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THE NHS BORDERS PREGNANCY SCREENING PROGRAMME SPECIFICATION AND PROTOCOLS

PURPOSE OF SPECIFICATION

The purpose of this specification is to inform all those involved about the Borders Pregnancy Screening Programmes. The specification:

- Clarifies the aims and scope of the pregnancy screening programmes.
- Seeks to ensure that relevant health professionals are clear about their respective responsibilities, liaise effectively to ensure a co-ordinated programme and work together to achieve continuous improvement in services.
- Seeks to ensure equity of care by ensuring a consistent level of service is provided across Borders.

AIMS OF THE PREGNANCY SCREENING PROGRAMME

The infections for which a routine screen is offered are:

- Hepatitis B, to identify women who are persistently infected with hepatitis B so that the baby may be immunised as soon as possible after exposure at delivery.
- Human immunodeficiency virus (HIV) infection, to identify HIV infected women at an early stage of pregnancy in order to offer advice, treatment and intervention during the pregnancy to reduce the likelihood of vertical transmission. By being aware of their HIV status, the women themselves may benefit from taking advantage of the new treatments available.
- Syphilis, to enable antibiotic treatment to be offered to the infected mother and to reduce the risk of congenital syphilis.
- Rubella immunity, to identify pregnant women who are not immune so that they can be offered immunisation after delivery so that they will be immune during any future pregnancies.
- Varicella Zoster immunity (although it is not national policy to screen for this) is to identify pregnant women who are not immune so that there is no delay in VZIG therapy after significant exposure to infection.

With the exception of VZ testing, these tests are provided in line with guidance from the Scottish Executive and NHS Scotland Screening Programmes. Current national policy is that signed consent is required for infectious disease screening and this is the current practice in the Borders.

OVERVIEW

COORDINATION OF THE PROGRAMME

Overall responsibility for the Antenatal Screening Programmes offered to women in Borders rests with the NHS Board Chief Executive. Responsibility for development, monitoring and co-ordination of the programme is delegated to the Director of Public Health. This individual will chair the Pregnancy Screening Steering Group.

The remit of the Pregnancy Screening Steering Group is to:

- Co-ordinate Pregnancy Screening in Borders.
- Agree policy in line with national pregnancy screening policies.
- Agree a service specification and monitor its implementation.
- Lead the implementation of any new developments in the pregnancy screening programme.
- Oversee communication with professionals and with couples relating to pregnancy screening.
- Agree an annual report to the NHS Board Clinical Governance Committee.
- Continuously monitor the quality of the programme and address any problems identified.
- Advise the NHS Board on service needs in relation to the pregnancy screening programme.

OFFER OF SCREENING

Responsibilities

NHS Borders is responsible for ensuring that all pregnant women known to the service are offered screening sufficiently early in pregnancy. The pregnant woman herself is responsible for:

- Registration of pregnancy in time to access antenatal screening;
- Accepting or declining the offer of screening
- Attending for testing;
- Notifying the NHS if no result is provided within the agreed timeframe; and
- If needed, for attending appointments for counselling or onward care.

Process

All pregnant women, of appropriate gestation, attending an antenatal booking clinic should be given written information on the screening tests available at least 24 hours in advance of the appropriate time for the screening test.

OBTAINING CONSENT & SPECIMEN

Consent

The booking midwife or obstetrician is responsible for ensuring that appropriate informed consent is sought. S/he will confirm that the woman has received and read the appropriate screening information leaflets will explain the purpose and process involved and will answer any questions.

A consent form, with details of the tests offered as well as those accepted, and a place for the woman's signature of consent, has been developed for use in Borders. If the offer of screening is accepted a separate request form is completed and sent together with the sample to the relevant laboratory.

RESULTS MANAGEMENT AND FAILSAFE REQUIRMENTS

The laboratory will cross check the data on the form against that entered into the laboratory computer to ensure that the data are correct before issuing a report. These same details, also given on the report, are cross checked against the patient details available to the midwife or clinician before the report is finally released.

If no result has been received when the patient is next reviewed at the clinic, the community midwifery team will contact the relevant laboratory to ensure a sample has been received. If a sample has been received, the laboratory will issue/re-issue a report as soon as possible. If no sample has been received the named midwife should take a repeat sample and send it to the laboratory as soon as possible.

Screening results are reported within 15 working days of sampling ?

- If the woman is found to be non-immune to rubella, she should be informed of this result, advised to avoid anyone who has a rubella-like illness and to report to her midwife promptly if she does come into contact with a rubella like illness. Her notes should be marked and she should be offered MMR immunisation postpartum. Immunisation is safe during breastfeeding but she should be advised to wait at least 4 weeks after immunisation before trying to conceive.

- If serology shows a pregnant woman to be non-immune to varicella zoster, she should be informed of this result, advised to avoid anyone who has a varicella zoster – like illness, including shingles, and to report to her midwife promptly if she does come into

contact with a varicella zoster – like illness. Her notes should be marked and she should be offered VZIG after significant exposure during pregnancy.

- If a woman is found to have syphilis confirmed antenatally, she should be referred promptly for specialist counselling and offered antibiotic treatment.

- If a woman is found to be positive for HBV surface antigen, confirmatory testing will be carried out. If confirmed, further testing is done to establish whether this is an acute or chronic infection. The woman should be offered specialist counselling. Public health should be notified to coordinate contact tracing. The baby should receive passive immunity (HBIG) and be actively immunised as soon as possible after delivery and should receive a complete course of hepatitis B immunisation, with follow up testing for immunity and infection (ie anti-HBs level and anti-HBcore) once the full course has been given (at 14 months). It is the responsibility of the midwives to inform the paediatiricians after delivery to ensure that treatment is started. The paediatricians should ensure that the GP is going to arrange further doses of vaccine at 1 month, 2 months and 12 months of age. They should also ensure that immunity is checked at 14 months. The SIRS database should be notified to stimulate prompts to attend for these immunisations.

- If a woman is found to be confirmed HIV positive, she should be offered specialist counselling and be offered antiretroviral therapy.

LABORATORY PROCEDURES

Clotted blood samples to provide serum are submitted to the Microbiology Laboratory at BGH (all five tests on one sample). The Virology Centre, RIE confirms any positive results.

Blood samples arriving in the laboratory must be correctly labelled and accompanied by the appropriate, fully completed request form. The assigned laboratory number is used to link sample, patient details and analytical results and appears on the final report.

HIV screening and confirmation. For first line screening for antibodies to HIV, both laboratories in Lothian use versions of the EIA (enzymeimmunoassay) test suitable for the equipment available. Confirmatory testing including a Western blot test is performed in the Specialist Virology Centre if repeat EIA tests are positive[1].

[1] **Parry JV, Mortimer PP, Perry KR, Pillay D, Zuckerman M. 2003. Towards error-free HIV diagnosis: guidelines on laboratory practice. Communicable Disease and Public Health 6: 334-350.**

HBV screening and confirmation
For first line screening both laboratories use versions of the EIA test for hepatitis B surface antigen. All confirmatory testing and further markers to differentiate acute from chronic hepatitis B are done in the Specialist Virology Centre.

Syphilis screening and confirmation
Screening is done at both sites using an EIA for antibody to *Treponema pallidum*, the agent of syphilis. Confirmation and further testing is carried out in the Specialist Virology Centre under the care of the consultant microbiologist with special expertise in this condition.

Rubella immunity screening and confirmation.
Rubella antibody screening is by an EIA at both laboratories. Any samples giving low level or negative results are re-tested with an alternative method in the Specialist Virology Centre.

Varicella Zoster screening and confirmation.
Needs added.

Serum or plasma samples stored.
In addition to the test sample, any left over serum is stored in numbered tubes in a freezer bank to allow repeat analysis in the event of an analytical problem. (These stored samples may also be used for quality control and teaching, and anonymised research for development of new tests).

LABORATORY REPORTS

Computer generated reports conforming to the agreed minimum dataset are issued. Over 95% of results should be available to the midwife within 5 working days of receipt of the sample by the laboratory.

Samples giving repeated reactive (positive) results for HBV or HIV or syphilis are first referred for specialist confirmatory testing (within the Specialist Virology Centre). Only once they have been confirmed are HBV or HIV or syphilis positive results given to the designated co-ordinating midwife responsible for dealing with positive results, without discussing them with the midwife involved with the screen.

Once it has been confirmed that the information on the report is accurate and any necessary amendments have been made, consideration should be given as to the most appropriate method and timing for relaying such results. Usually this will involve an appointment offered to women to attend the BGH high-risk clinic at the earliest opportunity when support and advice from an HIV specialist will be available when it is HIV positive. At that time a second sample is taken to confirm the correct identity of the first sample and to provide plasma for an HIV viral load assay if appropriate.

The laboratory provides copies of all reports to GPs and to the original referral midwife, via the coordinating midwife, if that differs from the unit where antenatal care is being provided, **unless the woman has declined permission for this.**

Results from samples giving a technical problem in the assays will occasionally lead to a request for a further sample for analysis and for additional clinical details.

All reports are retained in electronic format by each laboratory. Information and results relating to individual pregnancies held on the laboratories' screening database may be accessed by telephone enquiry. Most reports are also accessible via NEWLABS or SCISTORE.

All reports should where available contain the woman's CHI number to support the future integration of health records.

Data for Scottish regional and national statistics.

In the absence of standardised maternity information systems, the laboratory information management system will be used as a repository of aggregated data on the screening programme.

CONFIDENTIALITY

All staff involved in the screening programmes will comply with the provisions of the Caldicott Report. In particular, patient-identifiable information will only be used in clearly defined and monitored circumstances, only when absolutely necessary and should entail the use of the minimum necessary patient-identifiable information.

Access to patient identifiable information will be on a strict need to know basis, everyone in the organisation will be aware of his or her responsibilities with respect to patient confidentiality and the organisation will ensure that its use of patient-identifiable information is lawful.

Information on clinical activity for national data sets and monitoring must be submitted in anonymised format.

ADVERSE INCIDENTS

- As with any screening programme there is potential for significant adverse incidents. All adverse incidents should be managed appropriately to minimise the risks to, and effects on patients and NHS services.

Any healthcare professional involved in the NHS Borders pregnancy screening programme who becomes aware of a suspected problem will follow agreed local NHS Borders clinical governance procedures.

In the first instance, a clinical incident report should be made. The incident will be investigated. The outcome of this investigation may be:

- there is no problem.
- there is substandard performance that needs to be remedied by the service concerned.
- there is the possibility of a major problem, which needs further investigation. In this case a formal incident team should be established to carry out further investigation and any remedial action required.

The Board Antenatal Screening Coordinator should be informed of the incident at the time of initial investigation. If an incident team is set up, s/he may sit on or lead this depending on the nature and scope of the incident.

National Services Division (NSD) will be notified early in the process at the time of formal internal investigation. In view of the sensitivities of national screening programmes and the public interest in them, NSD may require an external peer review even if local management decide not to invoke this. The Board antenatal screening coordinator is responsible for liaison with NSD.

NSD will notify SEHD and decide if action is needed in other NHS Board areas.

These protocols are to be used in addition to, and do not replace, existing Clinical / Adverse Incident Reporting Procedures.