

To: HMC Madison Clinic Providers

From: Bob Harrington & Nina Kim

Date: 3/19/09

Re: Hepatitis B vaccination in our patients

Currently, we are providing double-dose 40 mcg recombinant HBV vaccine (2 doses of 20 mcg/ml Engerix-HB) to our patients, based on 2006 Guidelines from the Advisory Committee on Immunization Practices. However, 2008 Guidelines from the DHHS/CDC/HIVMA on Opportunistic Infections (see attached pdf, p. 116) do not recommend double-dosing up front, arguing that the data in support of this practice is inadequate. We have reviewed the primary literature and agree that there is insufficient evidence to support widespread use of double-dose HB vaccine. There is some data to support its use in revaccination of non-responders. Therefore, Madison Clinic guidelines on hepatitis B immunization will be as follows:

- 1) Primary vaccination: Immunize all patients seronegative for hepatitis B surface antigen and antibody with **20 mcg of Engerix-HB at months 0, 1 and 6**. [NOTE: 4 doses required only for double-dose). If patient is seronegative for both hepatitis A and B, then **Twinrix** – the bivalent vaccine for both HAV and HBV can be used **at months 0, 1 and 6**.

NOTE: Advised to start immediately soon after entry into care, esp if pt has early HIV infection and high CD4 counts. If pt has more advanced disease (esp nadir CD4 <200) and you anticipate starting HAART within next 6 months, advise waiting until viral suppression achieved as this has been shown in several studies to be associated with improved vaccine responses. It is less clear whether waiting for immune reconstitution to CD4>200 is warranted.

Isolated anti-HB core patients: The DHHS OI Guidelines note that the majority of HIV-infected patients with negative HBsAb, HBsAg and isolated anti-HBc antibody are not immune to HBV infection – i.e. studies have shown that these patients mount a slow response to vaccination similar to non-immune individuals. Therefore, these patients should receive vaccine series as described above.

- 2) Assess protective response: Check HBsAb titer 1-2 months after last vaccine dose to confirm seroconversion.
- 3) Re-vaccination: For non-responders to this primary series (esp if CD4 count now >350 and suppressed on HAART), administer 2nd vaccine series with double-dose 40 mcg of Engerix-HB at months 0, 1, 2 and 6. Again, check HBsAb titer x 1-2 months after completion of this series to assess response. There is no data to support vaccinating beyond a 2nd series for those who still do not respond.

No clear data to support annual HBsAb assessment or booster dosing beyond what is described above.