



Management of HIV-infected healthcare workers

A paper for consultation

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For Recipient's Use	

Management of HIV-infected healthcare workers

A paper for consultation

Prepared by Infectious Diseases and Blood Policy Branch, Department of Health

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Executive summary

1. A tripartite working group of the Expert Advisory Group on AIDS, the UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses and the Advisory Group on Hepatitis has reviewed current national guidance on the management of healthcare workers infected with HIV, hepatitis B and hepatitis C. This consultation paper seeks views on recommendations from the working group for changes to the current policy on HIV-infected healthcare workers. The working group's report is being published alongside this consultation paper, together with a consultation impact assessment and a draft equality analysis, which will be reviewed in the light of the consultation responses.
2. National guidance restricts HIV-infected healthcare workers from performing clinical procedures, known as "exposure prone procedures" to protect patients from the risk of infection.¹ 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 the healthcare worker could injure themselves and bleed into the patient's open tissues, with a consequent risk of infection. The tripartite working group has established that few other countries appear to have similar restrictions (Australia, Ireland, Italy and Malta).
3. There have only been four reported incidents world-wide of HIV transmission from an HIV-infected healthcare worker to patient and none in the UK, despite over 30 patient notification exercises between 1988 and 2008 in which nearly 10,000 patients were tested for HIV. The tripartite working group's assessment of available evidence and its expert opinion are that the risk of HIV transmission from an infected and untreated healthcare worker to a patient during exposure prone procedures is extremely low for the most invasive procedures² and negligible for less invasive procedures.³ The current overall risk of HIV transmission to any patient having the most invasive type of exposure prone procedure from any healthcare worker, regardless of HIV status, is estimated to be between 1 in 1,672,000 and 1 in 4,680,000.
4. The tripartite working group has concluded that the risk of HIV transmission from infected healthcare worker to patient can be reduced even further by combination antiretroviral drug therapy (cART), where the individual's plasma viral load⁴ is suppressed to a very low or undetectable level.

¹ [HIV-infected health care workers: Guidance on management and patient notification](#) (Department of Health, 2005).

² Such as open cardiac surgery, hysterectomy or caesarean section.

³ Such as local anaesthetic injection in dentistry, routine tooth extraction or appendicectomy.

⁴ This means the amount of HIV virus in the individual's blood.

5. The tripartite working group's main recommendations are that:
 - HIV-infected healthcare workers should be permitted to perform exposure prone procedures if they are on combination antiretroviral drug therapy (cART) and have a plasma viral load suppressed consistently to very low or undetectable levels (i.e. below 200 copies/ml);
 - HIV-infected healthcare workers should demonstrate a sustained response to cART before starting or resuming exposure prone procedures and should be subject to viral load testing every three months while continuing to perform such procedures;
 - HIV-infected healthcare workers who wish to perform exposure prone procedures whilst on cART should be under the joint supervision of a consultant in occupational medicine and their treating physician;
 - Any HIV-infected HCW who fails to comply with monitoring arrangements, or whose plasma viral load rises significantly above 200 copies/ml (i.e. to more than 1000 copies/ml), should be restricted from performing exposure prone procedures until their viral load returns to being stably below 200 copies/ml.
6. The Expert Advisory Group on AIDS has prepared a suggested implementation framework for these recommendations, which forms part of the tripartite group's report. There are no data available on the prevalence of HIV in healthcare workers in this country. However, by applying the general population prevalence rate for HIV to relevant NHS workforce numbers, it is estimated that the tripartite working group's recommendations could affect around 110 HIV-infected healthcare workers in England.
7. The Department of Health is aiming to maintain an appropriate, evidence-based balance between patient safety and the rights and responsibilities of HIV-infected healthcare workers in the light of the tripartite working group's advice. The Department will decide how to respond to the tripartite working group recommendations once it has had the benefit of responses to this consultation paper.

How to respond

8. The questions for consultation are listed in chapter 5 of this document, which provides more detail about the consultation process. This consultation starts on 1 December 2011 and will close on 9 March 2012.
9. You can contribute to the consultation by providing written comments, using the template on page 27 to:
 - By email: hivhcwsconsultation@dh.gsi.gov.uk

- By post: HIV Healthcare Worker Consultation
Department of Health, Room 531
Wellington House
133-155 Waterloo Road
London SE1 8UG

10. The proposals in this consultation document apply to England. The Devolved Administrations will be carrying out similar consultations.

1. Introduction

- 1.1. The vast majority of nursing and medical procedures do not pose a risk of human immunodeficiency virus (HIV) infection to patients, provided standard infection control measures are taken. However, there is a low risk of transmission of HIV from an infected healthcare worker to patients during invasive clinical procedures known as "exposure prone procedures".
- 1.2. Exposure prone procedures occur mainly in surgery, obstetrics and gynaecology, dentistry and some aspects of midwifery and specialist nursing (e.g. specific duties in operating theatre nursing). During such procedures, there is a risk that injury to the healthcare worker could result in their blood contaminating a patient's open tissues with a consequent risk of infection, as HIV is carried in the blood of those who are infected.
- 1.3. To protect patients from the risk of infection, current Department of Health guidelines recommend that healthcare workers who are known to be infected with HIV should not carry out exposure prone procedures.⁵ New healthcare workers who will do exposure prone procedures are tested for HIV.⁶ Existing healthcare workers are under a professional duty to seek medical advice on the need to be tested if they might have been exposed to HIV infection occupationally or otherwise.⁶
- 1.4. Evidence indicates that there is a far greater risk of transmission of HIV from infected patient to healthcare worker than vice-versa, as healthcare workers are more likely to come in contact with undiagnosed or diagnosed HIV-infected patients and be exposed to their blood through sharps injuries. There have been 5 patient-to-healthcare workers HIV transmissions reported in the UK to date.⁵
- 1.5. Following an initial suggestion by the [Expert Advisory Group on AIDS](#) in 2007 that restrictions on HIV-infected general dental practitioners should be reviewed, a tripartite working group of the Expert Advisory Group on AIDS, the [UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses](#) and the [Advisory Group on Hepatitis](#) was established to review current national guidance on the management of healthcare workers infected with HIV, hepatitis B or hepatitis C.

⁵ [HIV-infected health care workers: Guidance on management and patient notification](#) (Department of Health, 2005).

⁶ [Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers](#) (Department of Health, 2007).

- 1.6. This consultation paper summarises the tripartite working group's advice on the management of HIV-infected healthcare workers and poses a number of consultation questions, including about the working group's recommendations and their possible implementation, the consultation impact assessment and the draft equality analysis. It is suggested that the consultation paper is read in conjunction with the working group's report.
- 1.7. The Department is interested to receive responses to the consultation questions to help it assess the tripartite working group's advice and to help ensure that patients remain appropriately protected from the risk of HIV infection during exposure prone procedures.

2. The tripartite working group's assessment of risk and advice

2.1 In its review, the tripartite working group has focussed on examining evidence on the risk of HIV transmission from infected healthcare worker to patients and international policies on HIV-infected healthcare workers.

Assessment of risk of HIV transmission from an infected healthcare worker to a patient during an exposure prone procedure

2.2 The key points from the tripartite working's group assessment of the risk of HIV transmission from an infected healthcare worker to a patient are as follows⁷:

- In general, three conditions are necessary for HIV-infected healthcare workers to pose a risk of HIV transmission to patients:
 - the healthcare worker must have infectious virus circulating in their bloodstream;
 - the healthcare worker must be injured or have a medical condition (e.g. weeping eczema) that provides some other source of direct exposure to infected blood or body fluids;
 - the injury mechanism or medical condition must present an opportunity for the healthcare worker's blood or body fluids to come into direct contact with the patient's mucous membranes, wound or traumatized tissue.
- The risk of HIV transmission from an infected healthcare worker to a patient will depend largely on the infectiousness of the healthcare worker - which is determined by the concentration of HIV in the healthcare worker's blood - and the susceptibility of the uninfected person, which may vary naturally (e.g. perhaps related to genetic factors);
- Evidence on the risk of HIV transmission from an infected healthcare worker to patient has now accumulated;

⁷ References are not listed in the consultation paper, as they are cited in the tripartite working group's report, which has been published in parallel.

- There have only been four reports of transmissions of HIV from infected and untreated healthcare workers world-wide:
 - a dentist in the US (six patients infected - route of transmission unclear);
 - an orthopaedic surgeon in France (one patient infected);
 - a gynaecologist in Spain (one patient infected); and
 - a nurse in France (one patient infected - the route of transmission unclear).
- However, there have been no reported transmissions in the UK, even though since 1988, over 30 patient notification exercises connected with HIV-infected healthcare workers have taken place - with nearly 10,000 patients tested for HIV. There are limitations to this information, as explained in the tripartite working group's report, that should be borne in mind – for example, only a proportion of patients treated by infected healthcare workers were tested either because they could not be contacted or because they declined testing;
- National surveillance of HIV diagnoses in this country by the Health Protection Agency has not identified cases of infection acquired from infected healthcare workers despite widespread testing in antenatal, genito-urinary medicine and blood donation clinics, and follow-up of unexplained HIV diagnoses;
- Retrospective analysis of investigations in the US of patients of HIV-infected healthcare workers, including surgeons, obstetricians and dentists (apart from the US dentist mentioned above) revealed no evidence of healthcare worker-to-patient transmission among over 22,000 tested patients;
- Estimates of risk, based on the result of patient notification exercises in the UK connected with infected and untreated healthcare workers, suggest that even with infected and untreated healthcare workers the risk is extremely low, as no healthcare worker-to-patient HIV transmissions have been detected. Statistical analysis indicates that this risk could be in the range of 1 in 2,700 to about 1 in 7,000 for all exposure prone procedures and, for the most invasive exposure prone procedures (e.g. caesarean section or open cardiac surgery), about 1 in 620 to about 1 in 1,600;
- However, these estimates are influenced by the number of patients tested during these patient notification exercises and may overstate the risk. If more such exercises took place and it continued to be the case that no transmissions were detected, the estimated risk would decrease;
- The tripartite working group has concluded that the risk of HIV transmission from infected healthcare worker to patient during less invasive exposure prone procedures (such as a local anaesthetic injection or routine tooth extraction in dentistry or an appendicectomy) is negligible and in the most invasive procedures

(such as a caesarean section or open cardiac surgery) is extremely low.

- Evidence suggests that treatment with cART is effective in suppressing the viral load of HIV-infected individuals and reducing the risk of transmission between sexual partners and from infected mother to baby to low levels - generally less than 1 in 100. There is no evidence relating to HIV-infected healthcare workers on cART, as the few documented transmissions in other countries and numerous patient notification exercises relate to untreated healthcare workers, who are likely to pose a greater risk than individuals on cART. Expert opinion is that cART will significantly reduce the risk of transmission from HIV-infected healthcare workers;
- If a conservative assumption is made about the effect of cART on reducing the risk of transmission from an HIV-infected healthcare worker, the estimated risk from the most invasive type of exposure prone procedure, it is in the range of 1 in 33,000 to 1 in about 833,000.^{8,10} This estimate takes account of evidence about the risk of sexual or mother-to-baby HIV transmission if cART is taken and viral suppression is achieved.

Department of Health's assessment of risk of HIV transmission from any healthcare worker to a patient during an exposure prone procedure

- 2.3 The Department of Health has estimated the current overall risk of HIV transmission to any patient having the most invasive type of exposure prone procedure⁹ from any healthcare worker, regardless of HIV status (**see Appendix (i)**). Acknowledging the uncertainties in this area, such as the prevalence of HIV in healthcare workers who do exposure prone procedures, the current risk is estimated to be between 1 in 1,672,000 and 1 in 4,680,000. If the tripartite group's recommendations were implemented and there was no consequent increase in the diagnosis of HIV-infected healthcare workers, it is estimated that there would be a very small increase in risk to between 1 in 1,671,000 and 1 in 4,076,000, or one additional HIV transmission every 40 to 2,500 years.
- 2.4 However, if the tripartite working group's recommendations were implemented, it could lead to more healthcare workers with HIV being diagnosed and treated with cART. This would reduce the proportion of undiagnosed HIV-infected healthcare workers doing exposure prone procedures and the overall risk to patients because cART suppresses an HIV-infected individual's viral load to very low or undetectable levels. Therefore, if there was a large enough increase in the diagnosis of HIV-infected healthcare workers, this could offset the additional risk partially or completely - or the total risk could be reduced compared to the current position. Although there is no evidence for this, it

⁸ Combination antiretroviral drug therapy can reduce the transmission risk from an HIV-infected pregnant woman to her baby by up to 200-fold. The assumption made for HIV-infected healthcare workers is a 20-fold reduction.

⁹ Such as open cardiac surgery, hysterectomy or caesarean section.

seems reasonable that this could happen, since the proposed new policy would no longer mean an end to an HIV-infected healthcare worker's exposure prone procedure career, and there may be greater incentive for healthcare workers who consider that they are at risk of infection to come forward for HIV testing.

- 2.5 It is possible that these estimates overstate the risks, as there have been no HIV transmissions from infected healthcare workers observed in this country.

The tripartite working group's advice

- 2.6 The main points of the tripartite working group's advice, based on its risk assessment, are as follows:

- HIV-infected healthcare workers should be permitted to perform exposure prone procedures if they are on combination antiretroviral drug therapy (cART) and have a plasma viral load suppressed consistently to very low or undetectable levels i.e. below 200 copies/ml;¹⁰
- HIV-infected healthcare workers should demonstrate a sustained response to cART before starting or resuming exposure prone procedures and would be subject to viral load testing every three months while continuing to perform such procedures;
- HIV-infected healthcare workers who wish to perform exposure prone procedures whilst on cART should be under the joint supervision of a consultant in occupational medicine and their treating physician;
- Any HIV-infected HCW who fails to comply with monitoring arrangements, or whose plasma viral load rises significantly above 200 copies/ml (i.e. to more than 1000 copies/ml), should be restricted immediately from performing exposure prone procedures until their viral load returns to being stably below 200 copies/ml.
- There has been no distinction made between the three different categories of exposure prone procedures¹¹ for pragmatic reasons:
 - Restricting practice by category of exposure prone procedure would be difficult prospectively since the categorisation of procedures in different specialties is provisional and is affected by variations in technique and technical

¹⁰ The viral load threshold of 200 copies/ml reflects expert opinion about the current knowledge of viral load thresholds associated with transmission in different scenarios. Evidence from vertical (infected mother-to-baby) HIV transmission studies has demonstrated a plasma viral load threshold for transmission of 1000 copies/ml (i.e. no transmissions occurred below this viral load level) in the absence of other risk factors.

¹¹ To date in this country, the categorisation of exposure prone procedures into three categories (i.e. 1, 2 and 3 - reflecting a scale of increasing risk of an injured healthcare worker's blood contaminating a patient's open tissue), has been used only retrospectively in relation to patient notification exercises.

developments. Implementing a consistent approach to assessing and advising on the practice of individual HIV-infected healthcare workers would therefore be very complex;

- It would be difficult to ensure that any infected healthcare worker observed a restriction in practice to category 1 and 2 exposure prone procedures. In surgical specialties, for example, it is possible for a category 1 or 2 procedure to become a category 3 procedure because of some unforeseen event during the course of an operation. In this scenario, the operator would have to seek help from a colleague to continue the operation in the category 3 phase of the procedure – and such a colleague might not be available;
- Many exposure prone procedures fall between categories 2 and 3, depending on the technique employed by the healthcare worker.

Consultation 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?

Please provide explanatory comments for your answer.

Consultation question 2: 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? 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?

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

3. Suggested implementation framework

- 3.1 A crucial issue in considering the tripartite working group's recommendations is whether they can be implemented in practice without compromising patient safety. As part of the tripartite working group's report, the Expert Advisory Group on AIDS has produced a suggested implementation framework (see Appendix E of the tripartite working group's report). The main points of the implementation framework are summarised below:

Management of the healthcare worker

- HIV-infected healthcare workers, who wish to perform exposure prone procedures, whilst on combination antiretroviral drug therapy (cART), should be managed by an HIV/genitourinary medicine/infectious diseases physician who liaises closely with the healthcare worker's consultant in occupational medicine.
- HIV-infected healthcare workers should be permitted to perform exposure prone procedures if they are on cART and have a plasma viral load suppressed consistently below 200 copies/ml.¹² Healthcare workers will need to demonstrate a sustained response to cART (i.e. viral load below 200 copies/ml on two consecutive plasma samples taken at least three months apart) before starting or resuming exposure prone procedures, and they will be subject to viral load testing every 3 months while continuing to perform exposure prone procedures.
- If a healthcare worker's plasma viral load rises significantly above 200 copies/ml (i.e. to above 1000 copies/ml), they should be restricted immediately from carrying out exposure prone procedures until their viral load returns to being stably below 200 copies/ml. The significance of any increase in plasma viral load above 200 copies/ml, identified through routine monitoring, should be assessed jointly by the occupational medicine and treating physicians with input from appropriate local experts (e.g. consultant virologist or microbiologist).

¹² The proposed 200 copies/ml cut-off is arbitrary but has been chosen to reflect current knowledge of viral load thresholds associated with transmission in different scenarios. Evidence from vertical HIV transmission studies demonstrated a plasma viral load threshold for transmission of 1000 copies/ml (i.e. no transmissions occurred below this viral load level) in the absence of other risk factors. The 200 copies/ml cut-off is achievable in routinely used commercial viral load assays, provides a margin for inter- and intra-assay variability and allows for transient increases in viral load (blips), which have not been shown to be associated with virological failure.

- Although the emerging trend is for treatment for HIV to start earlier than previously recommended, it will be for the healthcare worker to decide, in collaboration with their specialist physician, whether they wish to take cART for occupational health reasons when it is not clinically indicated, taking account of possible advantages and disadvantages.
- Local arrangements should be made between the treating physician and the occupational health service to ensure that blood drawn from HIV-infected healthcare workers for viral load measurements conforms to standards suitable for occupational health monitoring purposes (i.e. the identity of the healthcare worker is confirmed and the chain of handling for specimens is secure).
- Laboratory testing should be done in local laboratories accredited by Clinical Pathology Accreditation (UK) Limited, that can carry out and report results of urgent viral load tests within 2 days.
- Healthcare workers should be advised by the treating physician and their consultant in occupational medicine of:
 - the importance of quarterly monitoring of their viral load, and that they will be restricted from performing exposure prone procedures if they fail to attend for this follow-up;
 - advising their treating physician of missed doses of cART, drug interactions or other factors (e.g. diarrhoea) that might influence their viral load, as soon as is practicable and before further exposure prone procedures are performed;
 - the action to take in the event of them experiencing an injury during an exposure prone procedure and bleeding into a patient's open tissues (see below).
- Healthcare workers would not be expected to disclose their HIV status to patients because of the negligible or extremely low risk of transmission (depending on the invasiveness of the procedure involved).

Management of blood exposure incidents

- In managing an incident in which a patient has been exposed to the blood of an HIV-infected healthcare worker on cART, the usual protocol for any occupational exposure incident should be followed. A preliminary risk assessment of the exposure incident should be conducted by another member of the clinical team. If the incident is assessed as significant, the healthcare worker should report the incident to the clinical supervisor, line manager or other person responsible according to local policies; inform the occupational health department, infection control lead or other nominated person; and inform their treating physician.

- Further detailed risk assessment should include consideration of the healthcare worker's latest HIV viral load measurement and the historical context (i.e. how long it has been undetectable). Only under exceptional circumstances (e.g. following a major bleed) should it be necessary for the source healthcare worker to have an urgent viral load test.
- A decision about whether to inform the patient about the exposure, and to offer HIV post-exposure prophylaxis (PEP), will depend on the risk assessment and what is in the best interests of the patient. Follow-up in the absence of PEP is not routinely recommended. It is likely that PEP would be indicated only very rarely.

Patient notification exercises

- Patient notification exercises for patients who have undergone exposure prone procedures by an untreated HIV-infected healthcare worker would take place according to current guidance on HIV-infected healthcare workers.¹³ Patient notification exercises connected with HIV-infected healthcare workers on cART would only be recommended in circumstances in which their viral load had risen above 200 copies/ ml. The need for patient notification would be determined by a risk assessment on a case-by-case basis in line with the principles in existing guidance, and the UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses should be consulted for advice.

HIV testing of healthcare workers

- New healthcare workers, including students, who will perform exposure prone procedures should continue to be tested for HIV when joining the NHS or returning to work in the NHS.¹⁴ If found to be infected, this no longer automatically restricts them from posts or careers involving exposure prone procedures, subject to successful treatment with cART and occupational health clearance. However, the demands of adhering to cART and strict monitoring arrangements would be significant and should be explored in any discussions about career options.
- Existing healthcare workers should continue to remain under a professional duty to promptly seek and follow confidential professional advice on whether they should be tested for HIV in situations where they have reason to believe they may have been exposed to infection with HIV, in whatever circumstances. Healthcare workers who are infected with HIV must promptly seek appropriate expert medical and occupational health advice.

¹³ [HIV-infected health care workers: Guidance on management and patient notification](#) (Department of Health, 2005).

¹⁴ [Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers](#) (Department of Health, 2007).

Possible oversight role for the UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses (UKAP)

- To ensure consistency in the application of the policy in its first year or two, all cases of HIV-infected healthcare workers who wish to perform exposure prone procedures whilst on cART should be referred to UKAP to advise on the approach to be taken and to help promote best practice. Cases where an HIV-infected healthcare worker's viral load rises above the recommended viral load threshold should be notified to UKAP, and their advice sought about the need to conduct a patient notification exercise. However, it would remain a local decision as to whether an individual HIV-infected healthcare worker were cleared to perform exposure prone procedures and whether a patient notification exercise is necessary.

National monitoring of proposed new policy

- UKAP could oversee the implementation and conduct of the policy, by considering individual cases referred to it and by periodic audits of NHS occupational health providers.
- Alternatively, subject to any necessary ROCR (Review of Central Returns) approval and consideration of resource implications, there could be a central, secure database run by the Health Protection Agency (which hosts UKAP),¹⁵ into which NHS occupational health providers could submit information about individual HIV-infected healthcare workers doing exposure prone procedures and their viral load monitoring whilst on cART. A unique identifier would be used for each healthcare worker to maintain confidentiality and to enable healthcare workers' records to be linked as they move between NHS employers. Such a database would help monitor implementation at a national level and help provide relevant information for any review of policy in future.

Number of healthcare workers who may be affected by the proposed new policy

- By applying the general population prevalence rate for HIV to relevant NHS workforce numbers, the tripartite working group has estimated that their recommendations could affect around 110 HIV-infected healthcare workers who carry out exposure prone procedures in England.

¹⁵ This responsibility could be taken over by the proposed national public health service, Public Health England when, subject to Parliament, the Health Protection Agency is abolished.

Consultation impact assessment and draft equality analysis

- 3.2 A consultation impact assessment and a draft equality analysis have been published alongside this consultation paper for comment.

Consultation 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?

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

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 e.g. because of an increase in a healthcare worker's viral load?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

4. International policies

- 4.1 In its review, the tripartite working group gathered information about international policies on the management of HIV-infected healthcare workers. Information was obtained for 25 countries (17 European Union (EU) member states and 8 non-EU countries); of these 25 countries, eight had published national guidelines or recommendations.
- 4.2 In five countries (Australia, Ireland, Italy, Malta and UK), HIV-infected healthcare workers were reported to be restricted from performing invasive/exposure prone procedures considered to pose a higher risk of transmitting HIV from infected healthcare worker to patient.
- 4.3 In many other countries (Austria, Belgium, Canada, Finland, France, New Zealand and Sweden), the management of an HIV-infected healthcare worker is decided on a case-by-case basis. The decision as to whether the healthcare worker is restricted from performing invasive procedures is undertaken by the employer or the clinician responsible for treating the healthcare worker (independently or in conjunction with an expert committee), or by a local or national expert committee. Germany and Spain do not appear to have national policies in place.
- 4.4 Even though there are guidelines published by the US Centers for Disease Control and Prevention and the Society for Healthcare Epidemiology of America, the US has no national policy for managing HIV-infected healthcare workers. The recommendations from France state that, if the healthcare worker is clinically well and has an undetectable viral load for at least three months, they should not be restricted from practice. However, as far as we are aware, this recommendation has not been adopted by the Ministry of Health and is not currently national policy.
- 4.5 The remaining responding countries reported that policies had not been developed, often because no cases of HIV-infected healthcare workers had been notified in the particular country.

5. The consultation process

How to respond

The questions for consultation are listed in Appendix (ii) below. This consultation will close on **9 March 2012**. You can contribute to the consultation by providing written comments, using the template on page 27 to:

By email: hivhcwsconsultation@dh.gsi.gov.uk

Online: <http://consultations.dh.gov.uk>

By post: HIV Healthcare Worker Consultation
Department of Health,
Room 531 Wellington House
133-155 Waterloo Road
London SE1 8UG

The proposals in this consultation document apply to England, but the Devolved Administrations will be carrying out similar consultations.

Criteria for consultation

This consultation follows the Government's Code of Practice on Consultation. In particular, we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation's process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:
[Link to consultation Code of Practice](#)

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE
e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#)

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as publication of guidance for the NHS, and will be placed on the Consultations website at <http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

Appendix (i): HIV-infected healthcare workers and the risk of HIV transmission to patients during exposure prone procedures

1. The effects of allowing HIV-diagnosed workers (HCWs) to carry out exposure prone procedures (EPPs) whilst on combination antiretroviral drug therapy are unclear in terms of possible change to the overall risk to patients from the current position, where HIV-infected HCWs with known HIV diagnosis are restricted from carrying out such procedures.
2. An attempt has been made to estimate the potential for changes in risk to patients having the most invasive type of EPP, which is called a category 3 EPP and includes procedures such as open cardiac surgery or hysterectomy. However, there are uncertainties around this estimate including the proportion of HIV- infected HCWs, how many may be doing EPPs and the risks of them infecting patients during EPPs.
3. Two assumptions have been made about the current position - firstly that only HIV undiagnosed HCWs are carrying out EPPs. No HIV diagnosed workers are carrying out EPPs. Secondly, the prevalence of HIV in HCWs is assumed to be the same as the general population, 1.4 per 1000¹⁶.
4. The rate of undiagnosed HIV in the HCW population is unknown, but approximated in two ways to create two scenarios. In one scenario, the diagnosed rate of HIV in HCWs is estimated using the number of cases of EPP workers with HIV referred to UKAP (33) from 2003-2009 over the expected number of HIV infected HCWs (111). The undiagnosed rate is one minus this diagnosed rate, since HIV infected HCWs are diagnosed or undiagnosed. This gives a rate of 70% undiagnosed HIV in HCWs. The alternative scenario takes the rate of undiagnosed HIV in the general population, 25%¹⁷.
5. As there is no definitive list of category three EPPs, only certain groups of such EPPs are included in this analysis, as outlined in **Annex A**. The risk of transmission of HIV to patients is assumed to be higher for undiagnosed HIV infected HCWs (1/1,639) than for diagnosed and treated HIV infected HCWs (1/33,000 to 1/833,000)¹⁸, who are assumed to be receiving treatment and therefore posing much less risk of infection to patients. The Tripartite Working Group report states that the less invasive category one and two EPPs have negligible probabilities of transmission.

¹⁶ Health Protection Agency, *HIV in the United Kingdom: 2010 Report*, http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1287145367237

¹⁷ Health Protection Agency, *HIV in the United Kingdom: 2010 Report*, http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1287145367237

¹⁸ The Report of the Tripartite Working Group, *Management of HIV-infected Healthcare Workers*, April 2011

6. The two scenarios estimate the maximum and minimum percentage increase in risk to patients, by choosing the undiagnosed rate and risk of transmission to generate the largest range possible. The risk to any patient undergoing an category 3 EPP of being infected with HIV is calculated as the prevalence of HIV in the population multiplied by the proportion of undiagnosed HIV, multiplied by the risk of transmission by an untreated HIV infected HCW.
7. The additional risk of allowing HIV diagnosed workers under treatment to carry out EPPs is calculated as the prevalence of HIV in the population, multiplied by the proportion of diagnosed HIV, multiplied by the risk of transmission by a treated HIV infected HCW. This is added to the current risk of undiagnosed HIV infected HCWs carrying out EPPs resulting in the probability of a patient undergoing a category three EPP contracting HIV, where HIV infected HCWs are allowed to carry out EPPs.
8. The expected number of transmissions is calculated by multiplying the risk per procedure by the number of procedures. Analysis suggests that the effect of allowing HIV infected HCWs to carry out EPPs would be to increase the very small risk to patients from one in 1,672,000 to 4,680,000 procedures, to one in every 1,671,000 to 4,076,000 procedures. This assumes that there is no additional diagnosis of HCWs with HIV, and undiagnosed workers continue to carry out EPPs at higher risk than if they were on treatment. The additional risk is from HIV infected HCWs under treatment being allowed to carry out EPPs.

	Increase in risk	
	Least	Greatest
Underlying risk of transmission one in XX procedures	4,680,000	1,672,000
Additional risk one in XX procedures	1,983,330,000	31,430,000
Total risk one in XX procedures	4,076,000	1,671,000

9. The expected number of transmissions per year would increase from 0.17 – 0.47 to 0.19 – 0.47, or an additional transmission every 40 to 2,500 years.
10. In order to offset the increase in risk by allowing diagnosed HCWs to carry out EPPs, detection of HCWs with HIV would have to increase by 0.08% to 16%. The estimated number of HCWs carrying out EPPs in secondary care is 57,173¹⁹. Applying the estimated rate of undiagnosed HIV infected HCWs for each scenario to the national prevalence rate of diagnosed HIV infers that 20-56 HCWs are infected with HIV but do not know it. In order to offset the increased risk of allowing diagnosed HIV infected HCWs to carry out EPPs, 0.07 to 12.6 undiagnosed HIV infected HCWs would have to be diagnosed.

¹⁹ The Report of the Tripartite Working Group, *Management of HIV-infected Healthcare Workers*, April 2011

11. It might be reasonable to assume that this would happen, since the proposed new policy would no longer mean an end to an HIV-infected HCW's EPP career and there may be greater incentive for HCWs who consider that they are at risk of infection to come forward for HIV testing. If this were to happen to a large enough degree, then the proposed new policy could reduce the risk to patients whilst allowing HIV-infected HCWs on combination antiviral drug therapy and subject to regular monitoring of viral load to carry out EPPs.

ANNEX A

Category 3 Exposure Prone Procedures (EPPs)

Definition:

Procedures where the fingertips are out of sight for a significant part of the procedure, or during certain critical stages, and in which there is a distinct risk of injury to the worker's gloved hands from sharp instruments and/or tissues. In such circumstances it is possible that exposure of the patient's open tissues to the HCW's blood may go unnoticed or would not be noticed immediately. Examples: *hysterectomy, caesarean section, open cardiac surgical procedure as well as other major surgical procedures.*

In general dental practice, procedures that are considered exposure prone usually fall into category 1 or 2. Hospital-based dental surgery will include category 3 procedures.

Calculation:

Using data on the main procedures and interventions (2009-10) from Hospital Episode Statistics²⁰, category 3 EPPs include, but are not limited to, the following:

Category 3 EPPs	
Main procedures and interventions: Summary code and description	Finished consultant episodes (FCEs)
R17 Elective caesarean delivery	63,692
R18 Other caesarean delivery	94,537
Q1 (Q01-Q20) Uterus	317,662
K (K01-K78) Heart	311,453
Total:	787,344

Although the FCEs for hysterectomy and open cardiac surgery procedures may have been over-estimated (as they include all Uterus/Heart procedures and interventions), overall the FCEs for the total of category 3 EPPs is likely to be underestimated since major surgical procedures and some hospital based dental surgery has not been included, given the difficulty of classifying such major surgery.

In 2009-10, there were a total of 9,747,584 finished consultant episodes, therefore implying that roughly 8% of finished consultant episodes are category 3 EPPs of the types referred to in the table.

²⁰ NHS Information Centre, *Hospital Episode Statistics*, 2011 www.hesonline.nhs.uk,

Appendix (ii): Consultation questions and response template

Consultation 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?

Please provide explanatory comments for your answer.

Consultation question 2: 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? 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?

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

Consultation 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?

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

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

Please provide explanatory comments for your answer.

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 e.g. because of an increase in a healthcare worker's viral load?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.

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?

Please provide explanatory comments for your answer.