



The purpose of this paper is to provide a summary of the current national activities in relation to antenatal screening for Down syndrome, pending the National Screening Committee's national guidance on policy and quality management. After each item, information is available on how to obtain further information.

### 1. Antenatal screening standards

The UK National Screening Committee has published working standards on antenatal screening, incorporating those for the National Down Syndrome Screening Programme for England (January 2003). They are split into the following nine areas:

#### Generic:

- 1.1 Policy
- 1.2 Clinical arrangements for antenatal screening programmes
- 1.3 Education and training for staff
- 1.4 Information and support for women and their partners
- 1.5 Antenatal ultrasound scanning
- 1.6 Audit and monitoring processes

#### Specific standards relating to the Down syndrome screening programme:

- 1.7 Audit and monitoring for Down syndrome screening
- 1.8 Laboratory standards for Down syndrome serum screening
- 1.9 Standards for ultrasound scanning in relation to screening for Down syndrome

The full standards are available in the UK National Screening Committee's publication *Antenatal screening: Working Standards Incorporating Those for the National Down Syndrome Screening Programme for*

*England*, January 2003 ([www.nelh.nhs.uk/screening/dssp/Standards.pdf](http://www.nelh.nhs.uk/screening/dssp/Standards.pdf)).

### 2. Ultrasound standards

The Ultrasound Standards Working Group has derived the following specific ultrasound standards from the above antenatal screening standards:

- 2.1 All pregnant women must have an early dating scan when undergoing Down syndrome screening. Ideally this should be:
  - before serum screening
  - ideally between eight weeks and 12 weeks and six days for most accurate dating
  - ideally between 11 weeks and 13 weeks and six days if nuchal translucency (NT) is to be measured.
- 2.2 There should be a regionally or locally agreed written policy and protocol that adheres to national standards and defines the purpose of the early dating scan including the possibility of detecting an abnormality.
- 2.3 Written information must be given and discussed with all pregnant women prior to the screening procedure, to enable them to make an informed choice.
- 2.4 Gestational age assessment is by measurement of crown-rump length (CRL) before 13 weeks and head circumference (HC) or biparietal diameter (BPD) after 13 weeks.
- 2.5 Techniques and biometric charts used for fetal measurements must meet nationally agreed standards:
  - CRL, HC, BPD as advised by the British Medical Ultrasound Society
  - NT - to be developed.
- 2.6 Any health professional undertaking an ultrasound scan must have an accredited certificate in obstetric ultrasound or equivalent.

- 2.7 Equipment standards must be in place for the specification, maintenance schedule and upgrading of scanning equipment.
- 2.8 There should be continuous assessment and monitoring of the quality of the ultrasound screening programme, which includes operator performance and patient satisfaction with the service.
- 2.9 There should be an identified professional lead in each maternity ultrasound or radiology unit who is accountable for service quality and responsible for local processes of dealing with poor performance and system failures.
- 2.10 Measurements and results of ultrasound scans should be recorded in the woman's pregnancy health record and in the ultrasound clinical information system or written record.
- 2.11 All health professionals performing ultrasound scans should attend an appropriate communication/counselling course.

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### 3. Down syndrome national surveys

A survey was undertaken in 2001 to assess the availability of Down syndrome screening to women and to identify gaps to direct future work. The following is a synopsis of the survey findings:

- 27% offered no service or an age-restricted service to pregnant women.
- Of those offering a service:
  - ◆ 15% offered NT screening service only
  - ◆ 72% offered a serum screening service only
  - ◆ 13% offered a combination of NT and serum screening.
- Of those offering NT:
  - ◆ 91% performed an annual audit of sonographers
  - ◆ 76% followed up the outcome of high-risk pregnancies
  - ◆ 54% provided a detection rate

- ◆ 63% provided a false positive rate.
- ◆ 13% did not perform a dating scan prior to serum screening.

A further survey is presently being undertaken throughout England to assess service capacity and delivery. It is in relation to the ultrasound screening service offered for all pregnant women. The survey is extensive and has been performed to assist future work on the fetal anomaly programme for England, which will commence during 2003. A report from this can be expected in the summer.

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### 4. New research: first- and second-trimester antenatal screening for Down syndrome

The results of a large collaborative serum, urine and ultrasound screening study (SURUSS) have now been published. The study was funded as part of the UK Health Technology Assessment (HTA) Programme and has provided some interesting additional research evidence which, when taken with the current literature, will help guide the development of best practice for antenatal screening for Down syndrome.

This prospective study looked at women who booked for their antenatal care at about 8-14 weeks of gestation, with follow-up to identify pregnancies with Down syndrome ascertained through second trimester screening or at birth. Twenty-five maternity units (24 in the UK and one in Austria) participated and the results are based on 47 053 singleton pregnancies, including 101 pregnancies with Down syndrome.

The results show that screening performance in the first trimester of pregnancy was virtually the same as that in the second trimester and in either it was much less effective than integrating screening measurements from both trimesters into a single test. Applying these results to screening practice, it was concluded that the following tests offer the most effective and safe method of screening:

- **Overall:** integrated test
- **If NT is not available:** serum integrated test

- For women who do not attend for antenatal care until the second trimester of pregnancy: quadruple test
- For women who choose to have a screening test in the first trimester: combined test.

<b>Combined test</b>	First trimester test based on combining NT measurement with free $\beta$ -human chorionic gonadotrophin ( $\beta$ -hCG), pregnancy-associated plasma protein A (PAPP-A) and maternal age.
<b>Integrated test</b>	The integration of measurements performed during the first and second trimester of pregnancy into a single test result (integrated test is qualified as integration of NT and PAPP-A measurements in the first trimester with the quadruple test markers in the second).
<b>Quadruple test</b>	Second-trimester test based on the measurement of $\alpha$ -fetoprotein, unconjugated oestriol, free $\beta$ -hCG (or total hCG) and inhibin-A, together with maternal age.
<b>Serum integrated test</b>	A variant of the integrated test using serum markers only (PAPP-A in the first trimester and the quadruple test markers in the second trimester).

At a constant detection rate, the cost-effectiveness of these four tests is broadly similar, any extra screening costs tending to be offset by fewer diagnostic costs. The evidence presented in this report indicates that the double test, the triple test or NT measurements on their own (with or without maternal age) would lead to many more women having invasive diagnostic tests without increasing the proportion of Down syndrome pregnancies detected. While the study suggests the superiority of the integrated approach it is important to remember that it says nothing about patient acceptability or the challenges of implementation.

The full report is available on the NCCHTA website: Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Mackinson AM. First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS). *Health Technol Ass* 2003;7(11). [[www.ncchta.org/ProjectData/3\\_project\\_record\\_published.asp?PjtId=907](http://www.ncchta.org/ProjectData/3_project_record_published.asp?PjtId=907)].

## 5. Future policy

Based on the above SURUSS report and other evidence, the National Screening Committee has prepared a paper on policy options and this is available on its website: [www/nelh.nhs.uk/screening](http://www/nelh.nhs.uk/screening).