18 May 2011
Medical Board of Australia
medboardconsultation@ahpra.gov.au

Dear Sir/Madam,

We are grateful for the opportunity to comment on the proposed guidelines for Medical Practitioners and Medical Students infected with blood-borne viruses (BBV). We were responsible for the preparation of the guidelines which were followed by the Medical Board of South Australia until June 30 2010.

In devising these guidelines we felt that this document should be framed in such a way as to be instructive and supportive to the individual infected with a BBV, indicating what they could expect from the Regulatory Authority in terms of restriction of privileges as well as providing constructive information about what could be done to minimize the risks of transmission of a BBV and which procedures would not be restricted.
We attempted to address areas of ambiguity as this draft also attempts to do. We attempted to provide a complete list of measures that would reduce the risk of transmission both from Practitioner to patient and vice versa (see Appendix 1). We also provided a specific list of procedures that were not considered to be exposure prone (see Appendix 2).

A copy of the final published and printed document should be available from the Adelaide office of the Medical Board of Australia.

In general terms we are in agreement with these guidelines.

It is clearly not possible to have guidelines prescribing a policy of zero risk of transmission of HIV,HBV or HCV from Practitioner or Student to patients.

We see a paradox between the guideline of voluntary testing and the recommendation of annual testing but we do believe that voluntary testing is desirable. With compulsion, there may be a reluctance for the Practitioner or Student to be tested with the consequence that they may be depriving themselves of appropriate management of their infectious disease.

We would disagree with the recommendation that 'Medical Practitioners and Medical Students who are infected and Hepatitis B e antigen (HBeAg) positive and/or hepatitis B DNA positive (by PCR test) must not perform any exposure prone procedure' (page 6). We believe that the eAg positive state is of little relevance if the individual is HBV DNA negative and that it is very difficult to justify or rationalise that an eAg positive individual with negative HBV DNA is more likely to transmit virus than an eAg individual with negative HBV DNA. The literature certainly doesn't give us any clear indication that this is the case.

We believe that answers to questions 1, 2 and 3 need to be resolved before the document is accepted.

Question 1.
There is an insufficient evidence base to recommend HCV RNA cut-offs in the case of HCV infection of a Medical Practitioner or Medical Student.

However, with HBV infection, a cut-off viral load of $2x10^3$ iu/ml is suggested by the literature for a significant risk of infectivity. This is in the case of both eAg positive and eAg negative HBV infection. This approach is supported by the evidence base available and leads to a consistent approach to the issue with UK and European guidelines and as promulgated in the European Association for the Study of Liver (EASL) Guidelines (J Hepatology 2009;50:227-242).

Question 2.
We believe that they should have a condition imposed on their Registration but that the only parties that need to know about this are the infected individual, their Medical attendants and the Medical Board (see below). Only those involved in EPPs should have this limitation of Registration.

Question 3.
We believe that the guidelines should provide clear information to the Medical Practitioner or Medical Student regarding withdrawal of restrictions for those performing EPP.
We would suggest

- A Medical Practitioner or Medical Student with chronic Hepatitis B who consistently has an HBV DNA level < $2x10^3$iu/ml, either untreated, previously treated or under treatment may perform EPP. The HBV DNA level should be reassessed 3 monthly.
- A Medical Practitioner or Medical Student with antibodies to HCV who is consistently HCV RNA negative, either untreated (spontaneous clearance) previously treated or under treatment may perform EPP. The HCV RNA should be reassessed 3 monthly or at intervals determined by their treating Specialist (the frequency of testing may be annually or less frequently once it is clear that the individual has had a sustained viral clearance).

A very important aspect of this issue has been the provision of limited registration to Medical Practitioners infected with a BBV. This limited registration has been applied even if a practitioner did not represent a risk to the public in a field where EPPs were not performed. In South Australia, the Practitioners name with a label of 'limited registration' would then be published on the Medical Board website. We both strongly hold that this was inappropriate and intruded on the privacy of the Practitioner without serving any purpose in protecting the public. There may be an innuendo associated with this labeling to suggest limited registration for other serious personal flaws or impaired performance in the practice of the individual. We strongly believe that the publication of limited registration on the basis of a BBV is improper and serves no purpose. It does nothing to protect the public and invades the privacy of the Medical Practitioner.

We also had a paragraph about Good Samaritan Assistance.

- Doctors and medical students with blood-borne viruses may render assistance in an emergency in order to preserve life, irrespective of their limitations in ordinary practice, and are advised to take whatever precautions are available at the scene.

A final matter that deserves the attention of the Board is a special situation that might exist where a Medical Practitioner who is infected with a BBV and who performs EPP may have special skills not otherwise available. Such a situation occurred in New York State with a Cardiac Surgeon. The Practitioner's practice was reviewed to lessen the risks of transmission but his/her practice continued with fully informed patient consent. Details can be provided if requested.

Appendix 1

Reducing the risk
Standard precautions should be used at all times.
A number of physical measures can reduce the risk of bi-directional blood and body fluid contact including:

- Routine wearing of gloves, or double-gloving, and eye protection when there is the possibility of contact.
- Use of blunt rather than sharp drawing up needles
- Injecting into bungs with blunt rather than sharp devices
- Immediate disposal of sharp needles and objects after use

- Never recapping needles
- Use of PVC rather than glass ampoules
- Widespread availability and use of sharps disposal containers
- Provision of suitable work surfaces, including needle-free zones, during procedures performed at the bed-side or in the operating room.
- Use of blunt rather than sharp suturing needles
- Use of instruments (rather than fingers) to grab needles when suturing.

Appendix 2

Unrestricted procedures

The following procedures are not considered high-risk exposure prone procedures, provided the Medical Practitioner or Medical Student complies with Standard Precautions, including re-gloving and using completely new, sterile equipment if contamination occurs:-

- External examination (gloves not required)
- Oral, vaginal and rectal examinations that do not involve sharp instruments
- External examination of facial trauma without fractured bones or glass fragments
- Venepuncture, phlebotomy, insertion of IV access including central venous lines
- Administering IV, IM, ID or SC injections
- Needle biopsy, needle aspiration, insertion of underwater seal drain, lumbar puncture, venous cutdown, angiographic procedures
- Excision of epidermal or dermal lesions
- Suturing of superficial skin lacerations
- Endoscopy, colonoscopy, bronchoscopy and cystoscopy
- Placement of nasogastric tubes, rectal tubes and urinary catheters
- Acupuncture
- Procedures where the use of sharps is superficial, well visualized and administered to compliant or anaesthetized patients where it is very unlikely that a HCW skin injury would result in exposure of the patient to the HCW's blood or body substances.
- Any other procedures that do not involve sharps

Yours sincerely

Hugh Harley
Clinical Associate Professor of Medicine
Head, Clinical Hepatology
Co-Director, Viral Hepatitis Centre
Royal Adelaide Hospital

David Shaw
Clinical Assoc Professor
Head, Infectious Diseases
Co-director, Viral Hepatitis Centre
Royal Adelaide Hospital