Summary of key recommendations

NHS Quality Improvement Scotland recommends that all pregnant women in Scotland should be offered both a first and a second trimester ultrasound scan.

- **Patient information** - Appropriate written patient information should be available, with time for the pregnant woman to consider and discuss this information with a health professional prior to attending for an ultrasound examination. This information should include details of the conditions which may and may not be detected by ultrasound and the rate of detection of these conditions, together with the risks associated with follow-up procedures.

- **Consent** - Ultrasound scanning is part of a programme of antenatal screening. Women who decide to participate in all or part of the screening programme should provide written informed consent.

- **First trimester scan** - The first trimester scan should be offered between 10 and 13 completed weeks' gestation for confirmation of fetal viability, assessment of gestational age and determination of multiple pregnancy.

- **Screening for chromosomal abnormalities** - The results of nuchal translucency measurement during the first trimester scan and maternal serum screening should be combined with gestational age at the time of scanning and maternal age to generate an assessment of the risk of chromosomal abnormalities.

- **Late presentation** - Women who present after 13 completed weeks' gestation should be offered an ultrasound scan for assessment of gestational age at the time of presentation and second trimester serum screening for chromosomal abnormalities.

- **Second trimester scan** - The second trimester anomaly screening scan is to exclude or detect where possible identifiable common fetal abnormalities and should be performed between 18 and 22 weeks' gestation, targeted for 20 weeks' gestation. This scan should not include the detection of soft markers to assess risk of chromosomal abnormalities.

- **Service requirements** - The recommended programme of scanning and screening should be performed by formally trained staff with suitable scanning equipment. There should be consistent record keeping in maternity services to facilitate internal and external quality assurance and audit.
1 Introduction

1.1 This Advice from NHS Quality Improvement Scotland is the outcome of a Health Technology Assessment (HTA) of the clinical and cost effectiveness of routine ultrasound scanning before 24 weeks of pregnancy. The Assessment sought to determine the optimal programme of ultrasound scanning and associated tests for fetal abnormality, which should be offered to pregnant women in Scotland. The HTA considered the needs and preferences of pregnant women.

1.2 Ultrasound scanning is currently offered to all pregnant women in Scotland, however there is variation in the number, timing and content of routine scans. The HTA evaluated strategies comprising first trimester scanning only, second trimester scanning only and first trimester plus second trimester scanning. These strategies were considered with and without additional maternal serum screening. Only abnormalities for which there were good data regarding detection were considered in the HTA. The HTA did not consider the additional use of ultrasound beyond 24 weeks' gestation or non-routine use.

1.3 This Advice is based on critical appraisal and analysis of evidence published in scientific literature and submitted by experts, professional groups, patient interest groups, manufacturers and other interested parties. The assessment process, evidence base, methodology, results and recommendations are described in detail in Health Technology Assessment Report 5: Routine ultrasound scanning before 24 weeks of pregnancy. To help users of this Advice locate additional information provided in the report, relevant sections are referenced in the margins of this document. The words which are in dark blue are defined in the Glossary.

1.4 The Advice represents the evidence-based views of NHS Quality Improvement Scotland. Health professionals in NHSScotland should take account of this NHS Quality Improvement Scotland Advice and ensure that the recommended actions are implemented to meet clinical need. However, this Advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patient, in consultation with the pregnant woman and her family.
2 Advice

2.1 Recommended programme of routine ultrasound scanning before 24 weeks of pregnancy

2.1.1 A first trimester ultrasound scan should be offered to women between 10 and 13 completed weeks' gestation for confirmation of fetal viability, assessment of gestational age and determination of multiple pregnancy.

2.1.2 A screening test for chromosomal abnormalities should be available between 10 and 13 completed weeks' gestation. The test should comprise ultrasound measurement of nuchal translucency during the first trimester scan (see 2.1.1) and measurement of two maternal serum markers (PAPP-A and free ß-hCG). Women who present after 13 completed weeks' gestation should be offered an ultrasound scan for assessment of gestational age at the time of presentation and second trimester serum screening (alpha-fetoprotein and hCG) for chromosomal abnormalities.

2.1.3 Risk assessment following nuchal translucency measurement should always be determined in combination with the results of first trimester serum screening, gestational age of the fetus at the time of scanning and maternal age. Parameters used to estimate the risk of a pregnancy being affected with trisomy 21 should be appropriate to the gestational age of the fetus at the time of screening.

2.1.4 An anomaly screening scan should be offered to women in the second trimester, between 18 and 22 weeks' gestation, targeted for 20 weeks' gestation.

2.1.5 Second trimester anomaly scanning should not routinely include the detection of soft markers to assess risk of chromosomal abnormality. However, in women considering an invasive test on the basis of age, or other risk factors, the absence of soft markers may lower the estimated risk and assist decision making.

2.1.6 Ultrasound scanning should be offered to women for the purposes of screening or clinical investigation and not primarily for any other indication e.g. to provide a visual record of the pregnancy.

2.1.7 Routine scanning should be transabdominal in the first instance. However, transvaginal scanning will sometimes be necessary and all services in Scotland providing routine scanning should be able to perform transvaginal scanning when required.
2.1.8 No specific assessment for cardiac abnormalities, over and above the routine second trimester anomaly scan, is warranted following an increased nuchal translucency measurement in a fetus with a normal karyotype.

2.2 Service requirements

2.2.1 All ultrasound measurements taken during a first or second trimester scan (e.g. crown rump length, biparietal diameter, nuchal translucency) should be subject to quality control.

2.2.2 A national working group should be established to determine the specification for ultrasound equipment, to ensure fitness for purpose for the requirements of both first and second trimester ultrasound scanning. Issues surrounding the safety, quality assurance, repair and maintenance of ultrasound equipment should also be addressed by this group.

2.2.3 Staff undertaking routine ultrasound scanning must have appropriate training and continuing professional development to ensure effective practice. Training should cover undertaking and interpreting scans, providing information and counselling to women, the need for written informed consent, ensuring consistent record keeping and participating in internal/external quality assurance and audit.

2.2.4 Routine ultrasound scanning should be audited locally against national standards. In addition, all units should audit fetal loss rates following invasive diagnostic procedures.

2.2.5 Data regarding prenatal identification of conditions and subsequent outcomes should be recorded and validated in order to evaluate the effectiveness of screening and scanning programmes. This should be facilitated by developments in electronic storage of maternity, birth and child surveillance records.

2.2.6 The safety of ultrasound use should be continuously monitored by units and the British Medical Ultrasound Society guidelines for the safe use of diagnostic ultrasound equipment should be adhered to at all times.

2.3 Development of protocols

The National Services Division's (NSD) national pregnancy screening programme specifications should be extended to cover all aspects of ultrasound scanning including gestational age assessment and second trimester anomaly scanning.
2.4 Information needs

2.4.1 All pregnant women should be informed that none of the components of the recommended programme of routine ultrasound scanning are mandatory and they can elect to participate in all, part or none of the programme.

2.4.2 Appropriate written patient information should be available, with time for the pregnant woman to consider and discuss this information with a health professional, prior to attending for ultrasound examination. This information should include details of conditions which may and may not be detected by ultrasound and the rate of detection of these conditions, together with the risks associated with follow-up procedures.

2.4.3 Informed written consent should be received from all women prior to screening procedures in accordance with current national guidelines from the Scottish Executive Health Department on antenatal screening.

2.5 Further research

Ethically approved research studies should be undertaken in Scotland to:

- establish the effectiveness of nuchal translucency measurement for detecting structural abnormalities in fetuses with a normal karyotype
- evaluate whether soft markers and other markers which may be associated with aneuploidy can be used in combination with results of other screening tests to assess the risk of chromosomal abnormalities
- determine the most appropriate content and format of information on risks and benefits of scans and the most effective process for giving this to pregnant women.

These studies should be designed to estimate the overall impact of such investigations during routine screening programmes.
3 Budget impact

3.1 The total budget required to upgrade the service in order to implement the HTA recommendations would be £5.4 million. This cost would be spread over the duration of the implementation period and includes £1.1 million for additional staff, £314 000 for training, £3.5 million for equipment, £70 000 for accommodation and £394 000 for national audit. An estimate of the cost of providing patient information leaflets has not been included as this is required regardless of this HTA.

3.2 The estimated cost of the current antenatal scanning service is £6.3 million *per annum*. Following implementation of the HTA recommendations, these annual costs are estimated to increase to a total of £9.6 million *per annum*, a 52% increase.

4 Summary of clinical and cost effectiveness

4.1 It is well established that ultrasound scanning can confirm fetal viability and allows earlier detection of multiple pregnancies. Furthermore, measurement of crown rump length and biparietal diameter during ultrasound enables a more accurate assessment of gestational age than does the date of a woman's last menstrual period. This accuracy is important for interpretation of screening tests. *(Supports Recommendation 2.1.1)*

4.2 Observational studies have demonstrated that ultrasound measurement of nuchal translucency together with measurement of serum markers (PAPP-A and free β-hCG) and maternal age detects more than 80% of fetuses with trisomy 21 at a 5% false-positive rate. Performance is superior to that of the individual markers or nuchal translucency measurement alone. *(Supports Recommendations 2.1.2 and 2.1.3)*

4.3 Nuchal translucency increases with gestational age in both affected and unaffected fetuses and it is important that gestational age specific parameters are used for first trimester screening that involves nuchal translucency measurement. *(Supports Recommendation 2.1.3)*

4.4 A discrete event simulation model, constructed to estimate the costs and benefits of different strategies, showed that all strategies involving a scan in the first trimester and an anomaly scan in the second trimester are more expensive than single-scan strategies. However, an anomaly scan in the second trimester maximises the identification of fetal abnormalities and therefore lowers the cost per anomaly detected. *(Supports Recommendation 2.1.4)*
4.5 The preliminary model demonstrated that the number of anomalies detected when a second trimester anomaly scan is carried out following first trimester screening is marginally greater when soft marker detection is included compared with anomaly scanning without soft marker detection. However, this small increase in anomaly detection rate is associated with a sizeable increase in procedure-related losses; there were 4.5 times more procedural losses incurred as a result of amniocentesis than there were trisomies detected at this scan.

In addition, the exclusion of soft marker assessment reduces costs due to the reduction in the number of false-positive follow-up ultrasound scans and of false-positive invasive tests for trisomy 21 and 18. (Supports Recommendation 2.15)

4.6 The British Medical Ultrasound Society has issued guidelines to keep the risks of ultrasound scanning in pregnancy to a minimum. (Supports Recommendation 2.16)

4.7 Nuchal translucency measurement and second trimester anomaly scanning are generally achievable using transabdominal scanning. In many studies, scanning was performed transvaginally when a satisfactory image could not be obtained transabdominally. (Supports Recommendation 2.17)

4.8 Reported rates of first trimester detection of cardiac defects in chromosomally normal fetuses identified using raised nuchal translucency measurement are not consistent between studies. If a 50% detection rate is assumed at a 5% false-positive rate, a sensitivity analysis showed that for a population of 50 000 pregnancies, 1360 investigations would be avoided if further examination for cardiac defects is not performed following an increased nuchal translucency measurement. This is at the expense of approximately two missed cardiac defects. (Supports Recommendation 2.18)

4.9 There was variation in reported sensitivities, prevalence rates and cut-off values used in studies to assess nuchal translucency screening for cardiac defects. (Supports Recommendation 2.5)
5 Implications

5.1 NHS Boards should ensure that all pregnant women in Scotland are offered both a first and second trimester ultrasound scan according to the recommendations in Section 2.1 of this Advice. NHS Boards should work together to develop Action Plans, in conjunction with NSD, to facilitate this.

5.2 Maternity units performing second trimester anomaly scanning should review their current practices to take into account the guidance given in Sections 2.1.4 and 2.1.5 of this Advice.

5.3 The introduction of a first trimester nuchal translucency scan and provision of second trimester anomaly scanning for all pregnant women who wish this will necessitate longer scanning appointments and additional training for staff.

5.4 NSD should facilitate discussion among NHS Boards to decide on guidance and systems for:

- the optimal timing and method of providing appropriate written information to pregnant women
- the process by which women who decide to participate in all or part of the programme of routine ultrasound scanning give informed consent
- increasing the capacity of services (e.g., extended hours and new facilities or equipment).
6 Review

NHS Quality Improvement Scotland will measure the impact of the HTA by updating the data collected from questionnaires completed by maternity units for this HTA in three years' time.

As NHS Quality Improvement Scotland chooses broad topics for HTAs, it is likely that new evidence will emerge which bears on the specific recommendations on an ongoing basis. Rather than having a fixed review period, NHS Quality Improvement Scotland will determine the importance of new evidence and produce report addenda in which the evidence is analysed and any alteration to the recommendations is explained. If a major change is required, the *Health Technology Assessment Report, Advice and Understanding our Advice* will be rewritten.

7 Further information

- *Health Technology Assessment Report 5 Routine ultrasound scanning before 24 weeks of pregnancy*

- *Understanding our Advice Routine ultrasound scanning before 24 weeks of pregnancy*

- In parallel with this Advice and HTA, NHS Quality Improvement Scotland is drafting Standards for Pregnancy and Newborn Screening.

- All NHS Quality Improvement Scotland documents are available in a variety of formats on request and from the NHS Quality Improvement Scotland website, [www.nhshhealthquality.org](http://www.nhshhealthquality.org)
### Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneuploidy</td>
<td>Any deviation from the normal number of chromosomes, whether fewer (hypoploidy, as in Turner’s syndrome characterised by the absence of an X chromosome) or more (hyperploidy, as in trisomy 21 where there are three copies of chromosome 21).</td>
</tr>
<tr>
<td>Completed weeks</td>
<td>10 to 13 completed weeks’ gestation includes the time span from 10 weeks’ gestation + 0 days to 13 weeks’ gestation + 6 days.</td>
</tr>
<tr>
<td>Gestation</td>
<td>The period of time, from fertilisation until birth, during which a fetus develops in the womb.</td>
</tr>
<tr>
<td>Iatrogenic</td>
<td>Resulting from the procedure.</td>
</tr>
<tr>
<td>Karyotype</td>
<td>The complete set of chromosomes of the fetus.</td>
</tr>
<tr>
<td>Nuchal translucency</td>
<td>Ultrasound can demonstrate the space between the skin and bone in the fetal neck. In the first trimester of pregnancy this can be measured and used to assess risk of chromosomal abnormality in association with biochemical tests. Increased nuchal translucency may be indicative of fetal problems that are not due to underlying chromosomal abnormalities.</td>
</tr>
<tr>
<td>Sensitivity analysis</td>
<td>An exploration of the impact upon results of changing parameter values within a model.</td>
</tr>
<tr>
<td>Soft markers</td>
<td>Anomalous ultrasound findings which only sometimes accompany diseases which are not directly observable on ultrasound. Examples include: choroid plexus cyst; ventriculomegaly; echogenic bowel; unusual head shape; nuchal pad; cisterna magna; cleft lip; echogenic foci in heart; dilated renal pelvis; short femur/humerus; talipes; sandal gap; clinodactyly; clenched hand; two vessel cord (Royal College of Obstetricians and Gynaecologists. 2000. <em>Routine ultrasound screening in pregnancy: protocol, standards and training</em> London: RCOG Press.).</td>
</tr>
<tr>
<td>Trimester</td>
<td>The nine months of pregnancy is traditionally divided into three trimesters; distinct periods of roughly three months in which different phases of development take place.</td>
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NHS Quality Improvement Scotland

NHS Quality Improvement Scotland was set up to improve the quality of health care in Scotland. Its role is to set standards and monitor performance and provide NHSScotland with advice, guidance and support on effective clinical practice and service improvements.
This document can be viewed on the NHS Quality Improvement Scotland website. It is also available, on request, from NHS Quality Improvement Scotland in the following formats:

- Electronic
- Audio cassette
- Large print

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