If the compound sodium lactate solution is run through the system after whole blood or plasma reduced blood a dilution gradient is produced through the system. When the dilution is 1/4 for whole blood, or 1/3 for plasma reduced blood, clotting occurs. Before the addition of the blood warmer, clotting takes longer in the system as the temperature is 15°C lower, about room temperature. Clotting may not clearly register in the recipient set because of slow formation, and diluent and streamlining effects of the sodium lactate solution. Initially the clots formed are soft and pass easily along the fluid pathway into the patient, the size and number depending on the rate of flow. If blood is then rapidly infused, using a pressure infusor, then probably all the clots formed in the system distal to the recipient filter pass into the patient.

This hazard is not mentioned in the *British Pharmacopoeia* 1980, the *European Pharmacopoeia* 1975, *Martindale: The Extra Pharmacopoeia* 1977, the *British Pharmaceutical Codex* 1973, or the data sheets issued with the product. The *British National Formulary*[2] does comment that if a giving set is not changed after transfusion, and is used for other infusion fluids, a precipitate of fibrin may form, which physically blocks the set and increases the likelihood of microbial growth. Printed on the back of the carton containing the blood warming bag under Notes is: a) "Use set only with fluids compatible with each other."

We do not know how common is the practice of giving compound sodium lactate through the same recipient system as blood, but, clearly, this could harm the patient. Although Fenwal equipment was used in this study, clotting would occur with any other similar equipment.

1 Mollison PL. *Blood transfusion in clinical medicine*. 7th ed. London: Blackwell Scientific Publications, 1983:34.
2 *British National Formulary, No 8*. London: British Medical Association and the Pharmaceutical Society of Great Britain, 1984:415.

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Regional Transfusion and Immuno-Haematology Centre, Long Road, Cambridge CB2 2PT
J BLAGDON, MD, DTMH, consultant in blood transfusion
T GIBSON, LRCP, MRCS, deputy director

Correspondence to: Dr J Blagdon.

Symptomatic reaction to hepatitis B vaccine with abnormal liver function values

We report the first case of a systemic reaction with abnormal liver function values in a healthy person receiving hepatitis B vaccine. We used H-B-Vax (Thomas Morson Pharmaceuticals).

Case report

A 43 year old woman who had been offered hepatitis B vaccination as part of a prophylactic vaccination programme for staff working in hospital theatre, was admitted on 28 April after five days of malaise, shivering, anorexia, loss of taste for cigarettes, and discomfort in the right upper quadrant of the abdomen. She had received the standard dose of vaccine (1 ml containing 20 μg hepatitis B surface antigen) on 7 March and 4 April. She did not declare any history of excess alcohol consumption and she had never suffered from jaundice. Examination showed that she was anicteric and had no signs of chronic liver disease, although a tender liver edge was palpable on inspiration. The spleen was not enlarged.

Investigations showed that haemoglobin was 13·1 g 100 ml and white blood cell count was $13{\cdot}6 \times 10^9$/l (76% neutrophils, 8% eosinophils, absolute count $1{\cdot}09 \times 10^8$ l); she was negative for antinuclear factor, smooth muscle, and antimitochondrial antibodies. The results of convalescent titres of complement fixing antibodies two months later were influenza A and B and *Coxiella burnetii*, all 1/4; psittacosis, lymphogranuloma venereum, *Mycoplasma pneumonia*, and leptospirosis 1/<4; adenovirus 1/8; and cytomegalovirus 1/16. Ultrasonographic scan of the abdomen indicated normal liver, bile ducts, gall bladder, and pancreas. The table shows the progressive changes in liver function values that occurred over the next five months.

At presentation she was negative for hepatitis B surface antigen with no antibodies by radioimmunoassay to hepatitis A. The patient had not formed antibodies to the surface antigen or the core antigen on 14 June, 9 August, or 27 September. She was symptomatically and biochemically normal five months after presentation and returned to work. A third dose of vaccine was not given. No relapse occurred in the subsequent year.

Comment

Hepatitis B vaccine, as currently available in the UK, is prepared from purified surface antigen using the plasma of chronically infected asymptomatic carriers of hepatitis B virus.[1] The manufacturing process comprises the purification of the surface antigen, the removal of extraneous material, and, finally, the destruction of the infectivity of hepatitis B and any other viruses which might be present.[2] Each batch of vaccine is tested for sterility, pyrogenicity, and innocuousness on animals in the laboratory. Each lot of vaccine is tested for safety in susceptible chimpanzees before being passed for human use. The safety of the vaccine has been confirmed in over 19 000 volunteers.[3]

Progressive changes in liver enzymes over five months. Normal values are given at the top of each column

	Alkaline phosphatase 20-95 IU/l	5 Nucleotidase 2-17 IU/l	Aspartate transaminase < 35 IU/l	Alanine transaminase < 35 IU/l
29 April 1983	243		45	66
3 May 1983	373	43·5	55	77
16 May 1983	318		28	47
3 June 1983	268		32	40
11 July 1983	182	27·7		
9 August 1983	91	8·1	25	22
27 September 1983	68		25	29

All values for serum bilirubin, albumin, and globulin remained within normal range at all times.

This vaccine is well tolerated except for occasional hypersensitivity reactions to any one of its components. Twenty five percent of the 2485 volunteers reported local soreness and erythema at the injection site with occasional low grade fever (< 38°C). Other systemic complaints are malaise, fatigue, rash, headache, nausea, myalgia, and arthralgia, but these are rare (brochure on hepatitis B vaccine, Thomas Morson Pharmaceuticals).

Our patient was offered prophylactic hepatitis B vaccination in accordance with recently reviewed policy for use of the vaccine for medical personnel.[2] We do not consider that the abnormalities of liver function resulted from occupational exposure to halothane in the operating theatre. The temporal correlation between the two vaccine doses suggests the mechanism of cause and effect.

We do not know of a previous report of a systemic reaction accompanied by abnormal liver function values after hepatitis B vaccination. We reported the case to the Committee on Safety of Medicines and the manufacturers, neither of whom informed us of similar cases. The clinical picture was of an anicteric hepatitis episode, where the patient had a hypersensitive reaction. It is unlikely that any adjuvant or additive in the vaccine was the cause. Interestingly, the patient did not develop antibodies to either the surface antigen or the core antigen, even when tested at six months. Normally 90% of those given the first two of the three doses will have developed antibodies to the surface antigen, as is the intention of the proposed vaccination programme.[1]

We thank Dr J M Graham, consultant microbiologist for his help, and Miss P A Farmer for preparing the manuscript.

1 Coleman JC. Hepatitis B vaccine: the horizon and beyond. *J R Soc Med* 1984;**77**: 335-9.
2 Zuckerman AJ. Who should be immunised against hepatitis B? *Br Med J* 1984; **289**:1243-4.
3 Interagency group. Hepatitis B virus vaccine safety. *MMWR* 1982;**31**:464-7.

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Royal Hampshire County Hospital, Winchester SO22 5DG
V RAJENDRAN, MD, MRCP, medical registrar
A P BROOKS, MD, MRCP, consultant physician

Correspondence to: Dr A P Brooks.

Correction

Endoscopic Teflon injection for a refluxing ureteric stump after simple nephrectomy

In this report by K N Bullock and colleagues (13 April, p 1109) the cystogram was obtained before operation and not postoperatively as stated in the legend.