THE SCOTTISH OFFICE

Department of Health

NHS
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NHS Management Executive
St. Andrew's House
Edinburgh EH1 3DG

10th August 1998

August 1998

Dear Colleague

SCREENING OF PREGNANT WOMEN FOR HEPATITIS B AND IMMUNISATION OF BABIES AT RISK

Summary

1. The National Screening Committee has recommended that all pregnant women should be offered antenatal screening for hepatitis B. All Health Boards should make arrangements, by April 2000 at the latest, for the implementation of such a screening programme and for the appropriate immunisation of babies born to mothers found to be infected.

Action

2. **Health Boards** should ensure that arrangements are in place by April 2000 at the latest:

- for all pregnant women to be offered antenatal screening for hepatitis B;
- for all babies born to infected mothers to receive a complete course of immunisation starting at birth;
- for co-ordinating the management and delivery of the programme;
- for local monitoring and audit of the programme.

3. **Health Board General Managers and Trust Chief Executives** are asked to ensure that the contents of this letter and annex are drawn to the attention of all appropriate managers and staff.

4. **Medical Directors of NHS Trusts** are requested to distribute copies of the attached letter to Consultants in Obstetrics and Gynaecology, Consultant Community Paediatricians and Consultant Virologists.

5. **Executive Nurse Directors, NHS Trusts** are asked to distribute copies of the attached letter to Heads of Midwifery Services/Senior Midwives NHS Trusts.

Addressees

For action:
General Managers, Health Boards
Chief Executives, NHS Trusts
Executive Nurse Directors, NHS Trusts
Medical Directors, NHS Trusts
Directors of Public Health/CAMOs
CANOs

For information:
Chief Executive, Health Education Board for Scotland
Executive Director, SCPMDE
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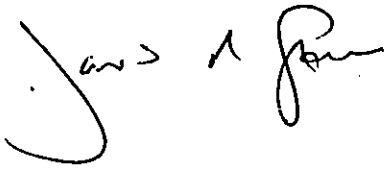
6. This guidance is available on the Department of Health website at http://www.open.gov.uk/doh/coinh.htm.

Yours sincerely



DAVID R STEEL

ANNEX

Background and other information

1. Hepatitis B infection can be transmitted from infected mothers to their babies at or around the time of birth (perinatal transmission). Babies acquiring infection at this time have a high risk of becoming chronic carriers of the virus. Such carriers, as well as being infectious to others, are at increased risk of developing chronic liver disease and some will die prematurely from cirrhosis or hepatocellular carcinoma (primary liver cancer). The development of the carrier state after perinatal transmission can be prevented in around 90-95% of cases by appropriate immunisation, starting at birth, of all infants born to infected mothers.

2. Guidance issued by the Joint Committee on Vaccination and Immunisation (JCVI) in 1988 recommended the screening of pregnant women considered to be at increased risk of having acquired hepatitis B infection. A number of studies subsequently showed that such selective screening fails to identify some carriers. This is due not only to a failure to identify correctly those with established risk factors but also to the existence of some carriers who have no obvious risks of hepatitis B. Some women may be reluctant to discuss previous risks during their antenatal care. In the 1992 edition of *Immunisation against Infectious Disease*, the JCVI recommended that antenatal clinics should consider offering screening to all antenatal patients, recognising that some clinics had already adopted such a policy.

3. The National Screening Committee (NSC) has recently considered this issue. It took into account that whilst the offer of antenatal screening for hepatitis B to all pregnant women has not historically been available everywhere in the NHS, many Health Boards and Health Authorities have adopted the practice in recent years, and that this has been possible without significant additional cost within the context of existing antenatal screening services. The NSC, after examining the merits of extending the coverage of the programme, including its cost effectiveness, has recommended that screening for hepatitis B should be offered to all pregnant women. The NHS Management Executive has decided that, within a timescale in keeping with the demands of other priorities but in any case by no later than April 2000, all Health Boards should have the necessary arrangements in place to implement this screening policy and to immunise babies born to infected mothers.

Screening of mothers in early pregnancy

4. All pregnant women should be offered screening for hepatitis B as one of a number of blood tests routinely recommended in early pregnancy. Screening should be offered during each pregnancy. The purpose and potential benefits of such screening should be explained to women. Those providing antenatal care should be sufficiently informed about hepatitis B to be able to discuss the test and its implications with women; where necessary additional training should be arranged. Although women have the right to choose whether or not to have the test, for this programme to be most effective and to offer protection for all babies at risk, it is hoped that virtually all women will agree to such testing.

5. It is appropriate to screen pregnant women for evidence of hepatitis B infection, at the booking visit, by testing individual specimens for hepatitis B surface antigen (HBsAg), using the blood sample already taken for other routine investigations at this time.

6. When the initial screening test for HBsAg is positive, confirmatory testing should be undertaken. Where infection is confirmed, tests for hepatitis B e-markers should be undertaken since these will determine whether babies born to such mothers should be given hepatitis B specific immunoglobulin (HBIG) in addition to vaccine (see paragraph 12).

7. Screening tests for HBsAg, confirmatory testing and testing for e-markers should be carried out in accredited laboratories which are experienced in performing such tests and which participate in appropriate external quality assurance schemes for hepatitis B testing. The identity of a positive result should be confirmed by repeating the test for HBsAg on a new sample from the patient.

8. After testing, all women diagnosed as infected with hepatitis B should be offered an appointment with an appropriate health care professional to discuss the implications for themselves, their pregnancy, their sexual partner and other family members as soon as possible after diagnosis. This will include information about the disease and how transmission to their baby and others in the family can be prevented. Such a discussion, and any written information, should if possible be in the mothers' first language.

Mothers who first present late in pregnancy

9. Where screening has not been done in early pregnancy, it should be possible to detect infected mothers later in pregnancy or even at the time of delivery and to provide vaccine to babies born to these mothers within 24 hours of birth.

Immunisation of babies

10. After obtaining parental consent, immunisation of babies of infected mothers should be commenced as soon as possible after birth. The table below shows the appropriate regimens for the use of hepatitis B vaccine and hepatitis B specific immunoglobulin (HBIG). In those cases where both vaccine and HBIG are recommended, the two injections should be given at different sites. Hepatitis B vaccine, but not HBIG, is recommended for babies born to mothers who are HBsAg positive but known to be anti-HBe positive.

	Baby should receive	
	Hepatitis B vaccine	HBIG single dose
Mother is HBsAg positive and HBeAg positive	✓	✓
Mother is HBsAg positive without e markers (or where they have not been determined)	✓	✓
Mother had acute hepatitis B during pregnancy	✓	✓
Mother is HBsAg positive and anti-HBe positive	✓	x

Administration of hepatitis B vaccine

11. For babies born to mothers infected with hepatitis B, the accelerated immunisation schedule recommended for post-exposure prophylaxis is preferred. For these babies this will mean an initial dose at birth, with further doses at one and two months of age and with a booster dose at twelve months, at a time when routine follow up of these babies is recommended (see paragraph 20). The first dose of vaccine should be available for administration shortly after birth. The vaccine dose for infants is the paediatric and not the adult one.

Dose and supplies of HBIG

12. The dose of hepatitis B immunoglobulin for the new born is 200 iu. It is obtainable from the Scottish National Blood Transfusion Service (SNBTS) and should be ordered for babies for whom it is indicated well in advance of the birth, so that it may be given shortly after delivery and in any case within 24 hours. SNBTS offer an `out-of-hours' service when HBIG is required urgently.

13. Further information on hepatitis B vaccines and on HBIG is to be found in the UK Health Departments' memorandum *Immunisation against Infectious Disease* 1996.

Ensuring delivery of a complete course of immunisation

14. Where universal antenatal screening for hepatitis B is already being undertaken, audit of delivery of a complete course of hepatitis B immunisation to infants born to infected mothers has shown that compliance is often poor with perhaps only two thirds of infants receiving more than two doses. Since many women who are infected with hepatitis B may not have English as their first language, arrangements for follow-up immunisation may not have been understood. Lack of adequate communication between different health service providers may also be a contributory factor.

15. Mothers should be made aware of the number of injections their baby requires to complete a full course of immunisation, and they should be given written information about when these injections should be given and who will be responsible for the administration of each dose.

16. Health Boards will therefore need to determine which local services will be responsible for providing immunisation at different stages. They should make arrangements to ensure complete courses of vaccine are administered through these services and ensure that arrangements are in place for information to be passed between them when responsibility for the baby's immunisation is transferred.

Co-ordination of the programme

17. Health Boards should arrange for a named individual to co-ordinate the screening and immunisation programme, to ensure that complete courses of vaccine are administered to babies of infected mothers, and to arrange for the programme to be monitored and audited. Health Boards will need to decide locally who should undertake this role, but may wish to consider Consultants in Public Health Medicine (CD & EH), Community Paediatricians etc. The individuals responsible should also satisfy themselves that those involved in discussing the screening and the test results with women are adequately informed about hepatitis B.

Follow-up of immunised infants

18. Although immunisation commencing at birth is 90-95% effective in preventing babies born to infected mothers from becoming carriers of the virus, a small number of babies, including those few who may have been infected earlier in utero, will become carriers. Follow-up testing (for HBsAg) of infants born to infected mothers at one year of age will identify those who are infected and will allow them to be referred for assessment and any further management. By arrangement with an experienced laboratory, this test may be done on a capillary blood specimen.

Immunisation of other household members

19. In accordance with existing JCVI recommendations, close household contacts and any sexual contacts of infected mothers identified by this screening should be tested for the presence of hepatitis B markers. Immunisation should be offered to those who are not already infected or immune. Contacts who are HBsAg, anti-HBs or anti-HBc positive will not require immunisation. Antenatal clinics should be made aware of the Health Boards' local arrangements for the immunisation of close contacts of an infected person.

Follow-up/referral of infected mothers

20. Health Boards should also ensure that arrangements are in place for women identified as being infected to be referred to a specialist with expertise in liver disease for further assessment. Depending upon circumstances, such referrals are best made after the birth has taken place.

Breast feeding

21. There is no contra-indication to breast feeding when a baby born to a carrier mother begins immunisation at birth and proceeds with a complete course of immunisation.

Monitoring and audit

22. The screening and immunisation programme should be subject to local performance monitoring and audit. As a minimum, this should include the number of women booked, screened, and found to be infected (i.e. HBsAg positive); the number of live births to women found to be infected; and the number of such children who receive the first dose of vaccine (and where appropriate HBIG) within 24 hours of birth, and subsequent doses of vaccine at times appropriate to the particular schedule chosen locally. It will be particularly important to investigate instances where babies born to infected mothers do not receive a complete course of immunisation.

Quality assurance

23. The National Screening Committee is in the process of developing a national strategic framework for quality assurance for NHS screening programmes. A sub-committee will be looking at standards for antenatal screening. Information on the strategic framework was included in the National Screening Committee's recent report. Further information on standards and quality assurance arrangements for hepatitis B screening will be included in future guidance.

Current advice about population screening programmes

24. Current advice to the NHS is that new screening programmes should not be introduced until the National Screening Committee has reviewed, evaluated and proven them effective.

(For further information about the National Screening Committee contact Mr Norrie Kernohan, Public Health Policy Unit, Room 420, St Andrew's House (0131-244 2495).

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