

# **REGIONAL AUDIT OF ANTENATAL INFECTION SCREENING**

## **Report & Recommendations**

**January 2008**

## **Audit of Antenatal Infectious Diseases Screening Programme**

### **Executive Summary**

An audit of the Antenatal Infectious Diseases Screening Programme funded by the Regional Multi-professional Audit Group was undertaken during 2005. It involved the then 10 Trusts which have antenatal clinics and 7 testing laboratories. In addition 6 of the Trusts also took part in a review of the practice of offering post natal MMR vaccination to women testing rubella non-immune during pregnancy. A total of 33 recommendations were made at the conclusion of the audit. A number of safe guards were identified as necessary including (a) the introduction of fail-safe arrangements to account for the receipt of all outstanding laboratory reports and (b) hospitals offering MMR vaccine to rubella non-immune women prior to discharge. A stream-lining of the laboratory arrangements for undertaking the tests associated with the programme was also considered to be desirable.

### **RECOMMENDATIONS**

1. Boards and Trusts should ensure that antenatal infection screening programmes are commissioned and provided to the standards outlined in the Department of Health: Screening for infectious diseases in pregnancy – standards to support the UK antenatal screening programme, August 2003.
2. There should be clear written protocols and policies within each Trust for the coordination, management and delivery of the infectious screening programme including clear lines of accountability.
3. There should be a fail-safe system in place to account for all expected laboratory reports.
4. There should be reporting, investigation and follow up of all adverse incidents within the programme.
5. Consideration should be given to a single laboratory undertaking all antenatal infection screening tests.
6. Postnatal MMR should be offered to rubella non-immune women before discharge from hospital. The offer and patient's response should be recorded in the patient's notes.
7. If deferral of rubella vaccination is unavoidable, there should be a written pro forma communication between the Trust and the General Practitioner.
8. Confirmatory laboratory tests for HBV, HIV, syphilis and rubella non-immunity, should be simplified through the use of a single confirmatory laboratory.
9. Trust clinic protocols should be re-written to complement any new laboratory arrangements.
10. IT arrangements should be updated to facilitate an integrated service and laboratories involved in the program should be capable of sharing data electronically.

11. Staff Training for those delivering the programme should be included at both induction and update sessions. Specific concepts that should be covered in the training should include: (a) the concept of a window period with infection; (b) the possibility of infection post screening, (c) result interpretation.
12. There should be a system for re-offering screening when it is initially declined.
13. There should be a uniform system for handling all laboratory reports, inclusive of HIV, in terms of: staff access; receipt in the clinic; computer input; addition to patient notes; laboratory computer look-up.
14. A patient information sheet should be available for patients with newly identified HBV infection to explain the significance for them and their family, and the referral options. This should be available in an appropriate selection of languages.
15. Patients with newly diagnosed syphilis should follow a regionally agreed management protocol.
16. There should be an agreed protocol for the follow up of children born to HIV, HBV or syphilis positive mothers identified through the programme.
17. Trusts should use the Late Booking Form for women who book later in pregnancy <http://www.bll.n-i.nhs.uk/micro2/viroreqformslist.htm>
18. Trusts should consider the need for a rapid HIV assay for women presenting in labour.
19. All Boards and Trusts should have follow-up protocol for children born to HBV positive mothers to ensure completion of the vaccine schedule and post-vaccine immune testing.
20. Trusts should have access to HBV vaccine for women presenting in labour where the mother's HBV status is unknown or the mother is found to be HBV positive.
21. HBV vaccination information should be available to women and their GPs regarding the infant vaccination programme when appropriate.
22. All women found to be positive for HV or HIV should be tested for Hepatitis C.
23. Patients with identified high risk activities for HCV should be counselled and offered a test for this infection.
24. All HCV positive women should be managed according to a clinical protocol.
25. Children born to mothers known to be positive for HCV should be followed-up using an agreed protocol.
26. The availability of information in appropriate ethnic languages should be reassessed regularly.
27. Consent issues should be reviewed including the need for recording of staff / patient signatures.

### **Laboratory Specific Recommendations**

1. All laboratories should have appropriate quality assurance programs in place.
2. There should be a uniform approach to communicating laboratory results in terms of: report generation; use of explanatory comments; use of written / electronic / telephone modes of reporting. This should be described in a written Standard Operating Practice (SOP) within each laboratory in the programme.

3. A second sample should be requested from any patient where specific antibodies to HIV, HBV and/or syphilis have been detected. This sample should be processed with an urgency appropriate to the infection detected e.g. laboratory results indicating active syphilis should not be subject to batch testing; tests in labour or if labour is thought imminent should be treated as emergencies.
4. Laboratories should only request a single serum sample from each patient to undertake the screening assays required of the programme.
5. All laboratories involved in the programme should store residual serum for one year.
6. Laboratory test protocols and reporting formats should be agreed between the laboratory and the Trusts.

## Introduction

In 2002 the Department of Health and Social Services and Public Safety (DHSSPS) formalised a policy (HSS(MD)11/02) to prevent serious congenital and perinatal infections through the offer of antenatal infectious diseases screening for hepatitis B virus (HBV), human immunodeficiency virus (HIV), syphilis and rubella immunity. Part of the rationale of the programme was emphasised in the Deputy Chief Medical Officer of England's letter of December 14 1998 concerning the unlinked anonymous HIV survey<sup>1</sup> which indicated that over 70% of maternal HIV infections in 1995-1996 were undiagnosed. Health Authorities in England and Wales were asked to arrange for all pregnant women to be offered an HIV test by 31 December 2000. The universal offer of antenatal screening for HIV commenced in Northern Ireland in April 2003. Although screening for hepatitis C virus (HCV) is not part of the programme, there is a risk of transmission of 6.2% when a child is delivered to a mother who is HCV PCR positive.

In August 2003, the Department of Health in England issued Screening for Infectious Diseases in Pregnancy – Standards to Support the UK Antenatal Screening Programme<sup>2</sup>. A number of standards were outlined regarding the process of offering tests in the antenatal setting and the mechanism of undertaking and reporting laboratory results. Arrangements for delivery of positive results and for confirmatory testing of a follow-up (second) specimen were to be prioritised. All women should expect to have confirmed positive test results explained to them in person. Women found to be positive for HIV and syphilis were also to be referred for specialist treatment and advised about interventions to reduce the risks of vertical and sexual transmission of these infections.

In Northern Ireland the DHSSPS issued circulars on the local provision of the screening programme:

HSS (MD) 17/98 Screening of pregnant women for Hepatitis B and immunisation of babies at risk.

HSS (MD) 24/01 Increased transmission of Infectious Syphilis in Northern Ireland.

HSS (MD) 11/02 Infection Screening for Pregnant women and Reduction of Mother to Baby Transmission.

HSS (MD) 26/02 also included Interim Quality Standards for Antenatal Infection Screening.

The Northern Ireland policy underpinned the audit into the application and compliance of hospital and community maternity services with the 2003 standards. The purpose of the audit was to assess how the Northern Ireland screening programme performed against National Standards and if its delivery would prevent perinatal infection with HBV, HIV<sup>3,4,5</sup> and syphilis and if those rubella non-immune women were being offered post-natal rubella vaccine where appropriate.

## Method

### Audit Team/Process

A multidisciplinary team of health care professionals undertook the direction of the audit (Appendix 1). It included personnel from: the Royal Group of Hospitals Trust (RGHT) Audit Department; DHSSPS; Area Boards; Communicable Disease Surveillance Centre CDSC(NI); Trust Antenatal Screening coordinators; Northern Ireland Blood Transfusion Service (NIBTS); Paediatrics; Obstetrics; General Practice; Regional Virus Laboratory (RVL). Audit direction and process was agreed at a series of meetings held in the Audit Department, RGHT. The direction of the audit reflected the priorities established at the meetings. The audit purpose was to provide objective evidence of the strengths and weaknesses of the current regional programme and facilitate recommendations for improvements where applicable.

### Chief Executive Consent

All Trust Chief Executives of the participating antenatal clinics and audit departments were contacted to inform them of the nature of the audit and to seek their consent to approach the respective antenatal clinics and laboratories for participation.

### Audit 1: Antenatal Clinic and Laboratory Testing Standards

It was agreed to use the DH document “Screening for Infectious Diseases in Pregnancy - Standards to Support the UK Antenatal Screening Programme” <http://www.dh.gov.uk/assetRoot/04/09/20/49/04092049.pdf> published in 2003, to assess how both the clinics and laboratories were complying with the delivery of the programme (Appendix 2). Ten clinics and 7 laboratories were invited to participate in the Audit and those agreeing are shown in Tables 1 and 2 respectively.

*Table 1 – Antenatal Clinics Participating in the Audit*

|                                  |
|----------------------------------|
| Lagan Valley Hospital            |
| Antrim Hospital                  |
| Daisy Hill Hospital              |
| Mater Infirmorium Hospital       |
| Erne Hospital                    |
| Causeway Hospital                |
| Altnagelvin Hospital             |
| Craigavon Area Hospital          |
| Ulster Hospital                  |
| Royal Jubilee Maternity Hospital |

*Table 2 – Laboratories Participating in the Audit*

|  |
|--|
| Regional Virus Laboratory - Royal Group of Hospitals Trust |
| Northern Ireland Blood Transfusion Service                 |
| Microbiology - Royal Group of Hospitals Trust              |
| Microbiology - Craigavon Area Hospital                     |
| Microbiology – United Hospitals                            |
| Microbiology – Causeway Hospital                           |

To facilitate the audit, separate pro formas addressing (a) clinic standards (Appendix 3) and (b) laboratory standards (Appendix 4) were developed. They were sent to named persons in each clinic and laboratory. The laboratory in Scotland providing the hepatitis B confirmatory service was not included in the audit.

### **Audit 2: Provision of Vaccine Cover for Rubella Non-immune Women**

An important aspect of the audit was to confirm that when a woman was found to be non-immune to rubella, she received an offer of rubella vaccination in the post natal period. The consent was sought from all obstetricians to review the relevant entries in their patient's notes where they had been recorded as rubella non-immune by Northern Ireland Blood Transfusion Service (NIBTS) during the 12 month period April 2004 – March 2005. A list of non-immune women was made available by NIBTS upon the receipt of the consultant consent letters.

Antenatal clinics were invited to participate through their respective audit departments and 6 agreed to participate as shown in Table 3. A list of women was selected for each of the hospitals from the NIBTS list.

*Table 3. Units participating in the Rubella audit*

|                          |                              |
|--------------------------|------------------------------|
| Lagan Valley Hospital    | Defer to community           |
| Antrim Hospital          | Defer to community           |
| Daisy Hill Hospital      | Defer to community           |
| Causeway Hospital        | Defer to community           |
| Craigavon Area Hospital  | Vaccinate prior to discharge |
| Royal Maternity Hospital | Vaccinate prior to discharge |

Of the 6 clinics, 4 deferred vaccination to the community and 2 offered the vaccine before discharge. Audit personnel in each participating hospital were responsible for undertaking the case note inspection.

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A questionnaire was compiled for this purpose and used by each audit department. It consisted of six questions, which were:

1. Is there a record in the patient's notes from NIBTS indicating the rubella status?
2. What is written in the discharge form against rubella status?
3. What is written in the discharge form against rubella vaccine?
4. Is it documented in the patient's notes that the rubella vaccine was offered?
5. Is it documented in the patient's notes that the rubella vaccine was refused?
6. Is it documented in the patient's notes that they were advised to have the vaccine at their G.P. Surgery?

The case notes were inspected to record the associated information for each question.

## RESULTS

### Chief Executive Consent

All Trust Chief Executives and audit departments who were approached consented to their Trust's involvement in the audit.

### Participating Antenatal Clinics and Laboratories

All 10 of the clinics approached agreed to participate in the audit and returned completed questionnaires. Six of the 7 laboratories responded by completing the audit pro forma.

### 1. Audit of the Antenatal Clinic and Laboratory Testing Standards

(a) Clinic Management Standards The summarised response to each question is recorded below.

|   |
|---|
| 1. Does your Trust or Board have written protocols in place for antenatal infection screening that accurately reflect Departmental standards? |
|---|

|                |
|----------------|
| Yes – 8 No – 2 |
|----------------|

|   |
|---|
| 2. Are the procedures for antenatal infection screening included in staff induction training? |
|---|

|                |
|----------------|
| Yes – 8 No – 2 |
|----------------|

|   |
|---|
| 3. Are the procedures for antenatal infection screening included in annual update training? |
|---|

|                |
|----------------|
| Yes – 8 No – 2 |
|----------------|

|   |
|---|
| Responsibility for which lay with different grade of Staff in every Trust but in 90% there was a named person for this. |
|---|

|   |
|---|
| 4. Are there clear management arrangements for co-ordinating the program? |
|---|

|                                 |
|---------------------------------|
| Yes – 6 No – 1 Not Answered – 3 |
|---------------------------------|

|  |
|--|
| 5. Are there clear management arrangements for monitoring the program? |
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|                                 |
|---------------------------------|
| Yes – 7 No – 2 Not Answered – 1 |
|---------------------------------|

|   |
|---|
| 6. In relation to antenatal infection screening are there systems for dealing with serious adverse events e.g. report delay or notification of false positive results to patient? |
|---|

|                |
|----------------|
| Yes – 7 No – 3 |
|----------------|

|   |
|---|
| Systems varied from Trust to Trust. Responses were: |
|---|

- |  |
|--|
| <ul style="list-style-type: none"> <li>• critical incident reporting</li> <li>• IR1 forms</li> <li>• responsibility of antenatal screening co-coordinator/senior midwife.</li> </ul> |
|--|

|   |
|---|
| 7. Are there systems in place for central reporting to Health Boards of serious adverse events? |
|---|

|                                 |
|---------------------------------|
| Yes – 6 No – 1 Not Answered – 3 |
|---------------------------------|

(b) Clinic Testing Standards The summarised response to each question is recorded below.

|   |
|---|
| 1. When are screening tests for Rubella, Syphilis, HIV, Hepatitis B offered?  |
| All Trusts offered tests for all pregnancies.   |
| 2. When was written information on antenatal screening offered?   |
| All Trusts offered this information pre-booking.  |
| 3. In addition to English, is information on antenatal screening available to women in other languages or other media formats?  |
| Other Languages – 5 Other Media Formats – 4 Not Answered -1<br>Languages specifically mentioned were Cantonese, Arabic, Hindu and Irish. The other format was an interpreter booked 'ad hoc'. |
| 4. If a screening test is refused, is there a protocol to allow for the screening test to be re-offered in a later clinic?  |
| Yes - 7 No – 3<br>All 10 Trusts sought information on high-risk activities, e.g. Intravenous drug user, during the antenatal visit.   |
| 5. Are women known to be in a high-risk group e.g. intravenous drug user, or known positive for HIV, HBV or syphilis, offered testing for hepatitis C virus during the antenatal visit?       |
| Yes – 3 No – 6 Not Answered – 1   |
| 6. How are positive HIV results received?   |
| Telephone & Written – 9 None to Date 1  |
| 7. How are positive HBV results received?   |
| Written 7 Telephone & Written 1 Not Answered 2  |
| 8. How are positive syphilis results received?  |
| Written 4 Written & Telephone 3 Not Answered 3  |
| 9. Are fail safe mechanisms in place to alert staff if specimen reports are not received in a timely manner?  |
| Yes – 8 No – 2  |
| 10. In explaining test result to the woman is it explained that the test does not exclude the small possibility of a 'window period' infection going undetected?                              |
| Yes – 3 No – 7  |
| 11. Is informing a woman of a negative test result used for explaining the dangers of becoming infected during pregnancy?   |
| Yes – 5 No – 5  |

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|   |
|---|
| 12. Do the written reports of positive results have interpretive comments?  |
| Yes – 8 No – 2  |
| 13. If interpretive comments are available, are they useful?  |
| Yes – 6 No – 2 Not answered – 2   |
| 14. Do all women have confirmed positive test results explained to them in person?  |
| Yes – 9 Not Answered – 1  |
| 15. Are positive written reports added to patients notes?   |
| Yes – 7 No – 1 Not Answered – 2   |
| 16. Is there a written protocol for the follow-up of women who are known to be positive for hepatitis C virus?  |
| No – 10   |
| 17. Are there any staff restrictions on who has access to positive results for HIV?   |
| Yes – 9 No – 1  |
| 18. Are there any staff restrictions on who has access to positive results for HBV?   |
| Yes – 5 No – 4 Not Answered – 1   |
| 19. Are there any staff restrictions on who has access to positive results for Syphilis?  |
| Yes – 5 No – 4 Not Answered – 1   |
| 20. Are the results for Rubella, Syphilis, HIV, and HBV held on computerised patient record system e.g. NIMATS?   |
| Yes – 6 No – 4<br>One Trust did not record HIV positives on computerised system.  |
| 21. For women screening positive for HBV, are the implications for themselves, their pregnancy, their sexual partners and other family members explained to them?   |
| Yes – 8 No – 1 Not Answered – 1<br>Explained by Consultant 5 Midwife 2 Sexual Health Nurse 1  |
| 22. For women screening positive for HBV, in what form is advice available to explain the need for administering the Vaccine and/ or HBV immunoglobulin to the newborn child?                                     |
| Written 3 Oral 6 Both 5.  |
| 23. Does the antenatal clinic have written information for the mother and her GP about the number of injections the baby requires when they should be given and who will be responsible for their administration? |
| Yes – 4 No – 6  |

|  |
|--|
| 24. How is parental consent for the baby's immunisation recorded prior to the birth? |
| Oral – 8 Not Answered – 2  |

|   |
|---|
| 25. Are partners and other children of women who screen positive for HBV offered counselling and HBV screening? |
| Referred to GP – 6 Not Counselling – 3 Not Answered – 1   |

|  |
|--|
| 26. For women who screen positive for HBV during pregnancy, are steps taken to arrange for the following?  |
| Refer to hepatologist - 6 Referred via GP - 1 Not Answered – 3<br>Some Trusts noted that referral was dependant on the consultant and that a majority of HBV positive women are from the Chinese community and are previously known to be HBV positive. Four clinics have a written information pack for patient and the GP (one lacked written information in other languages). |

(c) Laboratory Testing Standards The summarised response to each question is recorded below. One lab did not reply – the figures reflect the answers for the 6 who did.

**NIBTS test for HIV, HBV and Rubella immunity**  
**RVL test for HIV, HBV and Rubella immunity**  
**All microbiology laboratories test for syphilis only**

|   |
|---|
| 1. Are the test numbers handled by testing laboratories adequate? |
| Yes 6   |

|  |
|--|
| 2. Do the laboratories have accreditation? |
| Yes. 6                                     |

|  |
|--|
| 3. Have the assays adequate sensitivity and specificity. |
| Yes. 6   |

|                                     |
|-------------------------------------|
| 4. Are confirmatory tests adequate? |
| Yes. 6                              |

|                                 |
|---------------------------------|
| 5. Are kit guidelines followed? |
| Yes 6                           |

|                                       |
|---------------------------------------|
| 6. Is NEQAS performance satisfactory? |
| Yes 6                                 |

|  |
|--|
| 7 Do you run an internal Quality Assurance scheme? |
| Yes – 5 No 1                                       |

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|   |
|---|
| 8 Is >1 blood sample required for antenatal screening tests in your laboratory? |
| Yes – 2 No – 4  |

|   |
|---|
| 9. Are antenatal screening sera stored at -20°C or below for at least one year following testing? |
| Yes 2 No 3 Not Answered 1   |

|   |            |                           |   |
|---|------------|---------------------------|---|
| 10. How long does it take for a reactive screening assay to be confirmed? |            |                           |   |
| 24-48 hours   | > 48 hours | Not Answered/Not Relevant |   |
| HIV   | 1          | 1                         | 4 |
| HBV   | 1          | 1                         | 4 |
| Syphilis  | 1          | 3                         | 2 |
| Rubella Status  | 0          | 2                         | 4 |

|  |         |       |                           |
|--|---------|-------|---------------------------|
| 11. Do you confirm the initial reactive screening assay / non-immune rubella or refer to another laboratory? |         |       |                           |
|  | Confirm | Refer | Not Answered/Not Relevant |
| HIV  | 1       | 1     | 4                         |
| HBV  | 1       | 1     | 4                         |
| Syphilis   | 1       | 3     | 2                         |
| Rubella Status   | 1       | 1     | 4                         |

|  |
|--|
| 12. Do you have a protocol for reporting positive results for antenatal screening tests to the clinic? |
| Yes – 3 No - 3   |

|  |
|--|
| 13. Have your reporting protocols been subjected to review and agreement with the antenatal clinics/G.P practitioners? |
| Yes – 0 No - 5 Not Answered – 1  |

|   |     |    |                  |
|---|-----|----|------------------|
| 14. Is a second specimen requested for testing where the initial screening test has screened positives? |     |    |                  |
| Relevant  | Yes | No | Not Answered/Not |
| HIV   | 1   | 1  | 4                |
| HBV   | 1   | 1  | 4                |
| Syphilis  | 1   | 3  | 2                |

|  |     |       |      |         |    |
|--|-----|-------|------|---------|----|
| 15. In addition to the Antenatal Clinic to whom of the following are significant results notified? |     |       |      |         |    |
|  | RVL | NIBTS | CCDC | CDSC-NI | GP |
| HIV  | Y   | Y     | Y    | Y       |    |
| HBV  | Y   | Y     | Y    | Y       | Y  |
| Syphilis   |     |       | Y    | Y       |    |
| Rubella Status   | Y   | Y     |      |         | Y  |
| All HIV positive results are discussed with GUM  |     |       |      |         |    |

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16. Do all your reports to the antenatal clinic have advisory comments concerning the test results?

Yes – 2 No - 4

17. What tests are used for antenatal screening for Treponemal antibodies in your laboratory?

Treponemal - 2 Treponemal & Non-Treponemal - 2 Not Answered - 2

18. What tests are used for confirmation of Treponemal antibodies in your antenatal screening protocol?

Treponemal - 2 Treponemal & Quantitative VDRL – 2 Not Answered - 2

19. What tests are used for estimating the stage of the infection?

Treponemal EIA IgM - 2 Quantitative VDRL - 2 Not Answered - 2

20. Are Syphilis positive results reported in such a way as to alert to the possibility of confounding seroreactivity stemming from possible infection yaws, pinta and bejel?

Yes – 0 No – 4 Not Answered/Not Relevant - 2

21. Where sera are reactive for syphilis antibody, are the antenatal clinics advised to make a GUM referral?

Yes – 1 No – 3 Not Answered/Not Relevant – 2

22. Do positive HBV tests have a written comment that corresponds to the vaccination/immunoglobulin requirement of the newborn?

Yes – 1 No – 1 Not Answered/Not Relevant – 4

Late booking tests through virus laboratory uses standard report comments.

## 2. Audit of the Provision of Vaccine Cover for Rubella Non-immune Women - Rubella Case Note Audit

For the rubella case-note audit, all obstetricians agreed that patient notes could be used for the purposes of the audit. Six Trusts providing a total of 73 case notes of rubella non-immune women took part in the study as shown in Table 3. Three of the 73 case notes were rejected as the women were not delivered in the Units which left a total of 70 case notes. The audit included Trusts who offered the MMR vaccine pre-discharge and Trusts that deferred the offer to the patient's GP.

### 1. Does your hospital vaccinate or defer?

| Vaccinate or Defer | Casenotes | Percentage |
|--------------------|-----------|------------|
| Vaccinate          | 33        | 47%        |
| Defer              | 37        | 53%        |
| Total              | 70        | 100%       |

THE SUMMARIZED RESPONSE TO EACH QUESTION IS RECORDED BELOW

### 2. Is there a record in the patient's notes from NIBTS indicating the Rubella status (non-immune)?

| Record from NIBTS | Frequency | Percentage |
|-------------------|-----------|------------|
| Yes               | 69        | 98.5%      |
| No                | 1         | 1.5%       |
| Total             | 70        | 100%       |

### 3. What is written in the discharge form against rubella status?

| Discharge Rubella Status    | Frequency | Percentage |
|-----------------------------|-----------|------------|
| Audit question not answered | 1         | 1%         |
| Immune                      | 3         | 4%         |
| Non-immune                  | 60        | 86%        |
| Not known                   | 3         | 4%         |
| Blank                       | 3         | 4%         |
| Total                       | 70        | 100%       |

### 4. What is written in the Discharge Form against rubella vaccine?

| Discharge Rubella Vaccine | Frequency | Percentage |
|---------------------------|-----------|------------|
| Given                     | 16        | 23%        |
| Not Given                 | 47        | 67%        |
| Blank                     | 5         | 7%         |
| Other *                   | 2         | 3%         |
| Total                     | 70        | 100%       |

(\*2 Others – referred to G.P.)

IF RUBELLA VACCINE IS RECORDED AS NOT GIVEN, IS BLANK OR OTHER  
(N=54):

5. Is it documented in the patient's notes that the rubella vaccine was offered?

| Rubella Vaccine Offered | Frequency | Percentage |
|-------------------------|-----------|------------|
| Yes                     | 7         | 13%        |
| No                      | 10        | 19%        |
| N/A*                    | 37        | 69%        |
| Total                   | 54        | 100%       |

\*Trusts deferred to GP

6. Is it documented in the patient's notes that the rubella vaccine was refused?

| Rubella Vaccine Refused | Frequency | Percentage |
|-------------------------|-----------|------------|
| Yes                     | 6         | 11%        |
| No                      | 11        | 20%        |
| Not Applicable*         | 37        | 69%        |
| Total                   | 54        | 100%       |

\* Trusts deferred to GP

6a. Reasons for refusal (N=6)?

| Reasons for refusal   | Frequency |
|---|-----------|
| Not answered  | 1         |
| She was breastfeeding   | 1         |
| Did not want to have MMR vaccination  | 1         |
| Preferred to attend own G.P.  | 1         |
| As mother was breastfeeding she was advised to discuss with G.P. at check up and arrange. Advised very important                          | 1         |
| Sr cautioned about breastfeeding & getting pregnant within 3 months. Lack of understanding of English & lack of clear hospital guidelines | 1         |
| Total   | 6         |

7. Is it documented in the patient's notes that they were advised to have the vaccine at their GP Surgery?

| Advised vaccine with GP | Frequency | Percentage |
|-------------------------|-----------|------------|
| Yes                     | 15        | 28%        |
| No                      | 39        | 72%        |
| Total                   | 54        | 100%       |

Table 4. Results from records for Hospitals Offering Vaccine

| Results for hospitals offering vaccine         | Frequency | Percentage |
|--|-----------|------------|
| Record of vaccine administration               | 16        | 48%        |
| Record of refusal of MMR                       | 6         | 18%        |
| No record of refusal but advised to visit G.P. | 1         | 3%         |
| No record of refusal or administration         | 10        | 30%        |
| Total  | 33        | 100%       |

Table 5. Results from records for Hospitals Deferring Vaccination

| Results for hospitals Deferring vaccine              | Frequency | Percentage |
|--|-----------|------------|
| Record of Non-immune Status on discharge letter      | 34        | 92%        |
| Record of Immune Status on discharge letter*         | 3         | 8%         |
| Record of Patient Counseled to Attend GP for Vaccine | 8         | 22%        |

\*Relevant Trusts informed of this finding.

## Hepatitis B

### Provisions for Follow-up of Children Receiving HBV Vaccine at birth

The DHSSPS policy is for all babies born to hepatitis B positive mothers to be followed up and to complete the vaccination programme. The four Health Boards are required to put this policy into operation. There was no regional wide protocol for the follow-up of children born to HBV positive women, with only the Northern Board having a written protocol in place at the time of the audit. A draft protocol was under discussion by the Eastern Board during the audit period.

## Discussion

Antenatal HIV screening was initiated in 2003 and was the impetus for assessing how the antenatal infectious diseases screening programme was currently functioning. Through funding obtained from the Regional Multi-Professional Audit Group, a region-wide audit of the programme was possible. This demonstrated that while the overall programme was meeting its primary function in safeguarding against the acquisition of serious perinatal infection, there was a lack of uniformity in the application of the standards and a lack of safe guard measures to identify missing results. The laboratory arrangements were overly complex and lacked agreed protocols established between the respective laboratory and clinic. The current arrangement for syphilis screening and confirmation were particularly fragmented and appeared poorly responsive to the turn-around times required for the management of a complication of syphilis in pregnancy. In part this was linked to the batch testing of bloods to allow laboratories to operate more cost effectively. A more detailed audit of these services was therefore thought to be warranted.

Current practice does not fully meet the needs of particular vulnerable groups. This is due to a number of practical issues that put ethnic minority groups at increased risk of infection including: higher prevalence of infection with blood borne viruses; higher rates of rubella non-immunity; increased likelihood of presenting un-booked in late pregnancy; increased likelihood of presenting in labour; unusual HBV and HIV subtypes which could result in difficulties for diagnosing infection; language difficulties making appropriate counselling difficult; less certain group immunity due to travel back to country of origin.

It was found during the audit that a lack of a common IT platform made data hard to track. The uneven access to laboratory data held on the respective testing laboratory computers, especially for HIV, increased the likelihood of staff missing an important result.

## References

- 1 Unlinked anonymous HIV surveys PL/CO/ (98)3  
<http://www.dh.gov.uk/assetRoot/04/01/35/23/04013523.pdf>
- 2 Screening for infectious diseases in pregnancy – standards to support the UK antenatal screening programme August 2003  
<http://www.dh.gov.uk/assetRoot/04/09/20/49/04092049.pdf>
- 3 Guidelines for the management of HIV infected women in pregnant women and the prevention of mother-to-child transmission of HIV  
[http://www.hpa.org.uk/publications/2006/hiv\\_mother\\_child/report.pdf](http://www.hpa.org.uk/publications/2006/hiv_mother_child/report.pdf)
- 4 The Euro guidelines Group for HIV Resistance. Clinical and laboratory guidelines for the use of HIV-1 drug resistance testing as part of treatment management: Recommendations for the European setting. *AIDS* 2001;15:309-20.
- 5 Coll O, Fiore S, Floridia M, Giaquinto C, Grosch-Worner I, Guiliano M et al. Pregnancy and HIV infection: A European consensus on management. *AIDS* 2002; 16:S1-18.

## **Appendix 1**

### **Audit Group Members**

#### Regional Virology Laboratory

- Dr Peter Coyle - Chair

#### Audit Department

- Julie Caldwell
- Jacinta Wilson

#### DHSSPS

- Dr Margaret Boyle
- Jackie McGeagh

#### Antenatal Screening Co-coordinator

- Nora McClenaghan (Antrim)
- Margaret Kennedy (RVH)

#### CDSC-NI

- Dr Brian Smyth
- Dr Neil Irvine

#### NIBTS

- Dr Kieran Morris

#### HSS Boards

- Dr Carol Beattie EHSSB
- Dr Fiona Kennedy NHSSB
- Dr Tracey Owen SHSSB
- Dr Richard Smithson WHSSB

#### Paediatricians

- Dr Alison Livingstone
- Dr Paul Jackson

#### Obstetrician

- Dr Ralph Roberts

#### General Practitioner

- Dr Windsor Murdock

***Appendix 2***

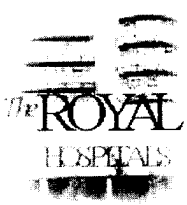
Standards to Support the UK Antenatal Screening programme – August 2003

Screening for Infectious Diseases in pregnancy:

<http://www.dh.gov.uk/assetRoot/04/09/20/49/04092049.pdf>

***Appendix 3***

**Clinic Questionnaire Pro forma**



**REGIONAL AUDIT OF THE DEPARTMENTAL PROVISIONS FOR THE PREVENTION OF CONGENITAL AND PERINATAL ACQUIRED INFECTION**

**Generic Standards**

**Trust/HSS Board - to be responded to by Trusts and Boards**

**Administration/Training**

Does your Trust/Board have written protocols in place for antenatal infection screening that accurately reflect departmental standards? **If yes, please forward a copy.**  Yes  No

Are there clear performance management arrangements for co-ordinating the program?  Yes  No

If yes, please give details \_\_\_\_\_  
\_\_\_\_\_

Are there clear management arrangements for monitoring the program?  Yes  No

If yes, please give details \_\_\_\_\_  
\_\_\_\_\_

Are the procedures for antenatal infection screening included in staff induction training?  Yes  No

Are the procedures for antenatal infection screening included in annual update training?  Yes  No

Is there a named person responsible for the coordination and monitoring of the program?  Yes  No

If yes, please give the staff grade of this person: \_\_\_\_\_

In relation to antenatal infection screening, are there systems for dealing with serious adverse events e.g. report delays or notification of false-positive results to the patient?  Yes  No

If yes, please give details \_\_\_\_\_  
\_\_\_\_\_

Are systems in place for the central reporting to Health Boards of serious adverse events?  Yes  No

Have serious adverse events occurred and been reviewed in your Trust?  Yes  No

If yes, please give details \_\_\_\_\_  
\_\_\_\_\_

Any additional comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Clinic - Antenatal infection screening test - Offer**

| <b>When is antenatal infection screening offered?</b> |                          |                          |
|---|--------------------------|--------------------------|
|   | <i>1st pregnancy</i>     | <i>All pregnancies</i>   |
| Rubella antibody                                      | <input type="checkbox"/> | <input type="checkbox"/> |
| Syphilis  | <input type="checkbox"/> | <input type="checkbox"/> |
| HIV   | <input type="checkbox"/> | <input type="checkbox"/> |
| Hepatitis B   | <input type="checkbox"/> | <input type="checkbox"/> |

At what stage is written information on antenatal infection screening given to pregnant women?

- Pre-booking*     
  *First antenatal booking*     
  *Other* **If other, please state:** \_\_\_\_\_

In addition to English, is information on antenatal screening available to women in:

- Other languages*     
  *Other media formats*     
 **Please state:** \_\_\_\_\_

Are details on the offer and uptake of the antenatal infection screening tests recorded in the woman's notes?

- Yes*     
  *No*

How is the woman's consent recorded?  *Woman's signature*       *Staff signature*       *Other*

If other, please state \_\_\_\_\_

If a screening test is refused, is there a protocol to allow for the screening test to be re-offered in a later clinic? (If yes, please enclose a copy)

- Yes*     
  *No*     
  *Unsure*

Are high-risk activities e.g. intravenous drug abuser sought during the antenatal visit?

- Yes*     
  *No*

Are women known to be in a high-risk group e.g. intravenous drug abuser, or known positive for HIV, HBV, or syphilis, offered testing for hepatitis C virus during the antenatal visit?

- Yes*     
  *No*

In the past 12 months, how many women have had to be tested a second time for all or part of the antenatal infections screen? \_\_\_\_\_

| <b>Could you indicate the main reasons in order for these retests?<br/>(1 = most common reason, 2 = Next most common reason, etc)</b> |       |
|---|-------|
| Insufficient blood for all tests  | _____ |
| Insufficient blood for some of the tests  | _____ |
| Reactive result needed further tests  | _____ |
| Positive result needed confirmed  | _____ |
| Blood did not reach testing laboratory  | _____ |
| Results not received/lost from laboratory   | _____ |
| <b>Other - please indicate</b>  | _____ |

Any additional comments \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Clinic - Antenatal infection screening test - Results General**

Tick one or more

|  |                                    |                                |                               |
|--|------------------------------------|--------------------------------|-------------------------------|
| <b>How are positive results for HIV received?</b>      |                                    |                                |                               |
| <input type="checkbox"/> Written report                | <input type="checkbox"/> Telephone | <input type="checkbox"/> Other | Other - please indicate _____ |
| <b>How are positive results for HBV received?</b>      |                                    |                                |                               |
| <input type="checkbox"/> Written Report                | <input type="checkbox"/> Telephone | <input type="checkbox"/> Other | Other - please indicate _____ |
| <b>How are positive results for Syphilis received?</b> |                                    |                                |                               |
| <input type="checkbox"/> Written Report                | <input type="checkbox"/> Telephone | <input type="checkbox"/> Other | Other - please indicate _____ |

How are laboratory results reviewed and acted on? Please give brief details

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Are there fail safe mechanisms in place to alert staff if specimen reports are not received in a timely manner?

Yes       No

Are NHS patients managed differently?

Yes       No

In explaining a negative test result to the woman is it explained that the test does not exclude the small possibility of a "window period" infection going undetected?

Yes       No

Is informing a woman of a negative test result used for explaining the dangers of becoming infected during pregnancy?

Yes       No

Do the written reports of positive results have interpretive comments?

Yes       No

If interpretive comments are available, are they useful?

Yes       No       N/A

Do all woman have confirmed positive test results explained to them in person?

Yes       No

Are positive written reports added to the patient's notes?

Yes       No

|  |                          |                          |
|--|--------------------------|--------------------------|
| <b>Are there any staff restrictions on who has access to positive results for:</b> |                          |                          |
|  | <b>Yes</b>               | <b>No</b>                |
| HIV  | <input type="checkbox"/> | <input type="checkbox"/> |
| HBV  | <input type="checkbox"/> | <input type="checkbox"/> |
| Syphilis   | <input type="checkbox"/> | <input type="checkbox"/> |

**Are there separate written protocols for the follow-up of women with confirmed results for:**

|                    | <b>Yes</b>               | <b>No</b>                |
|--------------------|--------------------------|--------------------------|
| HIV                | <input type="checkbox"/> | <input type="checkbox"/> |
| HBV                | <input type="checkbox"/> | <input type="checkbox"/> |
| Syphilis           | <input type="checkbox"/> | <input type="checkbox"/> |
| Rubella non-immune | <input type="checkbox"/> | <input type="checkbox"/> |

**If yes to any, please enclose**

**Is there a written protocol for the follow-up of women who are known to be positive for hepatitis C virus?**

*Yes*       *No*

**Are the results for Rubella, Syphilis, HIV, HBV held on a computerised patient record system e.g. PAS, NIMATS**

*Yes*       *No*

**Any additional comments**

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**Clinic - Antenatal infection screening test - Results Specific**

**HBV Positive Mothers**

For women screening positive for hepatitis B virus, are the implications for themselves, their pregnancy, their sexual partners and other family members explained to them?

Yes       No      If yes, who by?

For women screening positive for HBV, in what form is advice available to explain the need for administering HBV vaccine and / or HBV immunoglobulin to the newborn child?

Written Advice       Oral Advice       Both       Other  
If other, please specify:

Does such information include the importance of completing the full course of the vaccine immunisation schedule?

Yes       No

Does the antenatal clinic have written information for the mother and her GP about the number of injections the baby requires, when they should be given and who will be responsible for their administration?

Yes       No

How is parental consent for the baby's immunisation recorded prior to the birth?

Recorded written consent       Orally consent to staff

Are partners and other children of women who screen positive for HBV offered counselling and HBV screening?

By Antenatal staff       By referral to general practitioner       Not offered counselling & HBV screening

For women who screen positive for HBV during pregnancy, are steps taken to arrange for:

Referral to her GP to arrange for a hepatology / gastroenterology appointment

Direct referral to a hepatology / gastroenterology clinic

Any additional comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Syphilis**

**What antenatal tests are undertaken for screening for syphilis?**

- TPHA*    *VDRL*    *VDRL and TPHA*    *Other*

If other, please state:

**Are all women testing positive for syphilis antibody referred for a Genitourinary Medicine assessment?**

- Yes*    *No*

If no, please give details

**Where a woman has confirmed syphilis during pregnancy requiring treatment, who is responsible for:**

Follow-up and completion of appropriate treatment

Follow-up of newborn after delivery

Follow-up of existing children

Follow-up of partner(s)

Any additional comments:

**HIV**

**For a woman screening positive for HIV, are there written protocols for the management of the pregnancy and the post natal management of the mother and child?**

- Yes*    *No*

**Are there arrangements in place for undertaking:**

Joint care with the Royal Hospitals

**Yes      No      Unsure**

Transfer of care to the Royal Hospitals

Sole management of pregnancy if joint responsibility with staff at the Royal Hospitals is not acceptable to the patient

Management of an emergency delivery

Any additional comments

**Rubella**

**Are the following taken into account when offering a rubella test:**

|   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| Previous report of rubella-specific IgG | <input type="checkbox"/> | <input type="checkbox"/> |
| Previous rubella or MMR vaccination     | <input type="checkbox"/> | <input type="checkbox"/> |

**Does your unit have a protocol for follow-up of rubella non-immune women?**

Yes       No      **If yes, please enclose/forward a copy**

**Is a history of exposure to or possible recent infection with rubella in early pregnancy actively sought, particularly in recent immigrants from countries with low rubella vaccine cover, to alert the laboratory for the potential for primary rubella infection?**

Yes       No

**If a low level (<10 IU/ml) of rubella-specific IgG is reported in a woman with two or more documented doses of rubella vaccine, what does your protocol advise?**

- A further dose of vaccine*  
 *No further doses but advises the woman to report any rash illness or contact with a rubella-like rash for active investigation*  
 *Other*      **If other, please state:**

**Where women screen rubella non-immune are they:**

- Offered MMR before discharge*  
 *Referred to their GP for MMR cover*  
 *Offered MMR at the 6 weeks post natal appointment*  
 *Other*      **If other please state:**

**If MMR is administered by the antenatal staff, how is this recorded?**

- NIMAS*       *Woman's notes*       *Other*      **If other please state:**

**If MMR is administered by the antenatal staff, is a record of this made available to the patient's GP?**

Yes       No

**Late Bookers**

At what stage in pregnancy is the antenatal booking regarded as "late" i.e the stage where the routine NIBTS antenatal infection screening service is bypassed?

- 30wks     31wks     32wks     33wks     34wks     Other

If other, please state:

Do you have a written protocol for instituting antenatal infection screening for these late bookers?

- Yes     No

**Please indicate where late booking tests are sent for antenatal infection screening; please tick more than one if necessary**

|          | <b>NIBTS</b>             | <b>Regional Virus Laboratory</b> | <b>Local Bacteriology Laboratory</b> |
|----------|--------------------------|----------------------------------|--------------------------------------|
| HIV      | <input type="checkbox"/> | <input type="checkbox"/>         | <input type="checkbox"/>             |
| HBV      | <input type="checkbox"/> | <input type="checkbox"/>         | <input type="checkbox"/>             |
| Rubella  | <input type="checkbox"/> | <input type="checkbox"/>         | <input type="checkbox"/>             |
| Syphilis | <input type="checkbox"/> | <input type="checkbox"/>         | <input type="checkbox"/>             |

How many late bookers are handled on average each year in your unit?

**Labour / Near Labour Bookers**

Is there a written protocol for obtaining antenatal screening tests for pregnant women arriving in or near labour where results for antenatal screening tests are not available?

- Yes     No

How many women presenting in labour un-booked or, where results for antenatal screening tests are not available, are handled on average each year in your unit?

Is there a protocol for addressing language difficulties for informing / consenting women in labour?

- Yes     No

Are written protocols available for the management of women in labour who screen positive for:

- HBV     HIV     Syphilis

Are rapid HIV tests available in the labour suite in the event that a HIV test result will not be available before the delivery of the baby?

- Yes     No

Is hepatitis B vaccine available in the labour suite for immediate administration if so required?

- Yes     No

Is hepatitis B hyper-immune globulin available in the labour suite for immediate administration if required?

- Yes     No

In cases where consent is withheld for screening during labour, is there a system in place to ensure screening is offered again after delivery?

- Yes     No

Is there a policy of offering hepatitis B vaccine in the advent of a hepatitis B test result not being available at the time of delivery?

- Yes     No

***Appendix 4***

**Laboratory Questionnaire Pro forma**



How long does it take for a reactive screening assay to be confirmed for:

- (A) HBV  <24 Hours  24 - 48 Hours  >48 Hours  
(B) HIV  <24 Hours  24 - 48 Hours  >48 Hours  
(C) Syphilis  <24 Hours  24 - 48 Hours  >48 Hours  
(D) Rubella antibody  <24 Hours  24 - 48 Hours  >48 Hours

Do you confirm the initial reactive screening assay or refer to another laboratory:

- (A) HBV  Confirm  Refer  
(B) HIV  Confirm  Refer  
(C) Syphilis  Confirm  Refer  
(D) Rubella antibody <10IU/ml  Confirm  Refer

Do you have a protocol for reporting positive results for antenatal screening tests to the clinic?

- Yes  No **If yes, please enclose**

Have your reporting protocols been subjected to review and agreement with the antenatal clinics / General Practitioners?

- Yes  No

Is a second specimen requested for testing where the initial screening test has screened positive for:

- (A) Syphilis  Yes  No  
(B) HIV  Yes  No  
(C) HBV  Yes  No

In addition to the antenatal clinic, to whom are the following notified:

**HIV positive**

- RVL  NIBTS  CCDC  CDSC-NI  CDSC-HPA  GP **Other** \_\_\_\_\_

**HBV positive**

- RVL  NIBTS  CCDC  CDSC-NI  CDSC-HPA  GP **Other** \_\_\_\_\_

**Syphilis positive**

- RVL  NIBTS  CCDC  CDSC-NI  CDSC-HPA  GP **Other** \_\_\_\_\_

**Rubella antibody not detected**

- RVL  NIBTS  CCDC  CDSC-NI  CDSC-HPA  GP **Other** \_\_\_\_\_

What percentage of antenatal screening tests in the last 12 months gave rise to the need to request a second specimen for re-screening from the clinic? \_\_\_\_\_ %

Do all your reports to the antenatal clinic have advisory comments concerning the test results?

- Yes  No

If no, please indicate why this is not the case: \_\_\_\_\_

## Syphilis

What tests are used for antenatal screening for treponemal antibodies in your laboratory?

Non-treponemal       Treponemal       Both

EIA       Other      - Please state: \_\_\_\_\_

What tests are used for confirmation of treponemal antibodies in your antenatal screening protocol?

FTA-abs       TPHA       EIA       Quantitative VDRL/RPR

What tests are used for estimating the stage of infection?

Treponemal EIA IgM       Quantitative VDRL/RPR       Both

Are syphilis positive results reported in such a way as to alert to the possibility of confounding seroreactivity stemming from possible infection with yaws, pinta and bejel?

Yes       No

Where sera are reactive for syphilis antibody, are the antenatal clinic advised to make a GUM referral?

Yes       No

If no, when is this not recommended?

**Please enclose examples of reactive syphilis reports issued by your laboratory as part of the antenatal screening programme**

## HIV

Does the screening assay used for antenatal HIV screening have a sensitivity >99.9% and a specificity >99.5%?

Yes       No

Are specimens reactive for HIV retested in duplicate before referring to a confirmatory laboratory?

Yes       No

Are all reactive HIV results confirmed by a specialist laboratory, for instance one represented on the HPA HIV Laboratory Diagnosis Forum?

Yes       No

**Please enclose examples of reactive HIV reports issued by your laboratory as part of the antenatal screening programme**

## HBV

Does the screening assay used for HBsAg for antenatal screening have a sensitivity >99.9% and specificity >99.5%?

Yes       No

Are specimens reactive for HBV confirmed by neutralisation?

Yes       No

Are specimens reactive for HBV confirmed by a specialist laboratory?

Yes       No

What additional HBV markers are determined by your laboratory?

HBeAg       Anti-HBe       Core IgG       Core IgM

How are positive HBV tests reported?

- HBsAg only*       *HBsAg plus full marker profile*

Do positive HBV tests have a written comment that corresponds to the vaccination/immunoglobulin requirement of the newborn?

- Yes*       *No*

**Please enclose examples of reactive HBV reports issued by your laboratory as part of the antenatal screening programme**

**Rubella**

What tests are used for rubella antibody tests?

- ELISA*     *Radial haemolysis*     *Latex agglutination*     *Other* - Please state \_\_\_\_\_

Does the assay used for this purpose achieve sensitivity and specificity of >98%?

- Yes*       *No*

What cut-off level is used to define rubella antibody detection used in your laboratory? \_\_\_\_\_ IU/ml

Are all specimens that give negative or equivocal results on initial testing:

- Referred to a reference laboratory to perform further investigations*  
 *Re-tested using a second assay in order to confirm the result and to monitor the front-line assay*

What second assay is used for rubella antibody tests?

- ELISA*  
 *Radial haemolysis*  
 *Latex agglutination*  
 *Other* - Please state

| How are results reported?    | Yes                      | No                       |
|------------------------------|--------------------------|--------------------------|
| IgG detected/not detected    | <input type="checkbox"/> | <input type="checkbox"/> |
| Regard as immune/susceptible | <input type="checkbox"/> | <input type="checkbox"/> |

**Please enclose examples of rubella immune and non-immune reports issued by your laboratory as part of the antenatal screening programme**