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Supporting the HIV, Viral Hepatitis and Sexual Health Workforce

Submission to the MBA Consultation Draft Policy

Guidelines for medical practitioners and medical students infected with blood-borne viruses

Thank you for the opportunity to comment on the consultation draft. As the peak professional society representing and supporting the HIV, viral hepatitis and sexual health workforce, ASHM has a particular interest in this issue. The Society has participated in all previous policy development in this area and welcomes the opportunity to contribute further. The approach we have taken in drafting this response is:

1. Some opening introductory comments
2. Specific comments on your consultation draft – these appear as tracked changes in specific sections of your documents
3. Responses to your specific consultation questions
4. Concluding remarks, including possible future collaboration on the document, and its implementation

We note the difference in focus between the CDNA and the Medical Board and it is with this distinction in mind that many of the following comments are made. We believe that the CDNA document should be the document in which levels or conditions are set and that this should be evidence based to the extent that this is possible. Having said this, the CDNA is currently reviewing its policy and this comment is based on the 2005 (current) version of the policy, not any subsequent draft for consultation.

The only exception to this would be in the case where the Medical Board held the belief that the CDNA policy was not up to current evidential scrutiny or was in some other way inappropriate. But outside this exception, having two documents which are identical is redundant and having two documents which are in conflict is not helpful and could in fact be harmful.

Over and above this we believe the Medical Board should focus on the 'competency and safety' of particular individuals. The Medical Board should have at the centre of its interest both the welfare of the public and the welfare of the practitioner or student. Unlike CDNA this means forensically investigating specific events so that the profession can learn how best to deal with these situations.

Where some of the more 'scientific analyses' control for factors such as practitioner injecting drug use (SHEA, 2010, p210 reference to controlling for drug use), the medical registration board absolutely cannot do this. The Board is in the position to weigh up pathogenic risk, with procedural risk and balance this with the

practitioners capacity, limitation or impairment. This means, necessarily the Board needs to step in where judgment is required.

The numbers of patient to doctor transmissions are very low. SHEA provides a thorough analysis of these up to 2010:

- In HBV the number of transmissions is roughly 10 time the number of infected health care workers transmitting, suggesting that some practitioners, for individual factors be it viral load or performance transmit much more. This would suggest knowing much more about these cases could allow for the elimination of particular practices or possibly a refinement of the pathological limits above which a practitioner must have restriction placed upon their work.
- Again the number of transmission occurring from an individual practitioner are high. Once SHEA differentiates between those cases which are substance use related the number drop right down and are eliminated with the introduction of increased barrier protection.
- In HIV the cases are likewise low. The SHEA document makes reference to the case in NSW of the doctor who cross infected patients via a multiuse vial of anaesthic. They point out that the doctor was not infected, but had he been the source the outcome would have been the same.

Comments tracked in section 3. Summary

In clinical practice, the primary concern of medical practitioners should be the care of their patients. Medical practitioners have a professional responsibility to practise medicine safely and effectively. However, it is important for medical practitioners to maintain their own health and wellbeing. This includes being immunised against infectious diseases where there is a vaccine available and taking the necessary steps if the practitioner has been exposed to a blood-borne virus, including earliest possible access to treatment.

Infected practitioners have the same rights of confidentiality as other patients.

If a medical practitioner knows or suspects that they have been infected with a blood-borne virus, they ~~should~~ must consult an appropriately experienced, independent medical practitioner for their management. This includes seeking treatment, which may modify their illness and improve their health outcomes for personal benefit and to the extent that restrictions on practice ~~can~~ may be lifted. It also includes obtaining advice on the need to modify their practice. It is not appropriate for a practitioner to rely on their own assessment of the risk that they pose to patients.

Medical practitioners should be aware of their infective status particularly if they perform exposure prone procedures. Medical practitioners who perform exposure prone procedures ~~should~~ must be ~~voluntarily~~ tested, by a practitioner of their

choosing, for blood-borne viruses prior to the commencement of practice, following potential exposure to a blood-borne virus and on an annual basis.

A registered medical practitioner or registered medical student who is alleged to have breached these guidelines will be investigated by the Medical Board of Australia (Board) and if the allegations are found to be substantiated, the Board will take the necessary action to protect the public.

Comments tracked into item 6. Medical practitioners and medical students who are infected with a blood-borne virus

Medical practitioners and students who are infected with a blood-borne virus have an ethical duty to review their practice of medicine, health risks and health status. They must obtain and follow the advice of their treating specialist doctor and must never rely on their own assessment of the risk that their condition may pose to patients.

Medical practitioners and students who are infected with a blood-borne virus have the same rights of confidentiality as other patients. The exception to this is if through their practice, they are putting the public at risk (for example, by breaching these guidelines) in which case, they should be reported to the Board via the Australian Health Practitioner Regulation Agency. Medical practitioners who are infected with a blood-borne virus can practise medicine. However, they may need to modify their practice if they were previously performing exposure prone procedures.

Medical practitioners and medical students who are infected with a blood-borne virus must not perform any exposure prone procedures if they are:

- HIV antibody positive, and have a detectable viral load ~~even if virus levels become undetectable on appropriately monitored anti-retroviral therapy~~
- Hepatitis B e antigen (HBeAg) positive and/or hepatitis B DNA positive (by PCR test)
- Hepatitis C RNA positive (by PCR test)

A specialist medical practitioner must ascertain whether the infected practitioner or student is viraemic, using the most sensitive tests that are commercially available.

Medical practitioners or medical students should seek expert medical advice about their infectious status and whether it is appropriate for them to perform exposure prone procedures if they:

- test positive for Hepatitis B surface antigen (HBsAg) and are HBeAg and hepatitis B DNA negative or
- test Hepatitis C antibody positive and Hepatitis C RNA negative.

Note it may be useful to define the expert medical advice sought in the above paragraph.

Question 1

Should medical practitioners with any level of viraemia be permitted to perform exposure prone procedures? If you believe that they can safely perform exposure prone procedures in some circumstances, define the circumstances (for example, which viruses and what maximum level of virus?)

Response to Question 1:

Developments in treatment, pushing down viral load in HBV and HIV, have been dramatic and make reliance on any pre-treatment era influenced policy problematic. Developments in the measurement of viraemia also influence the levels at which confidence can be established. Many of the policies in this area were developed early in the era of HIV and have clearly been effective in reducing transmission (Lancet 377:1719 discussing HIV treatment as prevention) and the work we have seen in heterosexual couples conceiving in the context of HIV managed by antiretroviral therapy.

In relation to HIV there is considerable interest in tying restriction to viral load, particularly if this is going to be applied in relation to hepatitis B. Decision making around frequency of testing to establish viraemia is problematic as in both HIV and HBV viral load can rebound quickly in the advent of treatment failure (through resistance or cessation). But it must be noted that viraemia is very high soon after infection, at a time where a practitioner may not be aware of their infection and a number of documents transmission cases have occurred at or soon after seroconversion, sometimes resulting in the identification of the practitioners infection. Such cases will not be prevented by setting safety levels, and may not be significantly impacted by annual or twice annual testing of staff involved in exposure prone procedures.

ASHM was approached by the NHMRC when they were developing the new Infection Control Guidelines (ICG) http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/CD33_InfectionControlGuidelines2010.pdf) with specific reference to the question of what constitutes a high HBV DNA titre - with relevance to question 1 of the Board consultation paper.

In the end, the NHMRC decided not to specify. The current wording of the relevant section (p211-213) states;

Healthcare workers
Healthcare workers who undertake EPPs have a responsibility to know their infectious status with regard to bloodborne viruses such as hepatitis B virus,

hepatitis C virus and HIV, and should be given relevant information about the tests available and encouraged to have voluntary testing.

Healthcare workers who carry a bloodborne virus have a clear responsibility to follow the treatment recommended by their doctor and modify their involvement in direct patient care. They must not perform EPPs if they are: (28)

- *HIV antibody positive*
- *hepatitis B e antigen (HBeAg) positive and/or hepatitis B DNA positive at high titres (29)*
- *hepatitis C RNA positive (by nucleic acid test).*

Healthcare workers who carry a bloodborne virus and are not in these categories must not perform EPPs until specialist medical advice has been sought. Healthcare workers who are currently hepatitis B surface antigen (HBsAg) positive and hepatitis B DNA negative or hepatitis C antibody positive and hepatitis C RNA negative must obtain ongoing medical advice regarding their potential infectiousness and the appropriateness of their continued performance of EPPs.

with respect to the high titres footnote (29):
Previously published guidelines have stated that HCWs must not perform EPPs if they are HBeAg positive and/or hepatitis B DNA positive at high titres. Whether HCWs with any level of hepatitis B DNA should perform EPPs is under review by Australian infectious disease experts. When there is a nationally agreed approach this Guideline will be updated, but in the mean time, HCWs wishing to perform EPPs who are hepatitis B DNA positive should consult their local health authority for advice

In relation to HBV:
The previous version of the ICG (2004) raised the issue of using HBV DNA to stratify risk among HBsAg positive practitioners performing exposure prone procedures (EPPs) as a discussion point and cited a 2000 UK Health Department circular which called for exclusion from EPPs if the HBV DNA was > 1000 copies/mL, with annual testing for those with <1000 c/mL to confirm they remained below this threshold. This recommendation followed a series of transmissions of HBV from HBsAg positive / HBeAg negative surgeons in the UK to susceptible patients, one of whom died as a result.

In a study funded to investigate this issue following the transmissions in the UK, the lowest HBV DNA level of a surgeon known to have infecetd patients was about 40,000 c/mL (8,000 IU/mL) (Corden JClinVirol 2003) although the sample was taken about 3 months after transmission occurred (Buster JViralHep 2007). A subsequent European consensus paper (Gunson JClinVirol 2003) suggested applying a 10,000 c/mL threshold but concluded each country should determine their own level based on risk to patients vs loss of experienced practitioners. They also advised annual testing to confirm those below the threshold remained so,

and that all practitioners shown to be the source of transmission never perform EPPs again regardless of their HBV profile.

Following this, the UK kept their 1,000 c/mL threshold, and the Netherlands kept their higher threshold (100,000 c/mL). One concern is that no systematic follow-up of patients of surgeons operating under these 3 policies to establish actual risk of transmission (Daha EurJClinMicrobiolInfectDis 2009), so it is not possible to determine where the optimal trade-off between risk to patients vs restriction of practice for HCW with HBV.

The previous Medical Practitioners Board of Victoria policy recommended exclusion of any viraemic individual (regardless of HBV DNA level) from performing EPPs.

Another aspect is that many patients can be rendered aviraemic with potent HBV antivirals - a paper examining this strategy for HCW in the Netherlands was published in 2007 (Buster JViralHep 2007).

In relation to HIV:

Accumulating data support the notion that lower HIV viral load is associated with reduced transmission risk in a sexual setting, both in an untreated and treated population (Lancet 377:1719 HIV treatment as prevention - it works). With the incredibly rare number of reports of transmission of HIV from health care workers to patients and the ability to reduce the HIV viral load to less than 50 copies/mL in nearly all patients, the restriction of HCW with HIV performing exposure prone procedures needs review. The SHEA guidelines assess this issue from a number of perspectives that can inform this review.

Summary response to question 1:

The Australian Infection Control guidelines would benefit from the inclusion of limits. The SHEA policy provides a detailed evidence review for the establishment of limits. The Board should generally be able to rely on limits set by CDNA and. Or NHMRC, but where these are lacking we would support either a genral statement relating to whether or not the person has viraemia and in the case of HBV of 1000c/mL.

- A practitioner should not be restricted if s/he has transmitted infection, if it is this transmission which caused the practitioner to become aware of their infection, and subsequently appropriate precautions are taken.

- The conditions relating to the transmission of HCV may change as a function of the case currently under investigation
- Practitioners with drug and alcohol related impairment and a blood borne virus should be subject to indiviualised review which may include extended periods of drug testing and/or more frequent viral load testing.

Question 2

Is it reasonable to expect that medical practitioners and medical students infected with a blood-borne virus will comply with the Board's guidelines and their treating specialist doctors' advice, or should they have conditions imposed on their registration that prevent them from performing exposure prone procedures?

Response to Question 2:

The reasonableness of the restriction will influence the extent to which it is complied with or circumvented. Reasonableness must be assessed as a function of current evidence and opportunities to pursue effective alternatives.

The aim of therapy is cure (in relation to HCV and possibly some patients with HBV) or long-term highly effective suppression of viral replication (in HIV and HBV) and this is achievable in the patient population. If this can be achieved in the non-healthcare worker population, then in the healthcare worker it must reduce the need for the restriction on practice.

The risk of exposure to HIV through individual acts unprotected anal sex with a person with HIV and undetectable viral load is estimated at 0.05-0.08% (Kirby Institute, 2011) in this setting there is no barrier (condom) and known infection. It would appear that the addition of barrier in the health care setting would further reduce the exposure, though the risk of the exposure may increase as a function of the nature of the exposure ie in settings where the barrier is more likely to be breached such as wiring up a sturnum. In a setting with high prevalence and low treatment, treatment would cancel out risk. This is not the case in Australia, though the effectiveness of treatment in Australia is extremely high.

In some countries the small pool of practitioners able to practice exposure prone procedures may warrant their being able to perform exposure procedures. We do not think this supply issue is relevant in Australia.

Factors such as the frequency of testing and the durability of viral suppression will determine reasonableness. The role then of the Board becomes the application of these and the encouragement of the infected health care worker and their supervisor and treating doctor to apply these.

Question 3

Should these guidelines include details about the management of practitioners who appear to have cleared the HBV or HCV, whether that is the result of treatment or whether it is spontaneous? Should that be left to the treating specialist doctors discretion?

3.1 An untreated HBsAg positive practitioner can perform exposure prone procedures if they are HBV DNA undetectable and HBeAg negative, if there is regular three monthly testing overseen by a specialist and the HBV DNA remains negative

Response to 3.1

Yes, with the proviso that negativity is determined by sensitive Nucleic Acid Amplification based assay, then this would be acceptable. Equally, it would make it simpler if the "non-viraemia" was the criteria for EPP practice. There is some conflict between different guidelines as to the level of HBV DNA, but these appear opinion rather than evidence based.

3.2 A medical practitioner who was HBsAg positive and after treatment becomes HBsAg undetectable on two consecutive occasions at least three months apart, and becomes HBV DNA undetectable and HBeAg negative, can perform exposure prone procedures but must be tested annually.

Responses to question 3.2

Conditions do not need to be imposed by the Board in this instance as seroreversion to HBsAg positivity following durable HBsAg loss is very rare except in the case of immunocompromise

3.3 A medical practitioner who was HBsAg positive and after treatment remains HBsAg positive but HBV DNA undetectable and HBeAg negative may perform exposure prone procedures if there is regular three monthly testing overseen by a specialist, and the HBV DNA remains undetectable.

Responses to question 3.3.

Yes ongoing monitoring will be required in the context of HBV, but late relapse in HCV is very uncommon and more likely to be re-infection.

8. Notifications about an impairment (wording from your document)

The Board understands the issues facing medical practitioners and medical students infected with blood-borne viruses and the importance of confidentiality and their right to privacy. However these issues must be considered in the context of the Board's role to protect the public.

Medical practitioners, employers and education providers have an obligation to notify the Australian Health Practitioner Regulation Agency (AHPRA) if a medical practitioner or medical student has an impairment that places the public at substantial risk of harm. This would include a practitioner or student infected with a blood-borne virus whose health may impact on their ability to practise safely. However, it is not necessary to notify AHPRA where a practitioner or student who has a blood-borne virus is practising safely and is complying with these guidelines, and with the advice of their treating specialist doctor.

Medical practitioners are also required to declare if they have an impairment that impacts their ability to practice safely and effectively at the time of initial registration and annual renewal of registration. They are not required to inform the Board of their infective status if they are complying with these guidelines.

The Board would not impose conditions on the registration of a practitioner who is complying with these guidelines.

General comments on section 8:

It is unclear whether the impairment mentioned above relates to the condition with which the practitioner is infected or an additional impairment relating to drug and/or alcohol use. Cognitive impairment used to be a concern with the HIV infected health care worker. Treatment has effectively removed this. In HCV, the treatment (interferon) itself may cause psychiatric or cognitive complications and the Board, may want to consider advice they provide to practitioner patients under their care who are undergoing interferon based therapy for HCV.

Far more common, however, are impairments associated with alcohol or drug use and/or addiction. When teamed with infection with a BBV, impairment of the alcohol or drug use and/or addiction should elevate the concern of the Board. While the CDNA and NHMRC Infection Control Guidelines should set safety-acceptable practices these should not concern themselves with matters of impairment, the Board is best placed to consider individual situations which are complicated. It is also these cases which can potentially place patients at elevated risk and which attract greatest attention in the media. The review of cases performed by SHEA implicates drug use in many of the cluster outbreaks it examined in relation to HCV transmission.

Each of the conditions is transmissible through injecting drug use. Practitioners known to inject may be subject to conditions being placed on their practice. There is an argument to increase these restrictions in the event that a practitioner is also infected with a BBV. Accident or breach of infection control, which might occur as a function of reduced capacity because of alcohol or drug use related impairment. When the impaired practitioner is also infected with a BBV, the risk associated with that breach (even in the case of an undetectable viral load, as transmission risk may not be completely removed) is elevated. A number of the cases discussed by SHEA relate to drug diversion as the infection control breach. We would support the Boards ongoing supervision and support of a practitioner dually infected with a BBV and found to be impaired through drug or alcohol use.

Question 4 *Which of the following groups of medical practitioners infected with a blood-borne virus should be monitored by the Board and if so, how? For example, should they be required to provide regular results of tests to the Board?*

Response to Question4:

a. all registered medical practitioners; or
No. Medical practitioners infected with a BBV should not treat themselves and should be monitored by an appropriate expert clinician.

b. only registered medical practitioners who perform exposure prone procedures; or
Yes, but monitoring should be responsive to changes in treatment and the HIV or HBV infected practitioner remaining on effective treatment. Annual monitoring may be effective, with a mechanism for change of duties in the event that there is any change in viral load as identified during routine care.

c. only registered medical practitioners that may place the public at risk of harm because of their practice.

If c means practitioners with a BBV and impairment relating to drugs and alcohol then the Board should develop an **indivualised** monitoring schedule and take advice from the treating or supervising specialist. Breaches should be dealt with and impact on the conditions applied.

Question 5

Are there any other measures the Board should put into place (within the scope of its powers) to protect the public from potential infection by medical practitioners with a blood-borne virus?

Response to Question 5:

These are described in general comments under section 8 above.

In addition the Board should consider establishment of an impairment and BBV panel. Given that the Board now has national responsibility, it will be awkward and difficult for one Board to cover all cases. But the panel could consider complex cases and keep abreast of changes in the management of BBV. It should also try and understand the detail in cases where breaches have occurred. Getting a better understanding of how breaches occur may provide insight into how to protect the public.

The Australasian Society for HIV Medicine is very interested in this issue and has extensive experience in the HIV and viral hepatitis sector. We also have close collaborations with other relevant organizations including ASID and ALA. The Board may find it useful to further explore some of these contentious and very important issues in a more collaborative forum. ASHM would be interested in assisting in this. We are unaware of your timeframe for completion, but you may be interested in holding a discussion of these issues perhaps in conjunction with our Annual Conference in September this year.

Early on in the era of HIV comparatively many gay male health practitioners were infected with HIV. Their infection caused many of these individuals to gravitate toward HIV as a field of interest, with a number taking up research positions as a response to restrictions on practise. As we learned about HIV gay men were able to take steps to prevent their sexual exposure to HIV. The vast majority of those practitioners and students infected early in the epidemic are now dead as they

were infected too early to benefit from improved treatment. But in all cases the impact HIV had on their personal and professional lives was enormous. That impact should not be forgotten and a good, ethical and sound response to infected health care workers should be their legacy.

In closing, there needs to be a position from the board, where by the documented, extremely low risk of infection and dramatic improvements evidenced in antiretroviral therapy is balanced against the need for additional restrictions on practice. We hope this response has assisted in this process.

Prepared for and on behalf of the Board and membership of the Australasian Society for HIV Medicine.

End

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