CONSENSUS STATEMENT – 2001
RECOMMENDATIONS FOR HEPATITIS B, C, G AND HIV IN MAINTENANCE DIALYSIS PATIENTS
A CONSENSUS STATEMENT PRODUCED FOR AND BY THE DIALYSIS AND TRANSPLANT SUBCOMMITTEE OF THE AKF AND THE ANZSN.

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EXECUTIVE SUMMARY

- Outbreaks of viral infections, in particular hepatitis, have been reported in haemodialysis units since the introduction of haemodialysis therapy. Transmission of viral infections, including hepatitis in haemodialysis units, continues to occur and remains an important concern, as it is preventable. Viral transmission from infected patients can result in significant morbidity and mortality.
- Patients should be regularly screened for carriage of blood borne viruses, at regular intervals prior to and after commencement of dialysis. In particular patients should undergo Hepatitis B, Hepatitis C and HIV testing early in their management, when progressive renal failure can be predicted to inevitably progress to end stage renal failure and dialysis. Serology should be repeated just prior to starting dialysis to ensure results are available prior to instituting the procedure. The suggested frequency of subsequent testing is LFTs monthly, HbsAg/HbsAb 3-6 monthly, HCV Ab 3-6 monthly and HIV annually.
- Knowledge of the infective status of patients allows the implementation of measures to minimise the risk of cross-infection in the subsequent dialysis setting.
- Hepatitis B immunisation programs should be undertaken aggressively.
- Patients with chronic active viral infection should be referred for specialist review regarding potential anti-viral treatment. The risks and benefits of transplantation need to be carefully assessed prior to transplant waiting list enrolment in virally infected patients, and informed consent, regarding the risks versus the benefits, obtained prior to transplantation.

GLOSSARY

HBsAg: Hepatitis B surface antigen – indicates active infection and moderate infectiousness.
HBeAg: Hepatitis B e antigen: Marker of high infectiousness.
HBV: Hepatitis B virus.
HBcAb: Hepatitis B core antibody. Indicator of natural infection. Not produced after immunisation.
HBeIgM: Hepatitis B core IgM antibody. Indicator of recent infection.
HBsAb: Hepatitis B surface antibody. Antibody produced to surface antigen. Produced after immunisation or natural infection. Protective.
HBV DNA: Hepatitis B virus genetic material – marker of high infectiousness.
HB: PRE-CORE MUTANT: Pre core mutant strains of HBV have high level viraemia but do not generate HBeAg and are highly infectious.
HCV: Hepatitis C virus.
HCVAb: Antibody to hepatitis C virus. Total antibody (IgM and IgG) not protective.
HCV RNA: Hepatitis C genetic material. Marker of viraemia and high level infectiousness. Usually detected by PCR.
HGV  Hepatitis G virus
INTRODUCTION

Maintenance dialysis, involving the accessing of bodily fluids, provides an environment with increased risk of transmission of infective agents between patients and staff. Of these the viral infections such as HBV, HCV, HGV and HIV are prominent, with high infectivity, serious consequences and few effective treatments. Means to prevent transmission of viral infections in the maintenance dialysis setting have become a focus of interest and concern \(^{(1,2)}\).

RECOMMENDED DIALYSIS UNIT PRECAUTIONS

Also known as "Infection Control Practices Recommended for Haemodialysis Units" by the CDC \(^{(1,3,4)}\), these recommendations are more stringent than standard precautions for other patient settings and are designed to prevent transmission of blood borne viruses. General Standard Precautions \(^{(5)}\) also require the use of gloves for contact with blood and body fluids but do not restrict use of supplies, instruments and medications.

DIALYSIS UNIT PRECAUTIONS

- Gloves should be used by staff whenever patients or haemodialysis equipment are touched, with washing of hands and changing gloves between patients. Hands must be washed after glove removal.
- Use of protective eye wear or a face mask and gowns in situations where blood or infective fluids may splash.
- Patients should have specific dialysis stations assigned to them.
- Overcrowding should be avoided, by provision of adequate space between each dialysis patient.
- No sharing of instruments, medications or supplies between patients, regardless of serologic status.
- Medications should be prepared and distributed from a centralised separate, clean area. Medication carts should not be used. Avoid usage of multi-use vials.
- Any item taken to a patient's dialysis area should dedicated for use by that patient only, be cleansed and disinfected prior to return to a clean area or be disposed of.
- Contaminated supplies, equipment or blood samples etc should not be handled or stored in areas where medications and clean equipment and stores are handled.
- Routine staff training and education on infection control practices.
- Routine training and education for patients and their families on infection control practices.
- Dialysis machines should be effectively disinfected after each patient (for detailed discussion see ref 1). The exterior of the machine should also be effectively cleaned and disinfected using protocols following manufacturers instructions. Blood spills should be promptly and effectively attended using bleach (1%,10,000 ppm available chlorine) or a tuberculocidal disinfectant (see Table 2).
- Regular testing of HBV susceptibility and immunity leading to aggressive Hepatitis B vaccination of all susceptible patients and staff.
- Separation of HBs antigen +ve patients by room, machine, instruments, supplies and staff. Terminal Cleaning of isolation rooms should be undertaken after each dialysis.
- No re-use of dialysers for HBsAg +ve patients.
- Regular serologic testing for Hepatitis C and HIV of all susceptible patients and prompt review of results.

Hepatitis B (HBV)

Introduction

Dialysis is a recognised risk factor for transmission of hepatitis B (HBV) \(^{(6)}\), which is the most commonly transmitted blood-borne virus in the healthcare setting. Following acute infection, 5-90% of patients become chronic carriers, depending on age and immune competence. Chronic carriage has significant risks of chronic liver disease, cirrhosis, hepatocellular carcinoma and ultimately death.

HBV may be present in very high titres in the blood and other body fluids in chronically infected patients \( (> 10^8 \) virus particles per mm). HBV remains infectious on surfaces after drying and storage at 25° for one week \(^{(7,8)}\). Blood contaminated surfaces (including invisible contamination) which are not routinely cleaned and disinfected represent a reservoir for transmission of hepatitis B virus. Hepatitis B surface antigen (HBsAg) requires a high level disinfection to inactivate it \(^{(9)}\).

In the 60's and 70's, there were multiple documented outbreaks of hepatitis B in dialysis units. As a result of adherence to British \(^{(10)}\) or US guidelines \(^{(2,3)}\) on the control of hepatitis B in dialysis units in the 1970's the incidence of hepatitis B infection in haemodialysis units has decreased significantly. Subsequent reports of HBV
transmission amongst patients in haemodialysis units have generally identified breaches in infection control procedures; such as the use of multi dose vials (11,12), sharing of supplies (13), sharing of staff with infected and non infected patients (13,14) and blood contamination of equipment and environmental surfaces (15). Reports have also identified factors including failure to isolate patients by room, machine and staff.

Serology and Testing
Recommended HBV Testing on Maintenance Dialysis

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<tr>
<th>TEST</th>
<th>FREQUENCY</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>Liver function tests</td>
<td>monthly (see discussion in HCV section)</td>
<td>All patients</td>
</tr>
<tr>
<td>HBsAg</td>
<td>3-6 monthly</td>
<td>unless known positive or immune</td>
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<tr>
<td>HBeAg and HBV DNA</td>
<td>May be indicated in selected cases.</td>
<td>To assess infectivity, chronicity risk</td>
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<tr>
<td>HBCAb</td>
<td>early test in clinical acute hepatitis</td>
<td>IgM HBCAb-isolated presence in acute infection window period</td>
</tr>
<tr>
<td>HBsAb</td>
<td>6 monthly to annually post immunisation</td>
<td>to monitor immunity</td>
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To simplify protocols, many dialysis units test all patients for HBsAg/HBsAb 6 monthly, and interpret the result according to the patients clinical and dialysis history (see Table 1). IgM HBCAb may be useful to detect acute HBV infection in the window period (surface antigen negative, prior to HBsAb appearance) after infection. HBeAg may not be expressed in patients with precore mutant Hepatitis B infection and high level viraemia. HBV DNA assays are not standardised, can fluctuate and may be intermittently undetectable even in patients with chronic HBV infection.

Vaccination

Since 1982 hepatitis B vaccination has been recommended for susceptible HbsAg negative patients. This has reduced the incidence of HBV infection amongst haemodialysis patients (16,17). Approximately 20% of non-immune haemodialysis patients who are infected with hepatitis B during haemodialysis treatment will have spontaneous resolution of HBsAg. Chronic HBV carriage will occur in approximately 80% (18). These patients are at high risk of progressive hepatitis and provide a further reservoir of infection within the dialysis unit. Hepatitis B immunisation is highly effective in healthy individuals (95% protective antibody level), and universal vaccination of infants and adolescents is now carried out in Australia (19). Early vaccination of susceptible patients prior to end stage renal disease is recommended (20). Vaccine is less effective in patients already on dialysis and a protective anti-HBs level develops in only approximately 50-60%, when the 40 microgram dose (double dose) regimen is used (17, 21, 22, 23).

It is recommended that haemodialysis patients receive 40 micrograms of hepatitis B vaccine on at least 3 but preferably 4 occasions; usually at 0, 2, 4 and either 6 or 12 months. An accelerated schedule of 0, 7, 21 days and 12 months may be used. Post vaccination serological testing, 3 months after the third dose of hepatitis B vaccine is recommended (19). Up to 2 full courses (each of 4 shots) may be administered in an effort to immunise specific patients. Further booster doses of hepatitis B vaccine may be required if achieved immunity wanes on follow up testing.

Anti-HBs levels above 10mIU per ml are considered to be protective. The CDC recommends annual anti-HBs testing with administration of a booster dose of vaccine for haemodialysis patients whose anti-HBs levels fall below 10mIU per ml. (24). Although post vaccination anti-HBs levels in dialysis patients are frequently suboptimal, these patients do not tend to become chronic carriers of HBV if they become infected, suggesting some protective benefit. Currently used vaccines contain monoclonal recombinant surface antigen. Patients who have adequate antibody levels may rarely be infected with vaccine escape (surface antigen) mutants. Most HBsAg EIA tests will identify HBsAg in such infections, however if they do not, HBCAb should be identified on screening, indicating natural infection, and testing for HBV DNA may be helpful.

Isolation

Use of separate rooms and dedicated machines for the haemodialysis of HBV infected patients is universally recommended and has substantially reduced the risk for HBV transmission in the haemodialysis setting; in conjunction with screening, vaccination and Dialysis Unit Precautions (1,3,10).

Transplantation

There are significant risks associated with renal transplantation in HbsAg positive dialysis patients and such patients should be carefully assessed and informed consent obtained prior to activation on the transplant waiting list. The possible indications for placing HbsAg positive patients on the transplant waiting list, and the risk involved will be further assessed in the CARU process. However, in HbsAg positive patients being considered for transplantation referral to a Hepatologist is highly recommended. Hepatologist referral would facilitate assessment of possible antiviral treatment prior to transplantation and would allow careful assessment of post-transplant risk, eg by Liver
Biopsy. Liver biopsy remains the only reliable method of confirming the presence and assessing the severity of chronic active liver disease in patients with HBV infection. Additional tests indicated in such patients may include HBeAg and HBV DNA, as indices of infectivity and tendency to chronicity.

**Hepatitis C (HCV)**

**Introduction**

Chronic hepatitis C is the most common chronic liver disease at present and chronic hepatitis C virus infection is found with variable prevalence in dialysis populations in different parts of the world. Using first-generation ELIZA, the highest prevalence was 42-71% in the Middle East (25-28) with prevalence of approximately 4-14% in the UK (27, 28). Intermediate prevalences are reported from Mediterranean countries. The prevalence in Australia and New Zealand is 1.2-10% (29), with significant regional variability. The prevalence of HCV is consistently higher in dialysis populations than in healthy populations. The prevalence of HCV increases with age, the number of blood transfusions received, the mode of dialysis and the time on dialysis (29, 30, 31). The prevalence of HCV infection in the dialysis unit also has an important impact (32, 33). Usage of erythropoietin to reduce numbers of blood transfusions and screening of the blood donor population for anti HCV has reduced the incidence of hepatitis C infection (34).

HCV infection in the dialysis setting has recently been reviewed by Pereira and Levey (29). Hepatitis C circulates in the chronically infected individual at a much lower level of viraemia than hepatitis B [chimpanzee transmission study showing viraemia <10^7 infective units per ml compared with 10^8 infective units per ml (35) for HBe antigen positive sera (36)]. Nevertheless haemodialysis provides a significant risk of transmission of Hep C and outbreaks continue to occur in modern dialysis facilities (37). The prevalence of anti HCV in patients on continuous ambulatory peritoneal dialysis (CAPD) appears much lower (28), even though HCV has been identified in the peritoneal dialysis effluent (38).

There are multiple reports of patient to patient transmission on haemodialysis, with use of genotypic analysis and molecular typing revealing ongoing nosocomial transmission of hepatitis C in modern dialysis units (39, 40, 41, 42, 43). The risk of acquiring infection is higher for those patients treated in units with a high prevalence of HCV infection (31, 34, 44).

Acquiring HCV on dialysis has significant implications in regard to morbidity and mortality, with a high incidence of progressive chronic liver disease and its sequelae. Renal patients with HCV antibody detected by serology or HCV RNA testing have been found to have an increased relative risk of death approaching 1.8 to 2.0, respectively (45, 46).

**Serology and Testing**

The introduction of an enzyme immunoassay (ELISA) for detection of hepatitis C virus (HCV) antibody in 1989 has enabled serologic testing for hepatitis C infection and screening of the blood donor population. Current serologic testing for hepatitis C antibody utilises a third generation ELISA test. With a sensitivity of approximately 97% these tests have been configured to optimise sensitivity, in order to protect the blood supply. Specificity remains an issue, and false positivity may be a problem (47). In blood donors with no risk factors up to 50% of positive third generation anti-HCV ELISA results are considered false positive. Haemodialysis patients, being immunosuppressed as a result of their renal impairment, may not mount an antibody response to hepatitis C virus with HCV infection and early studies have shown that ELISA anti HCV negative dialysis patients may be HCV RNA positive (48, 49, 50, 51). These early studies used first and second generation ELISA tests for anti HCV with a lower sensitivity. Since then there have been studies showing good correlation between HCV RNA and anti HCV in haemodialysis patients (52, 53, 54). However even HCV viraemia may be intermittently undetectable in clinically infected persons due to spontaneous fluctuations (55).

Currently, when using third generation ELISAs it is thought not to be necessary to use HCV RNA testing for routine screening. (55). In clinical acute hepatitis with negative anti HCV, HCV RNA may be useful in confirming the diagnosis.

**Recommended HCV Testing on Maintenance Dialysis**

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<tr>
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<tbody>
<tr>
<td>Liver function tests</td>
<td>monthly</td>
<td></td>
</tr>
<tr>
<td>Hepatitis C antibody</td>
<td>3-6 monthly</td>
<td>depending on assessed risk</td>
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Haemodialysis patients tend to have sub-normal levels of hepatic transaminases (4, 56), and alanine aminotransferase levels are poor predictors of HCV infection in dialysis patients. HCV RNA testing may be appropriate to identify a
possible acute hepatitis C infection. The HCV third generation antibody assays detect antibody within 6-8 weeks of exposure and prior to this, acute hepatitis C may be diagnosed using HCV RNA PCR. It may also be used as a supplemental test to confirm HCV infection when required. Genotyping of hepatitis C virus strains and further typing using sequencing may be used to study epidemiology of transmission.

**Vaccination**
There is currently no vaccination available for HCV, which should tend to reinforce the importance of strategies to prevent transmission of HCV in the dialysis room.

**Infection Control and Isolation**
There is contention whether the current Dialysis Unit Precautions may be sufficient to prevent HCV transmission in units without isolation of anti-HCV positive patients. (44, 57, 58, 59, 60). Lack of implementation or breakdown in standard infection control practices is thought to have been responsible for documented instances of transmission of hepatitis C in haemodialysis units (39, 61, 62). These include failure to appropriately change gloves between patients, sharing of dialysis equipment, sharing of a multi dose heparin vial, and lack of disinfection of machines between treatments.

The sharing of dialysis machines for anti-HCV positive and negative patients has been clearly associated with transmission of hepatitis C. Use of dedicated machines has been linked to a significantly lower incidence of HCV infection (32).

An important reported risk factor for acquiring hepatitis C is the proximity of patient to patient, with high risk documented for a patient dialysed adjacent to an anti-HCV positive patient (63). The lowest incidence of HCV infection is in haemodialysis units which isolate anti-HCV positive patients in separate rooms, ideally with separate machines (32, 64, 65).

The above evidence should provide impetus for more widespread institution of Isolation Dialysis for HCV positive patients; given that there is no protective vaccine, HCV exposure leads to chronic infection in approximately 85% of those infected, the disease has a very high risk of chronic morbidity and mortality (with a higher risk of progressive hepatic disease than HBV infection) and that there is limited effective treatment. Isolation on haemodialysis is recommended by some authors and common in some parts of Europe (66), however the CDC do not currently recommend isolation, dedicated machines, nor does it ban reuse (65). Despite this, isolation should be considered as an additional measure to minimise the impact of any accidental breach in infection control procedures, as these occur despite Universal Precautions.

Isolation is effective in controlling HCV cross infection and recommended for units with a high HCV prevalence. In lower HCV prevalence units, the isolation of HCV positive patients may not be cost effective. Cohorting HCV antibody positive patients to a single room may help protect the anti-HCV negative patients from infection however, the anti-HCV positive patients may expose themselves to an increased risk of being infected by other HCV strains from adjacent patients (68, 69). This may have an impact on their response to hepatitis therapy and progression of disease.

The arguments against isolation of HCV patients include the lower infectivity of the HCV virus compared to HBV, the low circulating titres in infected blood and rapid degradation of virus at room temperature (69). It is recognised that HCV tests identify exposure rather than necessarily infectivity. In any case strict observance of Haemodialysis Precautions including the cleaning and disinfecting of instruments, surfaces and surrounding equipment etc. remain of paramount importance (67).

**Transplantation**
There are significant risks associated with renal transplantation in HCV positive dialysis patients (68, 70). There is a 2-30 fold increase in the serum viral titer and a five fold increased risk of post-transplant liver disease for recipients with anti-HCV prior to transplantation (71), resulting in posttransplant liver disease being detected in 19-64% of recipients (vs 1-30%) (72). While studies are conflicting, at least some well done studies suggest transplanting HCV positive patients results in a higher mortality of 2.8 odds ratio (73, 74).

HCV positive patients should be carefully assessed and informed consent obtained prior to activation on the transplant waiting list. The possible indications for placing HCV positive patients on the transplant waiting list and the risk involved will be further assessed in the CARI process. However, in HCV positive patients being considered for transplantation referral to a Hepatologist is highly recommended. Hepatologist referral would facilitate assessment for current and emerging antiviral treatments prior to transplantation (75). Interferon alpha therapy is recommended for HCV patients on the renal transplant waiting list (76). Liver Biopsy is recommended as part of the careful pre-transplant workup in patients being considered for renal transplant. Liver biopsy remains the only reliable
method of confirming the presence and assessing the severity of chronic active liver disease in patients with HCV infection.

**Hepatitis G**

Two further blood borne hepatitis viruses have been identified: hepatitis G virus (HGV) and hepatitis GB virus C (\(^{77,78}\)). These two are considered to be strains of the same virus (\(^{79}\)). HGV infection occurs in approximately 1-2% of the blood donor population (\(^{80}\)). Patients on long term haemodialysis are at increased risk of HGV infection. Rates of 3.1 to 29% positivity have been reported in chronic haemodialysis patients (\(^{81}\)). It has been observed that HBG viraemia does not coexist with seropositivity suggesting self-limiting infection (\(^{82}\)). Co-infection with other hepatitis viruses commonly occurs in these patients. Isolated HGV infection is not thought to be clinically significant and the clinical characteristic of patients with chronic hepatitis B and hepatitis C infection was not altered by the presence of HGV infection (\(^{83,84}\)). There is molecular evidence for nosocomial transmission of HGV and this is a further reason for adherence to infection control measures (\(^{84}\)). Current information suggests that HGV infection is benign and screening for this agent in haemodialysis patients is not recommended.

**HIV**

Haemodialysis is considered a low risk setting for the transmission of human immunodeficiency virus (HIV) infection, providing that Dialysis Unit Precautions are carefully observed (\(^{85}\)). However the consequences of transmission are generally fatal, in the long term. There have been a number of outbreaks of HIV infection in dialysis units in developing countries (\(^{86,87,88,89,90,91,92}\)). The largest of these was an outbreak of 82 HIV infections occurring at 3 renal dialysis centres (\(^{87}\)). These outbreaks were associated with the reuse of inadequately sterilised patient care equipment – haemodialysis access needles, dialysers and, in the most recently reported epidemic, shared syringes (\(^{92}\)). Patients early in the course of infection appear likely to have high level viraemia and therefore are more infectious. The importance of infection control precautions is stressed. All patients should be screened for HIV antibody prior to commencement of haemodialysis, and if a recent infection is likely HIV DNA or P24 antigen testing is suggested to detect patients in window period. A reasonable schedule for retesting HIV in dialysis patients is annually.

**Health Care Workers infected with HBV, HCV, HIV**

There is a significant risk for health care workers haemodialysing virally infected patients (\(^{93,94}\)). The risk of needle stick transmission of HBV to non-immune health workers varies from 2%-40%, depending on the level of viraemia and the e antigen status of the infected patient (\(^{95}\)). The average risk of transmission of HCV to health care workers with percutaneous exposure to blood from an anti-HCV positive patient is reported as 1.8%-10% (\(^{96}\)), however most studies place the risk of needle stick transmission at below 3%. The risk of occupational exposure to HIV is considered to be about 0.2% (\(^{95}\)).

It is considered that there is a low risk of transmission of blood borne viruses from an infected health care worker to a patient, in the Australian health care setting. High risk of transmission is considered mostly confined to exposure prone procedures (EPPs). Exposure prone procedures (EPPs) are a subset of invasive procedures (\(^{96}\)). They are procedures in which there is potential for contact between the skin of the health care worker and sharp surgical instruments, needles or sharp tissues in body cavities or poorly visualised or confined body sites including the mouth. Phlebotomy, placing and maintaining peripheral and central intravascular lines, or procedures where the use of sharps is superficial, well visualised and administered to a compliant or anaesthetised patient are considered not to be EPPs. Health care workers who do not perform EPPs do not require to have regular testing for blood borne viruses unless other risk factors are present. Health care workers who perform EPPs have a statutory requirement to be aware of their HIV, HBV and HCV status and perform testing regularly (at least 12 monthly).

The categories of infected health care workers excluded from the performance of EPPs are:

1. HIV antibody positive, irrespective of level of viraemia.
2. HCV antibody positive and HCV RNA positive by PCR (or HCV RNA PCR result undetermined).
3. HBsAg positive in whom HBeAg or HBV DNA is positive (or in whom HBeAg or HBV DNA status undetermined).

**Please note:** HCV antibody positive but HCV RNA negative staff members and HBsAg positive but HBe antigen negative and HBV DNA negative staff are not excluded from the performance of EPPs.
IN THE EVENT OF SUSPECTED NOSOCOMIAL BLOOD BORNE VIRUS TRANSMISSION

This situation would constitute a critical incident (47) and therefore would required to be reported to the General Manager/Director of the facility and to the local Public Health officer. An appropriate investigation would be required to be undertaken which may require involvement of the Public Health Officer.

### TABLE 1. Interpretation of serologic test results for hepatitis B virus infection

<table>
<thead>
<tr>
<th>Serologic Markers</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>HBSAg*</td>
<td>Total Anti-HBc&lt;sup&gt;*&lt;/sup&gt;</td>
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<sup>*</sup> Hepatitis B surface antigen.  
<sup>†</sup> Antibody to hepatitis B core antigen.  
<sup>‡</sup> Immunoglobulin M.  
<sup>§</sup> Antibody to hepatitis B surface antigen.  
<sup>**</sup> Transient HBSAg positivity (lasting ≤18 days) might be detected in some patients during vaccination.

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**Recommended Reading - Reference 1**
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