West of Scotland Paediatric Gastroenterology, Hepatology and Nutrition Network

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Guideline on the use of Hepatitis A&B Immunisations for Immunocompromised and Immunocompetent Hepatology Patients

WOMEN AND CHILDREN'S DIRECTORATE ACUTE SERVICES DIVISION	GUIDELINES

TITLE Guideline on the use of Hepatitis A&B Immunisations for Immunocompromised and Immunocompetent Hepatology Patients

Responsibility	Last Update	Review Date
Medical and nursing staff within the Paediatric Hepatology Teams. Primary care teams	April 2014	April 2016

Statement:
All children/young people with a chronic liver condition should be immunised against Hepatitis A&B (DoH 2011). Children and young people requiring Hepatitis A&B immunisations as identified by medical staff will have their treatment undertaken using this guideline and following the pathways identified below.

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1.0 Indications for use - Hepatology

Consensus agreement is that all children and young people with a chronic liver condition should be immunised against Hepatitis A&B. They are not any more pre-disposed to contracting either virus but contraction of the virus could lead to further deterioration of their liver condition. Prophylactic vaccination against Hepatitis A&B is therefore essential to protect against future additional damage to their liver.

2.0 Definitions of immunocompetent and immunocompromised liver patients

Immunocompetent liver patients:

- Not on immunosuppressive therapies
- Liver disease patients with stable albumin and clotting as classified by serum albumin >30g/l and PT <15sec

Immunocompromised liver patients:

- On immunosuppressive therapies (Liver Transplant/Autoimmune Hepatitis)
- Chronic liver disease patients as classified by serum albumin <30g/l and PT >15sec

3.0 Infectivity, exposure and chronicity risk

Hepatitis A and B virus differ in terms of transmission and risk of chronicity

3.1 Hepatitis A

Transmitted faecal/oral route – person to person spread, usually from contaminated food/drink. Incubation period 28-30 days (can be as little as 15 and as much as 50 days). It is an acute reaction with no risk of chronicity.

3.2 Hepatitis B

Transmitted via parenteral exposure to infected blood or body fluids (vaginal/anal intercourse, blood to blood contact, perinatal transmission). Incubation period 40-160 days (average 60-90). Infection mostly resolves however chronicity (HBsAg in serum > 6 months) will occur in 90% perinatally acquired cases, 20-50% 1-5yrs of age, <5% adults.

Immunocompromised patients are at an increased risk of chronicity.

Exposure risk: patient due to travel to Hepatitis B prevalent area
patient at risk of needlestick injury
patient living in close contact with HBV carrier
patient born to mother who is HBV positive

4.0 Hepatitis A&B: signs and symptoms

Symptoms are more common in adults. Loss of appetite, vomiting, lethargy and jaundice is present in both viruses. In the chronic state of Hepatitis B, progressive liver disease, cirrhosis and hepatocellular carcinoma can occur.

5.0 Vaccinations available

Hepatitis vaccinations are available as single Hepatitis A vaccines (HAV), single Hepatitis B vaccines (HBV) and combined Hepatitis A&B vaccines.

NB These vaccinations are inactivated (not live): they do not contain live organisms and cannot cause the diseases against which they protect.

5.1 Licence for use

Hepatitis A is only licensed for use in children over 1 year of age. This license also incorporates the combined Hepatitis A&B vaccine.

Hepatitis B vaccine is licensed for use from birth and timely immunisation schedule completion (1st dose given within 24 hours of delivery) can prevent development of persistent HBV infection in over 90% of vertical transmission cases.

5.2 Vaccination course

Hepatitis A:
Single dose – immunity lasts at least 1 year
A booster dose of Hepatitis A vaccine should be given 6-12 months after the initial dose. This results in a substantial increase in antibody titre and will give immunity beyond 10 years.
A further booster dose at 20 years is indicated for those at ongoing risk (i.e. immunocompromised patients).

Hepatitis B/Combined:
Consists of 3 doses, with or without a fourth booster dose.
The standard course is at 0, 1, and 6 months.
An accelerated schedule can be used for pre-exposure prophylaxis at 0, 1, 2 months however this has slightly reduced immunogenicity when compared to the 0, 1, 6 month schedule.
Similar response to the standard course can be achieved by giving a 4th dose at 12 months.

6.0 Contraindications

Hypersensitivity to the active substances or to any of the excipients (including neomycin in Hepatitis A and combined vaccine and yeast in Hepatitis B vaccine).
Hypersensitivity after previous administration of hepatitis A and/or hepatitis B vaccines.

The administration of these vaccinations should be postponed in subjects suffering from acute severe febrile illness.

6.1 Delaying treatment

Vaccinations should be delayed in patients whose uptake will be poor because of the following reasons:
Patient received a transplant in the past year.
Patient on high dose steroids (delay until 1 month after either stopping steroids or reaching maintenance dose).

Hepatitis A and the combined vaccine should be delayed until 1 year of age due to licensing restrictions.

7.0 Adverse side effects of vaccination

The most common adverse effects are listed below, however this list is not exhaustive and do not include the rare side effects. Report any adverse reaction using the 'yellow card' system.

- >10% injection site problems such as redness, swelling, bruising, pain, stinging or burning sensation
- >1% headache, fatigue, fever, gastrointestinal disturbances
- >0.1% diarrhoea, lung problems, muscle pain or tenderness, skin rash or rashes, stomach pain, vomiting

8.0 Dosage

Hepatitis A

Vaccine product	Age (yrs)	Dose	Volume
Havrix Monodose®	>16	1440 ELISA units	1.0ml
Havrix Junior Monodose®	1-15	720 ELISA units	0.5ml
Avaxim®	>16	160 antigen units	0.5ml
Vaqta Paediatric®	1-17	25 units	0.5ml
Epaxal®	>1	500RIA units	0.5ml

Hepatitis B

Vaccine product	Age (yrs)	Dose	Volume
Engerix B Paediatric®	0-15	10µg	0.5ml
Engerix B®	>16	20µg	1.0ml
HBvaxPRO Paediatric®	0-15	5µg	0.5ml
HBvaxPRO®	>16	10µg	1.0ml

Combined Hepatitis A&B

Vaccine product	Age (yrs)	Dose HAV	Dose HBV	Volume
Twinrix Adult®	>16	720 ELISA units	20µg	1.0ml
Twinrix Paediatric®	1-15	360 ELISA units	10µg	0.5ml
Ambirix®	1-15	720 ELISA units	20µg	1.0ml

9.0 Administration

Routinely given IM in upper arm or anterolateral thigh. Buttocks should not be used as this may result in a suboptimal response. For individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection. Do not administer this product intravenously or intradermally.

10.0 Measuring antibody levels

Hepatitis B surface antibody levels should be tested 2-3 months following completion of either course.

Hepatitis A antibody levels are not routinely reported after vaccination. As seroconversion rates are almost 100% after completing the recommended course, it is assumed that once the course is completed, the patient will be protected.

11.0 Requirement for booster/re-vaccination

Hepatitis A for all patients: assume seroconversion and protection if received either full combined vaccine course or single Hepatitis A course. A booster dose at 20 years is indicated.
Hepatitis B booster/re-vaccination: please see sections 12 and 13.

12.0 Immunisations in IMMUNOCOMPETENT patients

12.1 Desired Hepatitis B antibody levels in Immunocompetent patient

Aim for levels >100mIU/ml, although levels of 10mIU/ml are accepted as enough to protect against infection.

12.2 Immunocompetent patients having achieved immune response (antiHBS >10mIU/ml)

Hepatitis B: recheck antibody levels at 5 years and if <10mIU/ml, a booster dose of Hepatitis B vaccine is required.

12.3 Immunocompetent patients not having achieved immune response (antiHBS <10mIU/ml)

Hepatitis B: antibody levels <10mIU/ml is classified as a non-response to the vaccine. Repeat full course of the standard dose (as per Green Book) Hepatitis B vaccine and recheck 2-3 months after booster. If antibody levels<10mIU/ml, the patient is classed as a non responder and may need HBIG if exposed to the virus.

13.0 Immunisations in IMMUNOCOMPROMISED patients

13.1 Desired Hepatitis B antibody levels in Immunocompromised patient

Aim for levels >100mIU/ml

13.2 Immunocompromised patients having achieved immune response (antiHBS >100mIU/ml)

Hepatitis B: recheck antibody levels at 5 years and if <100mIU/ml, a booster dose Hepatitis B vaccine is required.

13.3 Immunocompromised patients not having achieved immune response (antiHBS <10mIU/ml)

Hepatitis B: antibody levels <10mIU/ml is classified as a non response to the vaccine. Repeat full course of the double dose (as per Green Book) Hepatitis B vaccine and recheck 2-3 months after booster. If antibody levels <10mIU/ml, the patient is classed as a non responder and may need HBIG if exposed to the virus.

13.4 Immunocompromised patients having achieved partial immune response (antiHBS >10 but <100mIU/ml)

Hepatitis B: single booster of Hepatitis B vaccine. Recheck antibody levels 2-3 months following booster. Levels >100mIU/ml, recheck antibody levels at 5 years and if <100mIU/ml, a booster dose of Hepatitis B is required. Levels <100mIU/ml, check antibody levels in 1 year unless significant exposure risk (see section 3.2). Patient may need HBIG if exposed to the virus.

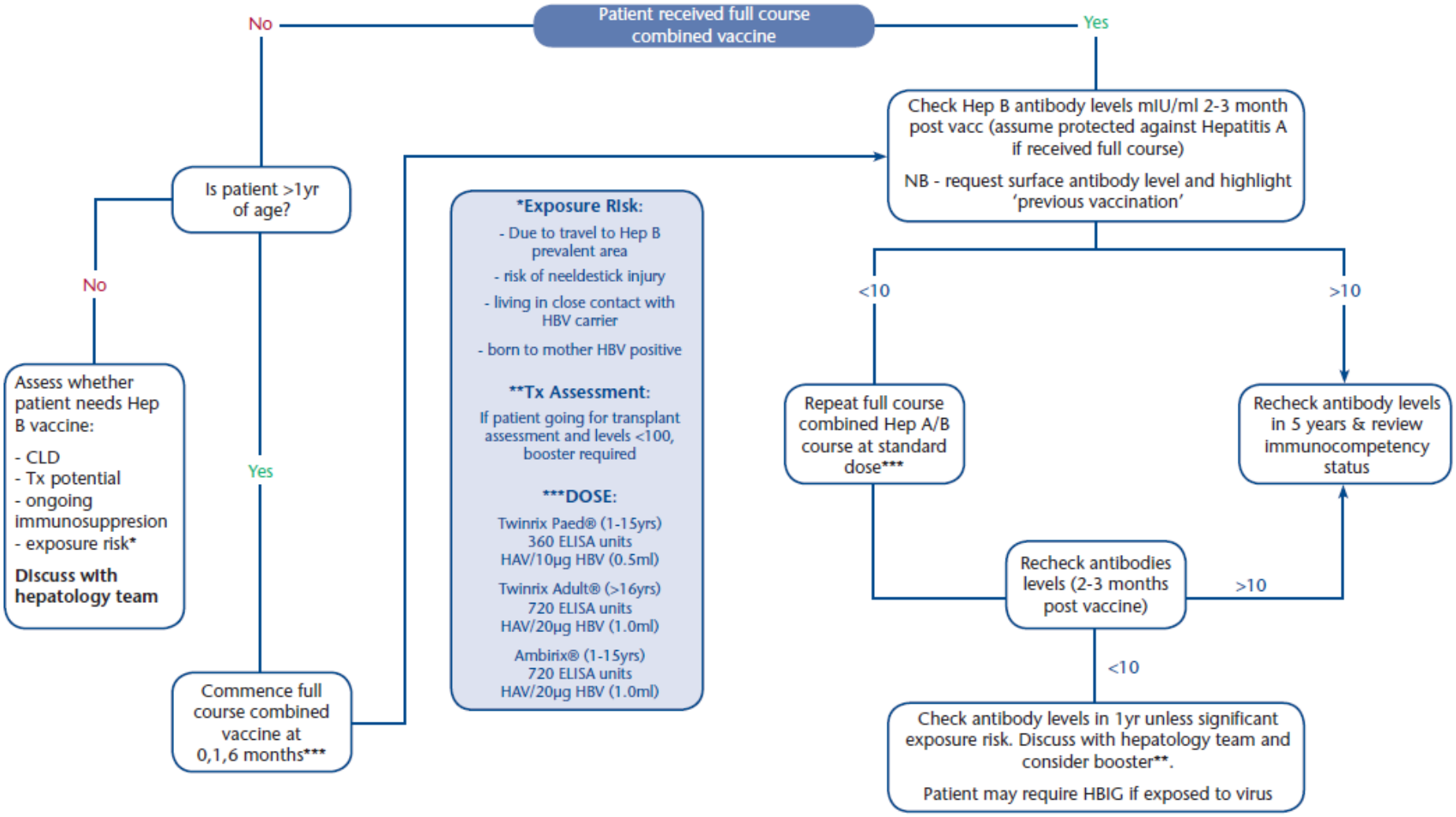
NB Patients expected to be listed for transplant with levels <100mIU/ml should receive a booster Hepatitis B vaccine and >100mIU/ml should be achieved.

14.0 Incomplete vaccination course

If the primary course of vaccination is incomplete, the missing doses of vaccine needed to complete the course can be given up to four years later without the need to restart the full course.

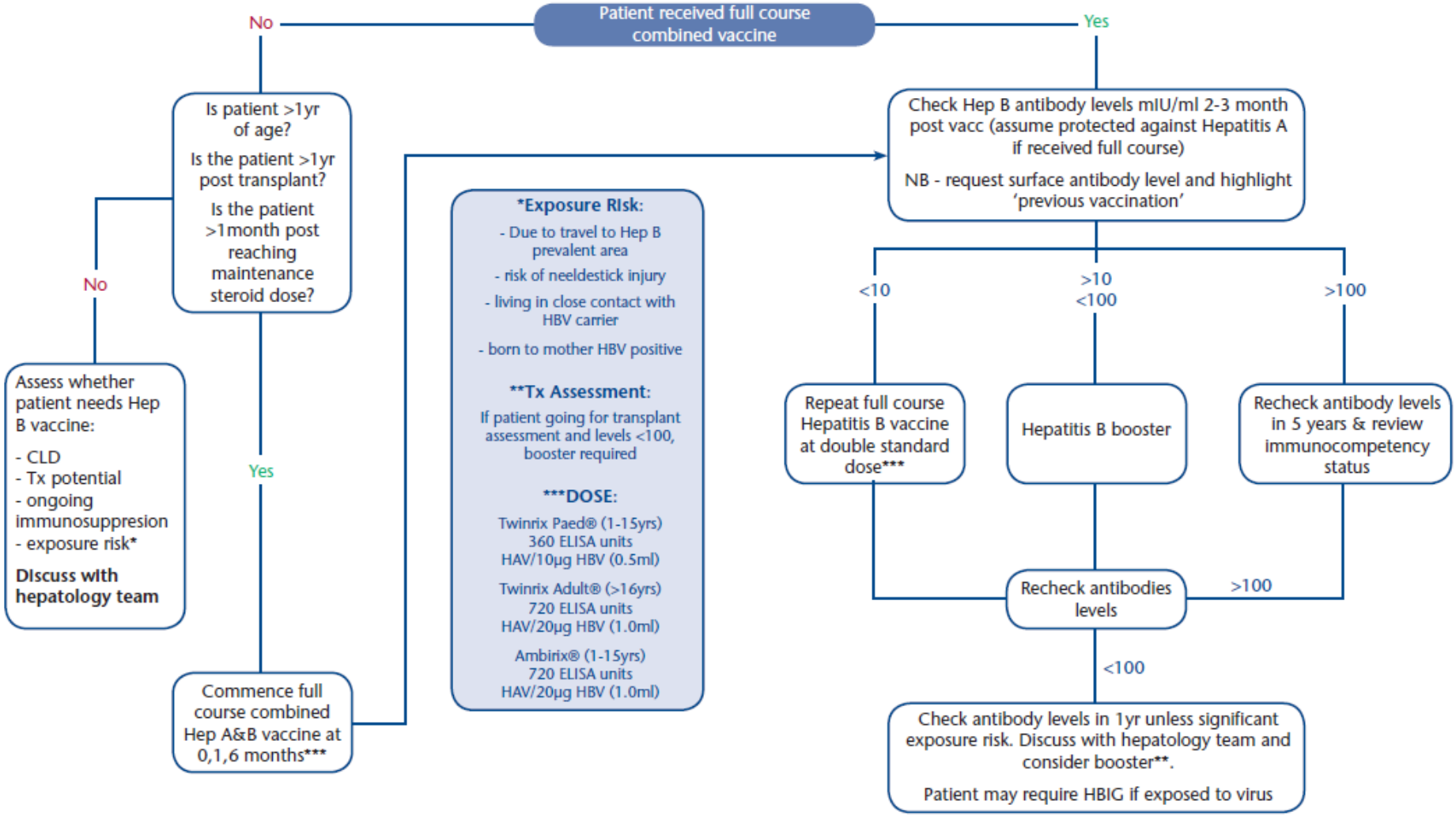
Hepatitis A&B immunisation in the immunocompetent child

(not on immunosuppresent medication/PT<15sec/Albumin>30g/l)



Hepatitis A&B immunisation in the immunocompromised child

(on immunosuppresent medication/PT>15sec/Albumin<30g/l)



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