# Management of HIV-infected Healthcare Workers
# The Report of the Tripartite Working Group
# April 2011

# Contents


1. Executive summary

2. Background

3. Review of UK and international policy for managing HIV-infected healthcare workers

   3.1 Management of HIV-infected healthcare workers: UK

   3.2 Management of BBV-infected healthcare workers: international

4. Risk of HIV transmission from HIV-infected healthcare workers

   4.1 Animal studies

   4.2 Human studies

   4.3 HIV transmission from infected healthcare workers to patients

      4.3.1 Published cases of HIV transmission

      4.3.2 Retrospective investigations of HIV transmission in the US

      4.3.3 Estimates from a modelling exercise

5. Healthcare worker to patient transmission of HIV: results from retrospective investigations carried out in the UK between 1988-2008

   5.1 Number of patient notification exercises undertaken

      5.1.1 Results by speciality

      5.1.2 Results by exposure prone procedure

      5.1.3 Results by healthcare worker symptoms

      5.1.4 Estimate of risk of transmission

   5.2 Estimated risk of transmission from an infected healthcare worker to patient using UK and US data

   5.3 Data limitations

6. HIV transmission risk from infected healthcare workers with undetectable viral loads and/or treated with antiretroviral therapy: a review

7. Conclusions and recommendations

8. HIV-infected healthcare workers and antiretroviral therapy: proposed implementation framework

9. Acknowledgements

10. Appendices

11. References

## 1. Executive summary

In 2007, the Expert Advisory Group on AIDS (EAGA) suggested that the current policy restricting the practice of HIV-infected primary care dentists should be reviewed. The UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses (UKAP) suggested that this should be undertaken as part of a wider review of restrictions on blood-borne virus (BBV) infected healthcare workers (HCWs).

A Tripartite Working Group, consisting of chairs and members of UKAP, the Advisory Group on Hepatitis (AGH) and EAGA was set up to review the current BBV policy. To address the Working Group remit (detailed in Section 3) a Scientific Sub-group was convened to consider the scientific evidence for the risk of HIV transmission from HIV-infected HCWs to patients. This evidence (set out in Sections 5 to 7 of this report) was presented to the Tripartite Working Group in September 2010.

Following consideration of the evidence presented and the expert opinions expressed, the Working Group concluded that a relaxation of the policy on HIV-infected HCWs could be justified and recommended that HIV-infected HCWs be permitted to perform any exposure prone procedure (EPP[1]), provided that the level of viral load is "non-detectable".

The key recommendations of the proposed change in policy, endorsed by EAGA, are listed below.

- *HIV-infected HCWs are permitted to perform any EPP if they are on combination antiretroviral therapy (cART) and have a plasma viral load suppressed consistently below 200 copies/ml. HCWs will need to demonstrate a sustained response to cART (i.e. viral load <200 copies/ml on two consecutive plasma samples[2]) prior to starting or resuming EPPs and will be subject to testing every three months while continuing to perform EPPs.*
- *HIV-infected HCWs will be under the joint supervision of a consultant in occupational medicine[3] 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, will be restricted from EPP work until their viral load returns to being stably <200 copies/ml.*
- *The decision on whether EPP practice can begin, should cease, the need for a patient notification exercise (to cover the period of potential infectiousness) and when EPP work can resume should be made by a consultant in occupational medicine informed by relevant experts.*

A detailed implementation framework addressing the management of HIV-infected HCWs and the implications for other policies was also developed by EAGA and is set out in Appendix E.

[1] Invasive procedures where there is a risk that injury to the worker may result in exposure of the patient's open tissues to the blood of the worker.
[2] Health clearance to perform EPPs should be granted for HIV-infected HCWs currently on therapy if the two most recent consecutive viral load results, taken at least three months apart, are <200 copies/ml. HIV-infected individuals starting antiretroviral therapy typically achieve an undetectable viral load after 3 months on treatment. Before resuming EPP work, a further undetectable viral load test one month later (i.e., a minimum of 4 months after starting therapy), is required for health clearance.
[3] A 'consultant in occupational medicine' is a doctor registered as a specialist by the GMC and appointed to an NHS consultant post by a process consistent with the National Health Service (Appointment of Consultants) Regulations 2005 or their equivalent.

## 2. Background

The Expert Advisory Group on AIDS (EAGA) suggested in 2007 that the current policy restricting the practice of HIV-infected primary care dentists should be reviewed. The UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses (UKAP) agreed with EAGA, but recommended that it would be sensible to do this as part of a wider review of restrictions on blood-borne virus infected healthcare workers (HCWs), rather than in isolation, because of the inter-relationships between the policies for the three blood-borne viruses (BBVs).

A Tripartite Working Group, consisting of the chairs and a subset of members of UKAP, Advisory Group on Hepatitis (AGH) and EAGA, their respective secretariats and other experts, was set up to review current BBV policy. A full list of the Membership of the Tripartite Working Group is given in Appendix A.

The remit of the Tripartite Working Group was:

- To undertake a review of the current policies on the restriction of HCWs infected with BBVs whose clinical duties rely on performing exposure prone procedures (EPPs).
- To make recommendations for changes to the guidance, if appropriate, for approval by AGH and EAGA before submission to the Department of Health and the Devolved Administrations.
- To consider whether the following principles should continue to underlie the guidance:
    - Policy should continue to be based on an assumption of high rather than sub-standard clinical and infection control practice.
    - Infected HCWs in different specialties should be managed consistently, including groups such as dentists and paramedics who face greater practical and financial difficulties when restricted either permanently or temporarily and for whom redeployment in a clinical role is unlikely.
    - The concept of 'exposure prone procedure' as an objective method of classifying and comparing the risk of bleed-back[4] in a wide range of procedures across different healthcare specialties (see Appendix B).
- To consider the following specific issues in relation to the guidance:
    - Whether to emphasise the duty of HCWs to seek occupational health advice when they are at risk of blood-borne virus infection, perhaps by incorporating this requirement into a single, consolidated generic guidance document on the management of HCWs infected with BBVs.
    - Whether variations in policy are required in relation to HCWs with BBV co-infection, in terms of the risk of transmission of the viruses to patients, patient notification exercises and the management of the infected HCWs.

The Tripartite Working Group met for the first time in December 2007 when a review of UK policy was discussed. Arising from this meeting, EAGA was specifically asked to consider amending its current

[4] When injury to the HCW results in exposure of the patient's open tissues to the blood of the worker.

guidance on practice restrictions of HIV-infected HCWs in the light of the latest evidence cited by the Swiss Federal AIDS Commission related to sexual transmission from HIV-infected individuals with undetectable viral load (Vernazza et al. 2008). Specifically, the Commission stated that HIV-positive people are not at risk for transmitting HIV to their partners if they meet all of the following requirements:

- they are adherent to highly active antiretroviral therapy.
- their viral load in the blood is consistently below the lower level of detection.
- they are in a "stable relationship".
- they do not have any sexually transmitted infections (STIs).

EAGA concluded over the course of two meetings that the risk of HIV-infected HCWs with undetectable viral load on treatment transmitting to a patient was likely to be negligible. However, there was insufficient evidence on which to base a change in the overall advice concerning HIV-infected HCWs using the current definition of EPP. EAGA suggested that the Tripartite Working Group review the definition of EPPs, taking greater account of the volume of a healthcare worker's blood likely to contaminate a patient's open tissues during different types of clinical procedure.

The Tripartite Working Group met in March 2009 to discuss the key issues raised by EAGA's response. These included:

- whether HIV-infected HCWs would be prepared to live with the uncertainty of unpredictable viral loads requiring restriction of practice.
- the level of confidence in the robustness of the categorisation of EPPs were the policy to change to enable all HIV-infected HCWs with an undetectable viral load to undertake only category 1 and 2 EPPs.
- whether an acceptable level of risk of HIV transmission from a HCW to a patient could be assessed based on the available evidence.
- the lack of data concerning the risk of transmission from category 1 and 2 EPPs.
- other variables needing to be taken into account in calculating risk, notably the likelihood of a needlestick injury occurring in different categories of EPP, and the amount of HIV virus transmitted which is determined by many factors, including volume of blood.

In the light of these issues, the Tripartite Working Group agreed that a Scientific Subgroup should be established to consider in more detail the scientific evidence for the risk of HIV transmission from infected HCWs to patients by category of EPPs, primarily using data from patient notification exercises.

A full list of the Membership of the Scientific Subgroup is given in Appendix C. The remit of the Scientific Subgroup was:

*To develop an evidence-based model to calculate the risk of HIV transmission from infected healthcare workers to patients by category of exposure prone procedure using data from patient*

*notification exercises and other situations such as maternal-fetal transmission, taking into account assessments that have been made in other countries, for example France and the US.*

The sub-group met on two occasions to: i) establish how the evidence should be presented; and ii) to review the evidence compiled. This evidence was presented at the third meeting of the Tripartite Working Group in September 2010, for final consideration of whether or not there should be a shift to a more liberal policy relating to HIV-infected HCWs in the UK. This report presents the work of the Scientific Subgroup: section 3 reviews the current UK and international policies for the management of HIV-infected HCWs; and sections 4 to 6 present the evidence on risk of transmission. Section 7 contains the Tripartite Working Group's conclusions and final recommendations, and Section 8 the proposed implementation framework for the change in policy.

# 3. Review of UK and international policy for managing HIV-infected HCWs

## 3.1 Management of HIV-infected HCWs: UK

The policy on the management of HCWs infected with HIV and their patients has evolved over time, guided by emerging evidence on the risk of HCWs transmitting BBVs to their patients.

In 1987, the General Medical Council published a statement on the duties of doctors infected with HIV or who had developed AIDS. This stated:

> *It is imperative, both in the public interest and on ethical grounds, that any doctors who consider that they may have been infected with HIV should seek appropriate diagnostic testing and counselling, and if found to be infected, should have regular medical supervision. They should also seek specialist advice on the extent to which they should limit their professional practice in order to protect their patients. They must act upon that advice, which in some circumstances would include a requirement not to practise or to limit their practice in certain ways. No doctors should continue in clinical practice merely on the basis of their own assessment of risk to patients.*

This was followed in 1988 by EAGA recommending that HCWs who knew or who suspected that they were infected with HIV and who ordinarily performed or assisted in surgical invasive procedures, where blood-to-tissue contact could occur, must seek expert advice on whether there was a need to limit or alter their working practice. All HCWs who had any reason to believe they might have been exposed to HIV infection, must promptly seek advice on whether they should be tested for HIV. These recommendations were made when there was no known case of HCW-to-patient HIV transmission. In making these recommendations, EAGA acknowledged the theoretical risk of such transmission based on existing knowledge of hepatitis B HCW-to-patient transmission. Assessment of the magnitude of the risk was based on reports of occupationally acquired HIV. This evidence pointed to a low risk of transmission but grave consequences if such a transmission were to occur, as effective treatment was not available to prevent progression to AIDS.

In 1991, following the Florida dentist incident, EAGA strengthened its advice stating that:

> *HIV-infected healthcare workers should not perform invasive surgical procedures in which injury to the worker could result in blood contaminating a patient's open tissues* (Department of Health 1991).

EAGA updated its guidance in 1993 (Department of Health 1993), recommending that HIV-infected HCWs should not perform EPPs (see Appendix B for full description of EPPs). Updated versions of the guidance were subsequently published in 1998 and 2005 (current version) (Department of Health 1998; Department of Health 2005).

In 2007, Department of Health guidance describing health clearance measures for new HCWs[5] was published (Department of Health 2007a). These new measures were intended to restrict BBV-infected HCWs from training and working in clinical areas where their infection might pose a risk to patients in their care, and were considered to complement existing policy which imposed restrictions on the working practices of known BBV-infected HCWs. The guidance recommends that all new HCWs who will perform EPPs have to demonstrate, through appropriate testing, that they are non-infectious for HIV, hepatitis B and hepatitis C. If found to be infectious, the HCW is ineligible for an EPP post.

### 3.2 Management of HIV-infected HCWs: international

A review of international guidelines for the management of BBV-infected HCWs undertaken for the Viral Hepatitis Prevention Board in 2005 and updated by the Scientific Subgroup, provided information on current policies for the management of HIV-infected HCWs from 25 countries (17 EU member states and eight non-EU member states); of these 25 countries, eight have published national guidelines/recommendations.

In six countries (Australia, Ireland, Italy, Malta and UK), HIV-infected HCWs were reported to be restricted from performing invasive/EPP procedures, that is, procedures considered to be at higher risk of transmitting HIV from HCW to patient. In many other countries (Austria, Belgium, Canada, Finland, France, New Zealand and Sweden), the management of an HIV-infected HCW is decided on a case-by-case basis. The decision as to whether the HCW may be excluded from performing invasive procedures is undertaken by the employer or the clinician responsible for treating the HCW (independently or in conjunction with an expert committee), or by a local or national expert committee. Even though the US has guidelines, there is no national policy for managing HIV-infected HCWs. The recommendations from France state that, if the HCW is clinically well and has an undetectable viral load for at least three months, they should not be excluded from practice; this recommendation has not, however, been incorporated into national policy by the Ministry of Health and is not, therefore, national policy. The remaining responding countries reported that policy had not been developed, often because no cases of infected HCWs had been notified in the country (Appendix D).

Recent guidelines from the Society for Healthcare Epidemiology of America (SHEA) also take into account either the clinical status of the infected HCW or the viral burden of the HIV-infected HCW (Henderson et al 2010). In summary, HIV-infected HCWs are not restricted from participating in category 1 and 2 procedures, and are allowed to perform category 3 procedures provided they have circulating HIV burden of less than $5x10^2$ GE/ml, and as long as the infected HCW:

- is not detected as having transmitted infection to patients;
- obtains advice from an Expert Review Panel;
- undergoes routine follow-up by occupational health and personal physician;
- observes optimal infection control procedures, for example double gloving and frequent glove changes for higher risk procedures.

[5] "New HCWs" include those new to the NHS; existing HCWs moving to a post or training that involves performing EPPs for the first time, and HCWs returning to the NHS.

SHEA acknowledged that the selection of the threshold of $5x10^2$ GE/ml was arbitrary, and was chosen in part because individuals who typically have their viral burdens suppressed to the "undetectable" level occasionally have levels that spike to $5x10^2$ GE/ml, despite ongoing effective antiretroviral therapy. It was recommended that this threshold be revisited on a regular basis in light of additional accumulating evidence.

## 4. Risk of HIV transmission from HIV-infected HCWs

Transmission of HIV can occur through sexual transmission, parenteral transmission (transfusion, needle sharing or needlestick injury) or between infected mother and child.

Transmission by whatever route depends on:

- Infectiousness of the "index case" (ie. the person who transmits the HIV virus). Infectiousness depends on the concentration of HIV and HIV-infected cells in the relevant body fluid (blood or genital tract secretions) (Levy 1988). This is exemplified by the fact that the concentration of HIV in the mother's blood at the time of delivery determines risk of neonatal infection. The volume of inoculum is also particularly important.
- Susceptibility of the naïve host Human susceptibility to infection with HIV is not entirely uniform. Resistance to infection reflects some combination of genetic factors, innate resistance, and (perhaps rarely) acquired resistance (Galvin and Cohen 2004).

Understanding the relative infectiousness of plasma virions at different stages of HIV infection/exposure provides an important insight into critical biological differences between transmitted and untransmitted virus. Many of the critical events associated with HIV pathogenesis seem to occur in the first few days after infection. As acute infection resolves, the viral load reaches a steady-state "set point"[6] that must reflect some combination of virus-specific properties, host genetics, and host defences (Fellay et al. 2007). Below is a summary of what is known about transmission risk from both animal and human studies.

### 4.1 Animal studies

In a recent study (Ma et al. 2009), simian immunodeficiency virus (SIV) transmission was not observed following infusion of 2ml of plasma from a macaque with "blip" viremia (731 vRNA copies/ml). This study also failed to show evidence of transmission of SIV following infusions of 40ml of plasma collected from 3 macaques that had been exposed to serial intravaginal SIV challenges and had evidence of low levels of SIV DNA and RNA in tissues but failed to develop systemic plasma viraemia. However, this study did demonstrate that a pre-ramp-up-stage[7] plasma pool, testing negative for vRNA (<3 copies/ml) and composed of plasma samples collected from six animals at least 1 week prior to the presence of measurable plasma vRNA, contains infectious virus that can be transmitted to naïve macaques by inoculation. It was apparent that the pre-ramp-up-stage virus was well adapted to replicate in the SIV-naïve host. Data demonstrated the infectious and pathogenic potential of pre-ramp-up-stage virus and underscored the point that, depending on the volume of the inoculum, even samples that test below

[6] The first 1-2 weeks of typical HIV infections are characterized by an "eclipse" stage following viral infection but prior to the development of detectable systemic viraemia. During this period, HIV replication is initially localised but then progresses to active replication in local lymphoid tissues.

[7] This eclipse period is followed by a 2-4 week "ramp-up" period of uncontrolled viral replication in all lymphoid tissues and is often associated with a clinically apparent retroviral syndrome.

stringent vRNA copy-per-millimetre thresholds may still transmit infection. Finally, this study conducted plasma transfer experiments using dilutions of pools of ramp-up and set-point-stage plasma (10 and 16 weeks) to demonstrate that the number of infectious virions per vRNA copy is significantly lower in set-point-stage plasma than in ramp-up-stage plasma.

### 4.2 Human studies

Similarly to animal studies, research has shown that the concentration of HIV in blood and genital secretions among human populations varies dramatically depending on the stage of the disease, and that the highest viral loads are detected in the first weeks after infection and in people with advanced disease.

A substantial amount of HIV transmission seems to result from sexual exposure to subjects with acute infection. Using empirical data from a study in Uganda, Wawer and colleagues reported that HIV transmission during the first 2.5 months after seroconversion of the index partner was 8.2 cases/1000 coital acts, compared to 7-15 cases/10,000 coital acts within 6-15 months after seroconversion of the index partner; and 2.8 cases/1000 coital acts 6-25 months before the death of the index partner (Wawer et al. 2005).

Additionally, the concentration of HIV in the blood of the infected index case can be correlated directly with the sexual transmission of HIV. In a landmark study of HIV discordant couples in Uganda, Quinn et al noted that HIV transmission was not observed when the concentration of HIV was <1500 copies/ml, and that the risk of transmission increased directly with increasing blood viral burden (Quinn et al. 2000). Potential limitations to this study were that viral loads of the index partner were often extremely low and sequencing to confirm the route of transmission was not therefore always possible.

Even among people who are at the same stage of HIV disease there can be important variations in the levels of HIV in the blood. Such variations in viral burden might reflect differences in the replication capacity of different HIV clades, co-infections that increase viral burden, host genetics or other as-yet-undefined factors (Galvin & Cohen 2004).

### 4.3 HIV transmission from infected HCWs to patients

In general, three conditions are necessary for HCWs to pose a risk for BBV transmission to patients:

- the HCW must be infected and have infectious virus circulating in their bloodstream;
- the HCW must be injured or have a condition that provides some other source of direct exposure to infected blood or body fluids;
- the injury mechanism or condition must present an opportunity for the HCW's blood or body fluids to come into direct contact with the patient's mucous membranes, wound or traumatized tissue (recontact).

The vast majority of HCWs pose no risk to patients because they do not perform procedures in which they risk suffering penetrating injuries or where their injury would occur unnoticed.

### 4.3.1 Published cases of HIV transmission

There are four published cases of HCW-to-patient transmission of HIV. In 1990, a dentist in Florida was found to have infected six of his patients with HIV out of approximately 1100 patients tested. The exact mode of transmission was never identified (Ciesielski et al. 1992). A French orthopaedic surgeon was found to have infected a patient with HIV probably during a total hip replacement in 1995. Testing of an additional 983 patients, out of 3004 at risk, did not identify any other related cases (Lot et al. 1999). A gynaecologist in Spain infected a patient with HIV during a Caesarean section in 2001. Testing of 250 patients, out of 275 at risk, did not identify any additional cases (Mallolas et al. 2006). In 1996, an atypical transmission of HIV from a nurse who was co-infected with hepatitis C to a patient was reported in France with an unclear history of EPPs having been performed by the HCW. No further cases of transmission were identified following testing of 2294 out of 7508 at risk patients (Goujon et al. 2000). Table 1 provides further details about these cases of HCW to patient transmission.

**Table 1: Details of the four reported cases of healthcare worker to patient HIV transmission**

| | Details of transmission | Was a lookback undertaken? | Was phylogenetic analysis performed? | Additional comments |
|---|---|---|---|---|
| **Dentist (Florida)** | Six patients infected between 1987 and 1989. Exact mode of transmission not identified. Epidemiological data supported direct dentist to patient transmission rather than patient to patient transmission. | After the first transmission was identified, former patients of the dentist were publicly requested to have an HIV test. 1100 patients were tested. | Infected patients had DNA sequencing analysis, showing a high degree of similarity among their strains and that of the dentist. This was supported by evidence from phylogenetic trees. | All infected patients had undergone invasive procedures after the dentist had had his AIDS diagnosis. |
| **Orthopaedic surgeon (France)** | One patient infected in 1992 during a hip operation (category 3 EPP). The operation was described as lengthy and difficult. | Infected patient was identified during a lookback, initiated after the surgeon was diagnosed with AIDS. No additional transmissions identified after testing 983 of 3004 (33%) at risk patients. | Molecular analysis indicated that the viral sequences obtained from the surgeon and the patient were closely related. The patient had tested negative for HIV shortly before the operation. | CD4 count of the surgeon at diagnosis was 46 cells/ml (in 1994). The surgeon reported frequent percutaneous injuries, and was suspected to have been infected by a patient in 1983. |
| **Nurse (France)** | One patient infected in 1996, exact mode of transmission unclear. The nurse had an unclear history of having performed EPPs. | No further transmissions identified following testing of 2294 of 7508 (31%) at risk patients. | Extensive phylogenetic analysis undertaken. Results strongly supported HCW to patient transmission. Patient was HIV negative on pre-op screening. | HCW had advanced stage HIV infection and was co-infected with HCV. |
| **Gynaecologist (Spain)** | One patient infected during a caesarean section (category 3 EPP) in 2001. | Additional testing of 250 of 275 (91%) at risk patients did not reveal additional transmissions. | Phylogenetic analysis revealed genetic similarity of the HCW and patient viruses. The average nucleotide variation was 3%. | Patient was HIV negative during a pregnancy screen, and developed HIV symptoms shortly after the operation. |

### 4.3.2 Retrospective investigations of HIV transmission in the US

Retrospective studies of patients of a number of HIV-infected dentists, surgeons and physicians in the US revealed no evidence of HCW-to-patient HIV transmission during patient care (Robert et al. 1995). A summary of all published and unpublished investigations up to January 1995, of which the US Communicable Disease Centre were aware (excluding the Florida dentist case), showed no documented cases of HIV transmission among 22,171 tested patients who had been treated by HIV-infected HCWs, including a breast surgeon, general surgeon, two obstetric/gynaecologic residents and several dentists.

Although not all patients were tested and there was a lack of information on procedure records and the severity of the HCW's infection during the time the worker undertook the procedures, these results indicated that the risk of HIV transmission from HCW to patients is very low. CDC concluded that these data supported current recommendations that retrospective patient notification need not be done routinely but should be considered on a case-by-case basis, taking into account assessment of specific risks. A similar analysis utilising UK lookback data is presented in Section 5 of this report.

### 4.3.3 Estimates from a modelling exercise

Prior to this retrospective US analysis, Bell et al estimated the risk of HIV transmission to a patient from an infected surgeon based on a model involving three probabilities:

- A, the probability that the surgeon will sustain a percutaneous injury during an invasive procedure (2.5%)[8];
- B, the probability that the sharp object causing the injury and now contaminated with the surgeon's blood will contact the patient's wound (32%); and
- C, the probability that infection would be transmitted to the patient after such an exposure (which to a large extent depends upon the level of the HCW's viral load) (0.03-0.3) (Bell et al. 1992).

The probability of HIV transmission from an infected surgeon to a patient during a single invasive procedure was estimated to be between 0.00024% (1 case for every 416,667) interventions and 0.0024% (1 case for every 41,667 interventions) (Bell et al. 1992). Bell concluded that the estimated probability of transmission to at least one patient would be between 0.12% and 1.2% during the course of one year (500 interventions per year) and between 0.8% and 8.1% over 7 years of activity. This estimate represented a population average and may not therefore apply to a particular procedure performed by a particular surgeon. It could be argued that this model would lead to an over-estimate of risk, since improvements in modern surgical practice have occurred since the model was

[8] Invasive procedure was defined as procedures requiring a skin or mucous membrane incision performed in an operating room by a general, orthopaedic, gynaecologic, trauma or cardiac surgeon. Endoscopic procedures were not included.

developed. Additionally, these estimates do not take into account the viral load level and the possible impact of antiretroviral treatments.

# 5. Healthcare worker to patient transmission of HIV: results from retrospective investigations carried out in the UK between 1988-2008

The risk of HIV transmission from an infected HCW to patient is further quantified in this chapter using available data from the UK. Results from patient notification exercises (PNEs)[9] undertaken in the UK between 1988 and 2008 have been analysed, and factors which may affect the risk of transmission, such as procedure and medical condition of the HCW, have also been taken into account. Estimates of risk of transmission with both midpoint estimate of risk and 95% confidence limits are presented.

## 5.1 Number of patient notification exercises undertaken

To the end of 2008, 39 PNEs involving HIV-infected HCWs had been undertaken in the UK and reported to UKAP. Results are currently available for 34 of these PNEs.

### 5.1.1 Results by speciality

In total, 26,978 patients were identified as being at risk following an EPP performed by an HIV-infected HCW. Of these, 9,849 (37%) patients were tested. No cases of HCW to patient HIV transmissions were identified. The HCWs performed in a variety of specialities (Table 2). Nine of the HCWs worked in obstetrics and gynaecology (26%, 9/34), with a further 18% (6/34) in dentistry, 15% (5/34) in midwifery and 12% (4/34) as a theatre nurse. Testing rates by speciality differed, from an overall 22% of patients treated by a dentist to 79% amongst patients treated by midwives.

It was not always clear from the data how many patients considered to have been put at risk were in fact contacted. Where these data were available (19/34 reports), of the 16,671 patients considered to have been at risk, 13,750 (82%) were contacted, mostly by letter. Of these patients, 5640 (41%) were tested. Many patients exposed to a risk of HIV were therefore untested.

### 5.1.2 Results by exposure prone procedure

Twenty nine (85%) of the reports reviewed contained information on category of EPP. In 15 of these cases, 4,375 patients were considered to have been put at higher risk of HIV infection through a category 3 EPP. Of these patients, 2283 (52%) were tested for HIV (Table 3). The estimated risk of

[9] Exercises to identify and notify patients who have undergone an EPP by an infected HCW are undertaken to 1) provide patients with information about the nature of the risk to which they have been exposed 2) detect any HIV infection, provide care to the infected person and advice on measures to prevent onward HIV transmission and 3) collect valid data to augment existing estimates of the risk of HIV transmission from an infected worker to patients during exposure prone procedures. Since 2001 lookbacks involving HIV-infected HCWs have been recommended only for category 3 EPPs, which are seen to carry the highest risk. Categories 1 and 2 EPPs would only be included if there were an index case of HCW-patient transmission or if there is evidence of poor clinical practice (e.g. poor infection control), evidence of physical or medical impairment which could affect the standard of practice or other relevant medical conditions e.g. skin diseases such as weeping eczema.

transmission through a category 3 EPP was 0.00%, with a midpoint estimate of risk of 1 in 1639 and an upper 95% confidence limit of 1 in 620.

#### 5.1.3 Results by healthcare worker symptoms

Of the 34 lookbacks reviewed, 10 HCWs were reported to have been symptomatic at diagnosis. In these cases, 11,625 patients were considered to have been at risk of acquiring HIV infection and 4,126 (35%) patients were tested for HIV (Table 4). Five hundred and ninety of these patients had had a category 3 EPP (risk of transmission 0.00%, midpoint estimate of risk 1 in 435 and 95% confidence limit 1 in 161). No HCW in these retrospective investigations would have been taking antiretrovirals whilst practising.

#### 5.1.4 Estimate of risk of transmission

The risk of HCW to patient transmission of HIV is undoubtedly low and these data are similar to those found in an investigation by CDC (Robert et al. 1995). Nearly 10,000 patients in the UK have been tested for HIV following an EPP performed by an HIV-infected HCW. No cases of transmission were identified. Using these data it is therefore estimated that the risk of transmission is low (0.00%), with a midpoint estimate of risk of 0.014% (1 in 7142) or an upper 95% confidence interval bound of 0.037% (1 in 2700 patients tested). In all 34 PNEs, whilst no transmissions from HCW to patient were identified, one incidental case which was not linked to HCW-to-patient transmission was found.

### 5.2 Estimated risk of transmission from an infected HCW to patient using UK and US data

The risk of transmission of HIV from an infected HCW to a patient during a category 1 or 2 EPP is considered to be negligible, and PNEs are no longer recommended for these categories of procedure.

The risk of HIV transmission from an infected HCW to a patient during a category 3 EPP in the UK is presented in Table 3. These data are summarised in Table 5, alongside data on risk of transmission during category 3 EPP procedures from the US CDC retrospective analysis.

Table 6 shows the numbers of HIV transmissions which could potentially occur during category 3 EPPs from an infected HCW to a patient if the clinical practice of HIV-infected HCWs were to become unrestricted. These estimates have been based on 1) the midpoint estimate risk of transmission using UK lookback data, 2) the midpoint estimate risk of transmission using combined UK and US lookback data. This table has focussed on category 3 EPPs as the main source of risk since the risk of transmission from category 1 and 2 procedures is considered very low. The mean risk estimate published by Bell et al is included in the table for comparative purposes (Bell et al. 1992). As stated previously, it should be noted that the Bell estimate was established in 1992, the definition of injury

was unclear, surgical techniques have changed since the analysis was undertaken and little account of 'bleed-back' (amount of inoculum) was incorporated into these estimates.

Using the UK lookback data it can be estimated that the midpoint estimate risk for transmission is 1 in 1639. The potential number of iatrogenic transmissions which could occur from all the HIV-infected surgeons who had been referred to UKAP for advice between 2004-2009 (n=11) would be 1.6 per year. This number would be expected to be reduced if further lookbacks were undertaken, thus increasing numbers of patients tested. We can, however, plausibly assume that combination antiretroviral treatment (cART) could reduce transmission risk by 20-fold (discussed in depth in section 6), meaning the estimated number of transmissions would be 1 per 12 years (see Table 6). Using these same assumptions, but applying the Bell risk of transmission of 1 in 41,666, the estimated number of transmissions for HCWs on cART would be 1 every 303 years.

The risk estimates for an HIV-infected HCW (on cART) transmitting the virus to a patient during a category 3 EPP are provided in Table 6, and range from 1 in 33,000 to 1 in 833,000.

If the risk of transmission presented in Table 6 was correct (1 in 1639 for untreated HCWs), we would have expected to observe 1.6 transmissions per year. However, no iatrogenic transmissions have been observed in the UK. A high proportion of the UK population has been screened for HIV, either through antenatal screening (over 90% of pregnant women receiving antenatal care), GUM screening (about 93% of STI attendees) or blood donor screening, and there have been no indications of positive cases being found that have been linked to healthcare. In addition, there has been no evidence from new HIV diagnosis reports submitted to the HPA that the cause of infection was through a HCW. In cases where the transmission route was undetermined, these reports would have received thorough follow-up.

### 5.3 Data limitations

The following limitations should, however, be borne in mind when interpreting the risk of transmission generated from the UK and US data:

1. In all cases, date of acquisition of HIV by the HCW was unknown. PNEs often went back 10 years, and many of the patients tested may have been treated by a HCW who had not yet acquired their HIV infection.
2. Many patients potentially exposed to HIV were not tested, either because they were not contactable or because the patients declined testing. We have assumed these patients to be no different from those patients who did take up the test offer.
3. The risk of HIV transmission is likely to be dependent on type of procedure and, in this analysis, specific procedure data was generally not available for those patients tested.
4. In most cases, the stage of the HCW's HIV infection when the procedures were performed was not known.

**Table 2: Numbers of patients at risk and numbers of patients tested by HCW speciality (no patients were identified as infected, HCW was untreated)**

| Speciality | Number of lookbacks | Number of patients at risk | Number of patients tested | % of patients tested | Range tested[1] | Plausible risk of transmission (a 3 in 4 chance the risk is less than this value and a 1 in 4 chance the risk is greater than this value) | Upper 95% Confidence limit[2] |
|---|---|---|---|---|---|---|---|
| Obs & Gynae | 9 | 10,650 | 4,940 | 46% | 29-100% | 0.028 (1 in 3571) | 0.075 (1 in 1300) |
| Dentistry | 6 | 12,328 | 2,745 | 22% | 9-43% | 0.050 (1 in 2000) | 0.134 (1 in 750) |
| Midwifery | 5 | 194 | 154 | 79% | 50-100% | 0.896 (1 in 112) | 2.367 (1 in 40) |
| Theatre Nurse | 4 | 583 | 306 | 52% | 42-100% | 0.452 (1 in 221) | 1.198 (1 in 80) |
| Multiple | 3 | 713 | 159 | 22% | 18-23% | 0.868 (1 in 115) | 2.293 (1 in 40) |
| Other | 7 | 2,510 | 1,545 | 62% | 5-100% | 0.089 (1 in 1124) | 0.240 (1 in 400) |
| **Total** | **34** | **26,978** | **9,849** | **37%** | **5-100%** | **0.014 (1 in 7142)** | **0.037 (1 in 2700)** |

[1] Range of proportion of patients tested by individual lookback for each speciality.
[2] The upper 95% confidence limit for the proportion of patients that could be found to be infected. As the numerator is zero, a lower bound confidence limit has not been presented. Some of the upper limits are low (for example 1 in 40 for midwifery), and this reflects the small number of patients tested for these categories of HCWs.

**Table 3: Numbers of patients at risk and numbers of patients tested by category of exposure prone procedure (no patients were identified as infected, HCW was untreated)**

| EPP category | Number of patients at risk | Number of patients tested | % of patients tested | Plausible risk of transmission (a 3 in 4 chance the risk is less than this value and a 1 in 4 chance the risk is greater than this value) | Upper 95% Confidence limit[1] |
|---|---|---|---|---|---|
| 1 and 2 | 19,950 | 5,939 | 30% | 0.023 (1 in 4348) | 0.062 (1 in 1600) |
| 3 | 4,375 | 2,283 | 52% | 0.061 (1 in 1639) | 0.161 (1 in 620) |
| Category not Stated | 2,653 | 1,627 | 61% | 0.085 (1 in 1176) | 0.226 (1 in 440) |
| **Total** | **26,978** | **9,849** | **37%** | **0.014 (1 in 7142)** | **0.037 (1 in 2700)** |

[1] The upper 95% confidence limit for the proportion of patients that could be found to be infected. As the numerator is zero, a lower bound confidence limit has not been presented.

**Table 4: Numbers of patients at risk and numbers of patients tested by whether or not the HCW was symptomatic at diagnosis (no patients were identified as infected, HCW was untreated)**

| HCW symptoms | Number of patients at risk | Number of patients tested | % of patients tested | Plausible risk of transmission (a 3 in 4 chance the risk is less than this value and a 1 in 4 chance the risk is greater than this value) | Upper 95% Confidence limit[1] |
|---|---|---|---|---|---|
| HIV/AIDS-related symptoms at diagnosis was reported | 11,625 | 4,126 | 35% | 0.034 (1 in 2941) | 0.089 (1 in 1120) |
| No HIV/AIDS-related symptoms at diagnosis reported | 8,501 | 2,556 | 30% | 0.054 (1 in 1852) | 0.144 (1 in 700) |
| Not Known | 6,852 | 3,167 | 46% | 0.044 (1 in 2273) | 0.116 (1 in 860) |
| **Total** | **26,978** | **9,849** | **37%** | **0.014 (1 in 7142)** | **0.037 (1 in 2700)** |

[1] The upper 95% confidence limit for the proportion of patients that could be found to be infected. As the numerator is zero, a lower bound confidence limit has not been presented.

**Table 5: Reported numbers of patients tested for HIV after undergoing a higher risk (category 3 EPP) procedure by an HIV-infected HCW: UK and international data**

| | Number of incidents/studies | Number of category 3 EPP patients tested | Number patients positive | Plausible risk of transmission (a 3 in 4 chance the risk is less than this value and a 1 in 4 chance the risk is greater than this value) | Upper 95% confidence intervals |
|---|---|---|---|---|---|
| UK lookbacks[1] | 15 | 2283 | 0 | 1 in 1600 | 1 in 620 |
| US lookbacks[2] | 5 | 1876 | 0 | 1 in 1400 | 1 in 510 |
| **Total** | **17** | **4159** | **0** | **1 in 3000** | **1 in 1120** |

[1] These data are adapted from Table 4 of the report.
[2] These data are adapted from Robert et al (1995), which summarised retrospective investigations of 64 HCWs infected with HIV as of January 1995. Five of the 64 studies analysed included information on level of risk of the procedure performed (1 breast surgeon, 1 orthopaedic surgeon and 3 obstetric and gynaecologists). The category 3 EPPs from these 5 studies were included in this analysis.

**Table 6: Possible number of transmissions (with and without effective cART) if HIV-infected HCWs undertaking category 3 EPPs were allowed to resume work.**

| | Level of risk used in calculation | Risk estimate expressed as 1 per xxxx | Estimated number of transmissions per year if HIV-infected surgeons referred to UKAP between 2004-2009 were allowed to perform category 3 EPPs[1] | Possible transmission risk estimate based on a 20-fold reduction with cART[2,3] | Estimated number of transmissions if HIV-infected surgeons referred to UKAP between 2004-2009 were allowed EPP3 practice and were taking effective cART |
|---|---|---|---|---|---|
| | | No antiretroviral therapy | | cART | |
| UK lookback estimate | Plausible risk of transmission | 1 in 1600 | 1.6 per year | 1 in 32,780 | 1 every 12 years |
| Total lookback estimate (UK + US lookbacks) | Plausible risk of transmission | 1 in 3000 | 0.9 per year | 1 in 60,000 | 1 every 22 years |
| Bell risk estimate[4] | Mean | 1 in 42,000 | 0.07 per year | 1 in 833,320 | 1 every 303 years |

[1] Between 2004-2009, 11 surgeons who had undertaken higher risk (EPP3) procedures were reported to UKAP. It was assumed an average surgeon would perform 250 EPP3 procedures per year. Therefore 2750(11x250) category 3 procedures per year would be performed by 11 HIV-infected HCWs if they were allowed to perform category 3 EPPs..
[2] Combination antiretroviral therapy defined as using three or more agents, with the aim of fully suppressing the HIV virus to undetectable levels in the blood.
[3] A 20-fold reduction is a plausible estimate based on what we know about reductions in transmission if effective cART is taken and viral suppression is achieved.
[4] All invasive procedures defined by Bell et al would be considered EPP3 procedures using the current system of classification employed in the UK.

## 6. HIV transmission risk from infected healthcare workers with undetectable viral loads and/or treated with antiretroviral therapy

Existing UK guidelines do not consider the effect of treatment on the viral load of the infected HCW in the decision about practice restriction. HIV-infected individuals treated with and adherent to combined antiretroviral therapy typically achieve suppressed viral loads and thereby reduced infectivity. The effect of therapy on HIV transmission risk from HCWs to patients is unknown and cannot be calculated due to the rarity of the occurrence, but the effect of therapy on transmission through other routes, mainly sexual and vertical, has been studied.

An unpublished review identified and compared published studies of HIV transmission where viral load and/or antiretrovirals were documented risk factors for HIV transmission. Studies exploring the risk of HIV transmission within HIV serodiscordant heterosexual couples have consistently found HIV viral load to be an important determinant of transmission. No transmission events were reported where viral load was suppressed to less than 1000 copies/ml (Brown 2011; Donnell et al. 2010). Likewise, results from randomised controlled trials assessing the efficacy of antiretrovirals to prevent vertical HIV transmission have shown that monotherapy, and to a greater extent combination therapy, is effective in reducing risk of transmission – to less than 2% in some studies. No studies, however, have shown the risk to be eliminated, even when viral loads were suppressed to below 500 copies/ml.

While the literature demonstrates that the sexual and vertical transmission rate from virally suppressed individuals is low – generally less than 1%, these data should not be extrapolated to the healthcare setting without an understanding of differential viral loads between body compartments and viral rebounds; these are two important factors to bear in mind when considering whether an HIV-infected HCW who is virally suppressed should be allowed to undertake EPPs.

Viral load is known to vary between body fluids and the association between viral load in blood and the viral load in semen and vaginal secretions remains unclear. Consequently, the low rates of sexual and vertical transmission may not be applicable to the risk posed by blood plasma.

Viral load suppression among those adherent to treatment is often accompanied by transient viral rebounds: infectivity is likely to follow suit. While these are frequent events, they are low-level, and rarely peak above 500 copies/ml. Their occurrence, nonetheless, highlights that the transmission risk cannot be eliminated among “virally suppressed” individuals.

In the absence of data on risk of HIV transmission by an HIV-infected HCW fully adherent to treatment during EPPs, one can look at the effects of treatment on the reduction of vertical transmission to estimate what could be achieved. In the UK, vertical transmission rates have been reduced from 20% where there is no intervention (Caesarean section or antiretroviral therapy) (Duong et al. 1999) to 0.8% amongst all pregnant women on treatment or 0.1% amongst pregnant women on treatment who achieved viral suppression. Caesarean section was not found to be of additional benefit to women taking antiretrovirals (Townsend et al. 2008). Therefore, treatment can reduce transmission risk by up to 200-fold amongst HIV-infected diagnosed pregnant women. In this report, a conservative 20-fold reduction in risk has been used to adjust for the effect of cART in the estimated risk of HIV-infected HCW to patient transmission (presented in Table 6).

## 7. Conclusions and recommendations

At the time of making the decision to restrict HIV-infected HCWs from performing EPPs in the UK, little information was available about the risk of iatrogenic transmission. Evidence on the risk of HCW to patient HIV transmission has now accumulated.

In summary:

- In the UK there have been no documented cases of HIV transmission from HCWs to their patients and only four have been reported worldwide. Two of these cases occurred during category 3 EPPs and, in the other two cases, the route of transmission was never established. These four cases of transmission involved HCWs who were untreated at the time of transmission.
- Data from UK patient notification exercises suggest the risk of transmission is low, less than 1 in 1600. There is no evidence that HIV infections attributed to HCW-patient transmission have been identified through other routine HIV testing programmes such as antenatal screening, GUM screening or blood donor screening.
- Retrospective US data also suggest a low risk of transmission.
- Current UK evidence indicates the risk of transmission from category 1 and 2 EPPs is negligible and from category 3 EPPs to be extremely low.
- Current policy does not take into account the viral suppression which can be achieved with effective cART. There is good evidence that this can have a considerable impact on virus transmission in other situations, for example discordant couples and prevention of mother to child transmission.
- UK policy is more conservative than in some countries, such as France and the US, but in line with countries such as Australia, Ireland and Italy.
- There is the potential for the UK policy on HIV-infected HCWs to be challenged through the Discrimination Disability Act or the Equality Act if it is not based on an expert assessment of up-to-date evidence or expert opinion, where evidence is lacking.

In addition, several important developments in the management of HIV have occurred, and more sensitive tests to measure viral load have been developed.

Following the presentation of the available evidence on risk of HIV transmission, the Tripartite Working Group was asked to consider whether or not an HIV-infected HCW could be allowed to undertake EPPs; whether or not they should be required to be on effective cART with viral load suppressed to a non-detectable level; and the implications of co-infection with other BBVs. The working group considered the following options:

1. Restriction from EPP 1-3 (extant UK policy).
2. Allow EPP 1-2 (with cART), restrict from EPP3.
3. Allow EPP 1-3 (with cART) (analogous to recommendations in place in France).
4. Allow EPP 1-2 (without cART), allow EPP 3 (with cART) (analogous to the guidelines from the Society for Healthcare Epidemiology of America).
5. Allow EPP 1-3 (without cART).

In the light of increased knowledge about the risk of transmission of HIV from a HCW, and the availability of effective treatment to reduce the infectivity of HIV-infected individuals, the working group considered that a relaxation of the policy on HIV-infected HCWs could be justified and recommended that HIV-infected HCWs be permitted to undertake all categories of EPPs, provided that the level of viral load is 'non-detectable' (Option 3). The working group was clear that the important issue was not so much that the HIV-infected HCW should be on cART, but that the viral load should be at an agreed 'non-detectable' level, with or without treatment. In the majority of cases, this was likely to be achieved only with cART.

The working group also stressed that the current obligations on all HCWs, to observe the duty of professional care to patients by seeking advice if they have reason to suspect they may have been infected with a BBV, should remain in place.

The working group acknowledged that HIV transmission has only been documented in connection with category 3 EPPs, and that allowing HIV-infected HCWs to perform category 1 and 2 EPP procedures without requiring the individual to be on effective cART with viral load suppression (Option 4), would be consistent with the UK policy on PNEs (i.e. that PNEs are recommended only for patients exposed to HIV-infected HCWs who have carried out category 3 procedures). However, following reflection on what was justified by the available evidence and what was practicable, the group considered the more restrictive approach of Option 3 (above) to achieve the right balance for the following reasons:

- To date in the UK, the triple categorisation of EPPs has been used only retrospectively in relation to PNEs. Restricting practice by category of EPP would be very hard to implement prospectively since the categorisation of procedures in different specialties is provisional and is affected by variations in technique and technical developments. Implementing a consistent approach to assessing and advising on the practice of individual HIV-infected HCWs would therefore be very complex.
- It would be difficult to ensure that any HCW observed a restriction in practice to category 1 and 2 EPPs. In surgical specialties, for example, it is possible for a category 1 or 2 EPP procedure to become a category 3 EPP as a result 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 – who might not be available.

- Many EPPs fall between categories 2 and 3, depending on the technique employed by the HCW.
- Requiring all HIV-infected HCWs undertaking EPPs to be on cART would normalise HIV testing and might encourage more HCWs to come forward for testing and thereby benefit from treatment.

In parallel with the Tripartite Working Group recommendation to lift the restriction on HIV-infected HCWs from practising EPPs, UKAP has recommended that the guidance on recommending PNEs should be updated to reflect the view that the risk of HIV transmission from an infected HCW, with a level of viral load that is non-detectable, is very low. Adopting a policy that is consistent with the view that the risk of HCW to patient transmission is low, will reduce the burden of PNEs, both in terms of the time and resources required to trace, counsel and test those potentially exposed – an estimated saving of £200-400K per exercise, excluding opportunity costs.

On 13th October 2010 EAGA endorsed option 3 above, and following that recommendation, the expert group was tasked with developing a detailed implementation framework. The recommendations from EAGA on implementation of the revised framework are summarised in section 8 and Appendix E.

## 8. HIV-infected healthcare workers and antiretroviral therapy: proposed implementation framework

HIV-infected HCWs are permitted to perform any EPP if they are on cART and have a plasma viral load suppressed consistently below 200 copies/ml. HCWs will need to demonstrate a sustained response to cART (i.e. viral load <200 copies/ml on two consecutive plasma samples[10]) prior to starting or resuming EPPs and will be subject to testing every 3 months while continuing to perform EPPs. Laboratory testing will be done in local CPA-accredited laboratories[11] that can carry out and report results of urgent viral load tests in 2 days. The number of HIV-infected HCWs whose profession relies on performing EPPs that will be affected by this policy is estimated to be in the region of 110 (see Appendix F).

HIV-infected HCWs will be under the joint supervision of a consultant in occupational medicine[12] 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 (see Appendix E under Monitoring), will be restricted from EPP work until their viral load returns to being stably <200 copies/ml. Clearance by a consultant in occupational medicine to resume EPP work will be determined on a case-by-case basis, depending on the reasons for the viral load breaching the threshold and the viral load level reached.

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.

The decision on whether EPP practice can begin, should cease, the need for a patient notification exercise (to cover the period of potential infectiousness) and when EPP work can resume should be made by a consultant in occupational medicine informed by relevant experts. There is an argument for all cases of HIV-infected HCWs who wish to perform EPPs to be referred to the UKAP (see Appendix E under Role of Expert Panel).

[10] Health clearance to perform EPPs should be granted for HIV-infected HCWs currently on cART if the two most recent consecutive viral load results from tests taken at least 3 months apart are <200 copies/ml. HIV-infected individuals starting cART typically achieve an undetectable viral load after 3 months on treatment. Before resuming EPP work, a further undetectable viral load test one month later (i.e., a minimum of 4 months after starting therapy), is required for health clearance.

[11] HIV viral load testing is part of routine HIV patient management and does not need to be performed by designated laboratories. An 'accredited laboratory' is one accredited by Clinical Pathology Accreditation (UK) Limited. A list of such laboratories is available from: www.cpa-uk.co.uk

[12] A 'consultant in occupational medicine' is a doctor registered as a specialist by the GMC and appointed to an NHS consultant post by a process consistent with the national Health Service (Appointment of Consultants) Regulations 2005 or their equivalent.

## 9. Acknowledgements

This report has been prepared by a working group of national experts and benefited from discussions, inputs and comments from members of the constituent groups (AGH, EAGA and UKAP), whose generous sharing of time, expertise and knowledge is greatly appreciated.

## 10. Appendices

### Appendix A

#### List of members of the Tripartite Working Group as at 28th September 2010

Professor Ian Weller (Chair) (outside expert)

Sir Bernard Ribeiro (outside expert)

Dr Barry Cockcroft (Chief Dental Officer, DoH)

Mr David Crundwell (EAGA)

Professor Geoffrey Garnett (EAGA)

Professor Brian Gazzard (current EAGA Chair)

Dr Jeremy Hawker (EAGA)

Dr Alison Rimmer (EAGA)

Professor Jeremy Bagg (UKAP)

Mrs Isabel Boyer (current UKAP Chair)

Professor Margaret Bassendine (AGH, UKAP)

Dr Sheila Cameron (UKAP)

Professor Keith Neal (UKAP)

Dr Julia Smedley (UKAP)

Mr Richard Smith (UKAP)

Professor Derek Alderson (UKAP)

Dr Sheila Burns (UKAP)

Ms Diane Gilmour (Association for Perioperative Practice)

Professor David Goldberg (UKAP)

Ms Deborah Jack (National AIDS Trust)

Professor Jean McHale (UKAP)

Mrs Joanna Hoskins (UKAP)

Dr Anton Pozniak (EAGA)

Professor Will Irving (current AGH chair)

Dr Peter Moss (AGH)

Dr Liz Murphy (AGH)

Dr William Tong (AGH)

**Previous members**

Ms Jean Reid (Association for Perioperative Practice)

Lady Winfred Tumim (former UKAP Chair, deceased)

Professor Howard Thomas (former AGH Chair)

Dr Kit Harling (AGH, UKAP)

Mr Christopher Russell (UKAP)

Mr Bill Thomas (UKAP)

**Observers**

Dr Sara Hayes (Welsh Assembly Government)

Dr Linda Lazarus (HPA)

Mr Chris Lucas (HPA)

Mr Gerry Robb (DoH)

Dr Andrew Riley (ScotGov)

Dr Delia Skan (HSENI)

Ms Tracey Gauci (Welsh Assembly Government)

Dr Hugh Nicholas (DoH)

Dr Elizabeth Stewart (ScotGov)

Dr Lorraine Doherty (HSENI)

**Secretariat**

Dr Fortune Ncube (HPA), Medical Secretary

Dr Susan Cliffe (HPA)

Ms Helen Janecek (HPA)

Dr Kirsty Roy (HPS)

Ms Sarah Tomkins (HPA)

# Appendix B

## Exposure prone procedures

The evidence-based definition of EPP embraces a wide range of procedures, in which there may be very different levels of risk of bleed-back (injury to the HCW resulting in the worker's blood contaminating the patient's open tissues). The definition of an EPP is as follows (Department of Health 2005):

*"Exposure prone procedures are those invasive procedures where there is a risk that injury to the worker may result in the exposure of the patient's open tissues to the blood of the worker (bleed-back). These include procedures where the worker's gloved hands may be in contact with sharp instruments, needle tips or sharp tissues (eg spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where the hands or fingertips may not be completely visible at all times. However, other situations, such as pre-hospital trauma care should be avoided by health care workers restricted from performing exposure prone procedures, as they could also result in the exposure of the patient's open tissues to the blood of the worker."*

A risk-based categorization of clinical procedures was developed by a joint working group of UKAP and EAGA and included in DH guidance on HIV-infected HCWs and patient notification in 2005. The categorization includes procedures where there is negligible risk of bleed-back (non-exposure prone procedures) and three categories of EPPs with increasing risk of bleed-back.

**Category 1**

Procedures where the hands and fingertips of the worker are usually visible and outside the body most of the time and the possibility of injury to the worker's gloved hands from sharp instruments and/or tissues is slight. This means that the risk of the HCW bleeding into a patient's open tissues should be remote. Examples: *local anaesthetic injection in dentistry, removal of haemorrhoids*.

**Category 2**

Procedures where the fingertips may not be visible at all times but injury to the worker's gloved hands from sharp instruments and/or tissues is unlikely. If injury occurs it is likely to be noticed and acted upon quickly to avoid the HCW's blood contaminating a patient's open tissues. Examples: *routine tooth extraction, appendicectomy*.

**Category 3**

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 procedures.*

Major surgical procedures (category 3 EPPs) have regularly been associated with hepatitis transmissions.

# Appendix C

## List of members of the Scientific Subgroup

**Participants**

Professor Ian Weller (Chair) (outside expert)

Mrs Isabel Boyer (current UKAP Chair)

Professor Geoffrey Garnett (EAGA)

Professor Brian Gazzard (current EAGA Chair)

Professor Noel Gill (outside expert)

Professor David Goldberg (UKAP)

Ms Deborah Jack (National AIDS Trust)

Sir Bernard Ribeiro (outside expert)

Dr William Tong (AGH)

Professor Myron Cohen (outside expert)

Professor Will Irving (current AGH Chair)

Professor Harold Jaffe (outside expert)

**Observers**

Dr Linda Lazarus (EAGA)

Mr Gerry Robb (DoH)

Mr Chris Lucas (AGH)

**Secretariat**

Dr Fortune Ncube (HPA),
Medical Secretary

Dr Susan Cliffe (HPA)

Ms Helen Janecek (HPA)

Ms Sarah Tomkins (HPA)

## Appendix D Summary of UK and international policies on the management of HIV-infected HCWs

| | Exclusion from invasive/high risk procedures | Practice restriction determined by | Source of information |
|---|---|---|---|
| **Argentina** | No | NA | Personal communication with Dr Pedro Cahn, Head of Infectious Diseases Unit at hospital Juan A. Fernandez, Buenos Aires, Argentina |
| **Australia**[13] | Yes. HCW not permitted to perform EPP | Expert committee | Guidelines for Managing Blood-Borne Virus Infection in Health Care Workers. Australian Government, Department of Health and Ageing. September 2005. Available online at: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdna-bloodborne.htm |
| **Austria** | Decided on case by case basis | Employer | Personal communication with Dr Franz Allerberger, Austrian Agency for Health and Food Safety, Vienna |
| **Belgium** | Decided on case by case basis | Medicine du Travail | Personal communication with Dr Andre Sasse, Scientific Institute of Public Health, Brussels |
| **Bosnia and Herzegovina** | No policy | NA | Personal communication with Dr Zlatko Cardaklija, Federal HIV/AIDS Co-ordinator |
| **Brazil** | No | NA | Personal communication with Prof Mauro Schechter, Universidade Federal do Rio de Janeiro |
| **Canada**[14] | Decided on a case by case basis | Expert committee | Public Health Agency Canada. Proceedings of the Consensus Conference on infected health care worker risk for transmission of bloodborne pathogens. *Canada Communicable Disease Report* 1998; 24S4. http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98vol24/24s4/index.html |
| **Cyprus** | No policy developed. (No reported cases to date) | N/A | Personal communication with Dr Anna Nouska, AIDS Programme Manager, Ministry of Health |

[13] Australia has a federal structure, so the states and territories interpret and implement the national infection control guidelines, producing their own (very similar) guidelines, implemented in slightly different ways.

[14] Though Canada has national endorsed guidelines on dealing with infected HCWs, several Provincial licensing bodies have established guidelines regarding HCWs and BBVs.

| | | | |
|---|---|---|---|
| **Denmark** | No | National Board of Health | Personal communication with Dr Susan Cowan , Department of Epidemiology, Epidemiology Division, Statens Serum Institut |
| **Estonia** | No policy developed. (No reported cases to date) | Chief Physician of Hospital | Personal communication with Dr Kuulo Kutsar, Chief Epidemiologist, Health Board |
| **Finland** | Decided on case by case basis. | No formal recommendation but in practice Infectious disease doctor | Personal communication with Dr Petri Ruutu, Head of Department, National Institute for Health and Welfare |
| **France** | If HIV-infected HCW clinically well and undetectable viral load for at least 3 months, no restrictions for EPP3 apply | National committee. (Not yet national policy[15]) | Conseil Supérieur d'Hygiène Publique de France. Relatif à la prévention de la transmission du virus de l'immunodéficience humaine (VIH) aux patients par les professionels de santé. 2005. http://www.sante.gouv.fr/htm/dossiers/cshpf/a_mt_170605_VIHsoignantssoignes.pdf |
| **Germany** | No policy developed | N/A | Personal communication with Dr Osmah Hamouda and Dr Uli Marcus Robert Koch Institut |
| **Ireland** | Yes. HCWs not permitted to perform EPPs | A local Expert Group | Department of Health and Children, Ireland. The prevention of transmission of blood borne diseases in the health care setting. 2005. http://www.dohc.ie/publications/transmission_of_blood_borne_diseases_2006.html |
| **Italy** | Yes. HCWs not permitted to perform EPPs | Hospital director, supported by an Expert committee | Commissione nazionale per la lotta contro l'AIDS MdS. Linee guida per prevenire la trasmissione del virus dell'immunodeficienza umana e del virus dell'epatite B dagli operatori infetti ai pazienti durante le procedure invasive che detminano un rischio di esposizione. *Giornale Italliano Dell'AIDS* 1995; 6: 20-3 |
| **Latvia** | No policy developed | NA | Verbal communication with Dr Inga Upmace, Head of HIV/AIDS Limitation Program Implementation Coordination Department, Infectology Center of Latvia, Riga |

[15] The expert advice has not yet been formally translated into recommendations of the Ministry of Health, and no national commission has yet been set up.

| | | | |
|---|---|---|---|
| **Malta** | Yes, depending on the risk category of the HCW | Superintendent of Public Health following advice from a committee with representatives from Infection Control/ Occupational Health, Public Health and Infectious Diseases | Personal communication with Dr Charmaine Gauci, Director Health Promotion and Disease Prevention, Ministry for Health, the Elderly and Community Care |
| **Mexico** | No policy developed | NA | Personal communication with Dr Juan Sierra madero, Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubaran, CIFBIOTEC Medica Sur |
| **Netherlands** | No policy developed | NA | Personal communication with Dr Marianne A.B. van der Sander, Head of Epidemiology and Surveillance, Centre Infectious Disease Control |
| **New Zealand** | Decided on case by case basis | Expert committee | Health Regulatory Authorities of New Zealand (HRANZ). HRANZ Joint Guidelines for registered health care workers on transmissible major viral infections. 2005. http://www.mcnz.org.nz/portals/0/guidance/TMVI%20-%20HRANZ%20guidelines.pdf |
| **Poland** | No | Director of hospital | Personal communication with Dr Andrzej Horban, Warsaw's Hospital for Infectious Disease |
| **Spain** | No national policy developed. In Catalonia policy is to re-deploy infected HCWs performing EPPs | Independent ethics committee | Personal communication with Dr Jose M Gatell, Hospital Clinic de Barcelona, University of Barcelona |
| **Sweden** | Decided on a case by case basis | Treating Physician of infected HCW obliged to ensure prevention of further spread which may require a change in working practice | Personal communication with Prof Anders Sonnenberg, Karolinska Institutet, Stockholm and Dr Torsten Berglund, The National Board of Health and Welfare, Stockholm |
| **UK** | Yes. HCWs not permitted to perform EPPs | An Expert Group | Department of Health, UK. Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers. 2007. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_073132 |

| | | | |
|---|---|---|---|
| **US** | Yes. Excluded from EPP 3 if viral load ≥5x10$^2$GE/ml. No exclusions from EPP1 or 2. Determined on a case by case basis. | Not yet national policy | Henderson DK, Dembry L, Fishman N, Grady C, Lundstrom T, Palmore T et al. SHEA Guidelines for Management of Healthcare Workers who are infected with Hepatitis B virus, Hepatitis C virus, and/or Human Immunodeficiency virus. http://www.shea-online.org/Assets/files/guidelines/BBPathogen_GL.pdf |

# Appendix E

## HIV-infected healthcare workers and antiretroviral therapy: proposed implementation framework

### Summary of proposed policy

HIV-infected HCWs are permitted to perform any EPP if they are on cART and have a plasma viral load suppressed consistently below 200 copies/ml. HCWs will need to demonstrate a sustained response to cART (i.e. viral load <200 copies/ml on two consecutive plasma samples[16]) prior to starting or resuming EPPs and will be subject to testing every 3 months while continuing to perform EPPs. Laboratory testing will be done in local CPA-accredited laboratories[17] that can carry out and report results of urgent viral load tests in 2 days.

HIV-infected HCWs will be under the joint supervision of a consultant in occupational medicine[18] 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 (see under Monitoring), will be restricted from EPP work until their viral load returns to being stably <200 copies/ml. Clearance by a consultant in occupational medicine to resume EPP work will be determined on a case-by-case basis, depending on the reasons for the viral load breaching the threshold and the viral load level reached.

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.

The decision on whether EPP practice can begin, should cease, the need for a patient notification exercise (to cover the period of potential infectiousness) and when EPP work can resume should be made by a consultant in occupational medicine informed by relevant experts. There is an argument for all cases of HIV-infected HCWs who wish to perform EPPs to be referred to the UKAP (see under Role of expert panel).

### Implications for other policies

Patient notification exercises:

Any patient notification exercises arising from implementation of this policy will follow the established criteria for lookback exercises (Department of Health 2005).

[16] Health clearance to perform EPPs should be granted for HIV-infected HCWs currently on cART if the two most recent consecutive viral load results from tests taken at least 3 months apart are <200 copies/ml. HIV-infected individuals starting cART typically achieve an undetectable viral load after 3 months on treatment. Before resuming EPP work, a further undetectable viral load test one month later (i.e., a minimum of 4 months after starting therapy), is required for health clearance.

[17] HIV viral load testing is part of routine HIV patient management and does not need to be performed by designated laboratories. An 'accredited laboratory' is one accredited by Clinical Pathology Accreditation (UK) Limited. A list of such laboratories is available from: www.cpa-uk.co.uk

[18] A 'consultant in occupational medicine' is a doctor registered as a specialist by the GMC and appointed to an NHS consultant post by a process consistent with the national Health Service (Appointment of Consultants) Regulations 2005 or their equivalent.

If an HIV-infected HCW on treatment and performing EPPs breaches the viral load threshold for clearance and is required to cease EPPs, a patient notification exercise may be warranted for patients who underwent category 3 procedures during the interval since the last viral load measured <200 copies/ml. This will be determined by a risk assessment, on a case-by-case basis. UKAP should be consulted for advice.

Health clearance for new healthcare workers:

As with the current policy (Department of Health 2007a), new HCWs, including students, who will perform EPPs should be tested for HIV infection early in the appointments/admissions process. If found to be infected, this no longer automatically restricts them from EPP careers, subject to successful treatment with cART and occupational health clearance. However, the demands of adhering to cART and strict monitoring arrangements are significant and should be explored in any discussions about career options.

Post-exposure prophylaxis for patients

The need for post-exposure prophylaxis for patients (Department of Health 2008), already likely to arise very rarely, should be virtually eradicated by only permitting treated HIV-infected HCWs to perform EPPs (see under HIV-infected healthcare worker bleeds into a patient).

**Rationale**

Evidence from patient notification exercises and the international literature suggests that the risk of transmission from HIV-infected HCWs to their patients is very low, even for those who are untreated. Any risk will be further reduced by effective treatment that suppresses viral load.

Selection of cut-off:

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) (Garcia et al. 1999) 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. The choice of a lower cut-off could result in unworkable periodic restrictions to practice without improved patient protection.

Categories of EPPs:

Exposure-prone procedures have been categorised into three groups according to their level of risk of bleed-back from 1 (lowest risk) to 3 (highest risk) (Department of Health 2005). A universal policy is favoured over one that differentiates between category of EPP (e.g. as per patient notification exercise policy where ‘looking back’ is restricted to category 3 procedures) because of the practical difficulties with distinguishing between category 2 and 3 procedures, the constant evolution of surgical

techniques and the risk that a category 2 procedure could escalate to a category 3 procedure in an emergency.

**Healthcare worker management**

HIV-infected HCWs who perform EPPs should be managed by an HIV/Genitourinary Medicine (GUM)/Infectious Diseases physician who understands risk assessment processes and the additional obligations associated with treating a fellow health professional. The consultant in occupational medicine should liaise closely with the HCW's treating physician - with the HCW's consent - and confirm that the HCW is cleared to undertake EPPs. The HCW should be reviewed every 3 months to ensure that their viral load remains below 200 copies/ml and they remain fit to practise.

If the HCW refuses to allow liaison between the treating physician and the consultant in occupational medicine, it will not be possible for this policy to apply in their case, and any withdrawal of consent for such liaison or disclosure of laboratory data would result in immediate suspension from EPP work.

HIV-infected HCWs cleared for EPP work will need to be advised about the action they must take in the event of a significant bleed-back occurring during an operation (see under HIV-infected healthcare worker bleeds into a patient), and that they will be restricted from EPP work if they fail to attend for regular follow-up.

In keeping with their duty of care to their patients, if an EPP HCW on cART is aware of missed doses, interactions or other factors (e.g. diarrhoea) that might influence their viral load, they should consult their physician as soon as is practicable and before further EPPs are planned.

Local arrangements should be made between the treating physician and the occupational health service to ensure that blood drawn from HIV-infected HCWs for viral load measurements conform to standards suitable for occupational health monitoring purposes (i.e. the identity of the HCW is confirmed and the chain of handling for specimens is secure).

The following main scenarios involving HIV-infected HCWs may be envisaged and the recommended course of action is proposed:

- *HIV-infected HCW currently restricted from EPPs and receiving antiretroviral therapy wishes to return to EPP practice:* recommend resumption of EPPs permitted if viral load has been sustainably undetectable for at least 3 months (see footnote 16).
- *HIV-infected HCW currently restricted from EPPs not on therapy wishes to return to EPP practice*: subject to health clearance following successful and continued cART for a minimum of 4 months (see footnote 16).
- *Newly diagnosed (or seroconverting) HIV-infected HCW already working in an EPP field:* recommend cessation of EPPs and conduct patient notification exercise to cover period since likely seroconversion.

- *Newly diagnosed HIV-infected student HCW seeking a career in an EPP field (see under implications for Health Clearance policy):* recommend student seeks counselling and advice from experienced occupational medicine and HIV physicians to ensure the student makes an informed decision knowing the potential difficulties for future practice of being HIV-infected.
- *HCWs co-infected with HIV and hepatitis B and/or hepatitis C under the above scenarios*: will have to meet the conditions for health clearance for all blood-borne infections to be able to perform EPPs.

Appropriateness of cART for occupational health reasons

cART is recommended for HIV-infected adults whose CD4 count is <350 cells/$mm^3$ (Gazzard and on behalf of the BHIVA Treatment Guidelines Writing Group 2008). Clinical trials are currently comparing outcomes for patients who start treatment immediately versus deferring therapy until the CD4 falls to <350 cells/$mm^3$ (Strategic Timing of Antiretroviral Therapy ( START trial). Latest treatment guidelines from the US Department of Health and Human Services are tending to recommend earlier treatment, at CD4 counts above 350 cells/$mm^3$ and even above 500 cells/$mm^3$ (Panel on Antiretroviral Guidelines for Adults and Adolescents 2011).

The 'Hepatitis B-infected healthcare workers and antiviral therapy' policy (Department of Health 2007b) has set a precedent for allowing treatment for occupational health reasons when it might not be indicated for personal health. In such circumstances, it is up to the HCW, in discussion with their physician, to weigh up the advantages and possible disadvantages to their health from such treatment. The situation for HIV-infected HCWs is no different, and cART should be available regardless of CD4 count, where the worker's practise is conditional upon receiving such treatment.

HIV-infected healthcare worker bleeds into a patient

Surgeons who have transmitted blood-borne viruses (primarily hepatitis B and C) to their patients have not always been aware that they had sustained an injury leading to a bleed-back into their patient's open tissues. This suggests that such injuries may be occurring and going unrecognised. However, the very small number of documented HCW-to-patient HIV transmissions worldwide provides reassurance that these events pose a very small risk of HIV transmission.

In managing a recognised bleed-back incident, the same protocol as for any occupational exposure incident should be followed (see Department of Health 2008). 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 HCW should inform the infection control lead and their treating physician. Further detailed risk assessment should include consideration of the latest 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 to request an urgent viral load

test for the source HCW[19]. A decision about whether to inform the patient about the exposure, and to offer 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 recommended. It is important to note that PEP would be indicated only very rarely and it will still be necessary to assess the risk of transmission of other blood-borne viruses.

**Occupational health provision**

It is recommended that healthcare commissioners ensure that an occupational health (OH) service is provided for all self-employed HCWs practising in their areas (or resident in the case of Agency and Locum staff). As a minimum, it would need to cover control of infection and public health issues that require OH input. All HIV-infected HCWs have a duty of care to ensure they have access to advice from a consultant in occupational medicine and clearance to perform EPPs and their OH providers have to be satisfied that the monitoring records are reliable (see under Healthcare worker management).

All healthcare organisations providing EPPs as part of their services must have access to an Occupational Health Service including to a consultant in occupational medicine able to manage HIV-infected HCWs and those with other blood-borne viruses.

Commissioners purchasing EPPs should ensure that the service provider is able to comply with this guidance by providing appropriate OH services for its employees.

**Monitoring**

Healthcare workers

If the HCW's viral load remains consistently below 200 copies/ml but detectable, no action is necessary to meet occupational health clearance requirements for performing EPPs. If the viral load is between 200 and 1000 copies/ml on a 3-monthly test, the test should be repeated on a fresh sample with the results available within a week. (Viral loads in this range probably represent non-significant fluctuation.) If the viral load remains above 200 copies/ml on repeat testing, clearance to perform EPPs should be withdrawn until the viral load returns to below 200 copies/ml. If the viral load is above 1000 copies/ml on a 3-monthly test[20], clearance to perform EPPs should be withdrawn immediately. Repeat the test after one week and allow resumption of EPPs when the viral load is stable below 200 copies/ml.

[19] Point-of-care tests for HIV viral load are expected to become available in the near future and could be useful in such a situation.

[20] Viral load rebounds above 1000 copies/ml are rare if adherence to treatment is good. HIV-infected HCWs are likely to be highly motivated to take their treatment regularly as prescribed, for both personal and occupational reasons.

**Options for monitoring policy**

| Option | Implementation process | Advantages | Disadvantages |
|---|---|---|---|
| **1. Do nothing** | | • No disruption.<br>• No additional cost burden to the NHS. | • No evidence on compliance with the policy and therefore no information on the safety of the policy.<br>• Loss of epidemiological data to inform reviews of policy.<br>• If requested, gaining information for audit purposes will be very difficult and labour intensive. |
| **2. Treating physician monitors. Periodic audit nationally to evaluate compliance with policy.** | The treating physician will organise the viral load tests and monitor adherence to national guidance by the HCW. With HCW's consent, treating physician will keep their consultant in occupational medicine informed of monitoring results and of any breaches in compliance with monitoring arrangements and/or viral load cut-off point. Manages the HCW in line with policy when viral load breaches cut-off point. | • Treating physicians already provide 3-monthly routine monitoring for all patients on antiretroviral therapy.<br>• Treating physicians understand the significance of fluctuations in viral load and can advise occupational health on the need for modifying practice. | • Treating physician will be required to 'police' the policy, raising potential conflicts of interest.<br>• A physician's primary responsibility is for the well being of his/her patient (the HCW), and not the well being of the HCW's patients.<br>• Conflict of interest may also arise where the treating physician is required to initiate treatment and take monitoring samples even if not merited clinically, leading to increased risk of non-compliance with the policy by the HCW<br>• Special arrangements may be required for taking monitoring samples from HCWs to comply with IVS that could lead to a breach of confidentiality.<br>• Loss of epidemiological data to inform reviews of policy. |

| | | | |
|---|---|---|---|
| **3. Occupational Health monitors. Periodic audit nationally to evaluate compliance with policy.** | Occupational Health will be responsible for taking IVS, receiving the test results and clearing the HCW for EPP practice. Responsible for withdrawing clearance for EPPs if the HCW is in breach of the monitoring interval or their viral load breaches the cut-off point.<br>Occupational Health to inform the treating physician and manage the HCW according to national policy when viral load breaches cut-off point. | • The role of occupational health is to ensure that HCWs are fit to work. Monitoring compliance with the national policy is therefore integral to their role.<br>• Mechanisms already exist in occupational health services to act on breaches in policy. | • The restructuring of NHS occupational health services, with outsourcing as a way of achieving efficiency being introduced, has the potential to fragment the service. Private companies may not be interested in taking on the role of policing the national guidance.<br>• In the community, not all HCWs are registered with an occupational health service.<br>• Potential cost for registration or service set up.<br>• Loss of epidemiological data to inform reviews of policy. |
| **4. Centralised monitoring system with built-in audit to evaluate compliance with policy.** | As part of clearance to perform EPPs, occupational health services will register all HIV-infected HCWs in EPP roles (possibly extend to hepatitis B-infected HCWs performing EPPs) with the centralised register, using a unique identifier to maintain confidentiality and to enable the HCW's records to be linked as they move between Trusts/employers/healthcare organisations. Occupational health services will report the monitoring test results to the central register annually. These will be reviewed by UKAP prior to publication of an annual audit report. | • This will provide the ability to monitor and audit compliance with policy.<br>• This will provide epidemiological information to inform the future review of the policy.<br>• When HCWs move Trusts, occupational health services are in a position to notify the next Trust of the HCW's clearance status for performing EPPs and therefore ensure continuity of follow-up. | • There will be a marginal cost attached to establishing and running a central register.<br>• There will be costs for occupational health in submitting information to a central register.<br>• There may be objections from HCWs feeling that they are under surveillance. |

**Cost impact**

The number of HCWs requiring cART for occupational reasons is likely to be in an estimated region of 110 (see Appendix F for details on the estimated number of HIV-infected HCWs in EPP-dependent specialities) and most, if not all, would receive treatment for health reasons in the future. There would be no extra cost associated with 3-monthly viral load monitoring, provided this was integral to routine care[21]. For HCWs currently restricted from performing EPPs, there may be costs associated with re-training/updating skills before they can resume EPP work. A small cost would be associated with setting up monitoring (e.g. a central registry).

The benefits of retaining highly-skilled and trained staff in the health service are likely to outweigh any additional treatment and monitoring costs. In addition, the future burden of patient notification exercises should be substantially reduced.

**Role of expert panel**

Subject to discussion with the UKAP chair and secretariat, UKAP could oversee the implementation and conduct of the policy, including periodic audit. To ensure consistency in the application of the policy, all cases of HIV-infected HCWs who wish to perform EPPs under the current guidance should be referred to UKAP to advise on the approach to be taken and to help promote best practice. Cases where the HCW breaches the viral load threshold should be notified to UKAP and their advice sought about the need to conduct a patient notification exercise. It will remain a local decision as to whether an individual HIV-infected HCW is cleared to perform EPPs.

[21] Arrangements would be needed to ensure laboratory monitoring tests are performed on an identified, validated sample.

# Appendix F

## Prevalence of HIV in England among healthcare workers engaged in exposure prone procedures

### 1. Introduction

Expert advice is that the risk of HIV transmission from an infected healthcare worker (HCW) to a patient is limited to exposure prone procedures (EPPs) (Department of Health 2005).[1] In the UK, it is neither known how many HCWs generally, or those conducting EPPs specifically, are living with HIV.

In the United States to end 2001, 5% (23,951/469,850) of adults and adolescents diagnosed with HIV, and for whom employment was indicated, were reported as HCWs.[2] In France, a study conducted in 1997, and updated in 2000, estimated that among the approximately 75,000 medical staff (22,000 of whom are surgeons) carrying out invasive procedures which involve a high risk of accidental exposure to blood with re-contact (including surgeons, dental surgeons and midwives), between 37 and 370 were infected with HIV.[3] In 2005, the Higher Council for Public Health in France estimated that 45 surgeons in France were infected with HIV. The council suggest that the figures presented by the 1997 study were an underestimate as they do not take into account interruptions in work due to medical reasons.[4] In South Africa, prevalence of HIV among HCWs has been reported to be the same as that in respective communities among adults aged 15-49 (17.8%).[5,6] Although South Africa has a generalised epidemic whereas that in the UK is concentrated, in both South Africa and the UK HIV is mainly acquired sexually.

A review of the guidance on the management of healthcare workers infected with blood-borne viruses is currently being conducted. This report presents estimates of HIV prevalence among HCWs, based on UK HIV estimates in the general population as well as these published data from other countries.

### 2. Methods

Data on HIV in the general population are presented from the cross-sectional annual Survey of Prevalent HIV Infections Diagnosed (SOPHID) which collects reports of all persons within a calendar year attending NHS sites offering HIV-services,[7,8] and the HIV and AIDS New Diagnoses and Deaths system which collects information relating to new HIV diagnoses, first AIDS diagnoses, and deaths among HIV-infected adults.[9,10] Both surveillance systems are held at the Health Protection Agency,[11] and strict attention to confidentiality is maintained at every stage of data collection, analysis and storage.

Overall numbers of HCWs relate to NHS staff headcounts as presented by the Monthly NHS HCHS Workforce Statistics in England from The NHS Information Centre for Health and Social Care.[12] Annual numbers of cases of HIV-infected HCWs (both NHS and non NHS) are those referred to UKAP for advice on the need for patient notification.[13] Due to data availability, HIV figures are presented by different years and different geographical areas.

# 3. Results

## 3.1 Number of HIV-infected HCWs referred to UKAP

Between 2003 and 2006, 45 HIV-infected HCWs in the UK were referred to UKAP (mainly surgeons, midwives and nurses).[14] Among the 44 HCWs for whom the information was available, 30% (13/44) were in an EPP role.[14] Therefore, on average annually, three HCWs in an EPP role were referred to UKAP in relation to HIV infection between 2003 and 2006. This represents a crude annual referral rate of 0.04 per 1000 among the 79,176 NHS staff and dentists performing NHS activities who are potentially engaged in EPPs. Although it has been highlighted that not all HIV-infected HCWs will be diagnosed, known to the NHS or referred to UKAP,[15] the rate of under reporting would have to be substantial for this annual rate of referral among HCWs to increase to being close to that among the general population (0.2 per 1000).

## 3.2 HIV prevalence and diagnoses in the general population

In 2009, an estimated 86,500 people were living with HIV (diagnosed and undiagnosed) in the UK,[16] equating to 1.4 HIV-infected persons per 1000 population. Among persons accessing HIV-related services in 2009, 96% were of working age (defined as 16 to 64).[17] The prevalence of HIV (diagnosed and undiagnosed) is highest among persons of black-African ethnicity[18] (estimated 4.7% in UK, 2009) and men who have sex with men (MSM)[19] (estimated 5.2% in UK, 2009). Between 2005 and 2009, on average 7100 people aged 16-64 were diagnosed annually with HIV in the UK,[20] equating to a rate of 0.2 per 1000 among the 40 million people of working age in the UK.[21]

## 3.3 Number of NHS staff potentially engaged in EPPs

In England, as of September 2010, approximately 1.2 million people were working for the NHS.[12] An estimated 23,417 medical staff of consultant, associate specialist, specialty doctor, staff grade, or registrar level worked in accident and emergency, obstetrics and gynaecology, or surgical (excluding ophthalmology) specialties, with 33,756 non-medical staff of nurse consultant, modern matron, registered midwife, or 1st or 2nd level working in maternity services.[12] In addition to these 57,173 NHS staff, 22,003 dentists performed NHS activities in 2009/10.[22] Therefore, an estimated 79,176 NHS staff and dentists performing NHS activities were potentially engaged in EPPs.

## 3.4 HIV prevalence estimates for HCWs in England

Due to staff turnover,[12] and evidence of nearly one-in-five of all adults living with diagnosed HIV in England being lost to follow up between 1998 and 2007 for reasons other than death,[23] it is not possible to gain a direct estimate of HIV prevalence among HCWs using UKAP data. Among HCWs, as in the general population, it is possible that HIV prevalence significantly varies across sub-groups, particularly those defined by sexual orientation and/or ethnicity. For example, the prevalence of HIV among persons of black-African ethnicity in England, the majority of whom are born in sub-Saharan Africa and infected heterosexually, greatly exceeds that of other ethnicity groups.[18,24]

Applying the rate of HIV among the general population (1.4 per 1000) to HCWs, we would expect 33 NHS medical staff and 47 non-medical staff engaged in EPPs, as well as 31 dentists performing NHS activities, to be living with HIV in England in 2010 (approximately 111 in total).

## References


1. HIV Infected Health Care Workers: Guidance on Management and Patient Notification. Department of Health, 2005
2. Do AN *et al*. Occupationally acquired Human Immunodeficiency Virus (HIV) Infection: National case surveillance data during 20 years of the HIV epidemic in the United States. *Infection Control and Hospital Epidemiology;* **24** (2):86-96
3. GERES. GERES Report on accidental exposure to blood and the risk of transmission of the hepatitis B, C and human immunodeficiency viruses from medical personnel to patient: A review-updated June 2000. Xavier Bichat Faculty of Medicine 2000.
4. Higher Council for Public Health in France, 2005. *Transmission of the human immunodeficiency virus (HIV) to patients by medical personnel.* France 27th May and 17th June 2005
5. UNAIDS. HIV and AIDS estimates (2009). 1st February, 2011. Available at http://www.unaids.org/en/Regionscountries/Countries/SouthAfrica/
6. Shisana O *et al*. HIV/AIDS prevalence among South African health workers. *S Afr Med J* 2004; 94: 846-850
7. Health Protection Agency. Numbers accessing HIV care unpublished surveillance tables. 2nd February, 2011. Available at http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1221482342808
8. Health Protection Agency. Numbers accessing HIV care. 2nd February, 2011. Available at http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1201094588844
9. Health Protection Agency. New HIV diagnoses unpublished surveillance tables No. 65. 04/4. 2nd February, 2011. Available at http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1237970242135
10. Health Protection Agency. New Diagnoses of HIV - methods and frequently asked questions. 2nd February, 2011. Available at http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1203084375072
11. Health Protection Agency. About the HPA. 2nd February, 2011. Available at http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebContentAreaLanding/Page/1153822623851?p=1153822623851
12. The Health and Social Care Information Centre. Monthly NHS Hospital and Community Health Service (HCHS) Workforce Statistics in England – March 2011, Provisional, Experimental Statistics. 12th April, 2011. Available at http://www.ic.nhs.uk/statistics-and-data-collections/workforce/nhs-staff-numbers

13. UK Advisory Panel for healthcare workers infected with bloodborne viruses (UKAP). 2nd February, 2011. Available at http://www.hpa.org.uk/ukap/

14. UKAP Second Report 1st April 2004 to 31st December 2006. 2nd February, 2011. Available at http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1228291495165

15. Tripartite working group of representatives from the AGH, EAGA and UKAP to review guidance on management of healthcare workers infected with bloodborne viruses. Minutes of meeting 17th December, 2007. Page 2

16. Health Protection Agency. HIV in the United Kingdom: 2010 Report. Health Protection Agency 2010

17. Personal communication with SOPHID team 2nd February 2011, Health Protection Agency

18. Health Protection Agency. Sexually transmitted infection in black African and black Caribbean communities in the UK: 2008 Report. Health Protection Agency 2008

19. Health Protection Agency. Sexually transmitted infection and Men who have Sex with Men in the UK: 2008 Report. Health Protection Agency 2008

20. Health Protection Agency, Health Protection Scotland and UCL Institute of Child Health. Unpublished HIV Diagnoses Surveillance Tables 01:2010

21. Office of National Statistics population data. 2nd February, 2011. Available at

    http://www.statistics.gov.uk/cci/nscl.asp?id=7433

22. The Health and Social Care Information Centre. NHS Dental Statistics for England: 2009/10. The Health and Social Care Information Centre 2010.

23. Rice BD *et al*. Loss to follow-up among adults attending HIV-services in England, Wales and Northern Ireland. Accepted for publication *STD*

24. MAYISHA II Collaborative Group. Assessing the feasibility and acceptability of community based prevalence surveys of HIV among black Africans in England. London: Health Protection Agency Centre for Infections. 2005.Baseline

## 11. References


Bell, D.M., Shapiro, C.N., Culver, D.H., Martone, W.J., Curren, J.W., & Hughes, J.M. 1992. Risk of hepatitis B and HIV transmission to a patient from an infected surgeon due to percutaneous injury during an invasive procedure: estimates based on a model. *Infectious Agents and Disease*, 1, 263-269.

Brown, A. HIV transmission risk from infected healthcare workers with undetectable viral loads and/or treated with HAART: a review. Unpublished

Ciesielski, C., Marianos, D., Ou, C.Y., Dumbaugh, R., Witte, J., Berkelman, R., Gooch, B., Myers, G., Luo, C.C., & Schochetman, G. 1992. Transmission of human immunodeficiency virus in a dental practice. *Annals of Internal Medicine*, 116, (10) 798-805.

Department of Health. AIDS and HIV-infected Healthcare Workers - occupational guidance for healthcare workers, their physicians and employers. 1991

Department of Health. AIDS-HIV-infected healthcare workers: Practical guidance on notifying patients. 1993

Department of Health. Guidance fo clinical health care workers: protection against infection with blood-borne viruses. Recommendations of the Expert Advisory Group on AIDS and the Advisory Group on Hepatitis. 1998

Department of Health. HIV Infected Health Care Workers: guidance on management and patient notification. 2005

Department of Health. Health clearance for tuberculosis, hepatitis B, hepatitis C and HIV: New healthcare workers. 2007a

Department of Health. Hepatitis B-infected healthcare workers and antiviral therapy. 2007b.

Department of Health. HIV post-exposure prophylaxis. guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS. 2008.

Donnell, D., Baeten, J., Kiaire, J., Thomas, K.K., Stevens, W., Cohen, C.R., McIntyre, J., Lingappa, J.R., & Celum, C. 2010. Heterosexual HIV-1 transmission after initiation of antiretroviral therapy: a prospective cohort analysis. *The Lancet*, 375, 2092-2098.

Duong, T., Ades, A.E., Gibb, D., Tookey, P.A., & Masters, J. 1999. Vertical transmission rates for HIV in the British Isles: estimates based on surveillance data. *British Medical Journal*, 319, 1227-1229.

Fellay, J., Shianna, K., Ge, D., Colombo, S., Ledergerber, B., Weale, M., Zhang, K., Gumbs, C., Castagna, A., Cossarizza, A., Cozzi-Lepri, A., De Luca, A., Easterbrook, P., Francioli, P., Mallal, S., Martinez-Picado, J., Miro, J.M., Obel, N., Smith, J.P., Wyniger, J., Descombes, P., Antonarakis, S.E., McMichael, A.J., Haynes, B.F., Telenti, A., & Goldstein, D.B. 2007. Whole-genome association study of major determinants for host control of HIV-1. *Science*, 317, 944-947.

Galvin, S.R. & Cohen, M.S. 2004. Sexual transmission of HIV. *Nature Reviews Microbiology*, 2, 33-42.

Garcia, P.M., Kalish, L.A., Pitt, J., Minkoff, H., Quinn, T.C., Burchett, S.K., Komegay, J., Jackson, B., Moye, J., Hanson, C., Zorrilla, C., & Lew J.F. 1999. Maternal levels of plasma human immunodeficiency virus type 1 RNA and the risk of perinatal transmission. Woman and Infants Transmission Study Group. *New England Journal of Medicine*, 341, 394-402.

Gazzard, B.G. & on behalf of the BHIVA Treatment Guidelines Writing Group 2008. British HIV Association guidelines for the treatment of HIV-1-infected adults with antiretroviral therapy. *HIV Medicine*, 9, 563-608.

Goujon, C., Scheider, V., Grofti, J., Montigny, J., Jeantils, V., Astagneau, P., Rozenbaum, W., Lot, F., Frocrain-Herchkovitch, C., Delphin, N., Le Gal, F., Nicolas, J.-C., Milinkovitch, M.C., & Dény, P. 2000. Phylogenetic analyses indicte an atypical nurse-to-patient transmission of human immunodeficiency virus type 1. *Journal of Virology*, 74, 2525-2532.

Henderson, D.K., Dembry,L., Fishman,N.O., Grady,C., Lundstrom,T., Plmore, T.N., Sepkowitz, K.A., Weber, D.J., for the Society for Healthcare Epidemiology of America. 2010. SHEA guidelines for the management of healthcare workers who are infected with Hepatitis B virus, Hepatitis C virus and/or Human immunodeficiency virus. *Infection Control and Hospital Epidemiology,* 31, 203-231.

Levy, J. 1988. The transmission of AIDS: the case of the infected cell. *Journal of American Medical Association*, 259, 3037-3038.

Lot, F., Seguier, J.C., Fegueux, S., Astagneau, P., Simon, P., Aggoune, M., van Amerongen, P., Ruch, M., Cheron, M., Brücker, G., Desenclos, J.C., & Drucker, J. 1999. Probable transmission of HIV from an orthopedic surgeon to a patient in France. *Annals of Internal Medicine*, 130, 1-6.

Ma, Z.-M., Stone, M., Piatak, M., Jr., Schweighardt, B., Haigwood, N.L., Montefiori, D., Lifson, J.D., Busch, M.P., & Miller, C.J. 2009. High specific infectivity of plasma virus from pre-ramp-up and ramp-up stages of acute simian immunodeficiency virus infection. *Journal of Virology*, 83, 3288-3297.

Mallolas, J., Arnedo, M., Pumarola, T., Erice, A., Blanco, J., Martinez, E., & Gatell, J.M. 2006. Transmission of HIV-1 from an obstetrician to a patient during a caesarean section. *AIDS*, 20, 285-299.

Panel on Antiretroviral Guidelines for Adults and Adolescents. 2011. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 10, 1-166. Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed 07.03.11.

Quinn, T.C., Wawer, M., Sewankambo, N., Serwadda, D., Li, C., Wabwire-Mengen, F., Meehan, M.P., Lutalo, T., Gray, R.H., & for the Rakai Project Study Group 2000. Viral load and heterosexual transmission of human immunodeficiency virus type 1. *New England Journal of Medicine*, 342, 921-929.

Robert, L., Chamberland, M., Cleveland, J., Marcus, R., Gooch, B., Srivastava, P.U., Culver, D.H., Jaffe, H.W., Marianos, D.W., Panlilio, A.L., & Bell, D.M. 1995. Investigations of patients of healthcare workers infected with HIV. *Annals of Internal Medicine*, 122, 653-657.

Strategic Timing of Antiretroviral Treatment (START) trial. Available at: http://clinicaltrials.gov/ct2/show/NCT00867048. Accessed 07.03.11.

Townsend, C.L., Cortina-Borja, M., Peckham, C.S., de Ruiter, A., Lyall, H., & Tookey, P.A. 2008. Low rates of mother-to-child transmission of HIV following effective pregnancy interventions in the United Kingdom. *AIDS*, 22, (8) 973-81.

Vernazza, P., Hirschel, B., Bernasconi, E., & Flepp, M. 2008. Les personnes séropositives ne souffrant d'aucune autre MST et suivant un traitment antirétroviral efficace ne tranmettent pas le VIH par voie sexuelle. *Bulletin des médecins suisses*, 89, (5) 165-169.

Wawer, M., Gray, R., Sewankambo, N., Serwadda, D., Li, X., Laeyendecker, O., Kiwanuka, N., Kigozi, G., Kiddugavu, M., Lutalo, T., Nalugoda, F., Wabwire-Mengen, F., Meehan, M.P., & Quinn, T.C. 2005. Rates of HIV-1 transmission per coital act, by stage of HIV-1 infection, in Rakai, Uganda. *The Journal of Infectious Diseases*, 191, 1403-1409.