Department of Health

The Management of HIV-infected Healthcare Workers

Department of Health's Response to Consultation

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ii. Introduction

On 1 December 2011, the Department of Health (DH) published a consultation paper concerning the management of HIV-infected (HIV positive) healthcare workers in England[1]. The Devolved Administrations have carried out similar consultations.

Current guidance[2] from DH restricts HIV positive infected healthcare workers from performing clinical procedures known as “exposure prone procedures” (EPPs) to protect patients from the risk of infection. Such procedures, which occur mainly in specialties such as surgery, obstetrics and gynaecology, dentistry and some aspects of midwifery and specialist nursing, carry a risk that healthcare workers could injure themselves and bleed into the patient’s open tissues, with a consequent risk of infection.

Following a review of the current national guidance, a tripartite Working Group (TWG) of the Expert Advisory Group on AIDS (EAGA), the UK Advisory Panel for Healthcare Workers infected with Blood-borne Viruses (UKAP) and the Advisory Group on Hepatitis (AGH) recommended that current restrictions on HIV positive healthcare workers performing EPPs be lifted, provided that healthcare workers were on effective combination antiretroviral drug therapy, with a very low or undetectable viral load, and were regularly monitored by both their treating and occupational health physicians.

The Department’s consultation on the advice received from the TWG ran from 1 December 2011 to 9 March 2012. This document provides a broad summary of the responses to the consultation questions, further advice from the TWG, the Department’s conclusions and planned next steps.

[1] https://www.gov.uk/government/consultations/management-of-hiv-infected-healthcare-workers

[2] http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4116416.pdf

iii. Consultation Process

The consultation was conducted in accordance with the Government's Code of Practice on Consultation. The duration of the consultation was 15 weeks, slightly longer that the minimum of 12 weeks required, to account for the consultation being held over the Christmas and New Year period.

The consultation document and accompanying draft impact and equality assessments were published on the DH website. The Consultation asked 11 questions on the TWG's main recommendations, focusing mainly on the assessment of risk, and the accompanying suggested implementation framework, which was prepared by EAGA.

How we raised awareness about the consultation

DH publicised the consultation by:

- Publishing the consultation package on its website
- Issuing a press release
- Announcing on the DH Twitter feed
- Posting announcements in the NHS Medical Directors' Bulletin, Chief Nursing Officer Bulletin, GP and Practice Team Bulletin, and The Week
- Directly alerting key organisations (a list of organisations contacted is at Annex A).

Number and range of responses

DH received 49 responses from a range of organisations and individuals, which have been summarised in the table on the following page. For a full list of respondents, please see Annex B. No responses were received from patient or patient safety organisations.

Type of Respondent	Number of Responses

Members of the public	11
Other individuals (healthcare professionals)	4
Royal Colleges	6
Healthcare professional regulatory bodies	2
Dental organisations	2
Other Health professional healthcare organisations and Unions	9
Local NHS organisations	5
HIV/AIDS sector organisations	6
Other Third Sector organisations	2
Medical or dental Defence Organisations	2
TOTAL	**49**

Following analysis of the responses, a number of issues/concerns were identified. DH therefore subsequently sought further advice from the TWG at a meeting on 25 September 2012, and their advice is summarised as part of this overall response document.

iv. Key Findings

The responses varied in depth and emphasis on various points. However there was general consensus on the following:

- Overall support for the recommendations of the TWG for a change in policy on the management of HIV positive healthcare workers and the suggested implementation framework;
- The risk of HIV transmission from an infected healthcare worker during an EPP is extremely low/negligible, and being on combination antiretroviral treatment is likely to make the risk even lower;
- Whilst healthcare workers not on treatment should, in theory, be able to perform category 1 and 2 EPPs, for clarity and practicality there should be no sub-division of EPP procedures;
- There should be an initial period where all cases of HIV positive healthcare workers who wish to perform EPPs are notified to UKAP to ensure consistent application of the policy;
- UK-wide monitoring of this policy should be implemented if it is adopted; and
- In response to both the impact assessment and the equality analysis, there was strong opinion that more weight should be given to the impact of the reduction in stigma and discrimination, both in healthcare settings and in general, that a policy which follows the TWG's recommendations would engender.

The table below shows the percentage of responses that were in support, not in support or did not state an overall view for each consultation question.

Number of responses in support of view in consultation paper	Number of responses not in support of view in consultation paper	Number of responses that did not state an overall view
Q1: Support the tripartite working group's assessment of the risk of HIV transmission from an infected healthcare worker to a patient during exposure prone procedures.		
30 (85%)	**2 (6%)**	**3 (9%)**
Q2 (part 1): Assessment of overall risk of HIV transmission to a patient having an exposure prone procedure of the most invasive type from any healthcare worker.		
18 (95%)	**0 (0%)**	**1 (5%)**
Q2 (part 2): More likely that healthcare workers who think that they are at risk of infection may come forward for HIV testing, if TWG's recommendations are implemented.		
19 (54%)	**6 (17%)**	**10 (29%)**
Q3: TWG's recommendations supported by the available evidence about risk.		
29 (85%)	**1 (3%)**	**4 (12%)**
Q4: Suggested implementation framework strikes an appropriate and feasible balance between patient safety and the rights and responsibilities of HIV-infected healthcare workers.		
25 (66%)	**9 (24%)**	**4 (10%)**
Q5: Adjustments needed by occupational health services to support HIV-infected healthcare workers affected by these recommendations.		
-	**-**	**-**
Q6: Referral of all cases of HIV-infected healthcare workers who wish to perform exposure prone procedures to UKAP necessary to ensure consistency.		
21 (66%)	**5 (15%)**	**6 (19%)**
Q7: Patient notification exercises should only routinely take place in connection with untreated HIV-infected healthcare workers, unless patients may have been at risk of infection.		
24 (73%)	**6 (18%)**	**3 (9%)**
Q8: National monitoring of policy implementation at the NHS frontline.		
27 (79%)	**2 (6%)**	**5 (15%)**
Q9: Estimate of the number of healthcare workers who may be affected by the policy.		
14 (54%)	**6 (23%)**	**6 (23%)**
Q10: Consultation impact assessment accurately reflects the possible costs and benefits of the policy.		
7 (30%)	**13 (57%)**	**3 (13%)**
Q11: Draft equality analysis adequately assesses equality issues in this context.		
13 (59%)	**8 (36%)**	**1 (5%)**

v. Summary of Responses

This section is a summary of the responses, further expert advice and DH's response to each of the consultation questions. Not all respondents answered every question; some answered each question directly while others commented more broadly on the overall content of the consultation document. Only where indicated was further advice sought from the TWG.

The Tripartite Working Group's Assessment of Risk and Advice

Question 1: Do you agree with the tripartite working group's assessment of the risk of HIV transmission from an infected healthcare worker to a patient during exposure prone procedures?

Responses

The majority of respondents to this question (30/35) agreed with the TWG's assessment that the risk of HIV transmission from an infected healthcare worker during an EPP was extremely low/negligible. Some thought that being on combination antiretroviral treatment was likely to make the risk even lower than stated (Emily Hamblin, UNISON, Terrence Higgins Trust (THT)). There were comments from four respondents around gaps in the data such as the possibility of unknown transmissions and the current prevalence of HIV in healthcare workers, which has resulted in estimates being used. (Lay Advisory Committee, Royal College of Physicians (LAC RCP), Occupational Health Services, Doncaster and Bassetlaw Hospitals (OHS D&B), Society of General Microbiology (SGM) and the Health Protection Agency (HPA)). One further respondent questioned whether even a 'negligible' risk is acceptable (Society of Occupational Medicine (SOM)).

> *"The working group's assessment of the risk of HIV transmission appears thorough and based on the best available evidence."* - ***General Dental Council***

> *"The group has high-level expertise. This assessment involves an element of judgement and the judgements made appear reasonable. It is accepted that the risk is low."* - ***Avon Partnership NHS Occupational Health Service***

Department of Health position

The Department is content with the TWG's assessment of risk and notes that in the main, respondents agreed, with some considering the estimate to be over-stating the risk. Whilst we acknowledge there are some limitations to the data, there have only been four reported transmissions of HIV from infected and untreated healthcare workers worldwide, and none have been reported in the UK. This is despite over 30 UK patient notification exercises having taken

place with almost 10,000 patients tested, and national surveillance, which follows up on unexplained HIV diagnoses.

Question 2 (part 1): Do you have any comments on the Department of Health's assessment of overall risk of HIV transmission to a patient having an exposure prone procedure of the most invasive type from any healthcare worker?

Responses

Respondents mostly (18/19) supported DH's assessment of overall risk and many (10) considered that it was likely to have been overestimated. One respondent was uncertain whether the evidence (which is based on vertical or sexual transmission) could be generalised to exposure in the healthcare setting (joint response by The Association of National Health Occupational Physicians (ANHOPS),Faculty of Occupational Medicine, Society of Occupational Medicine, Health and Work Network Board/NHS Plus and Higher Education Occupational Physicians). Another respondent suggested that an independent statistical review of the risk analysis would provide more reassurance (LAC RCP).

> *"We consider the risk estimate to be reasonable. The evidence supports the assessment that the risk of HIV transmission from infected and untreated healthcare workers to patients during less invasive exposure prone procedure is negligible, and in the most invasive procedures is extremely low."* - ***British Medical Association***

> *"With the sole exception of the Acer case, in 20 years it would seem that even the most exposure prone aspects of dentistry have not been implicated in transmission of the retrovirus regardless of any variables associated with undiagnosed HIV status of the workforce during that time. The DoH assessment of risk might be considered cautious but none the less patient focused."* - ***Dental Protection Limited***

Department of Health position

The Department remains confident in its assessment of the overall risk. We acknowledge the remaining uncertainties around the estimate, however, such as the rate of HIV infection in healthcare workers and the number of currently undiagnosed healthcare workers that will come forward.

Question 2 (part 2): Do you consider it more likely that healthcare workers who think that they are at risk of infection may come forward for HIV testing, if the tripartite working group's recommendations were implemented, and do you have any evidence for this?

Responses

Whilst just over half of respondents (19/36) thought that it was more likely that those who may be at risk of infection would come forward for testing if the recommendations were adopted, some respondents considered that this was difficult to assess. Reasons included having to agree to continuous treatment and testing for the rest of their career (with the possibility of restrictions in the future); concerns over anonymity; lack of evidence for this change in behaviour, and the fact that it was already a professional duty for a healthcare worker to come forward if they considered that they might be at risk of infection.

> *"The Association considers it more likely that healthcare workers who think they are at risk of infection may come forward for HIV testing if the working group's recommendations are implemented.*
>
> *Anecdotal evidence for this is supported by published literature that cites a popular reason for healthcare workers not coming forward if they suspect they are infected, or are at a high risk of being infected, as concern over the impact a positive diagnosis would have on their career.*
>
> *Practitioners have palpable fears that they will be forced out of practice should they be found to be HIV positive and can feel they have no choice but to deliberately breach current guidance or face losing their livelihoods.*
>
> *Should one reason of concern practitioners have over being tested, or indeed reporting their status, be removed it is logical to believe that those who do not come forward due to this reason will now feel more confident that they can observe their duty of self-declaration to an occupational health physician without the fear of having all they have worked for being taken from them for a reason that is at odds with contemporary medical opinion and has no scientific basis."* - ***British Dental Association***
>
> *"These recommendations should encourage healthcare workers not only to come forward but also to adhere strictly to treatment regimes. Indeed, it may be hoped that it will help to reduce the stigma of HIV and testing both within the healthcare environment and more widely."* - ***Royal College of General Practitioners***
>
> *"Removing a blanket ban on all HIV-positive healthcare workers being able to perform exposure-prone procedures might perhaps lessen the likelihood of individuals ignoring their risk factors for infection, but there is no evidence to support this view."* - ***Society for General Microbiology***

Department of Health position

The Department acknowledges that it is not possible to say definitively whether implementing the TWG's recommendations would result in more healthcare workers coming forward for HIV testing. We agree that it is possible that some of the reasons for not coming forward, which are mentioned in the consultation responses, may continue to influence some healthcare workers at risk of HIV infection. However, we believe it is fair to suggest that since the revised policy would

no longer automatically signal the end of a chosen career for a healthcare worker who performs EPPs, it would make it more likely that individuals at risk would come forward to protect both their own health and that of their patients.

Question 3: Are the tripartite working group's main recommendations supported by the available evidence about risk?

Responses

The majority of respondents (29/34) agreed that the available evidence on risk supported the recommendations. Several respondents (all using a template response originating from the National AIDS Trust (NAT)) pointed out that healthcare workers not on treatment should, in theory, be able to perform category 1 and 2 EPPs. However, they were convinced by the argument around the possibility of a category 2 EPP escalating to category 3 and therefore were supportive of the recommendation for a uniform approach to all EPPs. Two respondents (Dental Protection Limited (DPL) and Bindmans) felt that an exception should be made here for dentists, and this was put back to the experts for consideration (see below). One respondent (British Dental Association (BDA)) noted the findings of the 6th World Workshop on Oral Health and Disease in AIDS in April 2009, which concluded that oral healthcare professionals with HIV did not pose a risk of transmission to patients in the dental setting provided that they were under suitable on-going care, remained aware of their health status, and observed infection control procedures. One respondent felt that there was insufficient evidence to support the recommendations (OHS D&B).

> *"The evidence suggests that HIV-positive healthcare workers not yet on ART should be able to perform category 1 and category 2 procedures. However, the evidence put forward for not distinguishing between the different categories because of the difficulty in predicting when a category 2 exposure prone procedure may become a category 3 procedure, is persuasive and we support the group's recommendation.*
>
> *However, we would urge that this policy and the categories themselves are kept under review, to ensure consistency with current practice and based on accurate risk assessment."* - ***UNISON***
>
> *"THT is confident that the tripartite working group has carried out a thorough investigation of the evidence. We believe that their recommendations are proportionate and warranted. We also consider that the group has prioritised patient safety and has based its recommendations on a weighted interpretation of the evidence around risk."* - ***Terrence Higgins Trust***

Expert advice

There were two main points raised on risk that required clarification from the TWG:

1. Two respondents (DPL and Bindmans, which responded on behalf of a dental healthcare professional with HIV) outlined a less restrictive approach that they believe should be applied to general dental practitioners. They proposed that:
   - HIV-positive primary care dental practitioners should be allowed to perform category 1 and 2 EPPs with no restrictions
   - HIV-positive dental practitioners should be allowed to perform category 3 EPPs provided that their viral load is undetectable.

They commented that the TWG's reasons for not adopting a more flexible approach (ie difficulty in categorising EPPs) did not apply to the practice of primary care dentistry and that the restrictions proposed in the TWG's recommendations would have a greater impact on dental practitioners and their livelihoods than other healthcare specialities.

2. DPL made several references to the risk of HIV transmission from an infected healthcare worker to a patient, with the risk in a category 1 or 2 EPP being 'negligible'; and suggested therefore they should be able to undertake category 1 and 2 EPPs without the need for monitoring and treatment. DPL noted in particular that current guidance on patient notification exercises (PNEs) regarded it as usually necessary to conduct a PNE only where there had been a category 3 EPP carried out. ANHOPS et al joint response also noted that the TWG report made mention of negligible risk and considered that it required clarification.

The TWG advised that the risk of HIV transmission from an untreated HIV positive healthcare worker during category 1 or 2 EPPs was considered negligible as far as could be assessed from available evidence. However, there remained a risk and the implications for patients, were they to become infected, were very serious. Having an undetectable or very low viral load was the key factor in reducing the risk of transmission to patients during EPPs, which could be achieved by combination antiretroviral therapy (cART) (apart from rare cases in which the healthcare worker had a naturally low viral load that was sustained).

PNEs are not routinely carried out for patients who have had category 1 or 2 EPPs performed by an HIV positive healthcare worker, due to the low level of transmission risk when viewed relative to the psychological impact a PNE may have on the patients notified. However "cross-matching" of patient records is usually undertaken, with HIV diagnoses in the relevant geographical area and time period being compared with the list of patients treated by the healthcare worker to identify any possible transmissions. This is because there remains a risk of transmission and a consequent duty of care. It was recommended that this process should continue in future where untreated HIV positive healthcare workers have carried out only category 1 or 2 EPPs.

As the TWG pointed out in its report, its assessment of risk of HIV transmission from untreated HIV positive healthcare workers to patients had data limitations in relation to PNEs carried out in

the UK. These limitations included the proportion of patients tested for HIV (only 37% overall in 34 UK PNEs), and the fact that where it was unclear how long the healthcare worker had been infected, some patients tested through PNE may have been treated before the healthcare worker had acquired HIV infection. Because of these limitations, a cautious approach should be adopted.

DPL had misunderstood UKAP's advice on the risk of HIV transmission to patients if healthcare workers with HIV are bitten by them. This advice relates to specialties other than dentistry where healthcare workers may be at risk of biting, such as in mental health services or accident & emergency. It was agreed that dentists are not at a greatly increased risk of being bitten. However, where dentists infected with blood borne viruses use sharp dental instruments in the mouth there is an increased risk of an injury such as a cut finger occurring, and this could allow contaminated blood to be introduced into a patient's mouth during treatment.

The recommendation for all healthcare workers with HIV to be on cART (apart from rare cases in which they have a naturally low viral load that is sustained) was based on what the TWG considered was justified "by the available evidence and what was practicable". It was not solely related to issues of practicability, such as categorising EPPs and situations where category 1 or 2 EPPs may escalate to category 3 because of complications, but also to what is known about risks of HIV transmission from infected healthcare workers to patients.

The TWG acknowledged that there may be some practical difficulties for newly diagnosed HIV positive general dental practitioners or those who may experience significant increases in viral load once on cART, if the TWG's recommendations were implemented (eg potential temporary disruption to the practitioner's services). However, the proposed new policy would represent a significant shift to the advantage of all HIV positive healthcare workers who do EPPs and allow them to continue their careers.

Department of Health position

The Department accepts the expert advice on this issue. Whilst the risk of transmission may be considered 'negligible' or 'very low', there still remains a risk to patients if HIV positive healthcare workers are permitted to perform any category of EPP and it is imperative that this risk is minimised as much as possible. Whilst the Department is keen to advance the opportunities for healthcare workers with HIV by allowing them, where possible, to perform EPPs, it is of the utmost importance that this is not achieved at the expense of patient safety.

Suggested Implementation Framework

Question 4: Does the suggested implementation framework strike an appropriate balance between protecting patient safety and acknowledging the rights and responsibilities of HIV-infected healthcare workers, and is it feasible?

Responses

25 of the 38 responses to this question said that the suggested implementation framework struck an appropriate balance. Nine respondents did not agree, and thought that the requirement for three-monthly testing was burdensome, and a requirement to start HIV treatment before it was clinically indicated raised other issues such as going against the principle of treatment for clinical need and being discriminatory. Several respondents queried the position of HIV positive healthcare workers whose viral load was naturally below the suggested threshold. One respondent also raised the issue of elite controllers or long-term non-progressors.

Some feasibility concerns were raised around healthcare workers with HIV (in particular dentists) choosing to practice only in the private or independent sector, with the aim of avoiding scrutiny; ensuring a healthcare worker ceased practicing if their viral load increased; and maintaining a healthcare worker's confidentiality.

"Yes – patients have the right to expect safety from infection, but healthcare workers also have the right to practise without discrimination when the risk is assessed as low. By having a national policy, both these rights are openly addressed." - ***Royal College of General Practitioners***

"Regular testing of HIV viral load is an appropriate method to minimise risk to patients. Initial testing to ensure 2 consecutive viral load tests 3 months apart is a reasonable requirement to allow a HIV infected HCW to commence/resume EPP.

We feel that proposals should not place an onerous burden on already stretched occupational health services. We believe more evidence about the risk associated with specific ranges of viral loads may be necessary to help in the analysis of the frequency of testing that strikes the balance between risk, invasive testing of the infected HCW and the additional demands upon OH services." - ***The Association of NHS Occupational Health Nurses***

"Yes, and implementation will be feasible if good monitoring is in place.

Clarification would be required however on individuals whose viral load is less than 200 copies/ml but who are as yet untreated with anti-viral therapy because it is fairly early following diagnosis. If these individuals are under the treatment of a consultant and the control measure of joint review between OH and the treating clinician can be met, then consideration needs to be given as to why these individuals are different to those who have

commenced treatment. Taking a different approach to such individuals could force practitioners into early and unnecessary drug therapy to ensure that their careers are protected." - ***North West Ambulance Service***

Expert advice

There were a number of points raised around viral load and clearance for EPPs that were referred to the experts for advice:

1. The accepted viral load for allowing an HIV positive healthcare worker to perform EPPs should read as 200 and below, rather than below 200, to avoid confusion about the inclusion of 200 (ANHOPS et al joint response).
2. There were three objections to the 200 copies/ml threshold for clearance for EPPs (DPL/Bindmans, Dr Evans and NAT): one suggested that the threshold should be less than 50 copies/ml, and two suggested that it should be 500 copies/ml.
3. 'Significant rise' in HIV viral load needed to be more clearly defined, as 201-1,000 was large and could lead to a variation of practice (ANHOPS et al joint response).
4. Clarification was needed on the definition of 'stably returned to below 200 copies/ml following a rise in viral load' (Avon OHS).
5. Detailed guidance should be provided on how to deal with interruptions in treatment (Avon OHS, ANHOPS et al joint response, Defence Medical Services and HPA).
6. How should blips in viral load test results be dealt with? For example, TaqMan Assay blips and general variability in test results.
7. The issues raised around the requirement for a healthcare worker to commence cART before it was clinically indicated included:
    - It was discriminatory
    - It undermined the principle of treatment according to need
    - It might not be feasible in practice (some health authorities also restrict commencement of HIV treatment until a certain viral load/T cell trigger has been achieved, on financial grounds)
    - It was not clear what would happen if those for whom commencement of treatment was not clinically indicated refused to commence treatment (DPL, British Medical Association (BMA), Dr McIlwain**,** Consultant in clinical risk management, and the Association for Perioperative Practice (AfPP)).

The TWG agreed that a pragmatic approach was required to enable the policy to work in practice. Whilst many of the protocols for the clinical management of individuals with HIV should be used where possible, it was important to consider that the purpose of a new policy would be to minimise the risk of transmission to patients. Parameters around viral load were agreed by the TWG for a practicable approach to the clearance of HIV positive healthcare workers to undertake EPPs (see Annex C).

The TWG considered that diarrhoea was a common side effect of antiretroviral medication and was not known to have an adverse effect on viral load, but that prolonged episodes should be reported to the treating physician. They also considered that vaccination and inter-current illness would have no significant effect on viral load. If a healthcare worker interrupted treatment due to severe illness or for any other reason, EPP clearance should be revoked until the viral load had been re-assessed.

The TWG agreed that all HIV positive healthcare workers who wished to perform EPPs should be required to be on cART. This was considered justifiable as this was the approach that already applied to hepatitis B-infected healthcare workers who perform EPPs, and was recommended for serodiscordant couples to reduce HIV transmission risk. In addition, according to current UK data half of all newly diagnosed HIV patients will have a CD4 count below the threshold currently recommended for commencement of cART (less than 350 cells/mm^3), although the proportions vary by risk group. Therefore, it was possible that a similar proportion of newly diagnosed HIV positive healthcare workers would need to be on cART for clinical reasons[3].

There were 2 issues raised around monitoring that were referred to the experts for advice:

1. Would six-monthly testing be sufficient? Some respondents (Avon OHS, ANHOPS et al joint response, the Association of NHS Occupational Health Nurses (ANHONS), National Lesbian, Gay, Bisexual and Trans Gender Partnership (LGB&T)) felt that three- monthly testing was too burdensome and would create additional costs.
2. Who should take responsibility for monitoring the healthcare worker – the treating physician or the occupational health physician? How would joint supervision work in practice? Who would be better equipped to take samples? (ANHOPS et al joint response, Mona Guckian Fisher.)

It was agreed by the TWG, as proposed in the original TWG report, that for the purposes of monitoring, an HIV positive healthcare worker's viral load should be measured every three months. Whilst this was more frequent than was required for routine HIV care, its purpose was to assure patient safety. It was noted by the TWG that information gathered through central monitoring to evaluate the effectiveness of the policy might, over time, indicate that a less frequent testing interval was acceptable. However, any change to the recommended three-monthly testing interval would be as part of a review of the policy, and should not be applied on an individual basis.

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[3] Health Protection Agency. HIV in the United Kingdom: 2011 Report. London: Health Protection Services, Colindale. November 2011 - www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1317131679504 [accessed 13 August 2012]

All HIV positive healthcare workers that did EPPs should be monitored by both their treating physician and occupational health physician, and effective monitoring would require close working between these two parties to ensure that the policy was being followed correctly. However, the TWG did not think it was necessary to stipulate how this relationship would work in practice and considered it more appropriate for this to be determined locally for each case.

Department of Health position

The Department agrees that a pragmatic approach will need to be taken when applying a policy that allows healthcare workers with HIV to perform EPPs subject to certain safeguards. The parameters for EPP clearance that have been recommended by the TWG are set out in Annex C and these should be used to assist in the formulation of any new guidance. The Department accepts the advice of the TWG that viral load testing for HIV positive healthcare workers carrying out EPPs should be at three-monthly intervals to protect patient safety, and that decisions on how effective joint monitoring will work best should be made at a local level. With regard to elite controllers and non-progressors, EAGA has previously advised that this is a rare phenomenon. However, this issue should be addressed in any new guidance, which should recommend that healthcare workers to whom this applies should be referred to UKAP for advice on a case-by-case basis.

Question 5: What adjustments will occupational health services need to make to support HIV-infected healthcare workers affected by these recommendations?

Responses

There was a range of suggestions. Several respondents felt that occupational health (OH) should ensure that the burden for the healthcare worker was reduced as far as possible through minimising the time they needed to spend away from their job. It was thought that processes and procedures needed to be defined in any guidance for the following:

- monitoring and support of the healthcare worker
- what to do in the event of an exposure
- communication between the treating physician and OH etc
- whether these protocols should be determined on a local or national basis.

It was suggested that there were already systems in place for the management of hepatitis B infected healthcare workers and that these could possibly be adapted for HIV.

Several respondents stressed the need to ensure that OH departments were sufficiently resourced to be able to offer the support and quarterly testing required by healthcare workers with HIV, and the possible need for additional training in the management of HIV positive healthcare workers. One respondent was keen that arrangements for private, agency and locum workers were considered.

Several respondents felt that OH staff would require additional training to some extent on HIV. Areas where it was thought that training would be needed included:

- Understanding about the risk of transmission and the rationale for the new policy
- How HIV care is provided in the UK, including understanding of treatment and viral load etc
- How to work with the treating physician and how to support healthcare workers in adhering to monitoring arrangements
- Confidentiality (NAT, Royal College of Physicians (RCPh), SGM, THT.)

"It would help if the regular assessment of viral load could be done as quickly as possible and at a convenient time and place for the healthcare worker (possibly at a weekend) and at fixed intervals that can be diarised in advance in order not to cause any excessive time away from the surgery." - ***Dental Protection Limited***

"Effective occupational health support is essential (good record keeping, competent staff). NHS occupational health services must be effectively resourced to enable them to fulfil their role in managing HIV infected health care workers.

The RCN receives regular comments from members on the variability of support services for staff who are, or may be HIV positive. Whilst it is acknowledged that large cities are likely to have more resources to provide emotional support for staff this is not felt to be the case in other geographic regions, particularly rural areas. Investment in occupational services would help to support these staff and reduce current inequalities in services to staff." - ***Royal College of Nursing***

"It is important to realise that this would have training implications for occupational health units." - ***Royal College of Physicians***

Expert advice

The TWG did not believe that the proposed new policy would have a significant resource impact on OH departments, as there would be only a small number of healthcare workers affected. Similarly, training needs would be minimal, as many OH departments would need to apply this policy only rarely, and a small national panel comprising OH and HIV experts would be established for consultation on complex cases (see Annex C).

Whilst there was some concern over the provision of OH services for general practitioners (GPs), dentists and their staff across the UK (outside England), it was stressed that it was ultimately the responsibility of the healthcare worker to seek out appropriate OH support if they required it.

Providers using locums and agency staff are ultimately responsible for making sure that individual workers have the necessary health clearance to do EPP work. On a similar note, when a healthcare worker changes jobs, it is the responsibility of the receiving OH department

to ensure that the healthcare worker has the necessary health clearance. However, it was suggested by the TWG that this process could be made easier if the OH department of the receiving Trust was informed of the healthcare worker's health clearance status by the previous Trust. The TWG considered it the responsibility of the healthcare worker to inform their OH department that they were changing jobs and give their consent to supplying the new Trust with the necessary documentation. It was suggested that, for junior doctors on rotation, health clearance should be carried out by a lead department, to prevent the need for screening before each placement.

Department of Health position

The Department considers that implementation of the TWG's recommendations would not require a disproportionate amount of additional resources or adjustments for OH services. Because of the small number of healthcare workers that are likely to be affected, individual OH departments will only rarely be required to apply this policy, and will do so in conjunction with an HIV physician. It is acknowledged that access may be more difficult for those who do not have in-house OH, for example GPs and dentists, although ultimately it is the responsibility of the individual healthcare worker to seek out appropriate OH services if they need them.

Healthcare providers are already responsible for ensuring that healthcare workers working within their organisations, including agency and locum workers, have the necessary clearance to perform EPPs. This could potentially become easier under a policy that requires the continuous monitoring of a practicing HIV positive healthcare worker.

Consultation question 6: Is referral to the UK Advisory Panel for Healthcare Workers Infected with Blood-Borne Viruses (UKAP) of all cases of healthcare workers infected with HIV who wish to perform exposure prone procedures whilst on combination antiretroviral drug therapy necessary to ensure consistency in the application of the policy and to help promote best practice? If so, for how long should this continue?

Responses

21 of 32 respondents thought that there should be an initial period when all cases were referred to UKAP. Suggestions on how long this should continue for ranged from 1-2 years to indefinitely. However, most respondents who specified a time period said three years or shorter. Some respondents thought only those cases where further advice was required should ever be referred to UKAP.

Other respondents thought referring all cases would make it unclear whether the ultimate responsibility for decisions regarding the management of individual HIV positive healthcare workers would lie locally, or with UKAP. There was also some concern around the response

times of UKAP and how this could result in unacceptable delays in individuals being cleared for practice.

> *"Referral of all cases to UKAP in the initial rolling out of this new framework would ensure that the policy is properly applied and would reduce any potential resistance to implementing the new regime. It would also allow UKAP to monitor the application of the framework and share best practice."* - ***All Party Parliamentary Group on HIV and AIDS***
>
> *"Would be good practice to do so but there would be concerns regarding this process, however, unless there is a fundamental change in the responsiveness of UKAP. The experience of our Trust is that requests for advice made in HIV cases on our behalf by our occupational health provider, have often taken a significant amount of time to receive a response (in some cases up to 3 months). Using this process in the case of staff who meet the requirements set out in the consultation could mean an unacceptable delay in those individuals being able to practice, this could mean periods of sickness absence to be covered by trusts and it could also lead to the need for either explicit or deductive disclosure of the individuals condition. A system of notification running in parallel with local management of cases, rather than approval, would be more manageable."* - ***North West Ambulance Service***
>
> *"The problem about requiring referral to a national system but at the same time stating that decisions should be made at local level is that it could lead to ambiguity or confusion about who is ultimately responsible for the decision to permit the healthcare worker to undertake exposure prone procedures."* - ***Health Protection Agency***

Expert advice

The experts were asked to clarify the following two points:

- If decisions on individual healthcare workers were to be a local responsibility, what exactly would be UKAP's role? (HPA, Higher Education Occupational Physicians (HEOPS)[4] and Avon OHS)

- Given that UKAP only meets periodically and response times can be up to several months, how would UKAP process these referrals to ensure minimum delays in a healthcare worker being declared fit for practice? (North West Ambulance Service (NWAS), Royal College of General Practitioners (RCGP) and Avon OHS).

The TWG agreed that for the first two years of the policy, UKAP should be notified and provided with details of all cases of HIV positive healthcare workers who wished to carry out EPPs. This would provide useful oversight to ensure consistent application of the policy and good practice.

[4] HEOPS responded as part of a joint response from *ANHOPS, FOM, SOM, NHS Plus and HEOPS, however in some instances additional individual comments from HEOPS were provided.*

Decisions on the management of individual healthcare workers would remain a local responsibility. However, UKAP would provide advice on individual cases when requested.

Department of Health position

The Department agrees that UKAP should be notified of all cases involving healthcare workers with HIV who wish to perform EPPs for two years, to ensure consistent application of the policy. Whilst it is important that UKAP should be called upon for advice on the application of the policy as needed, decisions to clear individual healthcare workers for EPP work will ultimately remain the responsibility of the treating and occupational health physicians. In order to ensure that response times from UKAP - from the time of initial request for advice to resolution - are kept to a minimum, local teams requesting advice must ensure that UKAP are provided with as much information as possible at the time of submitting the request.

Consultation question 7: Do you agree that, if the tripartite working group's recommendations are implemented, patient notification exercises should only routinely take place in connection with untreated HIV-infected healthcare workers, as advised in current national guidance, unless patients may have been at risk of infection eg because of an increase in a healthcare worker's viral load?

Responses

24 of the 33 respondents to this question agreed with the proposal outlined. Some respondents (NAT-based responses) thought that a PNE should only be carried out if viral load was over 1,000 copies/ml. The HPA also commented that 200 copies/ml was a low trigger, and that the decision to undertake a PNE should be a local decision based on viral load and 'other factors'.

Two respondents thought that PNEs should be undertaken for all HIV positive healthcare workers so that the information collected could provide additional information on risk. HPA suggested that the criteria for undertaking a PNE as proposed should be developed further, and a PNE carried out only where there had been probable iatrogenic healthcare worker-to-patient transmission, as is the case for hepatitis B and C.

Several respondents commented that the proposed arrangements for managing healthcare worker-to-patient blood exposure incidents were unsatisfactory and inconsistent with current advice.

> *Patient notification exercises involving treated HIV positive healthcare workers would create unnecessary anxiety and stress and waste NHS resources. They would also needlessly compromise HIV positive healthcare workers confidentiality.*
>
> *Even if it is discovered that an HIV positive healthcare worker has inadvertently put people at risk by operating with a viral load above 200copies/ml, a patient notification exercise*

should only be carried out if there is a real risk of infection (eg viral load over 1,000 copies/ml).” - ***National Lesbian, Gay, Bisexual and Transgender Partnership***

Expert advice

The experts were asked to respond to comments that the currently proposed management of healthcare worker-to-patient blood exposures was inappropriate and inconsistent with current arrangements. Whilst in the main the proposed arrangements for managing a blood exposure would remain unchanged, current guidance does not provide advice for the scenario where exposure was to blood from a healthcare worker known to be HIV positive, on treatment, with a suppressed viral load and being regularly monitored.

Current guidance recommends that if a healthcare worker tests positive for any blood-borne virus, the patient should be notified of an intra-operative exposure. However, this guidance assumes that the healthcare worker was previously undiagnosed and not on treatment. The proposed management of healthcare workers who are diagnosed and cleared for EPPs, subject to the safeguards set out above, does not recommend that the patient should be notified of the exposure. A possible exception to this might occur if a detailed risk assessment, including consideration of the healthcare worker’s latest viral load measurement and historical context, indicated the need for an urgent viral load test.

It is expected that this will only be necessary in exceptional circumstances, as the healthcare worker would have been cleared for EPP work on the basis that they were not considered to pose a risk to patients.

The TWG was also asked to provide advice on the inconsistency between the proposed management of healthcare worker-to-patient exposure from a source with an undetectable viral load, and current advice on exposure of a healthcare worker to an undetectable source patient. EAGA had previously advised that, whilst post-exposure prophylaxis (PEP) was not routinely recommended where a healthcare worker had been subject to such exposure, they did recommend follow-up testing at three months as a sensible precaution and to reassure the worker. However, the proposed management of such exposures from healthcare worker-to-patient would not require informing the patient of the incident (in the case of those that happen whilst they are unconscious) and the offer of routine follow-up testing.

The TWG considered that, whilst the risk of HIV transmission was the same in both instances, a healthcare worker may, after an exposure, suffer psychological anxiety that a patient who was unaware of the incident and/or the HIV status of the healthcare worker would not. It would also be diligent for an employer to provide follow-up testing to the healthcare worker, because of their obligation to protect their employees from occupational hazards and from a future patient safety point of view. However, the advice was clarified that neither PEP nor HIV testing at three-month follow-up was *necessary* for either healthcare workers or patients exposed to a source with an undetectable viral load.

Department of Health position

The Department accepts the TWG's recommendations regarding patient notification exercises, and the further expert advice on the comments surrounding the inconsistencies between the proposed management of blood exposure incidents and current guidance.

Consultation question 8: Is national monitoring of policy implementation at the NHS frontline necessary? If so, how should it be done most effectively and proportionately, and what might be the cost implications? Is it appropriate or feasible for local occupational health services to submit local information about HIV-infected healthcare workers to the Health Protection Agency to allow national surveillance of policy?

Responses

27 of 34 respondents to this question commented that it would be a good idea to implement national monitoring of this policy, if adopted, across the whole healthcare sector (eg NHS, private sector and students), and that local information should be submitted to the HPA (now Public Health England)/UKAP for this purpose with appropriate safeguards for protecting confidentiality.

Two points were raised which should be taken into account if/when a monitoring system was established. These were that input from OH should be sought (Avon OHS, ANHOPS et al joint response), and that any monitoring system should allow for input from the independent healthcare sector (DPL, HEOPS, Independent Healthcare Advisory Service (IHAS)).

> *"We agree that the implementation of the recommendations should be monitored. This is likely to be achievable through a national data base/registry and regular monitoring of data. We believe that the registry should be developed under the leadership of occupational health experts and hosted by UKAP/HPA."* - ***Joint response from the Association of National Health Occupational Physicians, Society of Occupational Medicine, Health and Work Network Board, NHS Plus and Higher Education Occupational Physicians.***

> *"The importance of surveillance is recognised and supported in this context and, assuming their functions are not undermined by the current NHS reorganisation, the Health Protection Agency/Public Health England would be best placed to undertake this. Maintaining appropriate levels of confidentiality will be crucial if the trust of HCWs is to be maintained. Mechanisms for anonymisation of data, relating both to the personal details of the HCW and to the healthcare organisations in which they work, will be required within a surveillance system."* - ***British HIV Association***

Department of Health position

The Department agrees that there should be national, or UK-wide, monitoring of the new policy. Public Health England (PHE) have agreed to establish and run a confidential database, to which

OH providers can confidentially submit information about individual healthcare workers doing EPPs and their viral load monitoring information. PHE will seek input from OH specialists when designing the database, and explore the mechanisms needed to allow input from the independent healthcare sector. Costs of establishing and running the database will be met by PHE and have been used in the impact assessment, which has been published alongside this document.

Consultation question 9: Does the estimate of the number of healthcare workers who may be affected by the policy seem reasonable? Is there further information that consultees can provide and/or are there further sources of information that the Department should consult?

Responses

14 of 26 respondents to this question considered that the estimate was reasonable, based on the available evidence. Some believed that if the policy were changed, there would be an increase in the number of diagnosed HIV positive healthcare workers. One respondent said this was because more of those at risk would come forward (ANHONS) and three further respondents said this was because those who have moved abroad to continue practising may return to England/UK (ANHOPS et al joint response, South East London Dental Infection Control Committee (SE London), DPL).

> *"The method used to estimate the number of healthcare workers who will be affected by the policy in the future seems reasonable. We welcome the use of HPA prevalence rates to calculate this figure. We are not aware of a better source of information that could be used, though this figure may over estimate the number of healthcare workers affected as it assumes that the HIV prevalence amongst health care workers who perform exposure prone procedures will be the same as amongst the general public - evidence presented in the expert report suggests it may in fact be lower."* - ***National AIDS Trust***
>
> *"This is difficult to estimate. HCWs constantly move internationally and NHS certainly has a sizable number of foreign HCWs. It is therefore difficult to simply use the general population HIV incidence but we realise this is probably the only practical way.*
>
> *Additionally, some of the HCWs already diagnosed with HIV and inhibited from undertaking EPP have already migrated to other countries where they can practice. With a change in the policy there might be an influx of these HCWs and therefore the impact might be larger than expected."* - ***Joint response from the Association of National Health Occupational Physicians, Society of Occupational Medicine, Health and Work Network Board, NHS Plus and Higher Education Occupational Physicians.***

Department of Health position

The estimate of 110 healthcare workers was based on the assumption that the prevalence of HIV in the NHS workforce is the same as that in the general population. Whilst we accept that this assumption may not be entirely accurate, the Department is content that the estimate has been made using the best available evidence. We have not been made aware of any further sources of information through the consultation responses that will give a more accurate picture.

Consultation question 10: Does the consultation impact assessment accurately reflect the possible costs and benefits of the policy were it to be implemented? Is there further information that consultees can provide and/or are there further sources of information that the Department should consult?

Responses

7 of 23 respondents to this question felt that the costs and benefits of the policy were accurately reflected in the impact assessment. Four respondents considered that some of the costs set out in the impact assessment had been under-estimated. These included the estimate of £83 per hour for an OH consultant's time, and the other costs of monitoring the healthcare worker eg blood tests. In addition, the costs to the employer to release the employee for monitoring purposes and any absence due to viral load increase etc had not been factored in (Mona Guckian Fisher, AfPP, ANHOPS et al joint response, OHS Bristol). Nine respondents (NAT template-based responses) consider that the assessment failed to take into account the benefit of earlier testing in relation to onward transmissions through sexual contact. They also considered that the gain in terms of reducing stigma in healthcare settings should be included in the impact assessment.

One respondent commented that despite the low costs, the new policy would be a hard sell to the public in the current economic climate (RCP LAC), whilst another respondent considered the modest costs far outweighed the 'damage done' by the existing policy (DPL). A further respondent thought there was little information in the impact assessment about cost implications (East of England Ambulance Service (EEAS)).

Sources of further information suggested included Trusts which have conducted PNEs, which may be able to provide information on costs to reputation and distress to those contacted, and HIV charities that have been involved with healthcare workers with HIV.

> *"We feel there has been an underestimation of costs. At least two consultants will be involved in managing one case; HIV specialist and consultant in occupational medicine but it has been costed as one "medical consultant". The time required for each case at least for occupational medicine consultant is likely to be more than 2 hours per year considering huge amount of administration required. This would be significantly more if there is a complication or BFE.*

Consultant time is costed at £83 an hour. This is an underestimate of current charges especially for OH services that buy in consultant time.

Cost of tests, liaising with other specialists, collection of bloods, cost of time to the employer to release the employee for monitoring purposes and cost of absence due to side effects appear not to have been factored in." - ***Joint response from the Association of National Health Occupational Physicians, Society of Occupational Medicine, Health and Work Network Board, NHS Plus and Higher Education Occupational Physicians.***

"The impact assessment refers to the 'equity gain' for HIV positive healthcare workers who would be able to continue to perform exposure prone procedures. The assessment does not consider the wider gain in terms of reducing HIV related stigma more generally in healthcare settings. The current ban and misplaced fear about HIV transmission in healthcare settings has generated a lot of fear and discrimination, both against HIV positive healthcare staff and HIV positive patients. Removing this ban would have a positive impact, reducing fear amongst healthcare staff about HIV and the potential for transmission in a healthcare setting (though more work and education about HIV is required for healthcare workers)." - ***National AIDS Trust***

Department of Health position

The Department has taken on board comments relating to the cost of an OH consultant's time and the cost to employers of releasing the employee for monitoring purposes, and factored these into the costs in the impact assessment that has been published alongside this document. Overall costs of implementing a new policy based on the recommendations of the TWG are minimal. As previously stated, the HPA has also provided the costs relating to setting up and maintaining a database for central monitoring of the policy.

Consultation question 11: Does the draft equality analysis adequately assess equality issues in this context? Is there further information that consultees can provide and/or are there further sources of information that the Department should consult which may be relevant to the draft equality analysis?

Responses

13 of 23 respondents supported the equality assessment. However, eight respondents (the NAT template-based responses) did not agree that the overall impact of a change in policy for HIV positive healthcare workers would be small just because of the small number of people that would be affected. They felt that this would have a much larger positive impact on stigma and discrimination. These respondents and one other (All Party Parliamentary Group on HIV and AIDS) also made the point that retaining the current policy would be discriminatory and open to legal challenge. One respondent (NWAS) considered that adopting the recommendations would reduce the risk of disability discrimination-related challenges to Trusts, which may occur in light of the TWG's advice.

“This adequately assesses equality issues. The main effect is likely to be a positive impact on health care workers with disabilities (HIV positive HCWs).” - ***Avon Partnership NHS Occupational Health Service***

“In the section on the overall impact, the analysis states "the overall impact for HIV-infected healthcare workers would be relatively small because of the low numbers affected." We would argue that this fails to assess the huge impact on individual HIV positive healthcare workers and the wider impact on stigma and discrimination of the removal of the ban. As noted above many people living with HIV face stigma and discrimination in healthcare settings partly because of irrational fear from healthcare practitioners about transmission of the virus. Removing the ban would be an important step in reducing stigma and discrimination by making it clear that there is virtually no risk of HIV transmission in a healthcare setting. It would also send out an important message to people living with HIV, that policy related to HIV is based on evidence and risk, and not irrational fear and stigma.” - ***National AIDS Trust***

Department of Health Position

The Department is content that the equality assessment that has been published alongside this document reflects the equality issues in this context. It is agreed that the overall impact of the new policy on equality will be beneficial; in particular, that it will advance equality of opportunity for healthcare workers with HIV infection. Further to the comments received, emphasis on the impact on individual healthcare workers in the impact assessment has been strengthened.

vi. Conclusions and Next Steps

Conclusions

The Department would like to thank all of the individuals and organisations that responded to the consultation, and to the TWG for their continued expert advice.

The range of perspectives from different sectors that have been provided in the responses has been helpful. The specific issues raised that we have taken back to the TWG for clarification and further advice are particularly appreciated, as this has enabled us to be thorough and confident when making decisions on the future management of healthcare workers with HIV.

Overall, the responses to the consultation were supportive of the TWG's advice. Whilst there were some issues or concerns raised, these were mostly of a technical nature and have been resolved by obtaining further expert advice.

The Chief Medical Officer and Ministers have agreed to accept the advice of the TWG, that current restrictions on HIV positive healthcare workers performing EPPs should be lifted, provided that healthcare workers are on effective combination antiretroviral drug therapy, with a very low or undetectable viral load, and are regularly monitored by both their treating and OH physicians.

Next Steps

The Department has asked PHE to produce guidance for the NHS to implement the change in policy, and to establish a centralised database to monitor healthcare workers with HIV.

vii. Annex A – List of Organisations that were directly alerted to the consultation

The Academy of Medical Royal Colleges

The African Health Policy Network

The Advisory Group on Hepatitis

The Association of Professional Ambulance Personnel

The Association of Directors of Public Health

The Association of UK University Hospitals

The Association of Occupational Health Nurse Practitioners

The British HIV Association

British Dental Association

British Medical Association

British Infection Association

Care Quality Commission

The College of Emergency Medicine

Dental Professionals Association

Doctors.org.uk

The Dental Schools Council

Equality Human Rights

Essex Health Protection Unit

The Expert Advisory Group on AIDS

Faculty of Occupational Medicine

Faculty of Public Health

Feedback London

GMB

The General Medical Council

The General Dental Council

The Health and Safety Executive

The Health Protection Agency

Heart of England NHS Foundation Trust

Kings College London

The Medical Defence Union

Medical Protection Society

Medical Foundation for AIDS and Sexual Health

Medical Protection Society

Medical Schools Council

Monitor

Newcastle Hospitals NHS Foundation Trust

National Patient Safety Agency

The National AIDS Trust

The National Institute for Health and Clinical Excellence

NHS Plus

NHS Employers

NHS Professionals

The NHS Confederation

The Nursing and Midwifery Council

The Patients Association

Queen Mary University of London

The Royal Society of Medicine

The Royal College of Pathologists

The Royal College of Ophthalmologists

The Royal College of Obstetrics and Gynaecology

The Royal College of Psychiatrists

The Royal College of Paediatrics and Child Health

The Royal College of Nurses

The Royal College of Midwives

The Royal College of General Practitioners

The Royal College of Anaesthetists

The Royal College of Surgeons of England

The Royal College of Physicians

The Royal College of Radiologists

The Society of Occupational Medicine

The Terrence Higgins Trust

University Occupational Health Service

Unison

Unite the Union

Universities UK

University Hospitals Birmingham

The UK Advisory Panel for Healthcare Workers Infected with Blood-Borne Viruses

viii. Annex B - List of Respondents

Members of the public

Abdul Azaz Shamsaldeen

Tom King

Joe Richards

John Vivian

Brian Hartup

Danny West

Mona Guckian Fisher

Maurice Greenham

Roger Pebody

Emily Hamblin

Bindmans (on behalf of Healthcare worker AB)

Individuals (Healthcare Professionals)

Malcolm Morris FRCS, Retired Orthopaedic Surgeon

Dr Timothy Johnstone, former Provincial Epidemiologist, British Colombia, Canada and Public Health Physician

Dr Morgan Evans MRCP DipHIVNed, Consultant Physician, Infectious Diseases and HIV, NHS Tayside

Jeffrey C McIlwain MB BCh BAO MD FRCS Consultant, Clinical Risk Management, St Helens & Knowsley Teaching Hospitals NHS Trust

Royal Colleges

Royal College of Obstetricians and Gynaecologists

Royal College of Nursing

Royal College of General Practitioners

Royal College of Physicians

Royal College of Midwives

Royal College of Pathologists (Lay Advisory Committee)

Healthcare Professional Regulatory Bodies

General Dental Council

Nursing and Midwifery Council

Dental Organisations

British Dental Association

Faculty of General Dental Practice (UK)

Other Health Professional Healthcare Organisations and Unions

The Association for Perioperative Practice

Defences Medical Services

British Medical Association

Health Protection Agency

Association of National Health Occupational Physicians (joint response from ANHOPS plus Faculty of Occupational Medicine, Society of Occupational Medicine, Health and Work Network Board/NHS Plus and Higher Education Occupational Physicians)

The Association of NHS Occupational Health Nurses

Unison

Independent Healthcare Advisory Services

Society for General Microbiology

Local NHS organisations

Avon Partnership NHS Occupational Health Service

East of England Ambulance Service NHS Trust

South East London Dental Infection Control Committee

Occupational Health and Wellbeing Team, Doncaster and Bassetlaw Hospitals NHS Foundation Trusts

North West Ambulance Service NHS Trust

HIV/AIDS Sector Organisations

George House Trust

National AIDS Trust

Terrence Higgins Trust

All Party Parliamentary Group on HIV and AIDS

Body and Soul Charity

BHIVA

Other Third Sector Organisations

National Lesbian, Gay, Bisexual and Transgender Partnership

Lesbian and Gay Foundation

Medical or Dental Defence Organisations

Dental Protection Limited

Medical Defence Union

ix. Annex C – A practicable approach to clearance for exposure prone procedures (EPPs) for HIV positive healthcare workers (HCWs)

Initial health clearance for HIV positive HCWs who wish to perform EPPs:

The HCW would need to be on cART.

Viral load (VL) count test result: Reproducible and stable results <200 copies/ml	A pragmatic approach based on case-by-case clinical judgement would need to be taken. VL testing would be needed to ensure VL stability as specified in Appendix E of the TWG's report. At this point a decision would be made as to whether health clearance could be given and the HCW could be cleared to perform EPP activities. A small national panel made up of expert HIV and OH physicians – perhaps nominated by BHIVA and ANHOPS respectively – should be established and available for consultation by colleagues on complex cases to help with decision-making. Queries about on-going monitoring would also be sent to UKAP. UKAP should be notified before health clearance is given to an HIV positive HCW so that they could provide oversight for the process being followed in each case and promote consistency and good practice for an initial period of 1-2 years.

On-going monitoring of HIV positive HCWs undertaking EPPs following health clearance:

VL count test result: <50 copies/ml or below	No action – retest in 3 months

The rationale for this cut off is that <50 copies/ml is the optimal outcome for cART demonstrating treatment success. In addition, it has been demonstrated that an individual's VL is less likely to rebound if consistently <50 copies/ml.

VL count test result: 50-200 copies/ml	A case-by-case approach based on clinical judgement would be taken which may result in no action (as above) or it may be decided that a second test should be done 10 days later on a new blood sample to verify the first result. At this point a decision would be made as to whether any action was needed to limit the HCW's EPP activities.
VL count test result: >200 copies/ml	A second test would automatically be done 10 days later on a new blood sample to verify the first result. If the VL count was still found to be in excess of 200 copies/ml, the HCW would cease conducting EPPs. This limitation would continue until their VL count was reduced to <200 copies/ml again and stable.

The rationale for this approach is that it allows an individual's VL to fluctuate slightly without automatically interrupting their clinical practice. It is estimated that up to 1 in 20 people may experience VL fluctuations like this and if they had to stop practicing each time there was a temporary fluctuation or blip this would be very disruptive, but would probably not provide patients with any extra protection. This approach also allows for variations between assays.

This methodology also ensures that the HCW's VL would be monitored more closely in case of significant blips or rebound indicating that they should stop carrying out EPPs. Such blips/rebound may also suggest that the HCW's cART regime may need to be modified.

Cut-off point for ceasing EPPs immediately and triggering a risk assessment exercise which may lead to a patient notification exercise (PNE):

VL count test result: >1,000 copies/ml	The HCW would cease conducting EPPs immediately. A second test would be done 10 days later on a new blood sample to verify the first result. If the count was still in excess of 1,000 copies/ml a risk assessment would be triggered with patient cross-matching.

	UKAP advice may be sought at this stage. Based on the results of the risk assessment, a PNE may be carried out if it was felt that patients may have been put at risk. UKAP should advise on the need to carry out a PNE. It was suggested that HIV positive HCWs undertaking EPPs should be encouraged to keep a log of cases treated. This would be of great assistance if a cross-matching exercise (of patients treated by the HIV positive HCW against HIV diagnoses) was ever needed, by speeding up the process and reducing the need to interrogate hospital log books, etc which may inadvertently lead to the confidentiality of the HCW being compromised.

The rationale for this is that VL results of >1,000 copies/ml indicate that cART treatment has failed and that the HCW might be a risk to their patients if they continue to carry out EPPs. It was noted that a raised VL would not be the only trigger that may lead to a risk assessment being carried out. A significant HCW-to-patient blood exposure will also prompt a risk assessment.

i) Who should make the decision as to whether a PNE should be performed, and when?

Following a risk assessment exercise, including patient cross-matching, a PNE may be indicated. Further details can be found in the published guidance[5].

[5] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1317133297795