to go for an HIV test because they say they would not be able to access free HIV treatment or they are fearful that they might be picked up by the Home Office when they go for an HIV test. Information about access to treatment and confidentiality of information needs to be clearly expressed in the pre-test and post-test discussions. There is a missed opportunity to address and re-enforce the rights of people living with or affected by HIV by including a section on equality and human rights laws that apply.

According to the WHO¹⁵, the basic principle of a public health approach to the health of migrants is the avoidance of health inequalities between migrants and host population. Furthermore, migrants travel with their epidemiological profiles many of which are carried from their original communities and these profiles are irrespective of the legality of their immigration status. They continue to mix freely

¹⁵ WHO (2007) 'Health of Migrants' http://www.who.int/gb/ebwha/pdf_files/EB122/B122_11-en.pdf (Accessed 3 July 2008)

within themselves and within the host community as well. Illegal migrants should rather be seen as 'migrants with special needs' and thus the relevant authorities should be seen to be providing and publicising migrant-responsive and migrant-friendly public health services and health care delivery.

Recommendation

- Include a section in the Appendices on 'Pre-test and post-test discussions for undocumented migrants'.

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20. Comments from Sigma

Sigma Research, University of Portsmouth

Sigma Research is a social research group specialising in the behavioural and policy aspects of HIV and sexual health. In the last ten years, Sigma Research has undertaken more than seventy research and development projects concerned with the impact of HIV on the sexual and social lives of a variety of populations. Our expertise in the field places us in a strong position to respond to the proposals outlined and we welcome the opportunity to do so.

Researchers at Sigma have maintained an interest in HIV testing policy since the early years of the epidemic in this country. Most recently, two members of the team were invited by the British Medical Journal to write an introductory editorial for two opinion pieces on the expansion and delivery of opt-out HIV testing in France and in the UK (Dodds & Weatherburn 2007).

Our response to the proposed plans rests on three central principles:

1. Many arguments for changes in HIV testing policy to reduce 'undiagnosed prevalence' are made on the basis of cost. Sigma Research continues to hold that in an environment of limited funding for HIV prevention and diagnosis in the UK, voluntary testing interventions that target homosexually active men and Black Africans offer the best value for money. We assert that alongside interventions that better enable healthcare workers interacting with these populations to OFFER an OPT-IN test, targeted psycho-social and behavioural interventions that seek a reduction in the length of time between HIV infection and diagnosis offer the best chance of reducing onward transmission (see also Holtgrave 2007).

2. Even if funds for HIV prevention and detection were unlimited, Sigma Research opposes generalised opt-out testing for HIV on the basis that the potential social, psychological, legal, sexual, financial, and health impacts of HIV require that a competent individual is cognizant of these issues, before volunteering to take an HIV test. At its core, generalised opt-out testing is reliant on an individual who defers to the authority of health care workers. Selecting (or at best, attempting to select) members of particular sub-sections of the population in general health care settings for routine HIV testing will rightly be viewed with suspicion, because it is anything *but* routine. In turn this is likely to further drive homosexually active men and African migrants away from the NHS services that already under-serve them.

3. The proposed plans have little hope of implementation in a National Health Service that is fragmented, that is staffed by people who are continually identified as drivers of HIV-related stigma (Dodds *et al.* 2004, Department of Health 2007), and which has proven itself unwilling or incapable of implementing the provision of level one sexual health services by General Practitioners since the release of the National Sexual Health Strategy in 2001. Furthermore, the logical inconsistencies that run throughout these draft guidelines make it hard to see how they could ever come to fruition.

We submit that the arguments made in the executive summary and the background sections speak to the weaknesses of a health service that is, at best, fearful of suggesting HIV testing, or at worst incapable of recognising the clinical need for HIV testing, in situations where it is possible that a patient may be infected. The resolution to this issue is clear. Working to improve the extent to which non-HIV specialists are able to 1) identify clinical reasons for testing, and 2) have the requisite skills and confidence to begin a discussion about HIV testing with a patient – are to be broadly welcomed. Indeed, the Department of Health has funded MedFASH to undertake a project that aims to deliver on just such outcomes.

We remain thoroughly unconvinced, however, of the necessity for ‘opt-out’ testing in acute care, or in other health care settings. The WHO and UNAIDS (2007) have recently suggested that to decrease the extent of undiagnosed HIV globally there is a significant role to be played by non-HIV specific (and non-sexual health specific) health professionals in identifying potential HIV risk, identifying opportunistic infections suggestive of HIV infection and offering HIV testing. Although their recommendations support significant roll out of opt-out testing in countries with generalised epidemics, their approach is very different for low prevalence countries with concentrated epidemics such as the UK. In such circumstances, the international guidelines recommend provider-initiated testing and counseling:

- Where patients are symptomatic;
- in STI services;
- in health services for most-at-risk populations (as in, health services specifically designed for these populations, not just generic services that such populations may happen to use); and
- in antenatal, childbirth and postpartum services.

The guidance specifically points out that taking an opt-out approach to HIV testing among those most at risk of infection is likely to be inappropriate.

Populations most at-risk of HIV transmission may be more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result. Health care providers will usually require special training and supervision to uphold standards of informed consent and confidentiality for these populations. Additional discussion of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support needs may be required. An “opt-in” approach to informed consent may merit consideration for highly vulnerable populations.

(WHO/UNAIDS 2007: 25)

We wonder what the specific justification of those drafting this guidance is to implement ‘opt-out’ testing with those whose symptoms suggest infection, and among population sub-groups most likely to be involved in transmission. We can see no other justification than the fact that ‘uptake of testing is increased’. Yet the reason for this increase in uptake is not explored in the document. Where people are presented with little option other than to have a test by the person who is providing them with healthcare, they are unlikely to refuse. There is nowhere in the document that stipulates that patients have a right to refuse an HIV test, and that they should not be obliged give a reason (in fact, the final paragraph of section 5 implies that most patients can be talked out of refusal). Opt-out testing is ‘successful’ because of its heavy reliance on the passivity of the patient in the provider / patient relationship. We do not feel that these are ethical grounds on which to base a national HIV testing policy.

The minimisation of the needs of the patient in this approach is nowhere more apparent than the opening sentence in section 5 which states: ‘The primary purpose of the pre-test discussion is to establish informed consent for HIV testing...

This may be the primary purpose from the point of view of the clinician, but the primary purpose of discussing a test of such significance before deciding to take it is to determine how the patient feels about the potential outcome(s), to decide if they should go ahead and be tested on that day / in that setting, and to find out what exactly what may be involved if they are diagnosed positive.

Furthermore, HIV-related stigma is introduced and dismissed within one sentence in section 3. It is inferred that someone stigma can be ‘minimised’ through the implementation of medical

confidentiality. Taking this haphazard approach to the pervasive social inequality maintained by HIV-related stigma leaves us thoroughly unconvinced about the capacity for these guidelines to be implemented. The programme of change necessitated by these procedures would require an extraordinary degree of professional training, and wide-ranging strategies to tackle HIV-related stigma, homophobia and xenophobia among health professionals.

The secretary general of the United Nations has stated that improved epidemiological outcomes are dependent on people being able to have an HIV test in 'a social and legal environment that is supportive and safe' (UN General Assembly 2006). This needs to apply equally to people who receive a negative result as those who do not. Many of the benefits of having HIV diagnosed are not available free to people without legal status in the United Kingdom (of whom the Home Office estimates there are 430,000) because of the costs of drugs and continuing care (despite the recent victory on this matter that is currently being appealed by the Department of Health, it is unlikely that most untested irregular African migrants, or even most health practitioners will be aware of the vagaries of the high courts). Perceived and real lack of affordable access to HIV treatment and care among some of those who are most likely to be infected with HIV is another reality which the draft guidance glosses over.

The recommendations for testing specified in section 4 strike us as particularly unfeasible. Firstly, the list of 'Who should be offered at test?' extends from all those people using particular NHS settings, to members of specific population sub-groups. There is no recognition that in most general practice and healthcare settings, it is unlikely that men will discuss the gender of their sexual partners - fewer than half of homosexually active men have disclosed their sexual behaviour to their GP (Keogh *et al.* 2004) – and it is also not always the case that the migration history of an African patient will be known. We wonder, then, how such facts are meant to come to light? Will providers be expected to 'identify' who they think might be gay, for instance? We see substantial potential here for real and perceived discrimination based on stereotyping and 'profiling' of patients. Furthermore, what provision is to be made for those homosexually active men and Black African men and women who have had a recent HIV test? Will they be believed, or tested again regardless?

Finally, we point to the lack of feasibility of this approach to HIV testing based on cost. In a National Health Service that is driven by financial crisis, in which time for discussion and explanation in the clinical setting comes at a premium, we do not see how the implementation of an opt-out screening for specific groups attending general healthcare settings can be regarded as

realistic. In his own cost forecasting of a range of opt-out HIV testing models, Holtgrave (2007) concludes that the opt-out testing with minimised counseling and discussion about sexual behaviour is ineffective from a cost perspective, and that it can be likely to increase rather than decrease HIV prevalence. His conclusion is that the resources that would be required to implement an opt-out regime as that recommended in the US (and largely mimicked in this draft guidance for the UK) would be better spent, and would reach more people with undiagnosed infection, if invested in targeted, community-based interventions that work to increase uptake of voluntary counseling and testing.

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21. Comments from GMFA – the gay men’s health charity

Thank you for providing us with the opportunity to respond to these important guidelines.

Generally we welcome any interventions which provide a person with accurate and up to date knowledge about their own HIV status. Consequently we are supportive of the aims of these guidelines which set out to “facilitate an increase in HIV testing ... in order to reduce the proportion of individuals with undiagnosed HIV infection”.

However some of the recommendations in the guidelines would appear to reduce the likelihood that your strategic aim is achieved rather than support it.

We would therefore urge you to reconsider some of your recommendations and assess them against the aim of facilitating “an increase in HIV testing in order to reduce the proportion of individuals with undiagnosed HIV infection”.

Furthermore, some research suggests that an increase in HIV testing among high prevalence groups will also have undesirable outcomes for public health as well as benefits. These guidelines should therefore take into account the potential for undesirable outcomes and make recommendations to reduce these undesirable outcomes. In particular, the assertion that “knowledge of HIV status is associated with a reduction in risk behaviour” is not supported by some research¹⁶. Other research such as the INSIGHT study¹⁷ demonstrated that for some gay men who repeat test, a negative diagnosis may be used to convince themselves that their current unsafe behaviour is actually safe.

¹⁶ Williamson, LM et al. *Sexual risk behaviour and knowledge of HIV status among community samples of gay men in the UK*. AIDS 22(9): 1063-1070, 2008.

¹⁷ Elam G et al. *The role of HIV testing in risk perceptions and safer sex strategies: qualitative results from an investigation into risk factors for seroconversion among gay men who HIV test*. HIV Med 7 (supplement 1), abstract P83, 2006.

It is essential therefore that when receiving an HIV diagnosis, people also receive appropriate counselling / advice. It is not practical to simply pass people on to GUM services for this – unless of course you expand GUM and HIV services to enable them to cope with the increased numbers of people testing that these guidelines are aiming to achieve.

Confidentiality

The principles of confidentiality as laid down by the GMC are appropriate for all people.

“Patients have the right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care”.

It is unclear to us, why you have chosen to recommend that patients have their records passed to GUM clinics if they fail to receive a positive diagnosis.

First, what would be the rationale for people with HIV to have this “right” taken away from them?

Second, the statement that “ the local GUM/HIV team who are likely to have experience and resources to deal with this issue” is an assertion not based in fact. If a GP doesn’t have the contact details of a patient or is unable to persuade a patient to receive a test, exactly what additional resources would a GUM clinic have? Moreover many people do not use their “local” GUM service, how would a GP know which clinic to send this data too?

Third, in achieving “informed consent” “details of how the result will be given” and who will have access to this data are essential. Raising the possibility that the results will be passed on to a third party will not encourage people to consent to the test. The perceived benefits of passing on test results of people who do not return to receive them will therefore be outweighed by the number of people from high prevalence groups who will decline to test in a non-confidential setting. This is clearly counterproductive and works against the aims of these guidelines.

Fourth, the uncertainty of confidentiality of HIV test results in GP settings has meant that for over twenty years HIV organisations have consistently had a policy to advise people not to test in GP settings. This will do little to change that policy and indeed add to the rationale.

We would therefore urge you to reconsider the recommendation to pass on positive test results for non-attenders. It will only serve to undermine the likelihood that the aims of these guidelines are met.

Are the guidelines practical?

For any guidelines to be of value, they have to present recommendations that can be implemented. Given the financial constraints of the NHS, these guidelines are unlikely to be used if all the recommendations in section 4 remain as broad as they currently are.

Who can test? – While we agree these roles potentially should have the competence to test, the competence does not come ex officio. There would be a need for a substantial training programme to equip these roles for pre and post test competences and training around HIV discrimination.

Who should be offered the test? – The current list is a mixture of target groups and settings and this needs to be disentangled.

The guidelines should ensure that opt-out testing is primarily aimed at high prevalence groups otherwise the guidelines will be either too costly to implement or not result in a substantial decrease of undiagnosed infection. Furthermore, the guidelines should be built around the acceptability to and effectiveness for high prevalence groups rather than marginalise these groups as the current guidelines do. Having high prevalence groups central to these guidelines also impacts on who can test and the settings for the test.

The failure of the guidelines to have priority groups at its heart is demonstrated in section 5 (pre-test discussion) with the sentence “If a patient, or the clinician, is particularly concerned about the likelihood of a test being positive it may be appropriate to refer on to a specialist service (e.g. GUM or voluntary sector) where additional support is available”, and in section 6 (post test discussion for individuals who are negative) in relation to individuals at higher risk of repeat HIV exposure being referred to GUM clinics.

We take the position that if the guidelines have value and are designed to meet the aim of reducing undiagnosed infections, they need to be geared around people with a high expectancy of a positive test result. Moreover, clinicians or whoever conducts the tests need to have the appropriate competencies to handle post test discussions for both HIV negative and HIV positive

people. If neither of these issues are addressed then these guidelines will only serve to increase HIV testing in people from low prevalence groups and be inappropriate for high prevalence populations.

Which test to use? - Again, if the guidelines are to be implemented and their aims met, they need to be practical for both the healthcare system and the patient. While POCT has disadvantages, the convenience of being able to test for HIV and get the results in the same appointment is more likely to result in an increase in testing (particularly for high prevalence groups who should be tested on a regular basis). The simplified process of testing would also encourage more GPs to offer the test. Currently the timeframe between HIV infection and diagnosis in gay men is on average between 4 and 5 years and the window period is only a marginal issue for most undiagnosed people. Therefore for people who have not taken risks within a three month period and for GPs offering tests, the convenience of the POCT test is more aligned with the aims of these guidelines. POCT will also reduce the number of people who do not receive their diagnosis making the “need” to pass on positive test results to a third party less of an issue.

However, the reduced window period of 4th generation assays may also encourage HIV testing as it enables people to test in a period when HIV infection may be more salient.

Therefore to increase testing in high prevalence groups, we believe that both tests should be readily available to patients and the person offering the test should be trained to know which would be the most appropriate test to offer in any given situation.

Providing written confirmation of results

Any letter should also contain the meaning of an HIV test result, particularly for people who have received a negative diagnosis. Specifically, the letter should be clear that a negative result does not guarantee that a person does not have HIV for any period after the date of the window period and can not guarantee current HIV status.

Detailed post test discussion

If we are to reduce the number of men who use repeat testing to self-justify their unsafe behaviour, then post test discussion is important for both positive and negative test results. The guidelines should focus on this more and expanded the appendices to cover this scenario.

¹ Williamson, LM et al. *Sexual risk behaviour and knowledge of HIV status among community samples of gay men in the UK*. AIDS 22(9): 1063-1070, 2008.

¹ Elam G et al. *The role of HIV testing in risk perceptions and safer sex strategies: qualitative results from an investigation into risk factors for seroconversion among gay men who HIV test*. HIV Med 7 (supplement 1), abstract P83, 2006.

22. Comments from Roger Pebody

Please note that I'm sending this feedback in a personal capacity.

Firstly, I welcome the way the guidelines identify a wide range of different opportunities for testing.

However I feel quite strongly that this is a huge missed opportunity to expand the use of rapid point-of-care tests.

It's a shame that the Victoria Clinic and other centres that offer rapid tests to gay men in a GU setting haven't published data to demonstrate the greater acceptability of the tests to different groups of patients, and the impact this has on uptake of testing.

However a study from New York showed a 36.9% increase in uptake since the introduction of rapid tests, 100% receipt of results (14% didn't return for them before), and 96% of testers choosing rapid tests [San-Antonio Gaddy, JAIDS 2006]. Similarly, a study in Ontario found 91% preferred the rapid test, higher numbers of people received their test results, fewer people reported difficulties with the testing procedure, and total time spent went down [Guenter AIDS Patient Care STDs 2008].

Of course the objection to rapid tests is the false positive issue. It is clear that rapid tests aren't justified in many low prevalence contexts, but the proportion of false positives decreases as prevalence rises. I feel this makes point-of-care tests appropriate in communities and settings where prevalence is high. One disadvantage (the anxiety of a potential false positive) must be weighed against other disadvantages (the difficulty and stress of coming back another day, and the high numbers of people who don't do that). In fact I think, in many situations, the people best placed to make those judgements are the individuals taking the test, who can be given a choice between different testing methods.

Anecdotally, I know that many gay men who would otherwise be discouraged from testing are happy to attend services like those at the Victoria Clinic. As many people find that a GU service which has opening hours throughout the week is much easier to attend than a community service that is only available for two hours on a Tuesday afternoon, GU remains an appropriate setting for rapid tests.

On a separate point, it's notable that the new guidelines have relatively few references, and many decisions are not justified or explained. Implementation of these guidelines will require 'buy-in' from a wide range of other health professionals, and I wonder if they are likely to do so without this kind of information. In particular, there is no explanation of the rationale for the inclusion of the clinical indicator diseases.

23. Response from the National AIDS Trust

Overall comments

The National AIDS Trust congratulates BHIVA, BASHH and BIS for this much needed initiative to agree new HIV testing guidelines for healthcare settings. In addition to the text of the Guidelines itself, as important will be the strategy developed to secure political and professional support for further roll-out, as recommended, of routine opt-out HIV testing. Such a strategy needs to be explicitly drafted and agreed by the writing group, for support from the BHIVA, BASHH and BIS executives as well as from the CMOs and the relevant national departments of health.

It will be extremely important that the Guidelines are published with such a strategy in place and being implemented. It would, for example, be useful to secure agreement to the testing recommendations from the professional groups and colleges of those medical specialties responsible for the key conditions identified in the two Tables of the consultation document. As important will be political support, with necessary funding, and inclusion of auditable standards within any 'refreshed' national strategy for sexual health and HIV.

The draft Guidelines

1. Introduction

The Guidelines focus on HIV testing 'in all healthcare settings' but do not cover VCT, community testing and testing facilitated by voluntary sector organisations. It might be worth the Guidelines also stating that testing interventions outside healthcare settings remain immensely important and complement such provider-initiated tests in healthcare.

There is a statement that the move to 'normalised' opt-out HIV testing, if it is to be beneficial and ethically acceptable, requires access to treatment following a positive diagnosis. This statement is welcome and important.

5. Background

The benefits of early diagnosis, dangers of late diagnosis and the continuing need for earlier diagnosis and more accessible testing both to improve treatment outcomes and contribute to HIV prevention are all points which are well made. The information on US research both on HIV transmission and cost-effectiveness of testing is very useful. It will be important also to encourage research into cost-effectiveness of routine testing strategies in the UK (though we have no reason to believe there will be significant difference in results).

3. Recommendations for testing

NAT's comments below aim to balance our conviction of the need for more widespread HIV testing, and the appropriateness of an opt-out approach, with the need to develop Guidelines which are so framed that they prove acceptable, are adopted and demonstrate a degree of cost-effectiveness.

ix. Who can test?

Any doctor, midwife, nurse or trained healthcare worker should be able to 'obtain consent' for a test. It might be helpful to clarify here, if this is what is meant, that they should be able also to perform the test and provide initial post-test discussion.

NAT agree that any doctor, midwife, nurse or trained healthcare worker should be able to obtain consent for an HIV test, take blood or saliva as required, and provide initial post-test discussion. We emphasise, however, the need for training.

If HIV testing is to be rolled out in settings outside GU and Infectious Disease, effective training around the facts of HIV and on stigma and discrimination needs to be designed and provided to all those healthcare professionals who may be testing for HIV. BHIVA, BASHH and BIS should liaise with other relevant HIV organisations to produce such a training module to accompany the new HIV testing recommendations.

x. Who should be offered the test?

NAT notes the recommendation for the test is that it be performed on an 'opt-out basis' i.e the individual is informed that the HIV test will be performed as routine but they have the option to refuse. NAT supports opt-out HIV testing where the possibility of HIV infection is clinically indicated or where screening is supported by epidemiological evidence, as long as access to HIV treatment and care is guaranteed. We believe this approach accurately reflects the clinical recommendation to test and facilitates test take-up.

NAT has reservations about opt-out testing in prisons and other places of detention (for example, immigration removal centres), or where the individual is vulnerable. Testing in such settings should remain 'opt-in' and with care taken to ensure genuine informed consent to the test.

There follows in the draft document a list of bullet-pointed 'settings' where opt-out HIV testing should be routinely performed.

NAT supports opt-out testing in the first four settings mentioned – GU/sexual health clinics, antenatal services (where this is already the case), termination of pregnancy services¹⁸ and drug dependency programmes where individuals report a history of injecting drug use.

¹⁸ See HPA 'Testing Times' p.16 for elevated prevalence amongst women attending TOP clinics in inner London. Would the epidemiology justify such screening in all TOP services across the country?

NAT also supports opt-out HIV testing where individuals present with clinical indicator diseases. NAT is not expert in the clinical judgements necessary to decide on relevant conditions to include in the Tables.

There have for some years been recommendations similar to this to increase HIV testing where clinically indicated or appropriate. But many people are still not tested and diagnosed even when presenting with clear indications of possible HIV infection. As previously stated, what is necessary as much as a list of conditions where HIV testing should be routinely offered, is a detailed strategy to secure the adoption of such an approach by the relevant medical specialties.

Bullet points 7 to 10 are more controversial and possibly less clear.

Bullets 7 and 8 do not in fact describe 'settings' but populations – all individuals known to be from a high prevalence country; all who report sexual contact with individuals from areas of HIV prevalence, abroad or in the UK; all men who have sex with men.

NAT is unclear as to what exactly is being recommended here. Is it suggested that every time a gay or bisexual man, or someone, for example, born in Africa attend any healthcare setting they should be tested for HIV?

NAT is not convinced by this proposal, if this is in fact what is being recommended. It is important that any Guidelines are practicable and achievable – most healthcare settings have little experience of taking sexual histories or asking about sexual orientation, and there are similar sensitivities around enquiries into country of origin. Nor do we think such repeated testing would be acceptable to the communities concerned. It may well be better to focus population-based opt-out testing in some key settings where training can be rolled out and there will be a cost-effective yield of positive diagnoses.

In any event, the bullet points 7 and 8 need clarification, and should not refer simply to men who have sex with men and to those from high prevalence countries and their sexual partners in a list which is meant to identify settings. Instead the Guidelines should identify settings where such population-based testing can realistically be achieved. NAT considers primary care to be the obvious and appropriate setting where such issues of possible HIV risk can be most effectively addressed, though we are very aware of the continuing challenges. Given the HIV prevalence amongst MSM and amongst those from African countries, routine

opt-out testing for HIV of those registering in primary care from these groups is clearly justifiable. This would, however, require a wider willingness and competence to take sexual histories of all registering in primary care and ask about country of origin. Particular sensitivity is necessary in raising questions with those who may have worries over their residency status and entitlements to services, and who may have had poor experiences of dealing with services or responding to questions, whether in the UK or in their country of origin.

NAT believes primary care services should be encouraged to provide opt-out HIV testing to all MSM and those from high prevalence countries who register (with recommendations and provision of repeat testing as appropriate – see below). This will, however, first require a significant culture-shift in primary care in which sexual history can be taken, and country of origin discussed, without embarrassment, prejudice or discrimination and with full assurance of confidentiality. Best practice, training and support on how to do so should be disseminated across primary care.

Bullets 9 and 10 refer to opt-out testing for those registering in primary care 'where undiagnosed HIV prevalence estimates in the local population (PCT/LA) exceeds 1 in 1000' and all general medical admissions 'from a population where the local undiagnosed HIV prevalence exceeds 1 in 1000'.

This primary care recommendation is for all registering, not just MSM or those from high prevalence countries, and would be based on local prevalence data. A difficulty is that there are no robust PCT-specific estimates of undiagnosed HIV prevalence. Estimates of undiagnosed infection are national, and taken from a relatively small number of GU clinics from around the country. Primary care does seem to be an important opportunity to screen for HIV, and there is evidence in London that it is acceptable, but it is hard to know in any given PCT whether in fact opt-out testing of all those registering in primary care would result in many positive diagnoses.

It must be said that even in PCTs with the highest HIV prevalence the vast majority of those who might be diagnosed in primary care through such screening would be MSM or those from high prevalence countries – in which case the choice between targeted opt-out testing of new registrants and universal opt-out testing might relate to which is the more 'acceptable' and can provide the most justifiable and cost-effective 'yield' of positive diagnoses. There is

an argument that where prevalence justifies it, testing of all registering patients is easier to implement and achieve, particularly given the sensitivities referred to above.

It may be hard to persuade GP practices to perform opt-out HIV tests for all newly registered patients, or indeed for those registering from targeted populations. A 'demonstration fund' from the DH on a relatively short-term basis to incentivise primary care to pilot such testing and to assess effectiveness would be very useful. The Health Protection Agency could usefully identify some PCTs where there is at least a likelihood that such testing strategies would yield a significant number of new HIV positive diagnoses.

The recommendation on 'general medical admissions' needs clarification. Is 'a population' the general population (as for the previous bullet point) or does it refer to populations such as MSM, or those from high prevalence countries? The reservations raised above in relation to both approaches apply. Whilst not opposed in principle to opt-out testing in such settings, NAT does not at this stage believe that opt-out HIV screening amongst general medical admissions is likely to be taken up or be acceptable or cost-effective. Nevertheless, testing in general medical admissions could always be piloted in higher prevalence areas, possibly using the proposed 'demonstration fund'.

xi. How often to test?

Repeat testing advice is important but of course is relevant dependent on setting. The section on repeat testing should specify settings as appropriate. If we want other specialties to take-up HIV testing we need to be sure we are not imposing inappropriate GU-related testing and discussion requirements. A useful distinction might be drawn between 'providing' a repeat test, and in the right setting informing someone that a negative result would not necessarily pick up infection from a recent possible exposure, with appropriate referral for more information or a repeat test if required.

For example, the first recommendation that those who have had a possible exposure in the previous three months be retested seems appropriate for GU, possibly primary care, and settings where sexual history has been discussed, as well as where there are symptoms of sero-conversion, but less relevant to routine screening processes or presentation with clinical indicators of disease as identified in the two Tables.

NAT supports the recommendation on annual testing for sexually active MSM or currently injecting drug users. The accompanying phrase should read 'annually and additionally when clinical symptoms are suggestive of seroconversion'.

Annual testing provision for sexually active MSM and for IDUs should be explicitly linked to GU, primary care and drug dependency programmes, where there are most likely to be elements of continuity of care linked to risk factors.

NAT accepts the recommendation on repeated offers of an HIV test in ante-natal care but believes great care must be taken not to apply undue or inappropriate pressure to women in these circumstances.

4. Which test to use?

NAT supports the expectation that all primary screening laboratories use 4th generation assays. This is particularly important to improve sensitivity of tests and detection of recent/primary HIV infection.

On point of care testing, the draft document limits recommendation of POCT to community testing sites, urgent source testing after exposure incidents and circumstances in which venopuncture is refused. NAT believes this is an unnecessarily restrictive approach, especially give the ambition to make HIV testing much more widely available in healthcare settings, nor do we understand the justification for this approach.

The possibility of false positives must certainly be addressed and should probably affect how the test is described and presented, emphasising the place of POCT in identifying the need for a confirmatory test for possible HIV infection. But we do not believe false positives are a reason not to use POCT. Indeed evidence suggests that POCT may be crucial to test take up in new settings such as primary care.

There is an important issue also, as mentioned, of the reduced sensitivity of POCT compared with 4th generation assays. This requires careful consideration of testing protocols where POCT is used – for example, the need for a different sort of test where people present with symptoms of seroconversion or for a repeat test where recent possible exposure is identified. This does not, however, preclude its use where people present with clinical indicators of possible HIV infection as found in the two Tables in this document or where testing is taking place as part of a

population screening process – it can always be made clear in pre-test discussion very simply that the test will not pick up HIV infection acquired recently with advice of where to go if the individual is concerned at the possibility of recent infection.

NAT believes that there should be greater openness to the use of POCT in appropriate healthcare settings, and that the Guidelines should include advice on testing protocols to address issues of low specificity and reduced sensitivity (in particular relating to primary HIV infection).

Greater willingness to use POCT would address the problem identified of people not returning for test results.

5. Pre-test discussion

NAT welcomes the straightforward view of the purpose of pre-test discussion as about securing informed consent and of the need to be sensitive to issues of competence to consent and of language.

Discussion can usefully cover the benefits of testing and details of how the result will be given – we believe discussion of the window period is also important so that a full understanding of the implications of the diagnosis are conveyed. We do wonder whether the requirement to discuss ‘whether repeat testing is needed’ is something which if strongly insisted on for all healthcare professionals in all healthcare settings could limit the roll-out of opt-out HIV testing. Again, setting is all – GU and primary care should explore any need for repeat testing but this does not seem appropriate in, for example, a TB clinic.

There is useful discussion of the need to explore reasons to refuse a test which may relate to misconceptions about the virus or the implications of a positive diagnosis. But there is considerable room for inconsistency and difference of interpretation as to how this should be done and at what point advice and information turn into inappropriate pressure.

Such advice will require training for all those testing – again we recommend the DH ensure basic HIV training and guidance on identifying and addressing misconceptions in pre-test discussion are provided to all those engaged in HIV testing. It will be especially important that the person offering the test is aware of the rationale for the HIV test in that particular setting or set of circumstances. Whilst this may be fairly straightforward in relation to, say, clinical indicator conditions, it may not be as obvious in a case such as primary care screening.

6. Post-test discussion

Post-test discussion remains immensely important, especially in the case of a positive diagnosis. It may be obvious and implicit, but we do think the Guidelines could usefully stipulate that negative results should also be given.

NAT believes it should be made clearer in the document that anyone whose result is positive should have the news conveyed face-to-face.

In relation to negative results, we are not sure always how practicable or realistic is discussion of specific exposure in the last three months or of whether someone is at 'higher risk of repeat exposure to HIV infection'. Should it become clear this is an issue, then the advice to refer on to GU or HIV/voluntary sector services is very sensible. But the Guidelines as drafted do imply a degree of discussion and assessment of sexual behaviour and risk every time there is an HIV test and in every setting. We believe this will be a barrier to test roll-out. Again, we would argue for greater distinction in relation to post-negative test discussion between settings, with a clearer and more minimal requirement in certain settings for information provision on HIV risk and GU services.

NAT welcome the emphasis on referral pathways, and on follow-up of those not attending for positive results. It will be useful to have examples of good practice on referral pathways available on BASHH, BHIVA and BIS websites for all medical specialties to refer to.

The question of non-attendance for positive results could of course be addressed to a significant degree by use of POCT. The draft document recommends referral to the local GU/HIV team if attempts to contact the patient prove unsuccessful. Careful consideration will need to be given before these Guidelines are finalised to confidentiality requirements and appropriate use and transfer of sensitive patient information within the NHS.

NAT welcome the section on primary HIV infection. There is considerable evidence that primary HIV infection symptoms are frequently missed in primary care and acute medicine. The sentence – 'It is recommended that consideration be given to HIV testing in any person perceived to be at risk of infection' – seems unexceptionable but a bit circular as drafted. It would be better to state 'It is recommended that HIV testing be provided on an opt-out basis to anyone presenting with possible symptoms of PHI and consistent behavioural history. It is acknowledged .. [etc]'.

At the end of this section, it would be helpful to explain to the uninitiated what PCR testing is and what the 'specialist input' should consist of.

11. Auditable Standards

National standards – NAT supports the standards relating to offer and uptake of HIV testing in GU, drug services, ante-natal services and TOP services. It may also be necessary to ensure the offer is assessed not only quantitatively but on a selective basis qualitatively, to ensure an appropriate opt-out process is consistently understood and used, which also supports informed consent.

NAT also supports the standards of reduction in the proportion of undiagnosed and of those diagnosed late. Whilst disaggregated data by 'at risk group' is important where available, overall figures are also important standards. In relation to the number and proportion of new HIV diagnoses made in primary and secondary care settings, it would be good to specify that the secondary care settings are those apart from GU/Infectious Disease.

We also support the local standards. It may not be possible to define the number of tests performed in primary or secondary care 'by risk group' – it will depend on what basis the tests are performed.

For all these national and local standards, there will of course need to be identification in the final version of the Guidelines of who is responsible for agreeing specific targets and measures, and on how data is collected and reported.

Appendices

Appendix 2 – Detailed Post Test Discussion and Partner Notification

This Appendix is useful but there should be greater clarity as to whether the best practice identified is expected of all testing settings or is more applicable to GU. It would be a shame if settings decided not to test for HIV because of worries about competence in partner notification, for example. On the other hand, some settings such as primary care should be encouraged to

take on as and when ready aspects of partner notification, with perhaps some GU support provided onsite.

Appendix 7 – HIV Testing and Criminalisation of HIV Transmission

Reference to criminal prosecutions is probably necessary. On reflection, we are not sure the sentence 'This has included a prosecution of an individual who had not been tested' should be retained in the final version. It is true that the CPS Guidance does in very limited circumstances allow for the prosecution of someone who clearly knew they were HIV infected even in the absence of a positive HIV test result, but it is not clear whether the case in question would fall into that category. In any event, we suspect the barrier to testing will less be a belief that not testing will allow someone to remain safe from prosecution but instead a fear that testing will allow someone to be prosecuted for transmission which had taken place when undiagnosed. It is safest and simplest just to state prosecutions have taken place, that there could be misconceptions which act as a barrier to testing and that detailed advice is available both on prosecutions and on safer sex from the voluntary sector.

1. See HPA 'Testing Times' p.16 for elevated prevalence amongst women attending TOP clinics in inner London. Would the epidemiology justify such screening in all TOP services across the country?

24. Comments from Waverley Care, a Scottish based HIV charity

Whilst acknowledging that routine testing normalises the experience and can be effective in helping to de-stigmatise HIV concerns remain about the level of counseling/support that is available. There would have to be a minimum explanation and we would be concerned that many people could experience unnecessary anxiety. We know that the risk is low for many people. Would it be cost effective – and would money be diverted from service provision to pay for unnecessary testing?

We are very keen on the idea of developing community based testing because it does give an opportunity to target those communities who are most vulnerable to HIV. This can be either in fixed sites or mobile testing e.g. for people from African communities going to churches on pre-agreed dates and after preparation had been done with a congregations. The Uganda model is

interesting – congregations are prepared over a number of weeks with information and encouragement to test because there are benefits. There is then a post test club – for everyone, regardless of results. Over time the negative people seem to drop out but it de-stigmatises and builds in support mechanisms.

If GP testing is to be increased could they be given the resources to rapid test? Long waits for results are especially unhelpful for people.

Increasing rates of testing will inevitably lead to increased numbers of people who know their +ve status. Is there to be capacity building for the support services that will be needed?

We would like to see the development of policy based on the assumption that most people are responsible adults who will opt into testing if it's appropriate for them and they can see that they would benefit from knowing their status. The most "irresponsible" people probably won't respond to blanket testing any better than they respond to opt-in. Reaching those people is a different kind of task – about self esteem and self stigma we would suggest.

25. Comments from Dr Helen Lacey

As I am involved in the greater Manchester Chlamydia screening programme I wish to clarify what this testing guideline might mean for Chlamydia screening.

Although I can't see this in the draft guideline, a local GUM consultant has phoned us saying the new guidelines suggest everyone with a STI should be offered a test. Many testing sites are not sexual health clinics and patients with Chlamydia are treated by a range of health care professionals including pharmacists. Whilst our programme includes in the treating protocol an offer of referral to GUM for a full STI screen (our programme tests for GC on the same test, so a full screen for asymptomatic would be a blood test for HIV and STS) , this is not an opt out situation and to adopt this would mean making major changes in the availability of treatment sites which will impact on uptake of treatment .

The national Chlamydia screening programme has been concerned about any addition to the programme for fear that it might complicate the issue and discourage young people from testing and I wonder if they have commented on the guideline.

My interpretation of the guideline is that it wouldn't mean including an opt out HIV test for those wanting Chlamydia screening or treatment unless they met the specific risk criteria which should be addressed when treating them for a positive result.

26. Comments from John White

I have reviewed the draft guidelines and am in agreement with the content and feel that these provide a much more user-friendly framework within which to approach testing. Congratulations to the committee for a job well done.

I am concerned that there has not been an attempt to alter the statement regarding the 3 month window period with respect to 4th generation assays for HIV testing. It is clear that these tests have superior sensitivity to previous assays and I am yet to be convinced that anyone has seen a patient recently who has tested negative with one of these tests more than 4 weeks after their relevant episode of risk. Isn't it about time BASHH made a stand and produced a document that allows clinicians to have a consistent message to HIV window periods? I still see patients being told that they shouldn't have a test until 3 months after an episode of risk, including high-incidence populations such as MSM. The danger of this is that we may avoid testing patients at the time when they are seroconverting – a time when intervention may prevent onward infection and allow for treatment or further assessment. I accept that there are no clear data that can give a medico-legally watertight case for this issue; nevertheless the 3-month window period that has prevailed for over a decade is not based on watertight evidence either, rather it is the “generally-accepted view”. CDC guidelines suggest that rarely it may take up to 6 months. These tests have been around for a long time yet no organisation has been prepared to take a stand on this issue. At GSTT we have advised staff to inform patients that our test has a 6-week window but some individuals (especially non-medical staff) are reluctant to alter their practice as BHIVA/BASHH guidelines still name 3 months as the necessary window period.

I would appreciate it if you could raise this issue within the committee. I think there is sufficient confidence in these new tests for us to be able to advise a 6-week window period (which I believe is still too long!) unless someone has received PEP. Even if a caveat could be added such as “there is only an x% chance that a test at 6 weeks would fail to detect HIV infection”. Clearly if the risk at 3 months is anything less than 100% then we are failing to inform our patients properly under current BASHH guidelines.

The individual and wider public health consequences of delayed testing surely outweigh the very small risk of one person having “delayed seroconversion”, especially in highly at-risk populations.

27. Comments from Association of Medical Microbiologists

The AMM supports the proposals but commissioners and other users of pathology services need to be made aware of the cost implications, in particular the revenue consequences for laboratory services; reagent costs, staff time costs. This is likely to extend beyond HIV testing to include the revenue consequences for testing for other diseases such as other blood borne viruses.

28. Comments from Kevin Miles

Several colleagues and I have looked at the draft National HIV Testing Guidelines. We fully support these. They are well written and provide succinct and unambiguous information for all HCWs. We fully support the opt out approach with a simple information and consent procedure, rather than the historic 'counselling' session.

A few points though:

1) Providing written results (pg10) - you have stated that HCWs should ensure the identity of patient (using photo ID) when drawing blood and on provision of results. We don't believe that we should request photo ID for patients requesting written results any more than patients attending in person for verbal results, or those receiving SMS, phone or letter results. You have also stated that it is preferable to have a written signed letter rather than an actual copy of the result. With EPR approaches becoming more prevalent, online results can be easily printed and handed to the patient without any further administration time wasted. We see no legal or clinical governance reason why this shouldn't become the norm should patients wish to have a copy of their results under freedom of information.

2) Although there is a chapter on confidentiality our health adviser team felt it would be good to include confidentiality in the pre test discussion, as regardless of what setting the test is being done, it is important patients feel confident about this otherwise it might put them off testing, particularly in non-GUM settings.

29. Comments from Kavita Dass

I wondered if the guideline could be more explicit in guidance to health professionals regarding window period? Most UK labs use a the combined antibody and P24 antigen test. on the one hand this brings the window period down to 15 days yet into the guideline it advises the window period is 3 months. If the guideline is being revised, I feel this should be looked at as it's confusing.

30. Comments from Rudiger Pittrof

The guidelines recommend HIV testing in variety of setting. I am not certain how this related to specialist contraceptive services. Are contraceptive services the same as sexual health clinics as the guideline makes a difference between GUM and sexual health clinics?

I am also not certain if opt our testing in all the described scenarios is the most useful approach for all the settings mentioned. I suspect that the evidence for this is not there. It will make it difficult to initiate changes in the absence of evidence. Even for GUM departments it is not clear that opt out testing will result in increased case finding. I am very happy with new guidance, in particularly I am happy that like CDC BASH does not recommend HIV risk assessment as a part of HIV pre-test discussion. The Key to HIV testing is testing at primary care level and for most patients with HIV the risk factor will be evident from the demographic sheet

Otherwise I am very happy with the guideline.

31. Comments from the Terrence Higgins Trust

Terrence Higgins Trust (THT) is the UK's largest sexual health and HIV charity, with over 20 service centres across England, Wales and Scotland. THT delivers services to and campaigns on behalf of people living with or affected by HIV or poor sexual health. THT works in partnership with a number of PCTs and Local Authorities to deliver a range of clinical and social care services, including community-based testing and treatment for HIV and other STIs.

Our comments on this consultation are drawn from THT's experience of delivering HIV testing services and of working with people living with HIV.

1. Introduction

In order to increase uptake of HIV testing, it will be important to make tests as accessible as possible, including offering testing in a range of community and outreach settings. THT welcomes the recognition within these draft guidelines that HIV testing can be delivered in a range of settings, by a range of health professionals.

Whilst these guidelines relate specifically to tests administered within healthcare settings, it might be beneficial to explicitly state the value of community-based testing and to include a broader reference to healthcare workers throughout the guidelines, as at Section 4, "Recommendations for testing".

2. Background

Although everyone in the UK should have access to a GP, in reality, THT is aware that a significant number of people at risk of HIV are not registered with a GP and would find it difficult to do so. This is mainly an issue for recently arrived African migrants and those of uncertain immigration status.

It is also important that the guidelines consider the issues of stigma and discrimination in non-specialist healthcare settings.

THT agrees that opt-out testing will be extremely useful in certain settings, but that universal opt-out testing is neither feasible nor cost-effective in the context of the low prevalence of HIV in the general UK population. THT would support piloting of opt-out HIV testing in selected settings such as some medical outpatient departments, in order to evaluate this approach.

3. Confidentiality and HIV testing

THT welcomes the explicit commitment to confidentiality within the guidelines.

4. Recommendations for testing

The last four points of this section refer to populations at increased risk of HIV, for example MSM, rather than settings in which HIV testing could be offered. It would be useful to separate this section from the previous six points covering settings, and include more detailed guidance on when those from high-prevalence groups should be offered testing, as it would not be feasible or cost-effective to offer a test at every healthcare contact. It is important that the guidelines include community-based testing and outreach as potential routes to increasing uptake of testing amongst these higher-prevalence populations.

THT agrees that proactive case finding, such as through partner notification and offering of tests to those with HIV indicator conditions should be a key part of HIV testing strategies.

THT would also support the inclusion of a recommendation on proactive information campaigns and resources for people at HIV risk, both of information about the HIV test and information encouraging people to test. This is particularly important for those in high-risk groups, who should be encouraged to test regularly. Information provision should be an integral part of HIV prevention and testing work, and healthcare professionals should be encouraged to work with a range of partners both within and outside the health service to provide information to at-risk groups.

Greater involvement of primary care in diagnosing people from high-prevalence communities should also be encouraged, but only with an accompanying increase in skills and capacity to ensure primary care professionals are confident to do this. Rather than testing all newly-registered patients at GP practices in high-prevalence PCT areas, it may be more fruitful to target at-risk groups within higher-prevalence areas, such as MSM and those of African origin.

It would be helpful for the guidelines to include some recommendations about the need for local coordination of HIV testing work, which could be done through commissioners or public health teams.

Point of Care Testing (POCT) should be an important part of any overall strategy to increase uptake of HIV testing. The current guidelines are currently quite discouraging to healthcare professionals looking to explore the suitability of POCT for a particular service.

Although POCT is less specific and sensitive than 4th generation laboratory-based testing, it is an effective and very acceptable method of testing. POCT is very useful both where venopuncture is unacceptable to the patient and in settings where venopuncture is unfeasible, such as in a detached HIV testing session. Where recent infection is a particular concern, people should be advised on specificity and sensitivity issues in the pre-test discussion, and referred for further follow-up where necessary.

THT is keen to ensure that community-based testing should adopt the use of 4th generation lab tests wherever possible, whilst detached services should continue to use POCT in those circumstances where venopuncture is impractical. THT would welcome an amendment to the guidelines to reflect this.

5. Pre-test discussion

THT agrees with the guidelines' approach to pre-test discussion, and would like to highlight that this has also been successful in community-based testing. It would be helpful to indicate further sources of information around criminal prosecution of HIV transmission. The CPS guidance which is referred to in Appendix 7 is very long, and unsuitable for use as a reference guide. THT and NAT have explanatory notes on the CPS guidance and the issue of prosecutions available on their websites and it would be helpful to signpost to these within these guidelines.

6. Post-test discussion for individuals who are negative

THT welcomes the recommendation that individuals who test HIV negative should be offered health promotion and risk reduction advice. It would also be useful for the guidelines to explicitly mention the need for good referral pathways for STI screening and regular sexual health checks where appropriate.

In the section that discusses non-attendance for positive results it would be helpful to clarify where responsibility for following up results of investigations lies. The current wording in this section is ambiguous about whether this responsibility lies with the service user or healthcare professional.

The guidelines rightly state that late diagnosis is a major problem for people living with HIV in the UK. In this context, it might be helpful for the guidelines to make a statement about the need to increase skills and capacity to diagnose primary HIV infection amongst generalist healthcare practitioners, in order that opportunities for diagnosis are not missed.

7. Auditable Standards

It might be useful to have an additional national and local standard looking at the number of people who received their results and the length of time this took. It might also be helpful to consider auditing the number of positive clients who have not received their result and those who have not been followed up after receiving a positive result. It will be important to monitor these aspects of care for those newly diagnosed to ensure good linkages between diagnostic services, HIV treatment and care teams and social care colleagues.

THT would also recommend some consideration of service user experience within the standards, particularly where opt-out testing is being rolled out. It will be useful to assess how the new system is perceived by clients in order to maximise opportunities to make improvements where necessary.

The final guidelines should also make clear the lines of accountability for data collection, reporting and analysis in relation to auditable standards.

8. Appendices

The sections referring to obtaining consent for testing children should refer to legal guardians in addition to parents.

32. Comments from HIV Scotland

HIV Scotland submits this response to the draft guidelines, warmly welcoming what it considers a timely and helpful initiative. Given the time-scale, HIV Scotland has been unable to expose its response to consultation. In February of this year, however, a paper on HIV Testing was circulated to voluntary HIV agencies and was discussed at a meeting of the Lothian Coalition of HIV Agencies, receiving broad agreement and a request for inclusion of discussion on other HIV testing options. The first part of this response is based upon that paper, and helps in informing the specific responses in part 2.

1. Discussion points on policy and practice

Background

HIV testing and health promotion have been the mainstays of HIV prevention policy in the UK.

Methods in delivering these interventions have varied, but key throughout has been a comprehensive approach, combined with the right degree of scope, intensity and consistency.

High rates of undiagnosed HIV infection have compromised the health of infected individuals, hindered prevention efforts and impaired the effectiveness of care and treatment. This is observed in continuing high rates of HIV incidence and in late diagnosis with CD4 counts lower than 200 in some 30% of new diagnoses.

Despite quadrupling of HIV testing in five years, reluctance to test persists, often due to poor levels of information about treatment options, testing availability, fear of the consequences of testing, or inaccurate perception of personal risk.

Improving rates of diagnosis is a key target for HIV prevention and care services, providing as it does an opportunity to re-evaluate current policy and practice with a view to updated standards appropriate to a changing environment. This paper is intended to prompt discussion and direction both collectively as well as on the part of individual agencies.

Barriers	Remedies
1. Lack of knowledge	1. Information
2. Unaware of treatment options	2. Information
3. Fear of test result and reaction of others	3. Stigma associated with health and health-related behaviours should be considered socially unacceptable
4. Stigma/discrimination act as deterrents to HIV testing	4. Anti-stigma and support re decisions to disclose or not to disclose HIV status
5. Stigma inhibits sharing info, compromising prevention	5.a Test always in the individual's best interests; b Supportive legal, social and policy framework as the context of opt-out testing policy; c Build and support a strong movement of people living with HIV
6. Fear of loss of privacy/confidentiality	6.a Assurance of the right to privacy; b Robust policies to protect confidentiality, ie use of personal data in health care settings; c effective technologies which protect data; d a range of patient options clearly communicated in health care settings
7. Concern re confidentiality/security of information	7. Clearly communicated policy

8. Compulsion/undue pressure	8.a Voluntary and with consent b No testing against individual will
9. Lack of staff enthusiasm/commitment	9. Staff training and support
10. Inconsistency of practice	10. Clear direction and policy with regular monitoring and reporting
11. Low perception of personal risk	11. Raise awareness
12. No cause to visit clinic for anything else	12. Encourage regular check-ups
13. Primary care etc do not recognise symptoms	13. Staff training and clinic messages
14. Clinic staff do not recognise risk factors	14. Training and practice protocol
15. Over-emphasis of clinical/professional factors	15. Testing linked with prevention, care and Treatment

Contexts for high level testing policy	Approach
1. Presence of STIs	1. Always offer test with opt-out policy
2. High prevalence community	2.a Strong community/clinic links, eg presence of vol orgs in clinic settings 2.b Always offer test with opt-out policy (at least once <i>pa</i>) 2.c Consistent, accurate, regular messages via health promotion outlets 2.c Staff training and support
3. Risk incident	3 Always offer with opt-out policy
4. History of repeat testing	4 Always offer with opt-out policy
5. One-off visit or failure to return for results	5 Recall system – use of text/email/telephone/letter or use of regular reminders in broad-based health promotion interventions

Other options

Local protocols and clear pathways for referral between clinic and community agencies.

Accessibility of clinics by

- 1 Holding community clinics
- 2 Out of hours clinics

- 3 Host helpers/volunteers from affected community
- 4 Population-specific clinics for gay/bi men
- 5 Generic clinics and settings for Africans
- 6 Linking reproductive health services with HIV and GUM testing services
- 7 Linking HIV testing (or clear referral protocol) facilities to relevant specialisms, eg A&E, dermatology, dentistry, haematology, oncology

Greater focus upon those considered to be high risk due to factors such as concurrent STI, repeat testing, one-off testers failure to return for test results, refusal of test, con-concordant relationship, with psychological support etc provided across MCN areas

GP and nurse training – perhaps ensuring level of training and provision at primary care level dependent upon population or geographical spread, or linked to eg community schools approach

Monitoring and evaluation of testing policy and practice in specific areas and contexts

Linking HIV testing/sexual health info to the work-place, to alcohol and drug projects, to HBV vaccination outlets

Joint initiatives and planning – eg Lothian Coalition with NHS Lothian

Voluntary Sector Contributions and Examples of Good Practice

RoH – Community testing, trained, skilled staff, good clinic links, reaching community

GMH – supporting clinic staff, out-of-hours clinics

WCT – Community testing, Community events, worker located at clinic sessions

Churches/INERELA

ROAM team and Community HIV Team – Linking psychology with clinic/community

MRC Research – helping normalise HIV testing, proving acceptability

Sandyford - Linking STI screening with HIV testing

Connected resource for gay and bi men – online and paper-based

HIV Comeback Tour - Lothian

Suggestions

Create culture of regular 'MOT' sexual health checks and monitor QIS standards

Promote technical approaches, eg SMS messaging

Promote personal approaches, talking about it, raising it in clinic sessions etc

Promote regular training or discussions within GP local area forums

Create cultures of support in affected communities, of gay men and Africans

Consider other contexts, settings etc, such as gyms, clubs to promote testing

Other settings for HIV testing

Discussion re appropriateness also of HIV home testing kits. requires further consideration.

Settings are only one part of the equation - crucial is the level of competence, training and qualification of any individual providing HIV testing or support in connection with HIV testing.

Questions

What is our goal – testing of whole population? Resources? Realistic? American experience?

Given the current rates of HIV testing, what further improvements in overall numbers are required to reduce undiagnosed infection rates, or to reduce time lapse between sero-conversion and diagnosis? How can these two be measured? How may they be improved?

Focus targetted messages on the stage at which individuals find themselves in making decisions re testing, eg precontemplation, contemplation, decision, action, review, etc

How to improve diagnosis rates – test all or test those most at risk, repeat testers, one-off testers, those finding difficulty having safer sex, those with current STIs

Monitoring and evaluating policy and practice? At stages after implementing specific
HIV Testing Guidelines

policies or interventions? Measure base-line, record user/contact data, demographics. Record pathway of testing – history, intentions, actual, testing attitudes and behaviours.

Roy Kilpatrick

Chief Executive

HIV Scotland

February 2008