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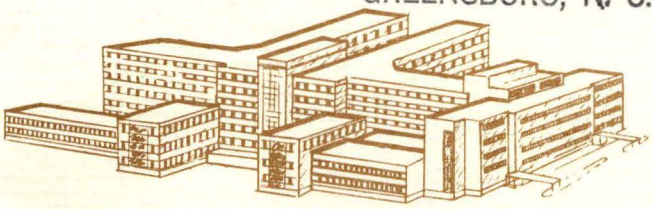

THE MOSES H. CONE MEMORIAL HOSPITAL

GREENSBORO, NORTH CAROLINA

PHARMACY COMMITTEE NOTES

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IMMUNE SERUM GLOBULIN, HEPATITIS B IMMUNE GLOBULIN, HEPATITIS B VACCINE - CURRENT RECOMMENDATIONS FOR USE

h concern has arisen in recent months concerning the use of Hepatitis B Vaccine, Immune Serum Globulin, and Hepatitis B Immune Globulin because of evidence linking the transmission of the Acquired Immune Deficiency Syndrome (AIDS) to blood products. Although HBV, HBIG and ISG are produced from pooled serum, there has been no evidence which shows an increased incidence of AIDS in patients receiving these products.[1,2] The methods for production of HBV, HBIG and ISG are designed to inactivate any known viruses. For these reasons, there have been no changes in the indications for use of these products. However, since the agent or agents which cause AIDS are not known, no absolute guarantees can be made. Based on current knowledge, the use of these three agents is dependent on the type of Hepatitis virus encountered.

Viral Hepatitis is divided into three types: Hepatitis A, Hepatitis B and Non-A Non-B Viral Hepatitis. Classification is dependent upon epidemiologic and serologic evidence. Often confusion arises in choosing the most appropriate prophylactic therapy for these diseases.

Hepatitis A, formerly called infectious Hepatitis, is caused by the Hepatitis A Virus (HAV). The incubation for the HAV is 15-50 days with an average of 25-30 days. The most frequent mode of transmission is the fecal-oral route; however, transmission may occur by contaminated food or water. Onset of symptoms is usually abrupt with fever, malaise, nausea, anorexia, abdominal pain and jaundice. Mortality with Hepatitis A is less than 1% and there is not a chronic blood carrier state identified.

Hepatitis B, previously called serum Hepatitis, is caused by the Hepatitis B Virus (HBV) and is associated with the Hepatitis B surface antigen or the Australia Antigen. The incubation period is 60-180 days with an average of 90 days. HBV may be transmitted by contaminated serum or secretion and can enter the host by almost any route. This includes contaminated needles, xual contacts and transfer of infected serum via inanimate objects, such as in hemodialysis its. Onset of symptoms is slow with anorexia, nausea, vomiting, abdominal pain and jaundice

mmon. Hepatitis B is associated with a chronic carrier state.

Non-A Non B Hepatitis, also called post-transfusion Hepatitis, is caused by unidentified viruses.

Hepatitis B Vaccine is derived from the plasma of human carriers of the HBV. The surface antigen subunit (Australia Antigen) is formalin inactivated and non-infectious. The vaccine is supplied as a sterile suspension for IM use in a 3 ml vial. Each milliliter contains 20 mcg of HBV surface antigen. Hepatitis B Vaccine is indicated for use in persons with increased risk of exposure to Hepatitis B. Individuals in this category include:

a) Health care personnel in contact with blood and other patient specimens. Included are dentists, doctors, nurses and laboratory personnel. Hospital employees who do not handle blood or other patient specimens are not at increased risk;

b) Hemodialysis patients and other patients receiving frequent transfusions;

c) Patients and staff of institutions for the mentally handicapped;

d) Household and intimate contacts of chronic HBV carriers;

e) Morticians and embalmers;

f) Homosexually active males and female prostitutes;

g) Persons from areas with high HBV endemicity;

h) Prisoners and

i) Users of illicit injectable drugs.[3]

The normal adult dose is three intramuscular injections of 1 ml (10 mcg) of HBV surface antigen.[3] The injections are given over a six-month period with the second and third injection at one and six months after the first injection. The same dosage schedule is followed for children and immunocompromised patients. Children between the ages of three months and ten years receive 0.5 ml/dose. Children greater than ten years of age receive the normal adult dose. Immunocompromised patients and dialysis patients are given 2 ml/dose. Protective antibody formation is seen in most patients receiving at least two of the three injections. Eighty-five (85%) to ninety-five percent (95%) of healthy adults who receive all three doses of the vaccine develop antibodies to the HBV.[3,4] The vaccine has been shown to be 80-95% effective in preventing infection.

Adverse reactions to the Hepatitis B Vaccine are minor and are generally limited to soreness, erythema, swelling, warmth or induration at the site of injections.[3,5] Low grade fever may occur any time up to 48 hours post vaccination. The period of protection provided by the vaccine is stated to be at least five years.[3] There is no evidence at this time to support the use of Hepatitis B Vaccine in chronic carriers of Hepatitis B Virus.

Hepatitis B Immune Globulin (HBIG) is derived from human plasma from individuals with high titers to Hepatitis B surface antigen.[6] HBIG provides passive immunity to HBV for periods up to two months post administration.[6] HBIG is indicated for post exposure prophylaxis following either enteral or direct mucous membrane contact with materials positive for Hepatitis B surface antigen. Treatment should begin as soon as possible, preferably within 7 days. HBIG should be given

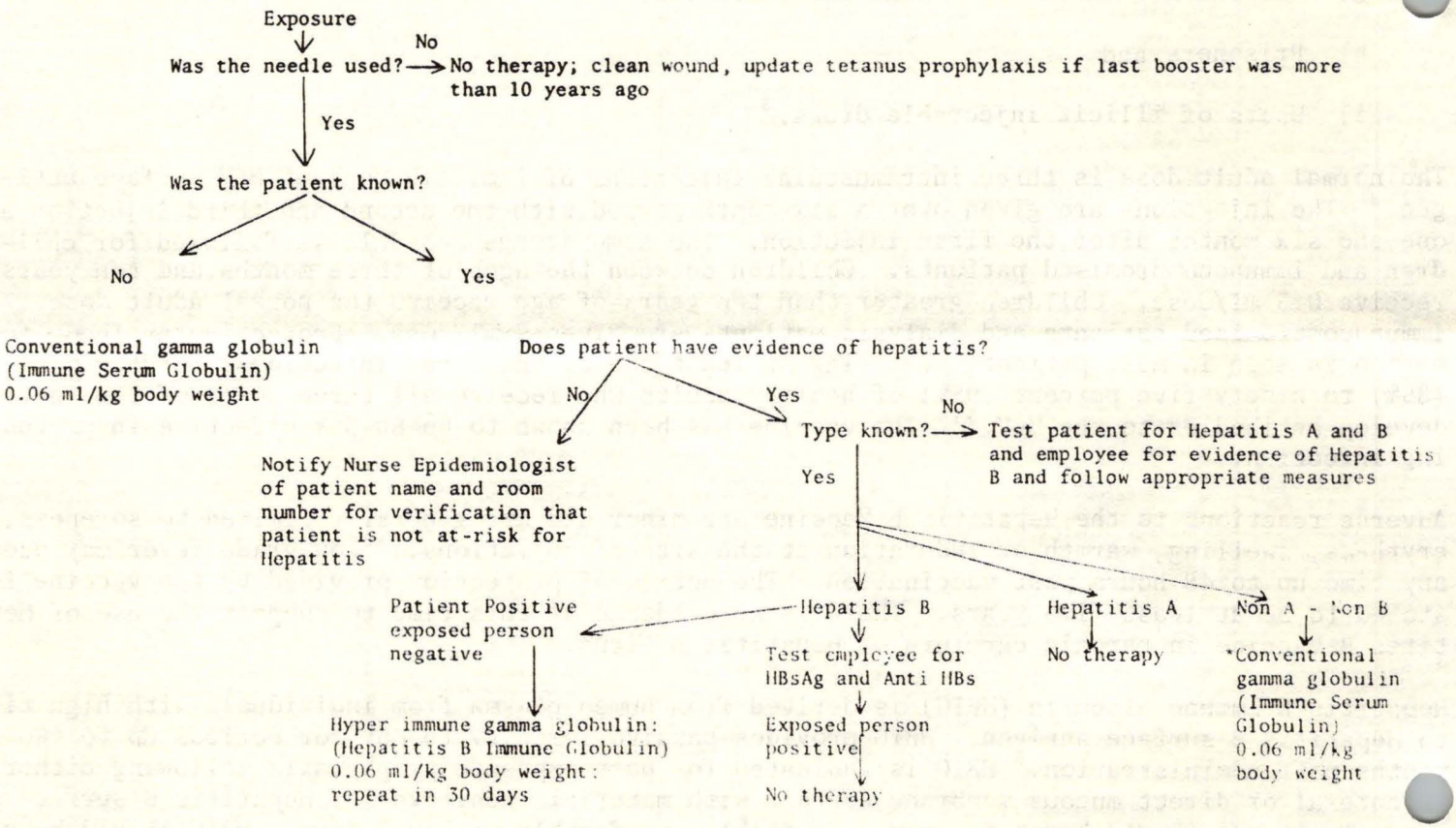
only by IM injection in a dose of 0.06 ml/kg. The dose should be repeated in 28-30 days.[6] Adverse reactions include pain and tenderness at the site of injection.[6] Urticaria, angioedema a anaphylactic reactions have been reported.[6] Live virus vaccines should be avoided near the time of HBIG administration since antibodies from the HBIG may interfere with the response to the vaccination. At this time there is no evidence to support the use of HBIG for the chronic carrier state or in pre-exposure prophylaxis.

Immune Serum Globulin (ISG) is prepared by cold alcohol fraction of pooled human plasma and is primarily IgG[7]. ISG is indicated for pre-exposure prophylaxis for individuals traveling to areas in which Hepatitis A is common. If the length of stay is less than three months, then the dose is 0.02 ml/kg and should be repeated every 4-6 months. ISG may be used for post-exposure prophylaxis of Hepatitis B if Hepatitis B Immune Globulin is not available. In this case, the dose is 0.06 ml/kg and should be repeated in 30 days. Non-A Non-B Hepatitis post-exposure prophylaxis is performed as for Hepatitis A.[7]

One area of Hepatitis prophylaxis which frequently causes confusion involves the treatment of patients post needle stick exposures. The following algorithm was developed by Dr. Tim Lane for use here at Moses Cone Hospital and outlines the proper procedures to follow for Hepatitis prophylaxis post needle stick exposure.

<u>The Moses H. Cone Memorial Hospital</u>

<u>Exposure Algorithm for Hepatitis Prophylaxis</u>



e following table summarizes the above text:

Products	Use	Dose
Hepatitis B[1] Vaccine	Pre-exposure prophylaxis (HBV) of persons at high risk for contracting HBV	Schedule-day 0, day 30, day 180 Children 3 months - 10 yrs 0.5 ml Children > 10 yrs and adults 1.0 ml Immunocompromised and dialysis patients 2 ml
Hepatitis B[4] Immune Globulin	Post-exposure prophylaxis (HBV) includes: needle sticks, mucous membrance contact with contaminated serum or secretions, sexual contact.	0.06 ml/kg repeat in 28-30 days
Immune Serum[5]	Post-exposure prophylaxis (HAV). Pre-exposure prophylaxis (HAV) for travelers	0.02 ml/kg Stay < 3 months 0.02 ml/kg Stay > 3 months 0.05 ml/kg Repeat in 4-6 months
	Post-exposure prophylaxis (HBV) Post-exposure prophylaxis	0.06 ml/kg Repeat in 28-30 days 0.02 ml/kg

Bill Silta, R.Ph.

References

1. Pharmacy Bulletin, The University of Iowa Hospitals and Clinics, Vol. 4:2, April 1983.
2. Personal Communication. CDC Hepatitis Lab, Phoenix, Arizona.
3. Package Insert, Heptvax - B., Merck, Sharp & Dohme, May 1982.
4. Krugman, S., Holley, H.P., Jr., Davidson, M. et al: Immunogenic Effect of Inactivated Hepatitis B Vaccine Comparison of 20 mcg and 40 mcg doses. J. Med. Virol. 1981; 8:119-121.
5. Szmuness, W., Stevens, C.E., Harley E.J., et al: Hepatitis B Vaccine: Demonstration of Efficacy in a Controlled Clinical Trial in a High-Risk Population in the United States. N. Eng. J. Med. 1980; 303:833-841.
6. Package Insert, Hyper Hep, Cutter Laboratories, July 1977.
7. Package Insert, Gamimune, Cutter Laboratories, April 1981.

GUIDELINES FOR I.V. POTASSIUM ADMINISTRATION

As a result of discrepancies encountered in the administration of I.V. potassium chloride, it was felt that a revision in the guidelines should be made. The guidelines adopted in 1979 have been revised as follows:

1. A pharmacist will verify orders to admix more than 80 mEq/1 or 40 mEq/500 ml with the physician.

2. Potassium should be diluted to a maximum concentration of 0.08 mEq/ml (10 mEq/hr = 125 ml) for administration through a peripheral vein. If the patient is fluid restricted with a serum K^+ of 2.5 mEq or less, the concentration could be increased to a maximum of 0.2 mEq/ml (10 mEq per 50 ml). After 3 hourly doses the need for this concentrated administration should be reassessed.

3. Potassium should be diluted to a maximum concentration of 0.2 mEq/ml (10 mEq/50 ml) for administration through a central line.

4. Nursing administration guidelines for I.V. potassium are as follows:

   A. Administration of potassium at a rate of 10-40 mEq/hr should always be done using a mini-drip I.V. set and volume control device (Buretrol or Volutrol).

   B. If the patient is on a general medicine nursing division (non-critical care bed), an IVAC should also be used when possible.

   C. Administration of more than 40 mEq/hr of potassium should follow the above criteria plus it is advisable for the patient to be monitored utilizing a telemetry bed or life-pak while receiving the potassium.

Jackie Roh, R.Ph.

FORMULARY REVISIONS

Non Steroidal Anti-Inflammatory Drugs

Diflunisal (Dolobid® - MSD) - admitted to Formulary
Piroxicam (Feldene® - Pfizer) - admitted to Formulary

Pediatric Multivitamin Preparations

Vitamins Previously Stocked	Vitamins to be Added or Retained
Tri-Vi-Sol® Drops	Tri-Vi-Flor® 0.25 mg with Iron Drops
Poly-Vi-Sol® Drops	Poly-Vi-Sol® Drops
Fer-In-Sol® Drops	Fer-In-Sol® Drops
Luride® Drops	Poly-Vi-Flor® 0.25 mg with Iron Drops

OSTOMY SERVICES

Effective June 15, Kathy Propst, R.N., Nursing Department Enterstomal Therapist, will provide ostomy, large wound drain and skin care services. Central Supply will be responsible for maintaining the supplies for this service. Pharmacy will no longer provide ostomy care.