



GUIDELINE ON BLOOD BORNE VIRAL INFECTIONS

MALAYSIAN MEDICAL COUNCIL

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1. PART ONE: INTRODUCTION

Since the release of previous guidelines in 2011, there have been significant changes in recommendations made in other countries such as Australia (2018) and United Kingdom (2019). In addition, new data is available on transmissibility of HIV infection and treatment options for Hepatitis C infection.

This MMC Guideline, which relates to blood-borne viral infections (BBV) which are of importance in possible infection of patients from healthcare workers, and *vice versa*, will address primarily HIV, HBV and HCV infections as they affect medical practitioners (and healthcare workers of all categories).

This guideline, while accepting that medical practitioners living with HIV or HBV or HCV need to be managed in the manner no different from that of any other person similarly afflicted, with adjustments in their professional duties, also takes cognisance of the rights of the patients (and member of the public) that they should not be affected or infected through any accidental transmission, however rare and remote, in the course of medical treatment or management.

If medical practitioner maintains low HIV, HBV, and/or HCV viral loads or if they are involved in clinical cares that do not involve blood exposure, the possibility of provider-to-patient transmission is considered extremely low.

The guideline aims to give updated recommendations that are intended to:

1. Reduce the risk of medical practitioner to patient transmission of BBVs
2. Promote voluntary testing and self-declaration of BBV infection amongst medical practitioners
3. Retain medical practitioners in workforce and reduce the societal and professional impact of living with BBV
4. Decrease the need for patient notification exercises

PART TWO: BLOOD-BORNE VIRUS INFECTIONS

2. OUTLINE OF BLOOD-BORNE VIRUS INFECTIONS

Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) infections are serious illnesses caused and spread by Blood-Borne Viruses. These viruses are considered transmissible by blood or other body fluids. The most effective means of preventing BBV transmission in health care settings is by strict adherence to standard (universal) precautions and established infection control practices. These decrease the opportunity of direct exposure to blood and body fluids for both medical practitioners and patients.

“If you know that you have, or think that you might have, a serious condition that you could pass on to patients, or if your judgment or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must ask for and follow their advice about investigations, treatment and changes to your practice that they consider necessary. You must not rely on your own assessment of the risk you pose to patients.”
(General Medical Council)

2A. HIV INFECTION

In this current era of potent antiretroviral therapy (ART), HIV infection has become a chronic manageable disease. The life expectancy of a person living with HIV are approaching those of non-infected. Despite the advancement in medical science, stigma remains a major problem in certain communities. Within healthcare facilities infected healthcare professionals suffer under pre-conceived notions of risk of transmission to their patients while performing their duties.

Risk of HIV transmission from infected health care workers (HCW) to patients

The risk of transmission of HIV from infected healthcare workers to their patients is extremely low, only four cases resulting in eight infections have been reported globally so far (**Appendix 1**). It is important to note that these infections occurred in the pre ART era. This is based on large scale look-back investigations (also called as patient notification exercises) that have been conducted ⁵⁻¹¹. Look-back investigations refers to the process of identifying, tracing, recalling, counselling and testing patients or HCWs who may have been exposed to an HIV infected health care worker.

As of 1995, US CDC has done 66 look-back investigations involving 22,759 patients and did not find any linked HIV transmissions^{5,6}. Similarly between 1998 and 2008, 39 look-back investigations done in UK involving 10,000 patients did not yield any linked HIV transmissions ⁷. In 2007, when a cardio-thoracic surgeon was found to have advanced HIV infection (CD4 count - 49/microL and HIV RNA level of >100,000 copies/mL) a look-back investigations involving all the patients who he had operated in the previous 10 years did not reveal any transmission⁸. The surgeon was subsequently allowed to practice, without restrictions on the type of procedure he can perform provided he agreed to adhere to additional infection control requirements and to routine monitoring of his HIV viral load.

None of the HIV infected health care workers who had transmitted their infection to the patients were on HIV treatment at the time of the incident. With advances in HIV treatment, HIV infected health care workers can get their HIV viral load suppressed (< 50 copies/ml) with 2-4 months of treatment. There is compelling data albeit from studies involving serodiscordant heterosexual¹² or MSM¹³ couples and mother to child transmissions¹⁴, that HIV viral load suppression renders the HIV infected individual non infective.

2B. HEPATITIS B VIRUS (HBV) INFECTION

HBV is the most readily transmitted BBV, and can be transmitted even in the absence of visible blood. Potent antivirals are available (e.g. entecavir, tenofovir) that would provide effective viral suppression. However, not all HBV-infected persons require treatment with antiviral as not all will have progressive disease.

Risk of HBV transmission from infected health care workers to patients

The high level of virus found in persons with HBeAg positive chronic hepatitis B means that very small volumes of blood can transmit infection. The risk of transmission from persons with HBeAg positive chronic hepatitis B to a susceptible individual following a single hollow bore needle stick injury has been shown to be around 30-62%. The risk of transmission from persons with HBeAg negative chronic hepatitis B is generally lower, around 6-37%, but is equally high in those with pre-core and/or the basal core promoter regions variants, who have a high viral load in the absence of the e-antigen.(1) Appendix 2 summarizes the published cases of hepatitis B virus (HBV) transmission from infected health care workers to patients and was extracted and modified from a recent review article. (2)Early reports of transmission occurred in association with dental procedures during which the dentist or oral surgeon did not wear gloves.(3-6)The transmission of HBV from infected health care workers in primary care or other specialties that do not perform exposure-prone procedures(EPPs) is rare. When transmissions did occur with these providers, they were more likely to be associated with breaches in infection control practices.(7-10) In the 35 cases in which HBeAg testing results were available, the majority (77%) of transmissions occurred from HBeAg positive health care workers. The lowest measured viral load at which transmission occurred was 2.5×10^5 copies/mL, which notably occurred in an HBeAg negative health care worker. (11) In another study that included six HBeAg negative surgeons, all were viraemic and the lowest HBV DNA viral load measured was 4×10^4 copies/mL.(12)Accordingly, the authors suggested that this viral load may represent the lower limit above which HBV transmission during invasive procedures cannot be excluded.(12)

2C. HEPATITIS C VIRUS (HCV)

The understanding of the HCV life cycles had led to the discoveries of direct acting anti-viral (DAA) since 2011, currently a short course of DAA given for 8 to 12 weeks cures more than 95% of HCV infected individuals. However, HCV with more advanced liver disease will require longer course of DAA (24 weeks) and have slightly lower cure rates.

Risk of HCV transmission from infected health care workers to patients.

Transmission of HCV from infected HCWs to patients had been reported since early 1990's typically by cardiothoracic surgeons and obstetrician-gynaecologists. (1, 2) The risk of transmission of HCV from HCW to patients had been reported at 0% to more than 3%. (1) Details on more recently published HCV transmissions from HCV-infected HCWs are summarized in **Appendix 3**. The identified risk factors for HCV transmission were mainly performance of EPP, failures to adhere to standard precautions like gloving and there were also reports of narcotic diversions by HCV-infected HCW.(1-3) Narcotic diversions occurred in HCV-infected HCW who consumed illicit drugs and used patient's injectable medications eg fentanyl for own consumption which can lead to large numbers of HCV transmission by sharing the needles. (3)

HCV transmission related to non-EPP procedures had been reported in a repair of a paraumbilical hernia, a midwife to a mother in the postnatal ward and an anaesthetist to a patient; the route of transmission in these cases has never been defined. (2)

Look back investigations sometimes revealed that HCWs were infected by HCV patients and subsequently transmit the HCV infection to another patient. (4,5) Currently there is no vaccine to protect against hepatitis C infection.

PART THREE: BLOOD-BORNE VIRUS INFECTIONS AND MEDICAL PRACTITIONERS

3. Medical Practitioner with BBV infection and the Procedures to be Adopted

3.1 Provisionally Registered Medical Practitioner

A medical graduate provisionally registered for houseman training and diagnosed to be infected with BBV, in whatever stage of houseman training, will be counselled and the following advice and options given:

- a. If he **chooses not to enter** into, or after commencing wishes to discontinue, the houseman training:
 - (i) he will not be fully registered by virtue of not completing houseman training;
 - (ii) he may be employed in administrative jobs as a graduate in medicine.
- b. If he **chooses to enter and complete** the houseman training he may be allowed to do so with special restrictions and supervision, as designed and permitted by the Fitness to practice committee of Malaysian Medical Council (FTP-MMC). Exceptions may have to be made in the postings currently required under a two-year houseman training program. He may be allowed to perform or assist in Exposure Prone Procedures (EPP) if he fulfils the criteria for health clearance for infected health care workers.
- c. Upon satisfactory completion of houseman training under 4(1)b above, he is eligible for full registration as provided for under the Medical Act 1971. He will however be subjected to evaluation by the FTP-MMC before full registration and conditions and limitations may be imposed on his practice.

3.2 Fully Registered Medical Practitioner

- d. If the diagnosis of BBV infection is made **any time** during the period of full registration, (including during compulsory service), whether in public or private practice, the practitioner will be counselled and he will be allowed to continue to practice with conditions and limitations imposed on his practice.
 - (i) A fully registered medical practitioner found to be living with BBV and not performing EPPs will be allowed to practice after evaluation by the FTP-MMC. An annual self-declaration of no change in work scope will be sought.
 - (ii) A fully registered medical practitioner found to be living with BBV and perform EPPs shall refrain from all EPPs until he fulfills the criteria for health clearance for infected health care workers. Subsequently he may be allowed to perform EPPs after evaluation by the FTP-MMC with conditions and limitations imposed on his practice.

4. Clinical Management of Health care workers living with BBV

Management of HIV-infected HCWs

Evidence from systematic reviews and cohort analyses indicate that untreated HIV infection may be associated with the development of several non-AIDS-defining conditions, including cardiovascular, kidney and liver disease, several types of cancer and neurocognitive disorders and initiating ART earlier reduces such events and improves survival. In addition large randomized controlled trials have shown that combination antiretroviral treatment (cART) substantially reduces sexual transmissions. Current treatment guidelines recommend lifelong treatment with cART to all regardless of clinical stage or CD4 count. Therefore all HCWs with HIV should be started on cART as soon as they were diagnosed. Aim of treatment is to maintain their HIV viral load less than the detectable range (<50copies/ml)

Management of HBV-infected HCWs

Current guidelines recommend that HBV-infected persons be treated with antiviral if they have persistent inflammation or significant liver fibrosis.(37, 38)Antiviral treatment is often long term and is associated with cost, possible side effects and risk of drug resistance. Health care workers who are HBeAg positive or HBeAg negative with high viral load are at the highest risk of HBV transmission to patients when performing EPPs. However, HBeAg negative persons with low viral load can develop high viral load at any time and there are no useful symptoms or signs to indicate this. There is also no useful test to predict this. Therefore, a HBV-infected health care worker should, in general, be on antiviral with effective viral suppression regardless of whether he or she is HBeAg positive or negative if he or she intends to perform EPPs. While the management of HBV-infected health care workers focuses on the balance between risk of transmission of the virus to patients and the right of HBV-infected health care workers to perform his or her work in a safe manner and without loss of right to confidentiality about his or her own health issues, the pros and cons on being on antiviral therapy should also be considered, especially when there is otherwise no indication for initiation of the antiviral therapy.

Management of HCV-infected HCWs

The presence of antibody to HCV (detectable anti-HCV) in an individual does not necessarily infer there is active or current HCV infection and more importantly it does not confer immuno-protection. A positive anti-HCV alone could mean one of these four scenarios:

- (i) Previous HCV infection with spontaneous clearance which had been reported to occur in 20-40% of acute infection (15),
- (ii) A current HCV infection if the individual is also viremic (detectable HCV RNA),
- (iii) Previous chronic HCV cured by anti-HCV therapies
- (iv) False positive antibody.

The management of anti-HCV antibody positive HCW starts with confirmation of HCV infection; *i.e* both anti-HCV antibody and HCV RNA are detectable. The HCV RNA assays should have a minimum sensitivity of 50 IU/mL; (16), this is important in particular to determine if an anti-HCV positive HCW is non infective with undetectable for HCV RNA. A newer assay called HCV core antigen is less sensitive than HCV RNA assays with the lower limit of detection equivalent to approximately 500 to 3,000 HCV RNA IU/ml, depending on the HCV genotype. (16)

A confirmed HCV-infected HCW (detectable HCV RNA) should abstain from performing EPP. HCV-infected HCW should follow standard precautions, including appropriate hand hygiene, use of protective barriers, and safe injection practices. Like any HCV infected individual, the person is also advised to cover wounds and cuts.

AntiHCV positive and HCV RNA-negative individuals should be retested for HCV RNA 12 and 24 weeks after a negative result to confirm definitive clearance as the viral load varies with period of undetectability during the acute phase of HCV infection (16)

The WHO 2016 guidelines on management of HCV prioritized the treatment of HCV-infected HCW because successful treatment minimizes the risk of transmission of HCV to patients. Most international guidelines recommended anti-HCV treatment of HCV-infected HCW moreover HCV treatment guidelines currently recommend all HCV infected individuals to be considered for HCV therapy (16,18,19). Therefore HCV-infected HCW should be referred to HCV treaters for medical evaluations and treatment.

The response to DAA is assessed by sustained virological response (SVR) defined as undetectable HCV RNA (by a sensitive molecular method with a lower limit of detection ≤ 15 IU/ml) at 12 or 24 weeks after the completion of a course of DAA. (16). A SVR corresponds to a cure of the HCV infection, with a very low chance of late relapse.

However if there is ongoing risk factors for HCV infection, monitoring for HCV reinfection by repeated HCV RNA assessments should be undertaken. These incidence rates led to estimated 5-year recurrence rates of 0.95%, 10.67%, and 15.02% in the low-risk, high-risk, and coinfection groups, respectively.

5. Monitoring and clearance for HCWs living with BBV to perform EPPs

5.1. HIV (also see table 1)

HCWs living with HIV must meet the following criteria before they can perform EPPs:

1. be on effective cART, and
2. have a plasma viral load that is undetectable (<200 copies/mL) on 2 blood samples taken no less than 3 months apart

and

3. be subject to plasma viral load monitoring every 12 -24 weeks, as decided by the FTP Committee
4. be under joint supervision of a responsible physician and occupational health unit of employing organisation (if self-employed must be under joint supervision of a responsible physician and MMC)
5. agree to inform MMC if there is any change in work scope

Table 1: HIV viral load monitoring and subsequent action

Viral load test	Action
<50 copies/ml or below	No action required. Retest in 3-6 months
≥50 but <200 copies/mL	A case-by-case approach based on clinical judgement should be taken which may result in no action (as above) or a recommendation that a second test should be done 10 days later to verify the viral load remains below the threshold of 200 copies/ml. Further action will be informed by the test result.
≥200 copies/ml but <1000 copies/ml	Cease EPPs pending a repeat viral load to verify the first test result. If the repeat viral load is >200 copies/ml, the HCW should cease conducting EPPs until their reading, in two consecutive tests no less than three months apart, is <200 copies/ml.
1000 copies/ml or above	The HCW should cease conducting EPPs immediately. A second test must be done to verify the first result. If the count is still >1000 copies/ml, a full risk assessment should be initiated to determine the risk of transmission to patients. At a minimum, this will include discussions between the consultant occupational physician and the treating physician on the significance of the risk of HIV transmission to patient. Following a risk assessment, patient notification may be indicated but would generally only be considered when a serious breach of infection prevention and control practices has been identified.

5.2. Hepatitis B (also see table 2)

HCWs who are living with Hep B must meet the following criteria before they can perform EPPs:

1. HBV DNA viral load undetectable or very low (<50 IU/ml)
2. Either from natural suppression or on continuous antiviral therapy
3. Be subject to plasma viral load monitoring every 12 - 24 weeks
4. Be under joint supervision of a responsible physician and occupational health unit of employing organisation (if self-employed must be under joint supervision of a responsible physician and MMC)
5. Agree to inform MMC if there is any change in work scope

Table 2: HBV viral load monitoring and subsequent action	
Viral load	Action
<50 IU/ml	No action required. Retest in 12 - 24 weeks.
≥50 IU/mL	Cease EPPs pending a repeat viral load 2 weeks later to verify the first test result. If the repeat viral load is ≥50 IU/ml, the HCW should cease conducting EPPs until their reading, in two consecutive tests no less than 4 weeks apart, is <50 IU/ml. A full risk assessment should be initiated to determine the risk of transmission to patients. At a minimum, this will include discussions between the consultant occupational physician and the treating physician on the significance of the risk of HBV transmission to patient. Following a risk assessment, patient notification may be indicated but would generally only be considered when a serious breach of infection prevention and control practices has been identified.

Note:

It is for the HCW to decide, in collaboration with their treating physician, whether they wish to take antiviral therapy for occupational health reasons when it is not clinically indicated, considering the advantages and disadvantages.

If a HCW stops antiviral treatment for any reason, they should immediately cease to perform EPPs and seek the advice of their treating physician. If the HBV DNA level remains below 50 IU/ml a year after cessation of treatment, it may be appropriate to allow the HCW to return to performing EPPs at that time, subject to the monitoring outlined above.

5.3. Hepatitis C (see also Table 3)

HCWs who are living with Hep C must meet the following criteria before they can perform EPPs:

1. if anti-HCV positive, must be repeatedly HCV RNA negative

Or

2. If HCV RNA positive, must be treated and be HCV RNA negative for at least 6 months after cessation of treatment (ie achieve sustained virological response at 24 weeks post treatment, SVR24)
3. Additional test for HCV RNA at 3 months after SVR24. However, in the presence of ongoing risk factors that could not be completely removed, annual HCVRNA is required.

Table 3: Test results and subsequent action	
Results	Actions
Anti-HCV positive, detectable HCV RNA (≥ 50 IU/ml)	Confirms HCV infection, abstain from performing EPPs. Refer for HCV treatment
Anti-HCV positive, undetectable HCV RNA (at least ≤ 15 IU/ml)	<u>No history of HCV therapy:</u> Abstain from performing EPPs. Re-tested for HCV RNA 12-24 weeks after a negative result to confirm definitive clearance as the viral load varies with period of undetectability in cases of acute phase of HCV infection. Those who are anti-HCV positive but repeatedly HCV RNA negative should be allowed to continue performing EPPs <u>Has history of HCV therapy:</u> If this negative HCV RNA was at least 6 months after completion of HCV therapy, the HCW had achieved sustained virological response. Able to perform EPPs and retest HCVRNA 3 months later.

6. Duties and obligations of HCW living with a BBV

- a. The practitioner shall be made aware that he is totally responsible for his own status of the disease and its implications.
- b. A medical practitioner who has any reason to believe he may have been exposed to BBV infection, in whatever circumstances, must promptly seek and follow confidential professional advice on whether he/she should be tested.
- c. Specifically, the onus of keeping himself infection-free (through treatment and avoidance of further exposure) and the onus of avoiding infecting others, particularly patients and other healthcare staff, **bear heavily and entirely on him**. He will be held totally responsible and accountable, if so proven, for any indiscretions or deviations from this requirement.
- d. The practitioner should be aware, or made to be aware, further that he is under ethical and legal duties to protect the health and safety of his patients at all times exercising reasonable care for the health and safety of his own self and of others, such as colleagues and other healthcare staff.
- e. The practitioner, who has the responsibility of direct clinical care of patients, has a duty to keep himself informed and updated on the Codes of Professional Conduct and guidelines on BBV infection laid down by the Malaysian Medical Council and the Ministry of Health, and any other relevant guidance issued by any other regulatory bodies.
- f. The practitioner should at all times comply with any restrictions which may be imposed on his practice by his employer and his supervisors, and co-operates with his employer, specialist occupational health physician and treating physician in health and safety matters.
- g. A self-employed medical practitioner living with BBV infection has the general duties and obligations to conduct his work so that he and others are not exposed to health and safety risks
- h. A medical practitioner living with BBVs must not undertake procedures which are thought to be EPP whilst expert advice is sought or until they meet the appropriate criteria to recommence EPPs.
- i. The medical practitioner should be aware that in the event of any breach of the restrictions and stipulations listed above he may be subjected to disciplinary procedures by the Malaysian Medical Council.

It is generally preferable that a medical practitioner living with HIV (and other BBV infections) and allowed to continue with his practice, should be cared for and helped in his practice by a fellow medical practitioner who works with him or is in a clinic near him, and who should understand the restrictions placed on the practice of the practitioner living with HIV or any other blood-borne viral infections.

All medical practitioners should comply with institutional policies and procedures designed to protect patients. Healthcare providers have an ethical responsibility to promote their own health and well-being, and a responsibility to remove themselves from care situations if it is clear that there is a significant risk to patients despite appropriate preventive measures.

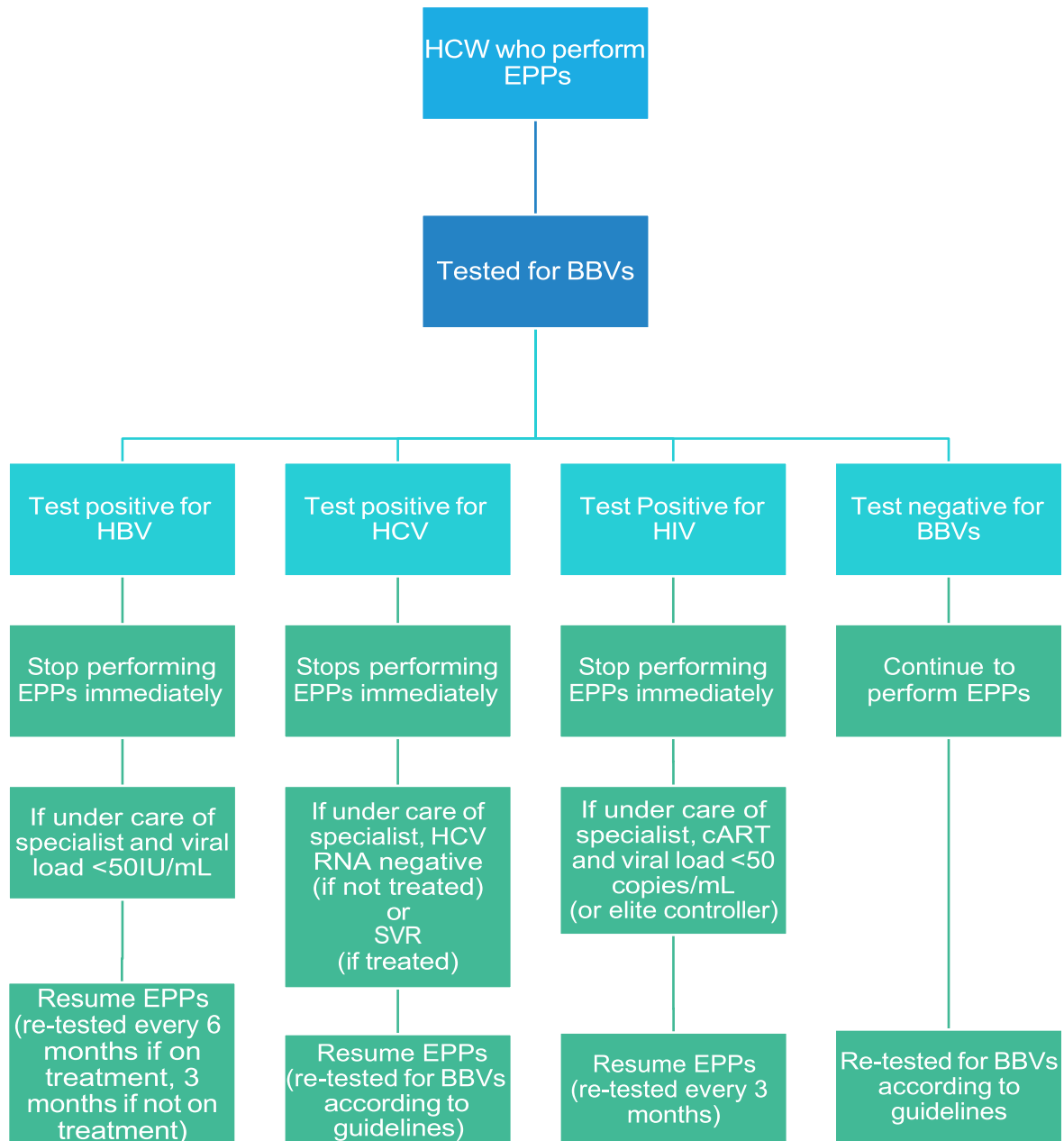
Procedures to be adopted by a medical practitioner WITH BBV Infection

A medical practitioner, who has reason to believe that he may have been exposed to BBV infection, or that he may be living with a BBV infection, is required to follow the steps laid down below:

- a. Take leave from his professional duties immediately by informing in confidence his supervisor.
- b. Seek confidential consultation with a Physician.
- c. Submit a latest medical report to MMC and attend the review with the FTP-MMC.
- d. Consent for the recommendations of the Fitness to Practice Committee to be submitted to the President of the Council in confidence.
- e. Comply with the decisions of the President of the Malaysian Medical Council with regards employment and restrictions to practice.
- f. Immediately report all incidents of exposure of the HCW with BBV's blood or bodily fluid to the patient's open tissues to the designated occupational physician in their health facility.

The practitioner may also in confidence directly contact the Secretary or the President of the Malaysian Medical Council, whereupon the President may direct, in confidence, that the matter be dealt with by an Infectious Disease Specialist or a Physician, referred to as the Responsible Physician, and a report submitted directly for his personal attention for further action.

Figure 1: BBV testing requirements for HCWs who perform EPPs



7. THE ROLE OF THE EMPLOYING ORGANIZATIONS

Patient safety and public confidence are paramount and dependent on the BBV infected, or potentially infected, medical practitioner who has been diagnosed with BBV infection and who has disclosed this information to his employer. Employers should promote a climate that encourages such confidential disclosure.

Healthcare facilities should provide an environment in which medical practitioner living with a BBV knows their privacy and confidentiality will be respected and maintained (section 13).

It is important that such a medical practitioner, upon confirmation of BBV infection, and if recommended to practice after review by the Fitness to Practice Committee and final endorsement by the President of MMC, should be allowed to practice.

All matters arising from and relating to the retraining and/or employment of HCWs living with BBVs should be coordinated through a specialist occupational physician. Where a healthcare establishment's OH service does not have its occupational physician, arrangements should be put in place for this advice to be sought from such a specialist outside the establishment.

The final decision about the place of employment and the type of work that may be undertaken by a medical practitioner living with BBV infection should be made on an individual basis, in conjunction with consultation with the Responsible Physician, specialist occupational physician and the Fitness to Practice Committee (if practitioner is self-employed, must be under joint supervision of a responsible physician and MMC)

8. THE ROLE OF THE RESPONSIBLE PHYSICIAN

The “Responsible Physician” is the physician (preferably specialist infectious diseases physician, specialist gastroenterologist, hepatologist, Family Medicine Specialist or similar) who manages the medical practitioner’s BBV infection and provides advice on matters relating to his practice. These may include:

- The infected practitioner’s personal Physician and / or
- The Physician chosen by the President of the Malaysian Medical Council.

It is extremely important that the infected medical practitioner, or suspected to be infected practitioner, receive the same rights of confidentiality as any patient seeking or receiving medical care. The Responsible Physician, who works within strict guidelines on confidentiality, has a key role in this process, since he is able to act as an advocate for the practitioner and advisor to the employing authority. The Responsible Physician shall send a report on the infected practitioner’s infection status to the President of the MMC.

The principle behind allowing practitioner living with BBV to undertake EPPs whilst on therapy relies on continuing care and regular viral load monitoring by their responsible physician. Effective monitoring requires a close working relationship between the infected practitioner, responsible physician, and specialist occupational physician from the employing organization to ensure that the policy is adhered to, thus minimizing the risk of transmission. Responsibility for the ongoing monitoring of HCWs living with HBV or HIV cleared to perform EPPs, in accordance with this guidance, rests jointly with the specialist occupational physician and the responsible physician. This includes ensuring infected practitioner has scheduled appointments of appropriate frequency for the level of monitoring required (see section 6), and actively follow up missed appointments to ensure timely rescheduling.

The Responsible Physician shall notify MMC and the specialist occupational physician or relevant person in the employing organization if the infected medical practitioner,

- does not attend their appointments or failed to be tested within the prescribed time frame (see section 6) without prior notification and adequate justification
- refused to have their viral load tested, or
- continue to perform EPPS when excluded by these guidelines.

9. THE ROLE OF THE SPECIALIST OCCUPATIONAL PHYSICIAN

Specialist Occupational Physician is a consultant who is on the specialist register for occupational medicine. All matters arising from and relating to the training and/or employment of practitioners living with BBVs should be coordinated through an accredited consultant occupational physician. Where a healthcare establishment's Occupational health (OH) services does not have its own Consultant Occupational Physician, arrangements should be put in place for this advice to be sought from such a consultant outside the establishment.

Occupational health services should adopt a proactive role in advising the practitioners about the necessary clearance they need before intending to perform EPPs. OH services should explain the testing arrangements for health clearance and how BBV infection might affect continued performance of EPPs.

10. THE ROLE OF THE FITNESS TO PRACTICE COMMITTEE

A registered medical practitioner with a BBV infection will be referred to the Fitness to Practice Committee to be appointed by the President of Council.

The Fitness to Practice Committee shall be composed of the Responsible Physician treating the practitioner, and at least four other members (including a specialist in the discipline of the practitioner if he has a specialist qualification), as appointed by the President of MMC.

The duties of the Fitness to Practice Committee will be to:

- a. Obtain a confidential briefing/report on the practitioner who is the subject of the Review from the Responsible Physician.
- b. Suggest on the most appropriate action to be taken with regards job placement, restriction of duties, monitoring, further treatment, etc.
- c. Review the application for practitioner who applies to perform high-risk EPPs together with the experts from the specialty involved. The ad-hoc Committee of experts will be elected by the Council following the recommendation from the FTP Committee and will be a case by case basis according to application.
- d. Submit the suggestions and recommendations to the President of Council for further action.

11. EXPOSURE PRONE PROCEDURES (EPPs)

(SEE APPENDIX 4: DEFINITIONS AND EXAMPLES OF EPPs)

12. CARE OF THE INFECTED MEDICAL PRACTITIONER

The interests of the medical practitioner and his family are very important. Where possible, the practitioner should be kept informed of decisions about the patient notification exercise. With their family, they may need immediate practical or psychological support including measures to protect privacy. If the health care worker has been only recently diagnosed, access to counselling and specialist medical advice will be needed, including a consideration of antiretroviral drug therapy.

The worker or their family may wish to seek their own independent legal advice. If they do seek legal advice it will be helpful for the authority's legal advisers to keep in regular contact with those representing the health care worker.

Infected health care workers who normally perform exposure prone procedures as part of their duties will need to seek retraining or redeployment. Advice on the former can be obtained in the first instance from a specialist occupational health physician who may wish to take advice from the Ministry of Health/Malaysian Medical Council.

13. CONFIDENTIALITY CONCERNING THE MEDICAL PRACTITIONER LIVING WITH BBV

- a. It is extremely important that a BBV infected practitioner, particularly with HIV infection, receives the same rights of confidentiality as any patient seeking or receiving medical care. Physicians or specialists, who work within strict guidelines on confidentiality, have a key role in this process, since they are able to act as an advocate for the medical practitioner and adviser to the employing authority. They should adopt a proactive role in helping the medical practitioner to assess if he/she has been at risk of BBV infection and encourage him/her to be tested for BBV if appropriate.
- b. There is a general duty to preserve the confidentiality of medical information and records. Breach of this duty is very damaging for the individuals concerned and it undermines the confidence of the public and of health care workers in the assurances about confidentiality which are given to those who come forward for examination or treatment.
- c. Every effort should be made to avoid disclosure of the infected worker's identity, or information which would allow deductive disclosure. The use of personal identifiers in correspondence and requests for laboratory tests should be avoided and care taken to ensure that the number of people who know the worker's identity is kept to a minimum.
- d. Any unauthorized disclosure about the BBV (particularly HIV) status of an employee or patient constitutes a breach of confidence and may lead to disciplinary action or legal proceedings. Employers should make this known to staff to deter open speculation about the identity of an infected health care worker.
- e. The duty of confidentiality, however, is not absolute. Legally, the identity of infected individuals may be disclosed with their consent or without consent in exceptional circumstances where it is considered necessary for the purpose of treatment, or prevention of spread of infection. Any such disclosure may need to be justified.
- f. In balancing duty to the infected health care worker and the wider duty to the public, complex ethical issues may arise. As in other areas of medical practice, a health care worker disclosing information about another health care worker may be required to justify their decision to do this. The need for disclosure must be carefully weighed and where there is any doubt the health care worker considering such disclosure may wish to seek advice from his or her professional body.
- g. The duties of confidentiality still apply even if the infected health care worker has died or has already been identified publicly.

14. CONCLUSIONS

- a) A registered medical practitioner may be infected with BBV (HIV, HBV or HCV) in the course of his professional work or due to behavioral indiscretions.
- b) All HCWs are expected to protect the health and safety of their patients. This obligation includes taking all reasonable measures to prevent transmission of BBVs from themselves to their patients.
- c) Medical practitioners living with BBV may be allowed to perform EPPs after evaluation by the Fitness to practice committee of Malaysian Medical Council with conditions and limitations imposed on his practice
- d) It is also important to take the necessary steps to ensure confidentiality of the practitioner's illness and holistic care of the practitioner's family while he is so employed and being treated.
- e) The steps to be taken if there is suspected or real transmission of BBV infection from the practitioner to a patient, which, on evidence however, is very rare if standard precautions are taken, are clearly important considerations.

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Appendix 1: Worldwide cases of HCW to patient transmission of HIV, 1992-2005

Year reported	Reference	Country	Occupation	EPP performed	Patients infected	Patients tested	% patients infected
1992	Ciesielski et al ¹	USA	Dentist	Exact risk of transmission was never established	5	1,100	0.45%
1999	Lot et al ²	France	Orthopaedic surgeon	Hip replacement	1	983	0.10%
2003	Bosch ³	Spain	Obstetrician	Caesarean section	1	250	0.40%
2002	Astagneau et al ⁴	France	Nurse in general surgery and gynaecology	HCW had not assisted EPP. Transmission route remains unclear	1	2294	0.04%

Appendix 2 Published cases of healthcare worker-to-patient transmission of hepatitis B virus

Ref.	Year	Location	Type of provider	HBeAg status	Viral load	No. of patients infected	Breach in infection control identified
(13)	1969	US	Nurse	Not done	Not done	11 possible	None
(3)	1969-1974	US	Oral surgeon	Positive	Not done	55 (10 probable, 45 possible)	Health care worker did not wear gloves
(14)	1973-1977	Switzerland	General practitioner	Positive	Not done	41 possible	None

(8)	1974	US	Respiratory therapist	Positive	Not done	4 probable	Health care worker did not wear gloves, had an exudative dermatitis on hands, and reused syringes when accessing indwelling arterial catheters
(15)	1975	US	Oral surgeon	Not done	Not done	43 probable	None
(16)	1976-1979	UK	Surgical registrar	Positive	Not done	9 (7 probable, 2 possible)	None
(17)	1977-1978	UK	Surgical registrar	Positive	Not done	8 (6 probable, 2 possible)	None
(4)	1978	US	Dentist	Positive	Not done	6 (2 probable, 4 possible)	Health care worker did not wear gloves
(18)	1978	Norway	Cardiac surgeon	Positive	Not done	5 probable	None
(5)	1978-1979	US	Oral surgeon	Positive	Not done	4 probable, 8 possible	Health care worker did not wear gloves and had a generalized eczematous dermatitis, including hand involvement
(19)	1979-1980	US	Obstetrician-gynecologist	Positive	Not done	4 (1 probable, 3 possible)	Health care worker held needle in hand rather than a needle holder when suturing, noted several episodes of blood on hands after removing gloves
(9)	1979-1981	The Netherlands	Cardiac surgeon	Not reported	Not done	3 probable	None

(9)	1979-1981	The Netherlands	Perfusion technician	Positive	Not done	11 (8 probable, 3 possible)	Bleeding warts on health care worker's hands
(20)	1980	US	Oral surgeon	Not done	Not done	3 probable	None
(10)	1980-1983	UK	Perfusion technician	Positive	Not done	6 probable	Health care worker did not wear gloves, and had cuts and abrasions on hands
(10)	1980-1983	UK	Surgical registrar	Not reported	Not done	5 possible	None
(10)	1980-1983	UK	House officer	Not reported	Not done	1 possible	None
(21)	1984	US	Obstetrician-gynecologist	Positive	Not done	6 probable	None
(6)	1984-1985	US	Dentist	Positive	Not done	24 (6 probable, 18 possible)	Health care worker did not wear gloves
(22)	1987	US	General surgeon	Positive	Not done	5 (3 probable, 2 possible)	None
(23)	1987	UK	Obstetrician-gynecologist	Positive	Not done	22 (6 probable, 16 possible)	None
(11)	1988	UK	General surgeon	Negative	1×10^7 copies/mL	1 confirmed	None
(11)	1988	UK	Obstetrician-gynecologist, trainee	Negative	4.4×10^6 copies/mL	3 confirmed	None
(11)	1988	UK	Obstetrician-gynecologist, trainee	Negative	5.5×10^6 copies/mL	1 confirmed	None
(11)	1988	UK	General surgeon, urologist, clinical assistant	Negative	2.5×10^5 copies/mL	1 confirmed	None
(24)	1988	UK	Cardiothoracic surgeon, trainee	Positive	Not done	17 (9 probable, 8 possible)	None

(25)	1991	UK	Surgeon	Positive	Not done	3 possible	None
(26)	1991	Canada	Orthopedic surgeon	Positive	Not done	2 (1 probable, 1 possible)	None
(27)	1991-1992	US	Thoracic surgeon	Positive	1×10^9 copies/mL	19 (9 confirmed, 4 probable, 6 possible)	None
(28)	1991-1993	UK	Cardiothoracic surgeon	Positive	Not done	20 (14 confirmed, 6 probable)	None
(7)	1991-1996	Canada	Electroencephalogram technician	Positive	Not done	75 (4 confirmed, 71 possible)	Health care worker did not wear gloves and used reusable subdermal EEG electrodes
(29)	1993	UK	General surgeon	Positive	Not done	2 confirmed	None
(30)	1993-1994	UK	General surgeon, trainee	Positive	Not done	11 (1 confirmed, 10 possible)	None
(30)	1994	UK	General surgeon, trainee	Positive	Not done	2 possible	None
(30)	1994	UK	Urologist, trainee	Positive	Not done	1 possible	None
(31)	1995-1999	The Netherlands	General surgeon	Positive	5×10^9 GE/mL	28 (8 confirmed, 20 possible)	Health care worker noted glove perforations
(32)	1996	UK	Orthopedic surgeon	Negative	Not done	1 confirmed	None
(33)	1999	UK	Cardiothoracic surgeon	Negative	1.03×10^6 GE/mL	2 confirmed	None
(34)	2001	UK	General surgeon	Negative	$>10^6$ copies/mL	3 confirmed	None
(35)	2009	US	Orthopedic surgeon	Positive	> 17.9 million IU/mL	8 (2 confirmed, 6 possible)	None

(36)	2010	Japan	Obstetrician-gynecologist	Positive	1.6 x 10 ⁹ copies/mL	1 confirmed	None
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Note: Confirmed transmissions were defined as cases where the health care worker and patient were epidemiologically linked and genetic relatedness of the viruses was confirmed through partial or complete DNA sequencing. Probable transmissions were defined as cases in which the subtype of HBV infecting the health care worker and patient were identical in investigations of epidemiologically-linked health care worker and patient HBV infections. Possible transmissions are defined as cases in which epidemiologic links were established, infected patients had no other risk factors for HBV acquisition but virologic subtyping data was not available to confirm transmission.

Appendix 3: Recent published cases of transmissions from HCV-infected HCW to patients

Ref	Year Reported	Location	Type of provider	Identified /suspected route for transmission	No. of patients infected	No of patients tested	% patients infected
6	1996	Spain	Cardiac surgeon	Open heart surgery	5	222	2.25%
5	2000	Germany	Anaesthesiology assistant	Wound in assistant's ungloved hand	5	833	0.60%
7	2002	Germany	Gynaecologist	Cannot access article EPP written in WJG	1	2286	0.04%
8	2002	Germany	Orthopedic surgeon	Total hip arthroplasty	1	207	0.48%
4	2002	USA	Anesthesiologist	Cannot be ascertain	1	348	0.28%
9	2005	UK	Anesthesiologist	Cannot be ascertain	1	NA	NA
10	2006	Germany	Anesthesiologist	Failure to use standard precaution	3	NA	NA
11	2007	Sweden	Thoracic surgeon	Thoracic surgery	2	456	0.44%
12	2010	Norway	Cardiac surgeon	Openheart surgery	10	270	3.7%
13	2012	USA	Technician in an interventional radiology area	Narcotic (fentanyl) diversion	5	3446	0.14%
14	2014	UK	Midwife	Cannot be ascertain, no EPP performed	1	NA	NA
3	2015	USA	Surgical technician	Narcotic (fentanyl) diversion	18	5243	0.34%

Appendix 4: Categories Of Exposure Prone Procedures (EPPs)

Category	Description	Examples
Non-EPPs	Procedures where the hands and fingers of the HCW are visible and outside of the body at all times and procedures or internal examinations that do not involve possible injury to the HCW's hands by sharp instruments and/or tissues, provided routine infection prevention and control procedures are adhered to at all times.	• insertion of a chest drain • routine oral examinations (gloved with mirror and/or tongue depressor) • removal of haemorrhoids • Locally anesthetized ophthalmologic surgery • minor surface suturing • venesection • percutaneous cardiac procedures (eg, angiography and catheterization) • percutaneous and other minor orthopedic procedures, eg. Closed reduction of fractures and minor amputations (eg, amputations of fingers, toes, hands, or feet) • subcutaneous pacemaker implantation • bronchoscopy • insertion and maintenance of epidural and spinal anaesthesia lines • minimum-exposure plastic surgical procedures (eg, liposuction, minor skin resection for reshaping, face lift, brow lift, blepharoplasty, and otoplasty)

Exposure Prone Procedures (EPPs)	Procedures where there is a risk of injury to the HCW resulting in exposure of the patient's open tissues to the blood of the HCW. These procedures include those where the HCW's hands (whether gloved or not) may be in contact with sharp instruments, needle tips or sharp tissues (spicules of bone or teeth) inside a patient's open body cavity, wound or confined anatomical space where hands or fingertips may not be completely visible at all times.	• Cardiothoracic surgery: generally all cardiothoracic procedures. • Gynaecological surgery: perineal surgery, trans-vaginal surgery and open abdominal gynaecological surgery. • Neurosurgery: that involves exposure to sharp bone fragments e.g trauma and some spinal surgery. • Obstetrics and Gynaecology: Caesarean birth, instrumental birth, infiltration of perineum with local anaesthetic, episiotomy, application of fetal scalp electrode, fetal blood sampling. • Open surgical procedures: open abdominal or thoracic general surgery, open abdominal or thoracic vascular surgery, open urological procedures. • Orthopaedic: procedures involving cutting or fixation of bones or the distant transfer of tissues from a second site (e.g thumb reconstruction), and open surgical procedures where there is possibility of bone fragments and/or bone spicules, mechanical drilling or procedures involving deep tunnelling using sharp instruments. • Otolaryngology, head and neck : in particular bony facial reconstructive surgery (elective or after trauma)
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		• Plastic surgery: where it involves extensive cosmetic procedures that involve bony reconstruction or free tissue transfer involving bone or in the thorax. • Trauma: including open head injuries, facial and jaw fracture reductions, extensive soft tissue trauma, rectal examination in presence of suspected pelvic fracture, deep suturing to arrest haemorrhage and internal cardiac massage.
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Examples of procedures that are generally considered to be non-EPP but have the potential to escalate to open or trauma procedures that will require access to a colleague who can perform EPPs include:

Minimally invasive procedures: including laparoscopy, endovascular procedures, thoracoscopic procedures, Natural Orifice Transluminal Endoscopic Surgery (NOTES), cytoscopic procedures, arthroscopic procedures and robotic surgery.

Trauma/emergency situations: there is the risk in trauma/emergency situations that a previously non-EPP may escalate (and quickly) into an EPP. This context must be considered for practitioners who work in rural or remote areas.

These lists are intended as guidance and do not cover all eventualities and must be interpreted with caution. Moreover, it is recognized that variations in practice may exist in Malaysia and may change over time. It is therefore recommended that the over-arching EPP definition given is used as the primary guidance when deciding whether a particular practice/procedure is exposure prone or not. The relevant specialist body can provide more detailed information about what procedures are considered exposure prone in their specialties; and may recommend a greater frequency of BBV testing for their specialty, particularly when high risk EPPs are commonly performed.

**adopted from Australian National Guidelines for the Management of Healthcare Workers Living with Blood Borne Viruses and who Performed Exposure Prone Procedures at Risk of Exposure to Blood Borne Viruses 2018*

ANNEXURE A: MEASURES TO PREVENT OCCUPATIONAL TRANSMISSION OF BLOOD-BORNE VIRUS

General measures to prevent occupational transmission of blood-borne viruses

1. Apply good basic hygiene practices with regular hand washing, before and after contact with each patient, and before putting on and after removing gloves. Change gloves between patients.
2. Gloves should be worn whenever there is contact with skin and mucous membranes and must be changed between patients.
3. Wearing double gloves in potentially unsafe operating fields provides some degree of protection.
4. Use instruments rather than hands for retracting and exploring tissue.
5. Avoid the simultaneous presence of the hands of two or more surgeons in the operative field;
6. Use sharps with injury prevention features (e.g. blunted suture needles, dental local anesthetic safety needles, retractable safety scalpel)
7. Follow approved procedures and use approved sharps disposal containers where sharps usage is essential, and exercise particular care in handling and disposal.
8. Transfer of sharp instruments between personnel such that only one person touches the instrument at a time, usually using a neutral zone (e.g., emesis basin or Mayo stand) from which instruments can be retrieved
9. For **all** clinical procedures, cover existing wounds, skin lesions and all breaks in exposed skin with waterproof dressings, or with gloves if hands extensively affected.
10. Health care workers with non-intact skin conditions and chronic skin disease such as eczema should avoid those invasive procedures which involve sharp instruments or needles when their skin lesions are active, or if there are extensive breaks in the skin surface. A non-intact skin surface provides a potential route for blood-borne virus transmission, and blood-skin contact is common through glove puncture that may go unnoticed.

11. Use protective clothing as appropriate, including protection of mucous membrane of eyes, mouth and nose from blood and body fluid splashes. Avoid wearing open footwear in situations where blood may be spilt, or where sharp instruments or needles are handled. Protection of the membranes of the eyes, mouth and nose from blood and body fluid splashes is especially important. Open footwear should not be worn in situations where blood may be spilt, or where sharp instruments are handled.
12. Clear up spillages of blood and other body fluids promptly and disinfect surfaces according to established protocols.
13. Follow approved procedures for sterilisation and disinfection of instruments and equipment and disinfection of treatment/operating room after each patient.
14. Follow approved procedures for safe disposal of contaminated waste.
15. In the event of an Exposure Incident, the protocol for its management must be followed.

ANNEXURE B: RECOMMENDATIONS FOR RESPONDING TO PATIENT EXPOSURE (POSSIBLE OR REALISED) TO THE BLOOD OR BODILY FLUID OF A HCW WITH A BBV

MANAGEMENT OF PATIENTS FOLLOWING EXPOSURE TO THE BLOOD AND/OR BODY FLUID OF A HCW WITH A BBV

1. When a HCW with a BBV accidentally exposes a patient to their blood; the incident should be reported to the appropriate person according to local policies.
2. A detailed risk assessment should be performed by the designated person, in discussion with the HCW's treating doctor that includes:
 - a. assessment of the significance of the exposure
 - b. the status of the exposed patient
 - c. the status of the HCW with a BBV, in particular their current viral load, and
 - d. the history of the HCW with a BBV including their adherence to treatment, the frequency and magnitude (if any) of fluctuations in their viral load and the presence of factors which might increase the HCW's viral load.
3. Standard procedure, as dictated in local policies, should be followed to evaluate the significance of the exposure and then determine the follow-up required for both the HCW and patient.
4. When completing the risk assessment, the following information should also be considered:
 - a. exposure to the blood or bodily fluids of a HCW with a BBV, who has been complying with these Guidelines would pose an extremely low risk of transmission of a BBV to a patient.
 - b. if there is concern that the viral load of the HCW is above what is stipulated in the Guidelines (200 copies/mL for HIV, 50 IU/mL for HBV or HCV RNA positive), the HCW's viral load should be tested immediately, and local policies should be followed in regard to offering appropriate post exposure prophylaxis and followup to the patient(s).

INDICATIONS FOR INVESTIGATION AND/OR LOOKBACK EXERCISES

1. POTENTIAL IATROGENIC BBV TRANSMISSION

If a patient presents with an acute BBV infection after undergoing an EPP, and the origin of the infection is unclear, the need for a full risk assessment should be decided in consultation with the relevant area of the jurisdictional health department, who may choose to consult their EAC (where available) or the NERP.

This should include an investigation into the circumstances of the transmission including possible system failures (such as staff to patient ratios, acuity of area/situation, faulty equipment, poor HCW training or supervision), HCW factors (such as inexperience, inappropriate deployment), and patient factors. If there is evidence of iatrogenic transmission of a BBV from a HCW, a lookback must be conducted.

2. New BBV diagnosis in a HCW who performs EPPs

When a HCW is diagnosed with a BBV infection, but no iatrogenic transmission to a patient has been identified, the decision on whether a lookback should be undertaken on all or some patients who have undergone an EPP performed by the HCW should be made on a case-by-case basis using the following assessment criteria:

- a. the nature and history of the clinical practice of the HCW, including the type of procedural practice
- b. HCW medical considerations such as viral load
- c. lookback exercises connected with HCWs with HIV on cART should generally only be considered in circumstances in which their viral load had risen above 1 000 copies/mL
- d. evidence of physical or mental impairment or behaviour which could have affected the HCW's standard of practice XIV The specialist Colleges can provide advice on which procedures in their respective specialties are EPPs. Their contact details are provided in Appendix 2: Roles. 39
- e. evidence of poor infection prevention and control practice by the HCW or at the relevant healthcare setting during the time the HCW was probably infected with the BBV
- f. known episodes of high risk exposure to a patient, for example sharps injuries, and
- g. any other relevant considerations.

Any investigation should be purposeful, practical and proportionate to the risk of transmission.

3. SIGNIFICANT RISK OF TRANSMISSION IDENTIFIED

In instances where the risk assessment and subsequent lookback identifies significant risk, the patient notification exercise may include contacting the patients, offering a pre-test discussion and encouraging testing for the relevant virus(es). The decision on how far back patient notification should go should be determined on a case-by-case basis.

HCW CONFIDENTIALITY

The disclosure of the identity of a HCW to a patient should not be necessary and the right to confidentiality of the HCW should be respected, even if the HCW with a BBV has died or has already been identified publicly. Healthcare facilities should provide an environment in which HCWs living with a BBV know their privacy and confidentiality will be respected and maintained.

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