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HEPATITIS B VACCINE SHORTAGES: PHE AND BASHH/BHIVA TEMPORARY GUIDANCE FOR MANAGEMENT OF PATIENTS IN GUM AND HIV SERVICES

Background

In light of the global shortage of hepatitis B vaccine (including combination hepatitis A/hepatitis B vaccine), PHE and DH have escalated the situation to a national incident since UK supply has been severely impacted in August and is expected to be below normal levels for the rest of the year. A CAS alert and a letter to NHS Medical Directors have been issued. PHE and the Department of Health have been working with vaccine manufacturers to institute further ordering restrictions to preserve and sustain stock for those at greatest need.

PHE temporary recommendations on hepatitis B vaccination

Public Health England has recently issued temporary recommendations around Hepatitis B immunisation: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/631145/Hepb_vaccine_temporary_recommendations_adults_and_children.pdf)

The recommendations include temporary dose sparing advice to preserve adult and paediatric monovalent hepatitis B vaccine stock for those at highest immediate need and with the greatest ability to benefit, and to sustain supplies over the period of shortage. A patient information leaflet has been developed to support communications with patients who have been advised that they need to wait for vaccine.

BHIVA/BASHH Guidance for hepatitis B vaccination to supplement PHE temporary recommendations for hepatitis B vaccination in adults and children (August 2017)

The following temporary guidance from BHIVA/BASHH supplements the PHE recommendations (and should be read in conjunction with the BHIVA Vaccination Guidelines 2015 – Chapter 8 (http://www.bhiva.org/documents/Guidelines/Vaccination/2015-Vaccination-Guidelines.pdf)

Patients with HIV-infection remain at 'high-risk' of HBV infection.

1) Determine HBV susceptibility fully by assessing HBsAg, HBcAb and HBsAb in all patients at first screening. The rationale is that current protocols vary and by determining who is truly susceptible, unnecessary vaccination can be avoided.

2) Temporarily reserve high dose/adjuvanted vaccines HBVaxPRO40 OR Fendrix as a primary course only for those with any of the following risk factors for non-response: CD4 count <500 cells, detectable viral load, off ART, above age 40 and overweight, heavy smoker, nadir CD4 <200, diabetes, with significant CKD, on dialysis. If these vaccines are not available, a double dose of the standard vaccines (see 3 below) can be considered.

3) Those patients who do not meet the criteria in (2) should receive either adult HepA/B vaccine (Twinrix Adult) or EngerixB (20mcg) or HBVaxPRO (10mcg).

4) Non-responders (HBsAb <10 U/L) to the primary vaccine course should receive revaccination (3 doses) with the higher dose /adjuvanted vaccines (HBVaxPRO40 / Fendrix) vaccine as per current guidelines.

5) Avoid using the super-accelerated schedule (0, 7, 21 days) for primary vaccination to preserve vaccine stock until supplies improve

6) Restrict immediate boosting at HBsAb >10 but <100 U/L to only those at ongoing risk of exposure including MSM, people with known or at risk for household or sexual contact with chronic carriers of HBV (if unknown, e.g. based on hepatitis B prevalence in country of origin, e.g. Africa, South East Asia), people with frequent and/or long stay (>1 month) travel to countries with high endemicity and anyone at significant ongoing and immediate risk of exposure as per recognised risk factors (e.g. sex workers).

7) When boosting patients, apply criteria for high dose / adjuvanted vaccines as above.

8) Boosting at HBsAb >10 but <100 U/L can be omitted for patients on Tenofovir-based ART as long as ART-interruption is avoided.

9) Longer intervals between testing (i.e. 2–4 years) may be indicated for subjects with initial HBsAb levels >100 IU/L, CD4 cell counts >350 cells/µL, and viral load suppression on ART. Other subjects should continue to undergo yearly HBsAb screening.

10) Ensure timely post exposure vaccination for those who have had a significant exposure event.

Vaccine stock management

As manufacturers have reduced maximum ordering quantities for NHS Trusts, GUM and HIV clinics will have further limits applied to their orders, while other customers (such as travel clinics and GPs) will not be receiving any adult vaccine until further notice.

Clinic leads and managers are therefore advised to:

- ensure that stock usage is coordinated and monitored across the service and (ideally within the Trust) to ensure that scarce stock is used responsibly
- only order essential vaccine stock (small amounts more frequently) and avoid stockpiling
- use alternative vaccines and presentations in place of the preferred or usual options
- provide appropriate reassurance to patients who cannot be vaccinated using the patient information leaflet as a resource.

A mechanism is in place to allow for exceptional orders through your supplier if there is an urgent and immediate need for an individual following risk assessment.

The situation is under constant review, to ensure that available supply is able to match the clinical need for the rest of the year. Further vaccine supply updates and information as they become available will be posted on the gov.uk webpage: hepatitis B vaccine recommendations during supply constraints. Your continued support is much appreciated.

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