

ANTENATAL CARE (UPDATE) – draft consultation 4 September – 29 October 2007

Sta tus	Organisation	Orde r no.	Version	Section no.	Page / line no.	Comments	Developer's Response
SH	Academic Division of Midwifery, University of Nottingham					This organisation was approached but did not respond.	
SH	Action on Pre-Eclampsia					This organisation was approached but did not respond.	
SH	Addenbrooke's NHS Trust					This organisation was approached but did not respond.	
SH	Adverse Psychiatric Reactions Information Link (APRIL)					This organisation was approached but did not respond.	
SH	All Wales Birth Centre Group					This organisation was approached but did not respond.	
SH	Antenatal Screening Wales	1	NICE	Genera l		Thank you for inviting us to comment on this very thorough and comprehensive document. We were pleased to note the depth of your consideration of antenatal screening within the guideline.	Thank you.
SH	Antenatal Screening Wales	2	NICE	Genera l		Although in general terms we agree with the recommendations and are pleased that they confirm the policies and protocols of Antenatal Screening Wales, we do have some comments on the recommendations in section 9. These relate directly to the Antenatal Screening programme provided in Wales which we co-ordinate.	Thank you.
SH	Antenatal Screening Wales	3	NICE		Page 31 Line 42	This recommendation is welcomed but as the recommendation is not necessarily welcomed by the maternity services who may not wish to change their current practice of using the LMP date to calculate gestation, it may be helpful if this recommendation was more strongly worded.	Thank you. The GDG felt it was not necessary to alter the wording of this recommendation.
SH	Antenatal Screening Wales	4	NICE		Page 32 Line 22	The concept of women being given information about screening tests on one visit and the opportunity to consider the verbal and written information before accepting testing is welcomed.	Thank you very much.

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SH	Antenatal Screening Wales	5	NICE		Page 32 Line 42	The recommendation that communicable disease screening should be undertaken by 16 weeks of pregnancy would mean that the screening test was undertaken too late to prevent congenital syphilis. In Wales the current standard is that all communicable disease screening should take place before 13 weeks of pregnancy if possible.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Antenatal Screening Wales	6	NICE		Page 39 Line 15-23	<p>Wales has developed and implemented an Antenatal Screening Question for Sickle cell and Thalassaemia which was implemented in 2004.</p> <p>A discussion with Stakeholders has concluded that there may be some benefit in using the approach recommended by the English NHS Antenatal and Newborn Screening Programme.</p> <p>It would be helpful if the recommendation was therefore modified to state in line 16 '..... based on the Family Origins Questionnaire' as some modification for the Welsh context and Welsh language may be required.</p>	Thank you for your comment. The Family Origin Questionnaire as developed by the NHS Antenatal and Newborn Screening Programme has been validated for use hence we prefer to include this in the recommendation. However, any close translation of this questionnaire would of course be equally suitable.
SH	Antenatal Screening Wales	7	NICE		page 151 Line 14	<p>This might read better as "Following the confirmation of an anomaly"</p> <p>In Wales women are also provided with written information following normal early and fetal anomaly scans explaining the findings and limitations of ultrasound scanning.</p>	Thank you. This is now amended.
SH	Antenatal Screening Wales	8	NICE		Page 151 Line 19	This recommendation is welcomed. Antenatal Screening Wales is currently undertaking a training needs analysis of sonographers in every Trust regarding the identification of four chambers and outflow tracks and considering a specific training programme.	Thank you.

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SH	Antenatal Screening Wales	9	NICE		page 204 Line 17 -19	<p>We would question why the offer of Serum Screening for Down's syndrome is extended to 20 weeks of pregnancy, as the sensitivity of the test is known to diminish as the pregnancy progresses and as there are now few samples taken at this gestation and therefore difficulties in establishing appropriate medians.</p> <p>It would therefore be preferable to state " as early as is possible after 15 weeks and up to 18 weeks of pregnancy"</p>	Thank you. Most large data bases will hold reasonable numbers up to 20 weeks. It is a shame to exclude women who book late from Down's screening so long as they appear by 20 weeks.
SH	Antenatal Screening Wales	10	NICE		Page 204 Line 42	<p>We would wish to question the evidence and rational for your recommendation that all women with two or more soft markers should be offered referral to a Fetal Medicine Department. The purpose of the referral is not indicated.</p> <p>As there is no UK consensus by Fetal Medicine Consultants on the significance of the majority of soft markers, this recommendation would lead to an increased number of referrals, cost and variation of advice across the UK with no stated objectives or method of measuring outcomes. We would strongly ask you to reconsider this recommendation which appears to be based on opinion and not evidence.</p> <p>A service review in Wales in 2001 indicated that reporting the presence of soft markers to women often causes women considerable concern. The reporting of ultrasound markers caused of difficulty for a number of maternity services. Explaining the significance of soft markers to women was reported as being very time consuming.</p> <p>Consequently Wales reports only specific</p>	The GDG felt that the presence of 2 or more markers was sufficiently significant to warrant referral to a fetal medicine specialist or doctor with a special interest in fetal medicine.

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						isolated markers and does not report to women or refer women to Fetal Medicine Departments if two soft markers are found as there was not felt to be significant evidence to offer the woman an invasive test. We have recently reviewed the evidence for maintaining this position and concluded that reporting soft markers would cause more harm than good because of fetal loss from an increased number of invasive procedures and increased maternal anxiety. Wales has prepared a research proposal to undertake a population based study on the significance of defined soft markers and is currently waiting for information on whether the bid for funding has been successful.	
SH	Association for Improvements in the Maternity Services					This organisation was approached but did not respond.	
SH	Association for Psychoanalytic Psychotherapy in the NHS (APP)					This organisation was approached but did not respond.	
SH	Association for Spina Bifida & Hydrocephalus (ASBAH)					This organisation was approached but did not respond.	
SH	Association of Breastfeeding Mothers					This organisation was approached but did not respond.	
SH	Association of British Clinical Diabetologists					This organisation was approached but did not respond.	
SH	Association of Medical Microbiologists					This organisation was approached but did not respond.	
SH	Association of Psychoanalytic Psychotherapy in the NHS					This organisation was approached but did not respond.	
SH	Association of the British Pharmaceuticals Industry,(ABPI)					This organisation was approached but did not respond.	
SH	Baby Lifeline					This organisation was approached but did not respond.	
SH	Barnsley Hospital NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Barnsley PCT					This organisation was approached but did not respond.	

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SH	BDF Newlife (Birth Defects Foundation)					This organisation was approached but did not respond.	
SH	Bedfont Scientific Ltd					This organisation was approached but did not respond.	
SH	Bedfordshire PCT					This organisation was approached but did not respond.	
SH	Berkshire Healthcare NHS Trust					This organisation was approached but did not respond.	
SH	Birmingham Women's Healthcare NHS Trust					This organisation was approached but did not respond.	
SH	Birth Trauma Association					This organisation was approached but did not respond.	
SH	BMFMS					This organisation was approached but did not respond.	
SH	Bournemouth & Poole PCT					This organisation was approached but did not respond.	
SH	Bradford & Airedale PCT					This organisation was approached but did not respond.	
SH	Bradford Teaching Hospitals NHS Foundation trust					This organisation was approached but did not respond.	
SH	Brighton & Sussex University Hospitals Trust					This organisation was approached but did not respond.	
SH	Bristol Health Services Plan					This organisation was approached but did not respond.	
SH	British Association for Counselling and Psychotherapy		Full	General		The definition used for counselling appears to be used broadly in a generic and relational sense throughout the new/amended sections of the guidelines. It is important that a definition is included for counselling in the glossary. BACP use the terms counselling and psychotherapy interchangeably and would be happy to advise on a definition for use within the guidelines.	Thank you very much for your help with this. The definition you provided is now included in the glossary of the guideline.
SH	British Dietetic Association					This organisation was approached but did not respond.	
SH	British Dietetic Association	1	NICE	1.1		The inclusion of this section makes it clearer what should be covered and the inclusion of	Thank you very much

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						forms of communication to make it accessible to all (1.1.1.2) is excellent.	
SH	British Dietetic Association	2	NICE	1.3.2.5		We welcome this additional guidance regarding Vitamin D. It should be noted that in most inner city areas this will mean routine supplementation to all pregnant women is needed due to the population types.	Thank you.
SH	British Dietetic Association	3	NICE	1.3.9.1		We welcome a revision regarding alcohol, however there will be a confusion of messages to women as this does differ from the Department of Health advice.	Thank you. Following stakeholder consultation the recommendation has now been amended slightly so as to remain in line with the evidence but with the "safe" level of alcohol intake expressed in terms similar to that used by the DoH so as to avoid causing confusion.
SH	British Dietetic Association	4	NICE	1.4.3.1		Should not read about fibre supplements as bran or wheat. It would be better to put increase fibre in the diet by using higher fibre products – breads and cereals and including more fruit and vegetables.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	British HIV Association (BHIVA)	1		1.7.2		There should be a recommendation that CVS or amniocentesis is not undertaken without checking that an HIV test has been done, and is negative. If it is positive these procedures are associated with increased risk to the baby which can be reduced by the administration of antiretrovirals	The updated version of the guideline does not include any recommendations to undertake CVS or amniocentesis therefore it is not appropriate to add this recommendation regarding HIV testing.
SH	British HIV Association (BHIVA)	2		1.8.7.1		Midwives/obstetricians seeing the woman should check that antenatal screening tests for infection have been done and that they are aware of the result. If the HIV test has not been done this should be revisited. Similarly, the result should be checked in any woman coming in in labour. Rapid tests can be performed if it has not been done, and much can still be done to prevent transmission to the baby.	Thank you for your comment, however HIV testing was outside the scope of this current guideline update.
SH	British Hypertension Society					This organisation was approached but did not respond.	

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SH	British Isles Network of Congenital Anomaly Registers	1	NICE	1.7.1.5		BINOCAR strongly supports the recommendation for participation in regional congenital anomaly registers, which is in line with those of the Chief Medical Officer [CMO Annual Report 2004].	Thank you.
SH	British Isles Network of Congenital Anomaly Registers	2	NICE	1.7.1.2		BINOCAR suggest changing the order of the list to reflect the frequency of each purpose i.e. intrauterine therapy to be at the bottom of the list.	Thank you, this has now been amended.
SH	British Maternal and Fetal Medicine Society	1	Full	General		Overall an excellent revision concentrating on key areas	Thank you.
SH	British Maternal and Fetal Medicine Society	2	Full	General		Separating the description of studies and their results and referring back to the former as e.g. 'The Australian study' or 'In the sixth study' is difficult to follow and a format that is not consistent. It would be better if study details and findings were presented together e.g. as in 11.1 Risk Factors.	Thank you. The reason study descriptions and findings are presented separately is to enable findings from a number of studies to be grouped together – thus aiding assimilation. However, it is recognised that this may not be the method of presenting preferred by all reader.
SH	British Maternal and Fetal Medicine Society	3	Full	General		Use of the term IUGR should be abandoned in favour of FGR	Thank you. We have amended the text accordingly.
SH	British Maternal and Fetal Medicine Society	4	Full	2.2		P32 L37 To be consistent with NSC recommendations the ultrasound scan should be at 18-20 weeks	Thank you. Amended.
SH	British Maternal and Fetal Medicine Society	5	Full	4.6		It would be very helpful for NICE to recommend the optimal charts (references) to use for dating using CRL or HC. Based on the available evidence dating after 14 wk using HC is preferable to BPD.	Thank you. We did not compare different charts so it would not be appropriate to make this recommendation.
SH	British Maternal and Fetal Medicine Society	6	Full	4.6		P88 L43-6 – Helpful to avoid terms like first trimester – suggest state weeks of pregnancy then there is no confusion.	Thank you. The GDG felt it was still appropriate to use "trimester" on occasion as they felt there was still a very strong understanding amongst clinicians over the use of this term.
SH	British Maternal and Fetal Medicine Society	7	Full	5.5		P97 L9 – it is not clear from the review how such a clear recommendation about women aged 19-24 years is reached.	Thank you. This figure was taken from the National Diet and Nutrition Survey (2003). However, following further discussion post consultation, the GDG felt the other risk factors were more pertinent and would capture the vast

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							majority of women at risk of vitamin D deficiency and so this category has now been removed from the recommendation.
SH	British Maternal and Fetal Medicine Society	8	Full	8.2		P129 Health economics – the cost-effectiveness of screening for haemoglobinopathies particularly as the cost per affected birth prevented in low risk areas is controversial – this is such an important topic it would be useful to see this data presented rather than just an unreferenced statement that 'screening would be cost effective'.	Given resource constraints it is not possible to undertake de novo economic modelling for all clinical questions. The evidence statement is based on the data presented in the review of four studies, immediately above the evidence statement.
SH	British Maternal and Fetal Medicine Society	9	Full	9.2		Presentation of ST values – need to be consistent – in some tables presented as % e.g. 89% others as decimals e.g. 0.26 (for e.g. see p186)	Thank you. This has been amended to ensure consistency.
SH	British Maternal and Fetal Medicine Society	10	Full	9.2		P199 L29 – e) Other findings that emerged – this appears to be an error	Thank you. The line has been deleted.
SH	British Maternal and Fetal Medicine Society	11	Full	9.2		Research recommendation – seems very unlikely that units will be able to study the IT when a) it is not recommended and b) women prefer early screening. Surely studies of first trimester contingency screening would be far more useful.	Thank you. We have amended the research recommendation taking this into consideration.
SH	British Maternal and Fetal Medicine Society	12	Full	11.1		All blood glucose levels should be in mmol/L not mg/dL	Thank you, these figures have now been converted.
SH	British Maternal and Fetal Medicine Society	13	Full	11.1		Interpretation of evidence – it would be useful to indicate the likely proportion of women who would need screening using the proposed risk factors	This would depend on type of population but would probably range from 10 to 20%. This information has been added as you suggest.

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SH	British Maternal and Fetal Medicine Society	14	Full	11.2		Uterine artery Doppler – it is unclear why the review has just focused on notching when much of the recent literature focuses on mean PI – as a result a lot of recent literature not been reviewed.	Thank you for your comment. There was a large volume of literature to review in this section so the GDG prioritised in terms of what was thought to be most useful clinically in current practice. We recognise this has meant some developing areas have not been reviewed but this was simply not possible to achieve within the time and resources available.
SH	British Maternal and Fetal Medicine Society	15	Full	11.2		Quoting predictive statistics as Se/Sp/PPV & NPV (e.g. p249 L8-16) is less useful than Likelihood ratios – this should be the standard format	Thank you for your comment. Whilst we recognise this to be the case it is not always possible to calculate these values from the data given in the research papers.
SH	British Maternal and Fetal Medicine Society	16	Full	11.2		The review has omitted to consider first trimester serum markers notably PAPP-A, as predictors of PET – indeed all biochemical markers used in DS screening have been shown to have some predictive value – the future lies in multimarker screening (as is now established for DS) as these tests are being done anyway.	Thank you for your comment. There was a large volume of literature to review in this section so the GDG prioritised possible predictive tests in terms of what was thought to be most useful clinically in current practice. We recognise this has meant some developing areas have not been reviewed but this was simply not possible to achieve within the time and resources available.
SH	British Maternal and Fetal Medicine Society	17	Full	11.2		Research Recommendation – a greater emphasis should be placed on the negative predictive value of screening for placental problems (PE, FGR, abruption, IUD) and the impact on ANC – a primip with negative uterine artery Doppler screening has a risk of placental problems lower than a multip and consideration should be given to trials of reducing ANC visits in such women.	Thank you. This research recommendation has been extended and now includes what the GDG believe to be the main points for the focus of research.
SH	British Maternal and Fetal Medicine Society	18	Full	12.12		Consideration should be given to include the Lindqvist & Molin study (Ultrasound Obstet Gynecol 2005; 25: 258-64 showing that with routine biometry and then Doppler surveillance the outcome for detected SGA fetuses was the	Thank you for your comment but we disagree. The relevant study is a retrospective study and had shown that there was a higher risk of adverse outcomes for

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						same as AGA fetuses and considerably better than undetected SGA fetuses.	the SGA babies not identified before delivery compared to those identified. The results do not imply improved outcomes with the use of routine biometry and Doppler.
SH	British Maternal and Fetal Medicine Society	19	Full	12.15		P342 –The data in the table lack confidence intervals to aid interpretation	Thank you. These were omitted in error and have now been added.
SH	British Maternal and Fetal Medicine Society	20	Full	12.16		Research recommendations – simply investigating detection of SGA is a fruitless exercise the key for future research is to demonstrate that use of late ultrasound improves outcome by detecting SGA and use of appropriate monitoring (ie UA Doppler).	Thank you. The research recommendation has now been amended and includes the investigation of late ultrasound.
SH	British Maternal and Fetal Medicine Society	21	Full	12.16		L43-5 SFH does not increase linearly with gestational age – there is a decline in the slope after 36 wk – hence a fixed 3 cm cut-off below the GA (in weeks) will miss more potentially SGA fetuses at term than preterm.	Thank you. Following stakeholder consultation this recommendation has been removed.
SH	British Maternal and Fetal Medicine Society	22	Full	14		P11 L17 Coagulation not dissemination P11 L28 Poor fetal growth – without a definition this is unhelpful P11 L34 Not clear what is 'Proven CPD' – do you mean CS for failure to progress P12 L39 Medications – is this specific to therapies for medical problems or all medications	Sorry, I cannot find the abbreviations you are referring to here on page 11 of the full version.
SH	British National Formulary (BNF)					This organisation was approached but did not respond.	
SH	British Psychological Society, The					This organisation was approached but did not respond.	
SH	Calderdale PCT					This organisation was approached but did not respond.	
SH	Chartered Society of Physiotherapy (CSP)					This organisation was approached but did not respond.	
SH	Chelsea & Westminster Acute Trust					This organisation was approached but did not respond.	

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SH	CIS'ters					This organisation was approached but did not respond.	
SH	CO-Awareness	1				My main concern is that pregnant mums are not tested for carbon monoxide during pregnancy. As you know carbon monoxide poison is a real health risk to both the pregnant mother and the unborn baby.	Thank you for your comment, and your care and concern for this condition is acknowledged, however carbon monoxide poisoning was outside the scope of this current guideline update.
SH	Cochrane Pregnancy & Childbirth Group					This organisation was approached but did not respond.	
SH	Commission for Social Care Inspection					This organisation was approached but did not respond.	
SH	Community Practitioners and Health Visitors Association					This organisation was approached but did not respond.	
SH	Connecting for Health					This organisation was approached but did not respond.	
SH	Conwy and Denbighshire NHS Trust					This organisation was approached but did not respond.	
SH	Cotswold and Vale PCT					This organisation was approached but did not respond.	
SH	Croydon PCT					This organisation was approached but did not respond.	
SH	Cytoc UK Limited	1	FULL	11.3	Pg 260 Line 47	We commend the Committee for its rigorous research and analysis; however, we believe a broader interpretation of the impact of fetal fibronectin (fFN) testing for its intended use should be considered. While the conclusions may follow from the assumptions, the guidance as currently presented may be somewhat misleading. By only including "studies on asymptomatic women (with no signs and symptoms of preterm labour) the analysis omits the validated clinical and cost benefits of fFN testing – namely a negative predictive value of > 99% related to the patient with symptoms of pre-term labour. Therefore, physicians, hospital administrators and payors worldwide may cite these conclusions without analyzing the context of the guidance and not implement (or pay for) fFN for its actual intended use.	Thank you for your comment, however high risk and symptomatic women are outside the scope of this update.

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SH	Cytec UK Limited	2	FULL	11.3	Pg 261 Line 2-3	Based on the evidence that was included, the guidelines do not recommend routine screening of low risk women. However, considering the primary intended use for fFN is the assessment of SPTL, we believe it would be helpful for clinicians to recommend a course of action for high risk women and particularly symptomatic women? Would the committee review or consider over 120 peer reviewed articles on the value of fFN for high risk women and/or symptomatic women?	Thank you for your comment, however high risk and symptomatic women are outside the scope of this update.
SH	Cytec UK Limited	3	FULL	11.3	p. 261 Lines 13-15	<p>We believe the following comments need clarification: 'Although cervical shortening identified by TVS and increased levels of FFN are associated with an increased risk of preterm birth, the evidence does not indicate that this information improves outcomes';</p> <p>If "improved outcomes" is limited to an actual reduction in pre-term births, then based on current evidence this is accurate. However, fFN testing is intended to be used to assess pre-term labour and to determine the likelihood of pre-term birth in symptomatic patients.</p> <p>'therefore neither TVS nor FFN should be used to predict preterm birth in healthy pregnant women.'</p> <p>The evidence in broad and consistently shows that a negative fFN test in symptomatic pre-term women is an excellent predictor that the patient will not deliver in the next 7-14 days (NPV 99.5 – 99.2%) therefore offering significant cost saving related to unnecessary hospital admissions and treatment as well as reducing patient anxiety.</p> <p>'There is high quality evidence to show that a</p>	<p>Thank you for your comment. As you rightly point out in your second comment "improves outcomes" does indeed relate to reduction in pre-term birth.</p> <p>Symptomatic women are outside the scope of this update.</p>

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						<p>single second trimester cervico-vaginal swab with a positive result for fibronectin levels has moderate value in predicting SPTD < 37 weeks, but a negative result decreases the probability of SPTD only minimally.'</p> <p>Considering the primary intended use for fFN in the assessment of SPTL for high risk women and/or symptomatic women we recommend the following papers for review: Peaceman et al 1997 Di Renzo et al 2006 Abenhaim et al 2005 Groom et al 2006 Giles et al 2000 Honest et al 2005 (meta-analysis)</p>	
SH	Cytec UK Limited	4	FULL	11.3	Pg 269 Lines 7-9	<p>'Meta-analysis was performed for the predictive accuracy of a single test in second trimester with outcome SPTD < 37 wks.</p> <p>Again the intended use of fFN testing is either a single test for symptomatic pre-term patients. The test is also used serially in conjunction with other assessment tools such as TVU and cervical shortening to predict pre-term birth in high-risk patients.</p> <p>One good quality study was excluded from meta-analysis as it evaluated SPTD < 33 wks as the outcome. (Table III).'</p>	Thank you again, however symptomatic women are outside the scope of this guideline update.
SH	Department of Health	1	Full	1.0 Intro duction		Although the unmarked areas in the introduction are not being consulted upon we felt that some were significantly out of date	Thank you, we have now updated references to DoH websites and other publications mentioned in the introduction.
SH	Department of Health	2		1.1	Page 19 line 30	The DH's NSF for Children, Young People and Maternity was published in Sept 2004, we would be grateful if you could amend.	Thank you. This is now amended as you suggest.
SH	Department of Health	3		1.1	Page 19 line	Would you please consider referring to "Maternity Matters " (DH 2007) especially	Thank you. We have now included Maternity Matters.

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					37	relating to Choice, Access and Continuity	
SH	Department of Health	4		1.1	Page 19 line40	Would you please consider referring to "NPEU study – Recorded delivery: a National survey of women's experience of maternity care 2006".	Thank you. The NPEU study is now referenced.
SH	Department of Health	5		1.2 Page 20 line 15		We would be grateful if you could amend to read "have been addressed" by the NSF	Thank you. Amended.
SH	Department of Health	6		1.6 Page 24 line 12		Evidence base is up to June 2007, would you please consider amending.	This is included as the end date for the evidence base.
SH	Department of Health	7		Summary		No comment was entered in this line of the table	
SH	Department of Health	8	Full	2.1	Page 29 line 10	Is this precise enough? The idea is to screen as early as possible to allow time for prenatal diagnosis but there is a need for informed counselling prior to testing. Would it be better (clearer) to replace the wording with that on page 39 line 9 and 10 "Screening for sickle cell disorders and thalassaemias should be offered to all pregnant women (ideally by 10 weeks), and preceded by counselling"	Yes – this change has been made as you suggest.
SH	Department of Health	9		2.1	Page 29 line 15	We felt that this was confusing, firstly it states that screening should be by the "combined test" but then giving an alternative. Therefore we felt that perhaps the phraseology needs changing to "between 11 and 13+6 weeks the "combined test" should be offered. Women presenting between 15 and 20...". We believe there are still units unable to offer 12 week scanning and NT scanning and are concerned that there are considerable resource, training and workforce implications in this potential increase in ultrasound provision. See page 40 line 10	Thank you for your comment. The wording of this recommendation has been changed to aid clarity. Your concern about implications for training are noted but the GDG felt it was still appropriate to recommend a test that was both accurate, acceptable to women and achievable. We believe this recommendation achieves this balance.
SH	Department of Health	10		2.2	Page 29 line	In our opinion, the terminology used relating to "first contact" and booking could cause a	The Guideline Development Group particularly wanted information to be

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					36 Page 30 line 8	problem. In our view the first contact could be with a GP who would not necessarily give out the information suggested. We suggest that the booking process involves two contacts, one primarily to give and receive information and another to plan the care and enable choice decisions	given out at first contact (be that with a GP or a midwife) so that important information about screening and dietary advice could be given as early as possible in pregnancy (ideally before 10 weeks). To use the term booking implies the later contact after this initial referral which usually takes place at 12 weeks or later. The use of information books and/or leaflets is encouraged to enable GPs to be able to perform this role. It is not sufficient for GPs to merely refer the woman on for a formal booking without providing this crucial early information.
SH	Department of Health	11		2.2	Page 30 lines 2 and 47	In our opinion, there seems to be confusion about when booking takes place and what happens. The intention in Maternity Matters is for booking (which may not be first contact because of planning the contact so that there is sufficient time) to include the giving of information, gathering of information about the woman and the risk assessment so that with that knowledge- base (both for the HCP and the woman) there is time for decisions about care and screening to be fully informed and confirmed at the next visit.	The initial or first contact is made with a midwife or GP and at the moment involves little more than a referral on for booking. We recommend that this contact be used to provide vital information (particularly about screening and dietary information) as early in pregnancy as possible. There are many screening tests and elements of dietary advice that apply to all women regardless of pregnancy risk and so do not require a formal risk assessment to be performed prior to this information being given. Risk assessment and planning appropriate care then takes place at the second contact known as booking. Booking also provides a further opportunity to provide further information and discuss/reinforce that given at first contact.
SH	Department of Health	12		2.2	Page 31 line 6 & 78 line 23	Is there evidence for GP-led care? In our opinion, there is really no place for GP-led antenatal care now. All women should be under the care of a midwife within Maternity	We agree, however who provides care was outside the scope of this guideline update.

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						services.	
SH	Department of Health	13		2.2	Page 31 line 42	We felt it was unclear just to mention the dating part of the scan here when the screening (page 29 line 15) says NT scanning should be done. Would you please clarify.	Thank you. In practice one ultrasound scan may be performed to undertake a nuchal translucency determination and for dating. However, the recommendations need to make it clear that the timing of the nuchal translucency scan is important, whereas this is not the case for the dating scan. Hence the recommendations are made separately.
SH	Department of Health	14		2.2.	Page 32 line 32	We would be grateful if you could mention haemoglobinopathy screening here?	Thank you. This is now added.
SH	Department of Health	15		2.2	Page 35 line 15	The evidence page 97 line 6 says women from low income households are vulnerable too. Would you please consider adding these to the examples then it would slightly alleviate the apparent anomaly (because of the published evidence) that women 19-24 years need it but not mention those younger than 19 who are likely to be from low income households	Thank you we have done this.
SH	Department of Health	16		2.2	Page 36 line 10	We felt that this statement is at odds with existing DH guidance as acknowledged on page 101 line 7. Since the evidence is conflicting and in many cases subject to confounding factors, wouldn't it be safer to put it slightly less positively such as "no convincing evidence that one drink a day does harm after first three months but in the absence of clear evidence of ill effects women may prefer not to drink at all" We would be grateful if you could consider amending.	Thank you. The recommendations have now been amended following stakeholder consultation so now recommendations ask that women be informed about the lack of clear evidence. The GDG felt that advising women not to drink alcohol at all during pregnancy was inappropriate given the absence of evidence of harm at low levels of consumption.
SH	Department of Health	17		2.2	Page 39 line 45 Page 151	Is "outflow tract view" sufficiently precise or could it be misinterpreted? I am not sure whether this has resource implications if this scan takes significantly longer, or requires more training or experience than looking just	Thank you. Certainly it would be clear to a health care professional. It does have resource implications and it will require training to perform. About 45% of units already do look at outflow

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					line 19	for a 4-chamber heart. Grateful for clarification.	tracts.
SH	Department of Health	18		2.2	Page 40 line 17, 38 Also 197 line 1	We could not find a definition of the "Integrated test", would you be able to clarify.	The integrated test has now been detailed in the introduction to this section and added to the glossary.
SH	Department of Health	19		2.2	Page 41 line 12-15 and 218 line 32	In our view, this could be misleading and seems to suggest that chlamydia screening should not be done in pregnancy. We felt, it may be better to reverse the two sentences and put lines 13 – 15 "Health care professionals..." before Chlamydia screening should not....	Thank you, we have reversed the order of the recommendations as you suggest.
SH	Department of Health	20		2.2	Page 41 line 27	In our opinion, accepting the lack of evidence to support routine testing as not cost effective from the woman's point of view, is there no place for testing women at risk eg from IV drug use or previous blood transfusion. Presumably, having a blood transfusion previously would not exclude women from the scope of the guideline, in order to inform the staff?	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Department of Health	21		2.2	Page 42 line 38-39 and 245 line 3-4	We were unable to find the evidence that "most women with GD will respond to changes in diet and exercise", and "a small number of women may need insulin therapy". In our experience, most of our GD women need insulin	Thank you for your comment. Please see ref: Persson B, Stangenberg M, Hansson U, Nordlander E. Gestational diabetes mellitus (GDM). Comparative evaluation of two treatment regimens, diet versus insulin and diet. Diabetes 1985;34:101-4 This paper reported 86% of women were adequately controlled with diet. This evidence is cited in Table 9, p386 of the draft consultation document.
SH	Department of Health	22		2.2	Page 43 line 24	Are mercury sphygs. still allowed? We would be grateful for clarification.	Thank you for flagging this up. Although still used in some places mercury sphygs should have now been replaced. The recommendation

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							has been amended and mention of mercury sphygms removed.
SH	Department of Health	23		2.2	Page 43 line 45 And page 47	We felt that this is inconsistent with the algorithm which says rescan at 32 weeks and again at 36 if placenta within 2 cm of the os. We would be grateful for clarification.	Thank you. This section has been updated due to the GDG noting a change in practice since publication of the first ANC guideline and the recommendation is now that the second scan should be performed at 32 weeks.
SH	Department of Health	24		2.2	Page 44 line 7 and page 343 line 43-44	We are unable to find the evidence to support "A fetal growth scan to detect small-for-gestational-age unborn babies should be offered to women if the symphysis-fundal height measurement is 3cm greater or less than the gestational age in weeks". We would be grateful for clarification.	Thank you. This recommendation has now been removed following stakeholder consultation.
SH	Department of Health	25		4.5	Page 83 line 27	In our view, fewer AN appointments for low risk women should mean that time will be released to give additional support to those that need it – but only if reduced visits do not result in increased case loads for midwives	Thank you for your comment, however the organisation of antenatal care appointments was outside the scope of this current guideline update.
SH	Department of Health	26		4.6	Page 84 line 17	"... head circumference or biparietal diameter" This appears to be inconsistent with page 32 line 3 suggesting just head circumference. We would be grateful for clarification.	Page 84 line 17 is referring to the previous recommendation. This update has altered the recommendation to that you now see ie. using crown-rump length or head circumference.
SH	Department of Health	27		8.2	Page 137 line 2	Preconceptual counselling for haemoglobinopathy is mentioned here as a recommendation – would it be possible to put it earlier eg page 29 since it is so important?	Thank you. It is not possible to put this recommendation in the schedule for antenatal appointments as it falls outside this schedule and is not identified as a key recommendation.
SH	Department of Health	28		8.2	Page 137 lines 5-6 and 9-11	In our view, these lines almost duplicate but do not offer clarity about what should actually happen and whether it should be in primary or secondary care.	Thank you. These recommendations have been combined to reduce duplication and increase clarity.
SH	Department of Health	29	Full	General		SACN welcomes the revision of the guidance	Thank you. After extensive debate and

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				I (Section 5.5)		but notes that there is discrepancy in the advice set out on vitamin D supplementation. The current Dietary Reference Value (DRV) for vitamin D for pregnant and breastfeeding women is 10µg (400 iu) per day, as recommended by COMA in 1991 ¹ . Dietary sources of vitamin D are limited and exposure of the skin to sunlight is the main source. At UK latitudes, there is limited sunlight of the appropriate wavelength, particularly during the winter to stimulate production of sufficient vitamin D. In most instances, intakes cannot be met from the diet and at the present time can only be guaranteed by supplementation – a recommendation of 10µg per day has been made for pregnant and breastfeeding women. This is recognised in NICE's draft guidance on Maternal and Child Nutrition ² , in which recommendations include "advising all women who have limited exposure to sunlight and/or have dark skin to take a vitamin D supplement during pregnancy". In addition, SACN have recently reiterated the current DRV's for vitamin D and also explicitly reiterate that "all pregnant and breastfeeding women should consider taking a daily supplement of vitamin D in order to ensure their own requirement for vitamin D is met and to build up fetal stores for infancy" ³ . It is important that there is a consistent message with regard to vitamin D recommendations within NICE guidelines.	reconsideration of the evidence the ANCu GDG do not feel that it is appropriate to advise all pregnant women to take a vitamin supplement based on the biochemical evidence of "insufficiency". Due to lack of clear evidence relating universal supplementation with improved clinical outcomes, and the low prevalence of poor clinical outcomes in a healthy population we feel our recommendations of supplementation being provided to women in high risk groups is the more appropriate for this population.
SH	Department of Health	30	Full	Section 1.2	page 20	Most birthweight references in current paediatric use do not display the 5th and 95th	Obstetrics does not use the same charts as paediatrics since it is not

¹ Department of Health (1991) Dietary Reference Values for Food Energy and Nutrients for the United Kingdom no. 41. London: HMSO.

² NICE (2007) Maternal and Child Nutrition: draft guidance. (<http://guidance.nice.org.uk/page.aspx?o=440481>)

³ Scientific Advisory Committee on Nutrition (2007) *Update on Vitamin D*. London: TSO. (<http://www.sacn.gov.uk/reports/#>)

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						centiles. Thus babies in categories <5th and >95th will not be identified. Better to use <0.4th or <2nd centile (-2 or -2.66 SD respectively), depending on the risk being sought. Of course, some babies of normal birthweight may also have experienced intrauterine growth restriction.	possible to accurately determine the weight of an unborn baby, it can only be estimated based on ultrasound measurements. For this reason the 5 th and 95 th centiles are more appropriate and are in use in maternity care throughout the UK.
SH	Department of Health	31	Full	Section 2.1 Vitamin D		What does the panel mean by “at risk of deficiency”? Does it accept the consensus definition based on a plasma 25-OHD concentration below 25 nmol /l? If so, can the panel estimate what proportion of pregnant women in the UK with plasma 25OHD below this level will be identified by the listed criteria, and what proportion will not? Since the prevalence of this condition (NDNS) in (non pregnant, not breastfeeding, mainly white) women aged 19-24 is 28%, and 13 - 15% in women aged 25-49, how will the panel ensure that the fetus has adequate vitamin D stores to meet demands associated with exclusive breastfeeding?	The GDG seem clear that risk lies mainly within a certain group of women. It accepts the low levels of 25-OHD but is not convinced by the evidence that this necessarily leads to a poor outcome. Indeed there is no evidence in healthy women who are the subject of this guideline.
SH	Department of Health	32	Full	Section 2.2 First contact with a health professional.		Information on “nutrition and diet” should be given by a “health professional” at first contact. What are the minimum training requirements for this person to advise on nutrition?	Minimum training requirements are not within the remit of NICE clinical guidance.
SH	Department of Health	33	Full	Section 5.3 Working in Pregnancy.		The importance of ensuring that eligible women are informed about “Healthy Start” and enabled to register with the Scheme should be specifically mentioned because encouraging continued contact with health professionals through pregnancy and beyond is a core principle of the Scheme.	Thank you. Healthy Start has now been added to the recommendations.

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SH	Department of Health	34	Full	Section 5.5 Nutritio nal Supple ments		The recommendation on oily fish could be strengthened, particularly as the public health advice on a healthy balanced diet is to include at least one portion of oily fish a week.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Department of Health	35	Full	Section 5.5 Nutritio nal Supple ments		Mention of prescribing 5mg folic acid is highly desirable. Whilst women who have previously had an NTD-affected pregnancy will be captured by the list in 1.2, those whose partners have a family history, or who have other risk factors will not be.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Department of Health	36	Full	Section 5.5 Nutritio nal Supple ments		The text currently states "Although the Food Standards Agency recommends vitamin D supplementation during pregnancy, there is no indication of what evidence this recommendation is based on". This should be changed to the Department of Health. The evidence is recounted in several COMA reports, and was revisited during the last year in the SACN publication referred to above. CMO had also previously endorsed this recommendation in 2005 ⁴ .	Thank you for your comment. The evidence in the SACN report (and previously in COMA reports) relates only to vitamin D levels in the blood, not clinical indicators of health or clinically relevant outcomes of pregnancy. Whilst it is true that there is evidence that vitamin D supplementation increases levels of vitamin D there is no evidence as how this translates to clinical outcomes. However, we agree the statement is misleading and it has been amended to afford greater clarity.
SH	Department of Health	37	Full	7.2 Breast examin ation.		Should not this be actively discouraged rather than just described as "not recommended"? One of the best RCTs (Alexander 1992) found that many women positively decided before birth not to breastfeed when told they may have a problem as the result of breast examination.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Department of Health	38	Full	Genera l		The guidance currently has a negative focus in terms of food not to be eaten during pregnancy. It should emphasise the	Thank you for your comment, however general dietary advice was outside the scope of this current guideline update.

⁴ CMO Update 42 (2005) http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/CMOupdate/DH_4115663

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						importance of consuming a healthy balanced diet throughout pregnancy.	The NICE public health guidance on Maternal and Child Nutrition, published at the same time as the Antenatal Care update, contains further advice on this issue.
SH	Department of Health	39	Full	General		There is no indication of action to be taken by women at high risk of NTD-affected pregnancy.	Thank you but not in our scope.
SH	Department of Health	40	Full	5.12	p101 Lines 7-9	<p>The current NICE text states that 'The Department of Health now recommends that pregnant women should not drink any alcohol during pregnancy (http://www.dh.gov.uk/en/News/DH_074968) but the evidence behind this statement is unclear.'</p> <p>This focus on only one part of the full DH advice is misleading for the public.</p> <p>The Department of Health actually recommends to women on the advice of the four UK CMOs: 'Because of the risk, pregnant women or women trying to conceive should avoid drinking alcohol. If you do choose to drink, to protect the baby, you should not drink more than one to two units of alcohol once or twice a week and you should not get drunk.'</p> <p>This is of particular concern as DH considers it is very important to try and ensure a consistent message to women, as far as interpretation of the evidence can properly support this. It may be that this was meant only as a reference to the particular article quoted, rather than representing NICE's understanding of the full guidance produced by DH on the issue. However, we do not think that would be easily understood by the reader with the current wording.</p>	Thank you. We have amended the text to more accurately reflect the DoH guidance, and our amended recommendations are now very similar to this.

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						NICE itself appears to have applied the precautionary principle in its recommendation advising that women should avoid drinking in the first trimester, so appears to be in line with DH advice in that respect.	
SH	Department of Health	41	Full	5.12	<p>p101 line 15</p> <p>p103, line 24</p> <p>p103, line 31</p>	<p>The main research review discussed in the draft NICE guideline, the National Perinatal Epidemiology Unit (NPEU) systematic review found 'there was no consistent evidence of adverse effects from low-to-moderate prenatal alcohol consumption but the evidence is probably not strong enough to rule out any risk.' We do not consider that the current wording of the NICE guideline has consistently applied sufficient weight to the last clause.</p> <p>The GDG interpretation of the evidence itself states a similar last clause questioning strength of evidence e.g: 'In the absence of clear evidence of a threshold it would appear that drinking no more than 1.5 units/day is not associated with harm to the baby but there remains a possibility that there is an increased miscarriage rate in association with alcohol consumption although the evidence is limited and of poor quality.' The evidence is not only limited in regard to miscarriage.</p> <p>However, the NICE GDG recommendation that follows this analysis states: 'Pregnant women should limit their alcohol intake to less than one standard drink (1.5 UK units or 12g of alcohol) per day and if possible avoid alcohol in the first 3 months of pregnancy.' We welcome the apparent application of a precautionary principle in the NICE advice to women to avoid drinking at all in the first three months. It is not clear why this only applies at</p>	<p>Thank you for your considered comment. This question depends very much on which way you choose to approach it – are you trying to rule out any risk (as the NPEU were) or are you looking for evidence of harm. If you take the latter position in the absence of evidence of harm it is reasonable to state this and inform women that at low levels of intake there is no currently no evidence of harm to the baby.</p> <p>The evidence for miscarriage is of a higher quality than that relating to other outcomes with 2 studies reporting a significant effect at low to moderate intakes of alcohol, findings related to other outcomes were more equivocal.</p> <p>The advice to avoid alcohol if possible in the first 3 months of pregnancy is based on the increased risk of miscarriage seen in evidence from the NPEU systematic review.</p> <p>The GDG have reconsidered the recommendations and have decided, as you suggest, to make the message more in keeping with DoH guidance in order to avoid the possibility of confusion and apparent contradiction.</p>

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						<p>this stage of pregnancy given potential for harm is known to extend throughout pregnancy.</p> <p>We believe that the guidance needs to take more account of the limitations in the evidence base. The four UK CMOs have concluded that with current understanding of the wide range of potential harms and the clear limitations of the evidence base, the precautionary principle needs to be applied much more strongly in the guidance we give women. This is reflected in our current advice that makes this much clearer to them. Whilst recommending avoidance, we do recognise in construction of our advice that there is little positive evidence of harm at very low levels of consumption (as identified in the NPEU review), and so the UK CMOs do not recommend the simple message that women should stop drinking altogether. It was considered that women were entitled to be advised on a sensible precautionary basis (given uncertainties in the evidence) that drinking should be avoided but were also entitled to be informed that very low levels of consumption may also present little risk. It is important that this message could be easily understood as a precautionary one and that such consumption should be very low. One concern had been that women who did drink could easily misunderstand the advice as quite permissive with the attendant risks to the foetus.</p> <p>In particular, we would ask GDG to consider in reviewing this issue, that:</p> <ul style="list-style-type: none"> • it is accepted that the studies to date do not establish a clear safe threshold for consumption; • it is recognised that very large studies 	<p>The 2 sets of recommendations are now very similar and, we believe, fairly reflect the evidence and its current state of uncertainty.</p>

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						<p>would be needed to identify some of the potential risks (e.g. congenital effects) and lack of such evidence should not be taken as evidence of no negative effect;</p> <ul style="list-style-type: none"> the evidence on low levels of consumption below 1.5 units per day 'is probably not strong enough to rule out any risk' and women are entitled to have this taken into account; risk of long-term harm by alcohol to the foetus (and its impact on the mother) is potentially completely avoidable by a short-term behavioural change by women to stop drinking or to drink very little, so where there is any uncertainty the onus should be on safety; and the emerging consensus on the likelihood that alcohol can lead to a range of foetal harms that are not necessarily always recognised in the absence of full 'Fetal Alcohol Syndrome', and because such harms might present as subtle impairments in childhood, associated with lower levels of alcohol consumption, one should be even more cautious in interpreting the evidence to date as definitive; and given the uncertainty about an exact lower threshold it is very important that NICE does not contribute in any way to the risk of confusion among women. We believe that NICE should take account of the considered advice of the four UK CMOs, as well as other health services, in taking a more precautionary approach (some of which have even erred on the side of advice to avoid drinking completely in pregnancy). 	Thank you.

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						<p>We welcome the fact that NICE GDG have concluded the same basic structure to their draft advice as DH. Both sets of recommendations advise elements of:</p> <ul style="list-style-type: none"> the avoidance of drinking altogether; setting a particular threshold for those who do drink; and advising clearly against binge drinking. <p>This approach is exactly consistent with the structure of the advice of the four UK CMOs.</p> <p>We would argue that it would make sense to reflect this in the use of similar advice to that provided by the four UK CMOs.</p> <p>There is great potential for misunderstanding, which could inadvertently substantially undermine the understanding by women of the risks of drinking in pregnancy. Clearly, that would not be the intention of the group or of these NICE guidelines but this could be its main impact.</p> <p>We believe that the current message from the guideline is likely to be understood as very permissive by those at most risk, even though we doubt that was the intention. It will also not be at all easy for women to make sense of a 3 month cut-off for avoidance of all alcohol (both a difficult risk period to determine accurately and it is also difficult to comprehend a drinking allowance that appears to increase from none to daily overnight).</p> <p>We are concerned, therefore, that this guidance as currently worded could undermine the recently updated UK-wide main public health messages on the issue along with programmes of health promotion and wider</p>	<p>This has now been achieved.</p> <p>The 3 month cut off is not too difficult for most women to ascertain – especially as the guideline recommends early dating scan to accurately assess the gestation of the unborn baby.</p> <p>Thank you. Your concerns have been taken into consideration by the GDG and the recommendations amended to avoid causing confusion and any appearance of permissiveness.</p>

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						<p>policy initiatives aimed at reducing risks to women and their babies. It is very important that NICE guidelines are able to contribute to improved public health and do not actually inadvertently undermine this where there is clearly not scientific certainty.</p> <p>If NICE cannot agree on reflection to supporting exactly the same guidance as DH, we would suggest that given the wide variation in interpretation of evidence internationally, the GDG might consider a statement to convey more clearly for the general public the uncertainty in this area. NICE should also consider carefully whether, if it accepts the various caveats set out above but cannot reach the same conclusion as the UK CMOs on interpretation and precautionary handling of the available evidence, it would be more appropriate to refrain from making explicit recommendations that will be taken by some women to contradict current UK-wide advice on the issue. In that eventuality we would invite the GDG to consider the accuracy and appropriateness of a statement along the lines of the following, which may allow some understanding by the public of this: 'We recognise uncertainties in the evidence base to determine exact thresholds of safe alcohol consumption in pregnancy, so that other reasonable interpretations can be made, which are also consistent with the evidence. Hence, this NICE analysis is not intended necessarily to be taken to contradict current alternative authoritative advice.'</p>	The NICE guidance is now very similar to that issued by the DoH.
SH	Department of Health, Social Security and Public Safety of Northern Ireland					This organisation was approached but did not respond.	

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SH	Derbyshire Mental Health Services NHS Trust					This organisation was approached but did not respond.	
SH	Det Norske Veritas - NHSLA Schemes					This organisation was approached but did not respond.	
SH	Diabetes UK	1	Full	11.1 recommendations	pp 244 lines 27 -40	There needs to be a mechanism for detecting diabetes in non high risk groups, not only gestational diabetes but undiagnosed Type 2 diabetes. Discouragement of simpler screening in all women will delay diagnosis of previously undiagnosed pre-pregnancy Type 2 diabetes or IGT. The costly implications to mother and baby of delaying diagnosis must be strongly considered, particularly as the benefits and clinical effectiveness of treating gestational diabetes have been identified by the GDG. The evidence the GDG considered also identifies the low sensitivity of risk factors for the identification of GDM, with a study identifying that 32.9 per cent of cases would have been missed if only selective screening was employed. Another RCT considered by the GDG also suggested that universal screening resulted in a significantly higher detection rate than using risk factors.	Thank you for your comment. The GDG have considered all the evidence and have made the recommendations based on the reported accuracy of all screening tests and the cost-effectiveness of all clinically viable options. The low sensitivities of RBG and FBG make them unsuitable for screening. The most cost-effective screening option is that recommended – risk factor assessment followed by full GTT.
SH	Diabetes UK	2	Full	11.1 recommendations	pp 244 line 31	Has the GDG considered evidence regarding a smaller weight cut off point for the size of macrosomic babies born to mothers from Black Asian and Minority Ethnic groups? This is already being implemented in practice in some places with a weight of 4.5 kg for White Caucasian and African babies and greater than 4.0kg for all other ethnic groups.	Thank you. This has now been added to the recommendation.
SH	Diabetes UK	3	Algorithm	Prior to 12 weeks		Include under screening tests: screening mechanism for gestational diabetes for all women.	Thank you. This is now included in the list of what to undertake at each appointment and will be translated into the Quick Reference Guide (algorithm).
SH	Diabetes UK	4	Algorithm	Gestational age 28		RE: Offer OGTT for women at risk of GD Is there any evidence to suggest that performing an OGTT earlier than at 24-28	There is no evidence to support offering screening for gestational diabetes earlier than 24 weeks.

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				weeks		weeks is clinically effective? As this would ensure that those with gestational diabetes are picked up and supported to manage earlier, therefore potentially improving outcomes for mother and baby.	
SH	Down's Syndrome Association					This organisation was approached but did not respond.	
SH	Dudley Group of Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	echo uk (the tiny tickers charity)					This organisation was approached but did not respond.	
SH	English National Forum of LSA Midwifery Officers					This organisation was approached but did not respond.	
SH	Epsom & St Helier University Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Evidence based Midwifery Network					This organisation was approached but did not respond.	
SH	Faculty of Family Planning and Reproductive Health Care					This organisation was approached but did not respond.	
SH	Faculty of Public Health					This organisation was approached but did not respond.	
SH	Foetal Alcohol Spectrum Disorders Trust	1	FULL - through out this response.	Pages 100 - 103, Section 5.12 Alcohol Consumption in Pregnancy - Throug hout this response		<p>We are writing to express our concern about the proposed recommended guidelines on alcohol consumption in pregnancy.</p> <p>Our first concern is that despite a plethora of worldwide evidence which has been available for centuries about the dangers of alcohol in pregnancy, the draft recommendation is contrary to:</p> <p>UK DoH - "none is best but one to two units per week maximum."</p> <p>WHO - "There is no known safe limit of alcohol intake in pregnancy therefore we recommend pregnant women avoid all alcohol".</p> <p>The US Institute of Medicine declared in the mid-1990s, "The effects from alcohol are more</p>	<p>Thank you for your comment.</p> <p>The "plethora" of evidence is mostly of very poor quality and relates to large amounts of alcohol consumed in pregnancy. There is very little good quality evidence on the effects of low levels of alcohol consumption during pregnancy.</p> <p>Our recommendation has been amended following stakeholder consultation to try to remain consistent with other guidance in this area whilst remaining true to NICE's principle of</p>

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						<p>serious than effects from Heroin, cocaine and marijuana on the developing foetus". Women in the USA have been advised not to drink when pregnant or trying to conceive for the last 26 years, since 1981.</p> <p>Advice to avoid all alcohol in pregnancy is also given to women in New Zealand, Canada, France and many other countries due to potential risk. The French Government, like the US Government have now insisted on compulsory labelling of alcoholic beverages to ensure pregnant women are aware of the potential dangers.</p> <p>It appears strange therefore that this report should be recommending a course of action that is contradictory to the rest of the world's medical and governmental authorities' advice and opinion, especially more in light of the statement in this report that, "No threshold level .. above which it is harmful and below which is safe ..was clearly identified."</p>	<p>being evidence-based. There is currently no evidence of a "safe" limit as you rightly point out, neither is there evidence of harm to the unborn baby at the low levels of alcohol advised in the ANCu recommendations, which now err on the side of caution by taking 1-2 UK units once or twice a week as their upper limit..</p>
SH	Foetal Alcohol Spectrum Disorders Trust	2				<p>It is our understanding (which may be wrong) that most international studies when they comment on "low to moderate" levels of drinking are referring to 2-7 units per week. The guideline being suggested here of 1.5 units per day equates to 10.5 units per week, which is much higher.</p> <p>We are also all aware that the general public do not understand in practice what a unit of alcohol looks like, that the tendency is to over-estimate and that women of all socio-economic backgrounds are consuming more alcohol. There is a potential for a serious public health risk as women drink more than they should, believing they are within guidelines.</p>	<p>Thank you for your comment. The original recommendation was based upon evidence that defined low-to-moderate intake as less than one drink per day (equivalent to less than 1.5 UK units per day) (NPEU, 2005). This definition was then used in our recommendation. However, following stakeholder consultation the GDG have now decided to reduce the recommended maximum in order to be more cautious and to avoid giving confusing messages to women. Thus the NICE recommendation now states no more than 1-2 UK units once or twice a week, the same level as</p>

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						The report highlights the dangers of binge drinking in pregnancy and it would be easy for a pregnant woman to over-estimate and consume more than she intends, without realising she has just had a binge.	recommended by the DoH, 2007.
SH	Foetal Alcohol Spectrum Disorders Trust	3				<p>To suggest that the consumption of alcohol is "safe" during the second and third trimester overlooks the fact that as humans we are born with an immature brain, the brain and central nervous system continuing to develop throughout pregnancy.</p> <p>The fact that the brain is particularly vulnerable to damage by alcohol is also accepted. We would query therefore the logic of suggesting it is safe to consume a substance which attacks the brain at a time when the brain is still developing.</p> <p>In addition to this, the ears have been shown to be at risk of functional defects and minor anomalies if exposed to alcohol in the second trimester, with the eyes, teeth and external genitalia at risk during both the second and third trimester.</p>	Thank you for comment. We acknowledge your concern but in the absence of evidence of harm at low levels of alcohol consumption the GDG felt it inappropriate to recommend that women avoid alcohol throughout pregnancy. It is important, however, that women are informed about the uncertainty of the evidence.
SH	Foetal Alcohol Spectrum Disorders Trust	4				<p>The report mentions the possibility of a slight increase of miscarriage if alcohol is consumed and also says, "there was no consistent evidence of adverse effects but the evidence is probably not strong enough to rule out any risk".</p> <p>It is our belief that NICE is working towards ensuring the best possible outcome for patients, therefore one would logically conclude that if a substance is potentially detrimental to an optimum outcome, that the</p>	Thank you for your comment. We acknowledge your concern but in the absence of evidence of harm at low levels of alcohol consumption the GDG felt it inappropriate to recommend that women avoid alcohol throughout pregnancy. It is important, however, that women are informed about the uncertainty of the evidence.

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						<p>guideline would be to exclude exposure to the substance (for example the recommendation on cannabis which states "the effect on the foetus is uncertain but may be harmful therefore women should be discouraged from use....").</p> <p>In this scenario, the optimum outcome of pregnancy for the baby and its life ahead and its mother could be missed by the consuming of alcohol during pregnancy. Is it not logical then that - even just from a public health perspective - the guideline should be to avoid alcohol during pregnancy, due to its potentially harmful effect on the foetus?</p>	
SH	Food Standards Agency	1		2.1 & general		<p>Oral Vit D supplementation. The FSA is of the understanding that government advice is that routine supplementation of all pregnant women is necessary, as recommended by COMA, in order to ensure adequate fetal supply and stores in the newborn. This is consistent with SACNs position statement in the 'Update on Vitamin D' 2007 report.</p>	<p>There is no evidence to show that routine vitamin D supplementation of all women during pregnancy confers clinical benefit to either the woman or the baby. However, the importance of adequate vitamin D status during pregnancy is recognised and it is recommended that health care professionals discuss this with women as well as informing them of the Healthy Start vitamin supplement should a woman wish to take this. It is also recommended that women who are at particular risk of vitamin D deficiency should be advised to take this supplement.</p>
SH	Food Standards Agency	2		2.2		<p>1. at first contact with health professional Amend the following bullet to include reference to vit D supplementation, in view of comment in 2.1. In addition add reference to eating folate rich foods as well as referring to folic acid supplementation</p> <ul style="list-style-type: none"> Nutrition and diet, including vitamin D, folic acid supplementation as well as 	<p>Thank you. Vitamin D supplementation has now been added, as well as reference to the Healthy Start Programme as suggested by a number of other stakeholders.</p>

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						consumption of foods containing folate, avoidance of vitamin A supplements.	
SH	Food Standards Agency	3		5.5? should this be 4.8? & general	page 35	<p>Nutritional supplements</p> <p>Although this section is not open to consultation following comments in 2.2 for consistency it is worth noting that with regards to vitamin A the Expert Group on Vitamins and Minerals (2003) considered the teratogenic risks associated with retinol and whilst acknowledging the threshold level for this effect is unclear but the lowest supplemental dose associated with teratogenic risk is 3000mcg RE/day. The group endorsed the current Government advice that women who are pregnant or wish to become pregnant should not take dietary supplements containing vitamin A except on medical advice.</p> <p>Raise that when referring to vitamin A supplements these include fish liver oils which also contain high levels of vitamin A.</p>	Thank you for your comment. As you identify vitamin A was outside the scope of this update and so has not been reviewed. We do however, acknowledge the need to work carefully with stakeholders in order to identify all areas where updating is necessary so that issues such as these do not arise in the future.
SH	Food Standards Agency	4		5.5 or 4.8?	page 35 2008 recom mendat ions	Oral vitamin D supplementation – as with comments in 2.1	Thank you. See response above.
SH	Food Standards Agency	5		5.4	Pg 94	<p>To support 2.2 suggest including the Government's Eatwell plate to pictorially provide advice on a balanced diet. Replace first set of bullets with the following:</p> <p>Plenty of fruit and vegetables</p> <p>Plenty of bread, rice, potatoes, pasta and other starchy foods – choose wholegrain varieties where you can</p> <p>Some milk and dairy foods</p> <p>Some meat, fish eggs, beans and other non-</p>	Thank you for your comment. Nutrition during pregnancy was not part of the scope of this update. However, the public health guidance on Maternal and Child Nutrition, will be published on 26 th March 2008 and will include advice on healthy eating during pregnancy.

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						dairy sources of protein Just a small amount of foods and drinks high in fat, sugar and /or salt	
SH	Food Standards Agency	6		5.5	Pg 96	The FSA has an updated line on folic acid and mandatory fortification: "In June 2007 the FSA Board gave the Agency the go-ahead to prepare plans to add folic acid to some food, to make sure the number of babies born with neural tube defects (NTDs) is reduced." Please see the following link for more information http://www.food.gov.uk/news/newsarchive/2007/jun/folateupdate Include in the recommendation: 'and consuming foods containing folate.'	Thank you for your comment. Nutrition during pregnancy was not part of the scope of this update. However, the public health guidance on Maternal and Child Nutrition, will be published on 26 th March 2008 and will include advice on folic acid supplementation during pregnancy.
SH	Food Standards Agency	7		5.5	Pg 96	Vitamin A -comments as above for pg 35.	
SH	Food Standards Agency	8		5.5	Pg 96	Vitamin D – comments as above in 2.1	Thank you
SH	Foundation for the Study of Infant Deaths					This organisation was approached but did not respond.	
SH	Gateshead PCT					This organisation was approached but did not respond.	
SH	Gloucestershire Acute Trust					This organisation was approached but did not respond.	
SH	Group B Strep Support	1	FULL	GENERAL		The issue of routinely screening women for GBS carriage late in pregnancy on the NHS was raised in 6 responses to the scope consultation, including the responses from the RCOG, the RCN and clinicians. The comment on these responses was that 'there is unlikely to be new UK data to inform current practice before this guideline is completed'. This is not in fact the case, given recent research - "Colbourn TE, Asseburg C, Bojke L, Phillips Z, Claxton K, Ades AE, et al. Prenatal screening and treatment strategies to prevent group B streptococcal and other bacterial	Thank you. As you rightly point out screening for Group B Strep is outside the scope of this guideline update.

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						<p>infections in early infancy: cost effectiveness and expected value of information analyses. Health Technol Assess 2007;11(29)"</p> <p>The research results showed that the most cost-effective option that minimises antibiotic usage is to treat all women in premature labour as well as all those in high risk situations, and to test all other pregnant women and then treat those found to carry GBS. The report recommended immediate extension of current practice.</p>	
SH	Group B Strep Support	2	FULL	10.9		<p>We welcome inclusion of the reference to the RCOG guidelines on the prevention of early onset neonatal Group B Streptococcal disease (due for review in November 2006), particularly in the light of the RCOG's Audit which showed that the majority of hospital protocols did not comply fully with the guidance.</p> <p>No reference has been made to the HPA BSOP 58 detailing how screening tests for GBS carriage should be carried out.</p> <p>Reference should be included to the NHS' National Electronic Library for Women's Health (NeLWH) online GBS learning package.</p>	Thank you for your comment, however this was outside the scope of this current guideline update
SH	Group B Strep Support	3	NICE	1.8.9		<p>The change referred to above (Section 10.9 of the full guidance) ie inclusion of reference to the RCOG guidelines, has not been included in this version.</p>	The NICE version only contains the recommendations. Other text is not reproduced here.
SH	Guys and St Thomas NHS Trust		Full	9.1	line 34	<p>"overall aim of fetal anomaly screening is to prevent fetal death and disability" – this devalues the lives of disabled people and should be re-written.</p>	We agree and have rewritten the sentence.
SH	Health Protection Agency					<p>This organisation was approached but did not respond.</p>	

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SH	Healthcare Commission	1	NICE	Overall		The Healthcare Commission welcomes this update which will facilitate our assessment programme for NHS organisations providing maternity care.	Thank you.
SH	Healthcare Commission	2	NICE	Pg 8, 1.1.1.1 and 1.2.7.3	(and Full pg 30)	The term "Booking" is being reconsidered – the PSA delivery agreement 19 definition as "health and social care assessment of needs, risks and choices" is a better, if longer, description which to some extent is covered by the term "care pathway" but this should be extended to social and environmental considerations. Sect 1.2.7.3. (presume unchanged) does not correlate with sect 1.1.1.1 in terms of descriptions.	The phrase "booking" is retained for this guideline update as currently it is widely used and well understood by all midwives and obstetricians. A detailed definition is given in the glossary to ensure clarity and consistency.
SH	Healthcare Commission	3	NICE	1.1.1.1 (and full pg 30)		Provision of "The Pregnancy Book" is indicated here as if that was an adequate substitute for discussion with the woman (and her partner) in an appropriate and accessible medium. The Pregnancy Book may assist with imparting information but it is important that the health professional ensures understanding of the relevant content.	Thank you. We have amended this recommendation to better reflect what the GDG mean – ie. it is a useful resource to support information giving not as a substitute for discussion.
SH	Healthcare Commission	4	NICE	1.1.1 (section)		Consider involving/ actively welcoming partners and/or supporters. The importance of engaging fathers in decision making and longer term wellbeing of woman and her baby should not be dismissed and is supported by a considerable body of evidence. Partners are welcomed at 96% of antenatal classes (HC survey – embargoed till publication due end November 2007) and encouraged to attend at 94% of births (NPEU recorded delivery March 2007) so evidence of their interest and women's need for them is clear.	Thank you for your comment. We did not review evidence relating to the involvement of partners for this guideline update therefore we can not address this issue through the systematic reviewing. However we agree with the general principle of involving and welcoming partners and so the term partners has been added to the introduction where appropriate rather than just referring to the "woman's family".
SH	Healthcare Commission	5	NICE		Pg 13 "First Appointment"	Consider listing specialist factors that require tailored antenatal care such as per section 1.2 of full guidance – this will facilitate use by women and their partners of the NICE guidance rather than having to refer across to full guidance which may seem inaccessible.	This list of factors will be given in the Quick Reference Guide which will be available via the NICE website after publication www.nice.org.uk

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SH	Healthcare Commission	6	NICE	Pg 17 "general" and 1.5.5	Pg 17 "general" and 1.5.5	Domestic abuse is considered by some a preferred term to domestic violence since it also covers psychological abuse which may not manifest itself in physical symptoms. Appreciate this section is not for consultation, but suggest his revision should be considered throughout.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Healthcare Commission	7	NICE	1.3.9/10 (and section)		No mention of substance misuse beyond cannabis. Appreciate not in scope. However, consider mentioning referral to specialist midwife/professional where concerns are raised over substance misuse (including alcohol) during pregnancy – cross reference page 13 of NICE and section 1.2 of full guidance.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Healthcare Commission	8	FULL	Pg 39 / 40 / 42		Acknowledge the impact of additional time taken in staff training/ discussion with women/counselling where additional screening is being introduced. Its existence as good practice already does not mean that cost to implement will be inherently zero – need a realistic estimate of resources needed to get from current state to fully achieved recommendation.	Thank you. Your comment has been forwarded to the NICE costing team. Information-giving is a key recommendation. We would like to point out, however, that all recommendations are considered for costing impact, not just key recommendations.
SH	Healthcare Commission	9	NICE	1.5.6		Cross reference to Antenatal and Postnatal mental health guidance? (appreciate this section is not for consultation)	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Healthcare Commission	10	NICE	1.6.2.6 and 1.6.2.11		Lack of clarity between these two paragraphs, and between the bullet points in the latter paragraph. Consider rewrite in style of the rest of the document	Thank you. Recommendation 1.6.2.6 is referring to preconception counselling for women before they are pregnant. 1.6.2.11 is referring to pregnant women – hence the apparent repetition.
SH	Healthcare Commission	11	NICE	1.7.1.4 and 1.7.2.6		Suggest inclusion of a sentence recognising and acknowledging the role of fathers in this decision making process.	Thank you. We have now added partners to the introduction to make it clear they are included throughout antenatal care.
SH	Healthcare Commission	12	NICE	4.1		Again, this recommendation could be extended to examine the role and information needs of	Thank you for your comment. We did not review evidence relating to the

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						fathers and other supporters in informing pregnant women and assisting with choices and decisions – it may be that a wider education campaign rather than just targeting pregnant women would be more effective in supporting healthy choices and understanding of the reasons for them	involvement of partners for this guideline update therefore we can not address this issue through the systematic reviewing. However we agree with the general principle of involving and welcoming partners and so the term partners has been added to the introduction where appropriate rather than just referring to the "woman's family".
SH	Healthcare Commission	13	NICE	general		Baseline data for many of the recommendations is being gathered during 2007 from maternity units in England by the Healthcare Commission and is expected to be published for comparative purposes in January 2008.	Thank you - a really useful audit.
SH	Healthcare Commission	14	Full	1.3		Probably bigger than this one guideline but consider use by all professionals across the care pathway – social care in particular.	Thank you for your comment.
SH	Healthcare Commission	15	Full	1.3		Include pharmacists in the listed professions as their involvement in information giving during antenatal period is significant.	Thank you, this has now been added.
SH	Healthcare Commission	16	Full	1.3		Include partners/supporters of pregnant women	Thank you. Partners have been added to the general introduction to show they are included throughout the guideline.
SH	Healthcare Commission	17	Full	1.4		The term consumers appears inappropriate – representatives of service users is more accurate unless these women were actually pregnant at the time of development of the guidelines.....my suspicion is that they are nominated reps from "consumer" organisations. I am sure that this has already been wrestled with and I don't aim to reopen a detailed debate if resolution has been recent.	Thank you. The "consumer" representatives are now referred to as service user representatives. This has now been amended.
SH	Healthcare Commission	18	Full	Diag 2.4 and section 3.1		Include at least a nod to the role of fathers in supporting decision making please!	Thank you for your comment. We did not review evidence relating to the involvement of partners for this guideline update therefore we can not address this issue through the systematic reviewing. However we

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							agree with the general principle of involving and welcoming partners and so the term partners has been added to the introduction where appropriate rather than just referring to the "woman's family".
SH	Homerton University Hospital NHS Foundation Trust	1	Full version		P19	As well as referring to Changing Childbirth-ref to maternity Matters 2007-more recent reference.	Thank you. Maternity Matters is referenced also now.
SH	Homerton University Hospital NHS Foundation Trust	2	Full version		P30	Bullet point 7 of first contact would read better if said "Lifestyle advice including smoking cessation and the implications of recreational drug use and alcohol consumption in pregnancy"	Thank you, this recommendation has been amended as you suggest.
SH	Homerton University Hospital NHS Foundation Trust	3	Full version		P30 Line 11	Call it pregnancy care pathway	Amended
SH	Homerton University Hospital NHS Foundation Trust	4	Full version		P36 Line 12&13	Code evidence for statement re: binge drinking and pregnancy	Thank you for your comment. Getting drunk has now been added to this recommendation to improve clarity of what we mean by binge drinking.
SH	Homerton University Hospital NHS Foundation Trust	5	Full version		P48 Line 36	Sentence refers to Standard 3 of NSF. I think you mean part 3 or standard 11 as Standard 3 relates to Children not women	Thank you for pointing this out. We meant to refer to Standard 11, section 3.
SH	Homerton University Hospital NHS Foundation Trust	6	Full version		P68 L17	Spelling face not fae	Amended.
SH	Homerton University Hospital NHS Foundation Trust	7	Full version		P88 Line 40	Spelling error	Thank you. Amended.
SH	Homerton University Hospital NHS Foundation Trust	8	Full version		P261- 264	To reduce confusion for the reader it would be helpful to be consistent throughout these pages and use either SPTB (spontaneous preterm birth) or SPTD (spontaneous preterm delivery) not mixing the two abbreviations.	Thank you. We have amended all references to SPTB for consistency.
SH	Homerton University Hospital NHS Foundation Trust	9	Full version		Genera l	Need mention of Healthy start in dietary advice	Thank you. Reference to Healthy Start is now included.
SH	Huntleigh Healthcare					This organisation was approached but did not respond.	
SH	Infermed Ltd					This organisation was approached but did not respond.	
SH	Leeds PCT					This organisation was approached but did not	

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						respond.	
SH	Leeds Teaching Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Liverpool Women's NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Liverpool PCT					This organisation was approached but did not respond.	
SH	Liverpool Women's NHS Trust					This organisation was approached but did not respond.	
SH	Luton and Dunstable Hospital NHS Trust	1	Full	1.7.2.5		The national screening committee now use the terminology of 'low risk' and high risk' as opposed to the statistical 'screen negative' and 'screen positive'. It would be best if the terminology used in the NICE guidance was consistent with the National Screening Committee to avoid potential confusion.	Thank you for your comment. The GDG carefully considered all terminology used in the recommendations and prefer the terms "screen positive" and "screen negative" so as to avoid the negative and anxiety-provoking term "risk" being applied to all pregnancies.
SH	Luton and Dunstable Hospital NHS Trust	2	Full	1.7.2.6		The national screening committee now use the terminology of 'low risk' and high risk' as opposed to the statistical 'screen negative' and 'screen positive'. It would be best if the terminology used in the NICE guidance was consistent with the National Screening Committee to avoid potential confusion.	Thank you for your comment. The GDG carefully considered all terminology used in the recommendations and prefer the terms "screen positive" and "screen negative" so as to avoid the negative and anxiety-provoking term "risk" being applied to all pregnancies.
SH	Luton and Dunstable Hospital NHS Trust	3	Full	1.10.1.2		Symphysis fundal height 3cm below the gestational age in weeks is normal in later pregnancy The 50th centile at 40 weeks is 36cm so on the basis of the NICE guidance over half the pregnant population would have a scan. Is this what is intended? If this guidance stays then would it be more cost effective to scan all women at 34-36 weeks? A centile chart needs to be used and if the SFH is below the 10th centile then a growth scan is indicated.	Thank you. This recommendation has now been removed following stakeholder consultation.

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						<p>(Ref National Maternity Record Project 1999 Calvert et al BMJ 1982 285:p846-9)</p> <p>I am not aware of any data to support the use of scan in large for dates at/near term. What action should be taken if the baby is shown to be large ie above 95th centile?</p>	
SH	Luton and Dunstable Hospital NHS Trust	4	DiP Short version	1.2.3.1		<p>Please see below for Gestational DM (GDM) comments from Diabetes in Pregnancy which are requested to be referred to the Antenatal guideline update.</p> <p>Women from the Philippines should be included as a High Risk ethnic group Evidence: Abstract of oral presentation at EASD 2007 Diabetologica (2007)50:suppl 1 S1-S538, presentation 0116 and table. The abstract did not give prevalence order but did give age adjusted prevalence for GDM as well as pregestational DM (PGDM) for each of 8 subgroups of 'Asians/Orientals'. Study was in California Pasadena looking at Asian American women and total of 24,166 births. Indians rank top for GDM (11.9) and PGDM (4.1), then Chinese for GDM (11.4), Filipino (11.3), and Vietnamese (10). For PGDM after Indians are Filipino (2.7), Korean (2.4), other Asians (2.2) and Japanese (2.0).</p>	Thank you for these references. We have reviewed this paper but feel the evidence presented is not sufficiently robust for inclusion here.
SH	Luton and Dunstable Hospital NHS Trust	5		1.2.3.1		<p>Clarify how many risk factors are considered to constitute a positive screen for GDM Is it one or several or a weighted score?</p>	Thank you. Just one risk factor constitutes a positive screen. This is now included in the recommendations.
SH	Luton and Dunstable Hospital NHS Trust	6		1.2.3.1		<p>Cut off BMI of >30 for screening will include a large number of women and have significant</p>	The GDG acknowledge that for some trusts this will mean a large number of

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						resource implications, especially for this Trust with a high ethnic minority population, currently not screening for GDM. It is estimated that approximately half of all women will be categorised as High Risk for GDM in Luton using BMI and ethnicity.	women receiving the full GTT, however the evidence and cost-effectiveness modelling suggests this is the preferred method otherwise an unacceptably high number of women with gestational diabetes would be missed.
SH	Luton and Dunstable Hospital NHS Trust	7		1.2.3.1		Disagree that a family history of Type 1 DM is a risk factor for GDM – evidence?	Evidence for family history as a risk factor for GD is quoted in the full version of the guideline (section 11.1) and includes evidence from a Health Technology Assessment (2002).
SH	Luton and Dunstable Hospital NHS Trust	8		1.2.3.3		Clarify whether all high risk patients are offered the choice of an oral Glucose Tolerance Test (GTT) and whether NICE intends to produce an information leaflet for patients stating the risk: benefit of diagnosis of GDM.	Yes, all women identified as being at risk as identified by the risk factors listed would be offered a full glucose tolerance test. Unfortunately, it is not possible for NICE to produce information leaflets on all screening tests/treatments/interventions reported in clinical guidelines, including gestational diabetes.
SH	Luton and Dunstable Hospital NHS Trust	9		1.2.6.3		Clarify follow up of women diagnosed with GDM who still have impaired fasting glucose (>6.0 mmol/l) at 6 weeks post partum and whether a GTT is required.	Postnatal follow up is outside the scope of this pregnancy guideline.
SH	Luton and Dunstable Hospital NHS Trust	10		1.6.2.3		Recommend Desmond or similar structured education (eg.Expert). No guidance given on how lifestyle advice should be delivered.	The evidence reviewed suggests one-to-one discussion, group participant-led discussion and the use of multi-media are all effective in delivering lifestyle messages.
SH	Luton and Dunstable Hospital NHS Trust	11		1.3.7.1		Clarify whether monthly ultrasound monitoring is for pre-existing DM only or includes GDM.	The monthly ultrasound is for women with pre-existing diabetes.
SH	Luton and Dunstable Hospital NHS Trust	12	Algorithm			Clarify which patients are included in the right arm of the algorithm, currently labelled "Gestational Diabetes no previous history". Are these patients those which are High Risk for GDM? If so, this should be made clear as it	This algorithm has now been updated and replaced by the NICE Quick Reference Guide which we hope will provide clearer guidance on this issue.

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						is confusing as it stands. At the start, it is not known that patients have Gestational Diabetes.	
SH	Mast Diagnostics					This organisation was approached but did not respond.	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)					This organisation was approached but did not respond.	
SH	Mental Health Collaborating Centre					This organisation was approached but did not respond.	
SH	Mid and West Regional Maternity Service Liaison Committee (MSLC)					This organisation was approached but did not respond.	
SH	Milton Keynes PCT					This organisation was approached but did not respond.	
SH	Monica Healthcare Ltd					This organisation was approached but did not respond.	
SH	MRC Centre for Epidemiology of Child Health	1	NICE	1.3.2.4.		<p>Routine supplementation with vitamin D (at 400IU based on COMA recommendation from 1998) is endorsed for all pregnant mothers in the recent SACN Update on vitamin D (2007) and in the NICE consultation on optimal nutrition for the mother and child.</p> <p>The draft on recommendation for antenatal care contradicts this recommendation by stating that routine supplementation should not be offered to healthy pregnant mothers.</p> <p>Is there a plan to ensure that NICE recommendations for antenatal care coincide with NICE recommendations for maternal and child nutrition?</p>	Thank you We are in discussion with the MCN group.
SH	MRC Centre for Epidemiology of Child Health	2	NICE	1.3.2.4		Sunlight induced synthesis of vitamin D is a key determinant for endogenous vitamin D intake. Britain is located between 50°N and 60°N, which corresponds to the latitude of Canada up to the southern tip of Alaska. In Canada, dietary intake is increased by vitamin D fortification of milk, which is not done in the	Thank you the GDG were aware of these facts. However they were concerned with healthy women (their scope (and have found little evidence in support of supplementation in this group. They have highlighted its importance in at – risk women

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						<p>UK. Prevalence of hypovitaminosis D in Britain is higher than in Canada. (See Hypponen and Power, AJCN 2007 and references there in).</p> <p>Recent recommendation from the Canadian Paediatric Society suggests that all pregnant mothers need 2000IU vitamin D per day throughout pregnancy. (please see http://www.cps.ca/english/statements/II/FNIMO7-01.htm) This is 5 times more than the COMA recommendation for UK from year 1998.</p> <p>The Canadian report notes, that “emphasis is no longer solely in preventing rickets, which requires relatively small amount of vitamin D supplementation. The focus is now also on the prevention of childhood and adult diseases. New findings suggest that adequate vitamin D status in mothers during pregnancy and in their infants may have lifetime implications”.</p> <p>Has the scientific evidence that was used as basis for the Canadian recommendation been considered when determining the UK recommendation?</p>	however.
SH	MRC Centre for Epidemiology of Child Health	3	Full	5.5.	page 96, line 15	<p>It seems that the main problem with the evaluation of the evidence on vitamin D, arises from the way the “Clinical question” has been set up. For example, the following important considerations have not been systematically (if at all) addressed/evaluated:</p> <ol style="list-style-type: none"> 1. What is the prevalence of vitamin D deficiency during pregnancy? 2. Is vitamin D deficiency a public health problem beyond women at high risk groups? 	<p>Thank you.</p> <p>1. Unfortunately the answer to some of these questions are just not available However it is known that Vit D levels are lowered in pregnancy – but the real consequence of this in healthy women is unknown.</p> <p>2&3. We can identify the high risk groups from the available evidence although there would be a degree of uncertainty about the severity of the</p>

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						<p>3. What are the high risk groups for vitamin D deficiency?</p> <p>4. How much vitamin D do women at high risk groups (who commonly have extremely low 25(OH)D concentrations) need?</p> <p>5. Is vitamin D intake sufficient to prevent vitamin D deficiency in healthy pregnant women living in the UK or is supplementation required? This is particularly important, as milk in the UK is not fortified with vitamin D. Results from the National Dietary and Nutrition Survey, indicate that intakes in the UK are extremely low.</p> <p>6. What are the consequences of low vitamin D intake/status to the pregnant mother, to the pregnancy, to the child?</p> <p>Much of the evidence has arisen relatively recently, and it has mainly been obtained by studies other than randomised controlled trials. Well designed clinical trials are likely to bring further clarity into how improvements in vitamin D status in the pregnant mother alter health outcomes related either to her own well being, the pregnancy or the health of the new born. However, it will not be possible to carry out randomised controlled trials on vitamin D deficiency per se, as failure to offer treatment to a pregnant mother presenting with vitamin D deficiency/with very low 25(OH)D can not be ethically justified. The fetus relies directly on the mother for vitamin D supply, and deficiency in the mother is known to be associated with extremely serious complications in the child, including hypocalcemic seizures and heart</p>	<p>Vit D deficiency in individual groups</p> <p>4. We have not come across replacement requirements apart from 10ug</p> <p>Our GDGs issue is with the lack of evidence that healthy women and their babies are suffering as a result of their lowered Vit D levels.</p> <p>Thank you for all your suggested references. These have been looked at however none answers our clinical question ie. the effectiveness of antenatal vitamin D supplementation to improve perinatal and maternal outcomes. Indeed many of these papers are of poor quality research eg. small case series, or non-research papers.</p>

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						<p>failure (in addition to exposing the child to rickets).</p> <p>Relevant references include (but are not restricted to) the following:</p> <p>Prevalence rates:</p> <p>Hollis BW, Wagner CL. Vitamin D deficiency during pregnancy: an ongoing epidemic. <i>Am J Clin Nutr.</i> 2006 Aug;84(2):273.</p> <p>Bodnar LM, et al. High prevalence of vitamin D insufficiency in black and white pregnant women residing in the northern United States and their neonates. <i>J Nutr.</i> 2007 Feb;137(2):447-52.</p> <p>Bodnar et al. Prepregnancy Obesity Predicts Poor Vitamin D Status in Mothers and Their Neonates. J Nutr. 2007 Nov;137(11):2437-2442)</p> <p>Basile et al. Neonatal vitamin D status at birth at latitude 32 degrees 72': evidence of deficiency. <i>J Perinatol.</i> 2007 Sep;27(9):568-71</p> <p>For UK prevalence, suggest to contact Professor Cyrus Cooper / Dr Barbara Boucher directly (see refs by Javaid and Boucher below) to obtain season specific data for maternal vitamin D status in the Southampton study.</p> <p>Vitamin D intake/related discussion:</p> <p>Calvo MS, Whiting SJ, Barton CN. Vitamin D intake: a global perspective of current status. <i>J.Nutr.</i> 2005;135:310-6.</p> <p>Calvo MS, Whiting SJ. Prevalence of vitamin D</p>	

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						<p>insufficiency in Canada and the United States: importance to health status and efficacy of current food fortification and dietary supplement use. Nutr.Rev. 2003;61:107-13.</p> <p>Henderson, L., Irving, K., Gregory, J., Bates, C., Prentice, A., Perks, J., Swan, G, and Farron, M. The National Diet and Nutrition Survey: adults aged 19 to 64 years –vitamin and mineral intake and urinary analysis. Volume 3. 2003. London, HMSO. http://www.food.gov.uk/multimedia/pdfs/ndns3.pdf</p> <p>Hyppönen,E, Power,C: Hypovitaminosis D in British adults at age 45y: nationwide cohort study on dietary and lifestyle predictors. Am.J.Clin.Nutr. 85:860, 2007</p> <p>Health effects: Camargo CA et al. Maternal intake of vitamin D during pregnancy and risk of recurrent wheeze in children at 3 y of age. Am J Clin Nutr 2007; 85(3):788-795. Devereux G et al. Maternal vitamin D intake during pregnancy and early childhood wheezing. Am J Clin Nutr 2007; 85(3):853-859. Litonjua and Weiss. Is vitamin D deficiency to blame for the asthma epidemic? J Allergy Clin Immunol. 2007 Oct 3; [Epub ahead of print] (see also references there in)</p> <p>Bodnar et al. Maternal vitamin D deficiency increases the risk of preeclampsia. J Clin Endocrinol Metab. 2007 Sep;92(9):3517-22.</p> <p>Hyppönen E. Vitamin D for the prevention of pre-eclampsia? –a hypothesis. Nutrition Reviews 2005, 63(7):225-32. (see also</p>	

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						<p>references there in)</p> <p>Javaid et al. Maternal vitamin D status during pregnancy and childhood bone mass at age 9 years: a longitudinal study. Lancet. 2006 Jan 7;367(9504):36-43.</p> <p>Boucher BJ, Robinson S, Shore S, Noonan K, Hales CN, Godfrey KM. Maternal vitamin D status contributes inversely to cord porinsulin and directly to abdominal girth in white babies born in Southern England. Pediatr.Res. 56[6, 2/2], 14A, P110. 2003.</p> <p>Wharton,B, Bishop,N: Rickets. Lancet 362:1389-1400, 2003 (see also references there in)</p> <p>Anatoliotaki,M, Tsilimigaki,A, Tsekoura,T, Schinaki,A, Stefanaki,S, Nikolaidou,P: Congenital rickets due to maternal vitamin D deficiency in a sunny island of Greece. Acta Paediatr. 92:389-391, 2003</p> <p>Camadoo,L, Tibbott,R, Isaza,F: Maternal vitamin D deficiency associated with neonatal hypocalcaemic convulsions. Nutr.J 6:23, 2007</p> <p>Maiya,S, Sullivan,I, Allgrove,J, Archer,N, Tulloh,R, Daubeney,P, Malone,M, Mok,Q, Yates,R, Brain,C, Burch,M: Hypocalcaemia and Vitamin D deficiency: an important, but preventable cause of life threatening infant heart failure. Heart 2007</p>	
SH	MRC Centre for Epidemiology of Child Health	4	Full	5.5.	page 96, line 15	<p>The key problem with the way evidence on the need of vitamin D supplementation during pregnancy has been considered is, that the importance of prevention of vitamin D deficiency per se, has not been appreciated (For a recent review on general effects on health, please see Holick NEJM 2007). The dosage recommended by Department of</p>	<p>Thank you. The GDG has considered the public health viewpoint, namely that vitamin D insufficiency needs to be addressed, but in the absence of any evidence linking this to clinically relevant outcomes, and with the knowledge of large annual variation, did not feel this was sufficient reason</p>

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						<p>Health (1998), SACN update on vitamin D and NICE consultation for mother and child nutrition (2007) is 400IU/day, which is historically known to be safe and effective in preventing the most extreme form of deficiency (See for example reviews by Vieth, e.g. AJCN 1999).</p> <p>The evaluation of scientific literature fails to take into account the high prevalence of vitamin D deficiency in the UK (especially during winter and spring), and that pregnant mothers are per se a high risk group for vitamin D deficiency.</p> <p>It has not been taken into consideration that in the UK (where milk is not fortified with vitamin D) dietary intakes are very low, and hence supplementation with vitamin D is needed.</p>	for recommending routine supplementation. However the recommendation has now been reworded so that all women are informed of the importance of adequate vitamin D levels and that women are informed of the Healthy Start multivitamin supplement which they may choose to take to ensure good vitamin D intake.
SH	MRC Centre for Epidemiology of Child Health	5	NICE	4.5		<p>Although 400IU/day (endorsed by COMA, SACN and NICE maternal nutrition) is sufficient to prevent the extreme form of deficiency, it is not believed to be sufficient to ensure optimal vitamin D concentration. (See e.g. Holick NEJM 2007 review on vitamin D deficiency, various paper by Hollis B, including Hollis and Wagner: Assessment of dietary vitamin D requirements during pregnancy and lactation. Am J Clin Nutr. 2004 May;79(5):717-26.).</p> <p>A research recommendation is needed for the evaluation of the dose of vitamin D supplementation during pregnancy that is optimal for healthy pregnant women, and the dose that is optimal/required by women in the high risk groups.</p> <p>Further research is also needed to establish</p>	<p>Thank you for these suggestions, Hollis et al (2004) has now been included in the review.</p> <p>Thank you. The GDG agrees that research is needed to investigate the potential benefits (and any harms) of vitamin D supplementation during pregnancy and have made a research recommendation to suggest this is undertaken.</p>

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						the full importance of variations in vitamin D status to the health of the mother, the pregnancy/fetus, and for the long term health of the child.	
SH	MRC Centre for Epidemiology of Child Health	6	NICE	1.3.2.5		<p>There is a wealth of evidence that obesity is an important risk factor for vitamin D deficiency. (E.g. Hypponen and Power AJCN 2007, Looker JCEM 2005, Vilarrosa et al. J Endocrinol Invest 2007, see PubMed for further references). Recently it has been shown to directly predict vitamin D deficiency in the mother and her offspring. (Bodnar et al. Prepregnancy Obesity Predicts Poor Vitamin D Status in Mothers and Their Neonates. J Nutr. 2007 Nov;137(11):2437-2442)</p> <p>Mothers who are obese should be classified as a high risk group.</p>	We now acknowledge this fact and have added it to our list of risk factors. Thank you.
SH	MRC Centre for Epidemiology of Child Health	7	NICE	1.3.2.5		<p>While routine supplementation of 400IU is generally considered as sufficient and safe in preventing the extreme forms of vitamin D deficiency (i.e. rickets/osteomalacia) in a population level (Vieth AJCN 1999) available evidence does not support the suggestion that 400IU/day is sufficient to improve vitamin D status in pregnant women who have very low vitamin D stores (such as women at the high risk groups).</p> <p>The literature should be evaluated, in order to determine the dose of vitamin D that is sufficient to improve vitamin D status in high risk women.</p>	Thank you. Please see the NICE Maternal and Child Nutrition public health guidance "The effectiveness and cost-effectiveness of interventions to promote an optimal intake of vitamin D to improve the nutrition of pre-conceptual, pregnant and post-partum women and children, in low income households" for more detailed discussion of this topic.
SH	MRC Centre for Epidemiology of Child Health	8	NICE	1.3.9.1		The proposed allowance of up to 1.5 units of alcohol per day contradicts the recent government guidance (based report by British	Thank you very much for your comment.

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						<p>Medical Association).</p> <p>Very high levels of alcohol consumption during pregnancy are known to lead to severe health problems in the infant (fetal alcohol syndrome) while there is a lack of evidence on the possible harms with moderate/light consumption. Presumably both the NICE committee and BMA have evaluated the same evidence.</p> <p>The discrepancy in the conclusions made by the two health authorities has most likely arisen from a differing philosophical set up of the basic question, with BMA evaluating the evidence on the light of "Is it known to be safe ?" ("Do no harm"), while NICE has assessed "Is it known to be harmful ?" (respecting the woman's right to choose).</p> <p>Such differences in the guidance are going to be very confusing to the pregnant woman.</p> <p>Furthermore, there is a concern that setting a daily allowance will provide the implicit message that it is fine to drink every day during pregnancy, while a slightly more restrictive weekly guidance (such as 3-4 units / small glasses of wine, no more than 1 per day) would better provide the message that caution is needed when consuming alcohol during pregnancy.</p>	<p>Yes, we agree.</p> <p>Yes, this seems very likely.</p> <p>The GDG have reconsidered the recommendations and have decided, as you suggest, to make the message more in keeping with DoH guidance in order to avoid the possibility of confusion and apparent contradiction. The 2 sets of recommendations are now very similar and, we believe, fairly reflect the evidence and its current state of uncertainty.</p>

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SH	MRC Centre for Epidemiology of Child Health	9	Full	10.9 (page 223)		There is no reference to the recent Health Technology Assessment Programme report (and publication in the BMJ) of the cost effectiveness of alternative prenatal preventive strategies for GBS and other neonatal bacterial infections. This report represents the most comprehensive synthesis to-date of the available evidence. Its recommendations should therefore be reflected in the guideline. Although not published till August 2007, the full report was given to Peter Brocklehurst and Rhona Hughes one year ago.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	MRC Centre for Epidemiology of Child Health	10				The absence of a separate section and specific recommendations on the management of preterm prelabour rupture of the membranes is a cause for concern (also missing from the 2003 guidelines). This condition affects one-third of all preterm deliveries and this group is at high risk of adverse neonatal and maternal outcome. There is clear evidence that treatment with oral antibiotics reduces adverse outcomes (see Cochrane systematic review on this topic).	Thank you for your comment but this is outside the scope of this guideline which is for low risk pregnancy without complications.
SH	MRC Centre for Epidemiology of Child Health	11				A separate section with recommendations for the management of prolonged rupture of membranes at term should be included. This condition affects over 8% of all pregnancies and is associated with an increased risk of adverse neonatal outcome.	Thank you for your comment but this is outside the scope of this guideline which is for low risk pregnancy without complications.
SH	MRC Centre for Epidemiology of Child Health	12		10.11		Toxoplasmosis. This section should refer to a recent systematic review and individual patient data meta-analysis of all available cohort studies (Lancet 2007, Thiebaut et al), and recent evidence on the accuracy of testing for neonatal IgM (Thalib et al J Med Screening 2007). The findings would not alter the recommendations.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	National Childbirth Trust	1	Full	General		It is really good to see these additional sections now included in this guideline, like breastfeeding, healthy eating etc.	Thank you.

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SH	National Childbirth Trust	2	Full and NICE	General		We have not had time to check, but have all the Cochrane reviews included in the guideline been checked for updated versions, with someone checking whether the findings have changed? This has not happened with asymptomatic bacteriuria, and this omission has led to a serious problem with the section and a recommendation that is now incorrect (see comments for page 207). Information was to the group that the findings of this review on asymptomatic bacteriuria were substantially changed at updating. The Cochrane Pregnancy and Childbirth Group is very keen to support the work of NICE, and the GDG could have communicated the Cochrane PCG, as was done during the development of the Intrapartum Care guidelines, where reviews were released confidentially to the GDG ahead of publication.	Thank you for your comment. It was not the intention of this update to update all areas of the guidance, just areas specified by the scope. However, during the course of the guideline development process the GDG highlighted the problem you describe here in relation to screening for asymptomatic bacteriuria. For this reason this recommendation had been amended and the findings from the updated Cochrane review included in the guideline in order to address this change in evidence and the reason behind current screening for asymptomatic bacteriuria.
SH	National Childbirth Trust	3	Full	General		Will the final document indicate which parts are updated and which were the original guideline? We are aware that members of the original guideline were not invited to be on the guideline development group for the updating, nor invited to referee this draft version. Hence, unless there is a demarcation on what is new, then it could be misunderstood who is responsible for the information within the guideline. It would seem that if it is the policy that new people will always be invited to do the updating, then either 1) there needs to be some demarcation in the responsibility for the different sections, 2) the agreement of the previous GDG should be sought for the new version or 3) the new GDG takes responsibility for the whole guideline and the original GDG acknowledged. There may be other ways too.	Yes, we will indicate in the final full version of the guideline with a bar in the right hand margin which areas are updated and make clear that these sections are those agreed by the new GDG.
SH	National Childbirth Trust	4	Full	General		Since the EFM guideline has now been incorporated within the intrapartum care guidelines, where will guidance on antenatal	Routine care of the healthy pregnant women would not involve fetal monitoring in the antenatal period by

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						CTG monitoring be found now?	definition and therefore would be outside of the scope of this guideline since it involves women who have complications in pregnancy.
SH	National Childbirth Trust	5	Full	General		Antenatal perineal massage still does not seem to be covered by a NICE guideline. This is a great pity as it helps to reduce perineal trauma and is something that women can do to help themselves, yet most will not know about its benefits.	Antenatal perineal massage was not part of the scope for this update.
SH	National Childbirth Trust	6	Full and NICE	General		It is a huge retrograde step to omit the grading of the new recommendations. Clinicians and women need to know on what basis these recommendations are being made. Are they just good practice points or is there strong evidence behind them? Without the grading, people will not know. It seems almost a waste of time for the GDG and the research team to take such trouble assessing the quality of the evidence if it is then ignored when making recommendations.	Thank you for your comment. The decision not to grade recommendations was taken by the NICE Board in March 2006 following consultation to changes in the guidelines methods manual. Views from stakeholders were divided on this issue. On balance NICE concluded that the grading of recommendations should not continue as the letter system implied an importance to the recommendations themselves rather than the strength of evidence alone. The grading of evidence continues to be our practice.
SH	National Childbirth Trust	7		P29		The recommendation on vitamin D seems a little confusing and might be better to omit 'healthy' and just say 'women at risk'. It is hard to know if the research on which this is based was carried out in income-rich countries or in income-poor countries where vitamin D deficiency can be a major problem. It would help to discuss this.	Thank you this is being rewritten. The country of each research study is now included in the review which is reproduced in the full version of the guideline.
SH	National Childbirth Trust	8		P30		Information about place of birth should be early in pregnancy as suggested here, but it is important for women not to be asked to choose at this point. Women should be given time during pregnancy to gather information and think about their opinions etc. Also if complications arise then their choices may	Yes, we agree. The recommendation refers to information giving and is not a prescription for when decisions need to be made. This is emphasised by the recommendation that time needs to be provided at each antenatal appointment for women to discuss

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						change.	issues and ask questions.
SH	National Childbirth Trust	9		P30		I am so glad to see antenatal breastfeeding information included now.	Thank you.
SH	National Childbirth Trust	10		P35		It is difficult to know if the research recommendation on vitamin D is appropriate without knowing more about the research already undertaken on women at risk of vitamin D deficiency.	Thank you.
SH	National Childbirth Trust	11		P35		It is also important when proposing research into a suggested routine intervention for all women (as is being suggested here), for there to be a rationale for the benefits expected. So what benefit might routine vitamin D bring for women and the babies? What is the theoretical basis for thinking that it might be of benefit? I think this is especially so for a fat soluble vitamin where people can overdose and possibly cause harm.	Thank you the current literature is unclear as to the benefits of routinely giving Vit D to all women. The GDG share some of your concerns over safety.
SH	National Childbirth Trust	12		P40		In the screening for Downs – women need to be informed of the risk of losing a healthy baby if they follow the screening process through – i.e. the 1/100 chance of losing a healthy baby when it comes to the amniocentesis. If women do not want to take that risk if they get that far then they may not wish to embark on the process at the beginning.	Thank you. The various sources of information do discuss this fact. The GDG feel this importance of accurate information to women is covered in their recommendations.
SH	National Childbirth Trust	13		P40		It would help to have a systematic review before embarking on any further research on tests.	Thank you for your comment. The ANCu guideline update contains the systematic reviews that underpin these research recommendations.
SH	National Childbirth Trust	14		P40		Asymptomatic bacteriuria – this is not correct – see comments on p207	Thank you for your comment. It was not the intention of this update to update all areas of the guidance, just areas specified by the scope. However, during the course of the guideline development process the GDG highlighted the problem you describe here in relation to screening

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							for asymptomatic bacteriuria. For this reason this recommendation had been amended and the findings from the updated Cochrane review included in the guideline in order to address this change in evidence and the reason behind current screening for asymptomatic bacteriuria.
SH	National Childbirth Trust	15		P44		Symphysis-pubis measurements – there should be further explanation for women so they can make sense of why a measurement is being taken and what is measured and its accuracy (see below).	Thank you. The Understanding Nice Guidance (UNG) will ensure all terms are explained fully.
SH	National Childbirth Trust	16		P54		The evidence summary of dietary advice comes later but would be better under each specific section – like the breastfeeding.	Thank you, this has now been moved as you suggest.
SH	National Childbirth Trust	17		P61 line 42		The wording that fewer women may take up the offer if screening when given good information implies this is considered a negative or adverse outcome for this intervention. I think this should be considered positive in that more women with good information understand the downsides of the testing and so exercise a better informed choice. For example, what women often do not realise is that agreeing to screening for Downs carries an increased risk of losing a healthy baby (have heard a risk of 1/2000).	Thank you for your comment. We agree and this statement has been amended to remove the suggestion that decreased uptake is an adverse outcome.
SH	National Childbirth Trust	18		P84		It would be good to explain to women that the fundal height measurement is only a vague guidance to the size of the baby (something which is obvious when you think about it with the variable volume of amniotic fluid) because using a tape measure implies accuracy that is not there. Using a tape measure is really because the women see a different midwife each time.	Thank you. We agree and would expect midwives to take time to discuss this as they are carrying out the measurement.
SH	National Childbirth Trust	19	Full	P96		If there is a systematic review by the centre in press, it would have helped to have it as an appendix in this draft document. In addition, it	Thank you. This systematic review has now been included in the ANC guideline update.

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						would help readers if the studies reported in this section had been references. It seems impossible to check this work and so be confident that this is the right recommendation.	
SH	National Childbirth Trust	20	Full	5.12 p.103		It is good to see national guidance that reflects the evidence on alcohol consumption and its effects during pregnancy. However, to make the recommendations clearer and less confusing it would be good to define 'one standard drink'. Do you mean for example a small glass of wine or half a pint of larger? These constitute one unit which makes the recommendation of one standard drink (1.5 units) confusing. Please also see comments on the alcohol recommendations in the NICE version.	Thank you for your comment. We have now amended the recommendation to include UK units of alcohol and have defined these as you suggest.
SH	National Childbirth Trust	21	Full	P207		<p>This guideline is reporting on a Cochrane review no longer in the public domain as it has been updated with Smaill F, Vazquez JC. Antibiotics for asymptomatic bacteriuria in pregnancy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD000490. DOI: 10.1002/14651858.CD000490.pub2.</p> <p>The updated review no longer shows a significant reduction in preterm birth – as the old review had done although the old review did point out the uncertainty of this data due to the poor quality of the included trials – something the guideline did not, unfortunately, also report. The updated review has the following results and conclusion in its abstract:</p> <p>Main results Fourteen studies were included. Overall the study quality was poor. Antibiotic treatment compared to placebo or no treatment was effective in clearing asymptomatic bacteriuria (risk ratio (RR) 0.25, 95% confidence interval (CI) 0.14 to 0.48). The incidence of</p>	Thank you for your comment. During the course of the guideline development process the GDG highlighted the need to update the section on screening for asymptomatic bacteriuria. For this reason this recommendation had been amended and the findings from the updated Cochrane review included in the guideline in order to address this change in evidence and the subsequent change in the reason behind current screening for asymptomatic bacteriuria.

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						<p>pyelonephritis was reduced (RR 0.23, 95% CI 0.13 to 0.41). Antibiotic treatment was also associated with a reduction in the incidence of low birthweight babies (RR 0.66, 95% CI 0.49 to 0.89) but a difference in preterm delivery was not seen.</p> <p>Authors' conclusions</p> <p>Antibiotic treatment is effective in reducing the risk of pyelonephritis in pregnancy. A reduction in low birth weight is consistent with current theories about the role of infection in adverse pregnancy outcomes, but this association should be interpreted with caution given the poor quality of the included studies.</p>	
SH	National Childbirth Trust	22	Full	P208		The recommendation on asymptomatic bacteriuria is incorrect as there is no longer a reduction in preterm birth with antibiotic treatment.	Thank you for your comment. During the course of the guideline development process the GDG highlighted the problem you describe here in relation to screening for asymptomatic bacteriuria. For this reason this recommendation had been amended and the findings from the updated Cochrane review included in the guideline in order to address this change in evidence and the reason behind current screening for asymptomatic bacteriuria.
SH	National Childbirth Trust	23	NICE	general		Good to see clarification and support for women with regards to being given relevant information and opportunity to ask questions and discuss with regards to informed decision making. These changes acknowledge the discrepancies that often exist for women in the decision making process. The strong emphasis on choice, good, unbiased information and a woman's right to choose are all welcome.	Thank you for your support.
SH	National Childbirth Trust	24	NICE	1.7.2.3		Its not clear what test, if any should be offered for screening for Down's syndrome at 14 weeks.	No test is recommended for 14 weeks – the woman would be advised to wait until 15 weeks of pregnancy if she

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							had missed the opportunity for the earlier test.
SH	National Childbirth Trust	25	NICE	1.1.1.2		"this can be achieved by..." but the potential need for further discussion should not be overlooked	Thank you. We have altered the wording of this recommendation to replace "achieved" by "supported" so as to clarify meaning.
SH	National Childbirth Trust	26	NICE	1.1.1.7- 1.1.1.1 0		Strongly support all recommendations	Thank you.
SH	National Childbirth Trust	27	NICE	1.3.9.1		Again, it is good to see national guidance that reflects the evidence on alcohol consumption and its effects during pregnancy. However, this recommendation should be made consistent with the recommendation in the full guideline – which refers to 1.5 unit rather than 1 unit (please see previous comments above). Consistency should also be maintained in relation to the recommendation in the full guideline about avoiding all alcohol consumption in the first three months of pregnancy.	Thank you. We have amended the recommendation to refer to UK units of alcohol and will ensure the same recommendation is reproduced in the NICE version.
SH	National Childbirth Trust	28	NICE	1.7.1.2		Strongly agree that women should be given information regarding the purpose of the anomaly scan	Thank you.
SH	National Childbirth Trust	29	NICE	1.7.1.4		Women should be given UNBIASED information AND SUPPORT – fully support recommendation	Thank you.
SH	National Childbirth Trust	30	NICE	1.7.2.5		The fact that screening does not provide a definitive diagnosis – POSITIVE or NEGATIVE	Thank you, it was not felt necessary to add "positive or negative" as the GDG felt the recommendation was clear as it stands.
SH	National Childbirth Trust	31	NICE	1.7.2.6		Strongly agree	Thank you.
SH	National Childbirth Trust	32	NICE	1.9.1.1		The NCT has serious concerns about introducing a major national screening programme on the back of one piece of evidence (ACHOIS). There are a number of questions that arise out of this evidence which would make it unwise to introduce a national	Thank you for this comment. There was a great deal of discussion in both the ANC update guideline group and the diabetes in pregnancy group about this issue. Perinatal death can of course be due to a number of causes

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						<p>screening programme at this time. Firstly, looking at the outcome – perinatal death, the deaths in the routine care group were not attributed to GD and were consistent with perinatal death rates in a normal healthy population. As the deaths were not caused by GD, introducing screening would not have avoided them. However, the intervention group had 0 perinatal deaths which is extraordinary and unexpected and does not reflect a normal healthy population. This surely raises the question – would the normal, healthy population not benefit from the intervention? It is certainly arguable that most pregnant women would gain benefit from dietary and lifestyle advice in pregnancy, particularly if they were aware of the potential improvement to outcomes. It must also be noted that the secondary outcome measured, shoulder dystocia DID NOT REACH STATISTICAL SIGNIFICANCE. The routine care group shows results in line with a normal healthy population, it is the intervention group that shows remarkable results – it would be a misinterpretation of the evidence to introduce screening on this basis. It is also felt that most women would opt for dietary advice in preference to screening if they were fully aware of the implications of both. Diabetes is a problem for the whole population and it should be tackled at this level. Avoiding diabetes for future generations could be best achieved by supporting all pregnant women to maintain a healthy diet and lifestyle. It is felt that a national screening programme is inappropriate until there is more evidence to this effect and potentially that all pregnant women should be given appropriate dietary advice.</p>	<p>– indeed the adverse outcomes were an amalgam of outcomes one of which was perinatal death. Others were to do with morbidity. Both guideline groups considered this evidence with great care and on balance felt it was sufficiently significant to warrant the recommendation to screen for GD in pregnancy.</p> <p>The method of screening was also problematic and after debate it was decided that risk factor screening was the preferred method remembering that this is already often the only method in current practice. The general view was that the position taken by the original ANC guideline was incorrect and in fact maternity services continued to screen in spite of the original advice. The feeling was therefore that the revised guideline was only formalising and refining what was already fairly common practice.</p>
SH	National Childbirth Trust	33	NICE	1.9.1.3		Fully support information giving. Would add that a diagnosis of GD may lead to increased	Thank you, we have added intervention as you suggest.

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						monitoring AND INTERVENTION	
SH	National Childbirth Trust	34	NICE	1.9.2.1		Strongly support	Thank you.
SH	National Childbirth Trust	35	NICE	1.10.1. 2		There is no need to recommend a fetal growth scan to detect small for gestational age babies if the sfh measurement is 3cm greater. This would lead to referrals for suspected large for dates babies and would be in conflict to 1.10.1.3 This should be amended to less for clarification	Thank you. This recommendation has now been removed following stakeholder consultation.
SH	National Chlamydia Screening Programme	1	FULL		Pages 5 to 7	It is not clear that the headings numbered 4 (GDG), 24 (Acknowledgements), 37 (Stakeholder Organisations) on page 5 and Peer Reviewers on page 7 apply to the original document and not the 2008 update.	Thank you – a new heading has been inserted to make this clearer.
SH	National Chlamydia Screening Programme	2	FULL	Section 2.1	Summary page 29	Wish to add 'chlamydia screening for under 25s if no previous test in the last year'.	Thank you. The discussion of Chlamydia screening will take place with all women but no actual screening is recommended to take place in the antenatal clinic.
SH	National Chlamydia Screening Programme	3		Section 2.2 Summary 10.3	Chlamydia trachomatis page 41.	Wish to suggest: 2008 Recommendations <ul style="list-style-type: none"> Health professionals need to inform all pregnant women under the age of 25 about the high prevalence of chlamydia infection in their age group and offer the opportunity for screening. Women aged 25 years and over should not routinely be offered chlamydia screening. Research Recommendation Review / investigate the involvement of midwives in the management of screen positives and their partners.	Thank you. We have reversed the order of the recommendations to highlight the importance of screening in the under 25 age group. After full consideration of all stakeholder comments the GDG have decided to retain the wording of the recommendations to make clear that the screening for Chlamydia infection should not be undertaken by staff in the antenatal clinic as it was felt this would be too time-consuming and require additional training that was outwith the usual sphere of practice of midwives.
SH	National Chlamydia Screening Programme	4	Algorithm + FULL		Pages 46 and 47	In the box below Nulliparous & Parous we would like added: Inform all under 25s about chlamydia and offer screening	Thank you. This algorithm is now being replaced by an updated NICE Quick Reference Guide. We will ensure information about chlamydia

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						<p>Included in the box " to be arranged early in pregnancy"</p> <p>Self taken vaginal swab or first catch urine for asymptomatic Chlamydia trachomatis (under 25s only)</p> <p>In the far right box " the following NOT recommended":</p> <p>Alter 'Chlamydia trachomatis' to read 'Chlamydia trachomatis in those 25 and over'.</p>	and chlamydia screening is included in the care pathway included in the guide.
SH	National Chlamydia Screening Programme	5	FULL	Section 4.7	page 89	<p>Recommendations – first appointment: suggested to add</p> <p>Inform all under 25s about chlamydia and offer screening</p> <p>Line 44 page 89 – suggested to add</p> <p>If screening accepted - Self taken vaginal swab or first catch urine for asymptomatic Chlamydia trachomatis (under 25s only)</p> <p>Generally suggested to add:</p> <p>Check re Chlamydia trachomatis screening at subsequent visits</p>	Thank you. We have amended the ordering of these recommendations so as to highlight the need to inform all women under 25 years of the prevalence of chlamydia in that age group and provide information about the national Chlamydia screening programme to these women. The GDG does not feel it appropriate that this testing should be undertaken within the antenatal clinic due to the extra burden this would place on antenatal resources, including midwifery staff.
SH	National Chlamydia Screening Programme	6	FULL	Section 5.11	page 100 SI in pregnancy	Consider adding: Unprotected sexual intercourse can increase the risk of a sexually transmitted infection or HIV	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	National Chlamydia Screening Programme	7	FULL	Section 6.6	page 115 Vaginal discharge	Although C. trachomatis is usually asymptomatic, it can result in vaginal discharge. We feel Ct should be included in this section and mention made of reference to section 10.3	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	National Chlamydia Screening Programme	8	FULL	Section 10.3	page 210	<p>Clinical question</p> <p>Please add vulvo vaginal swab – physician or self taken</p> <p>This is becoming increasing the swab of</p>	Thank you. It is not intended that this screening takes place in the antenatal clinic but that the woman will be referred to her local National

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						choice for women; it is preferred over urine by laboratories & has a greater sensitivity than urine for most platforms.	Chlamydia Screening Programme provision.
SH	National Chlamydia Screening Programme	9	FULL	Section 10.3	page 210	Diagnostic accuracy LCR not longer exists. Suggest rewording as: 2) Nucleic acid amplification tests (NAAT) - any platform currently marketed.	Thank you. These tests were identified for inclusion at the onset of the systematic reviewing process, hence it would not be appropriate to remove them at this late stage.
SH	National Chlamydia Screening Programme	10	FULL	Section 10.3	page 210	Previous NICE guidance and Future research The last guidance called for further investigation into the benefits of screening for genital chlamydial infection in pregnancy. The NCSP has identified several other relevant cohort studies that could be used to improve the systematic review. See table embedded below on the presentation of literature: entitled 'Relationship between C trachomatis infection and pregnancy outcome'.	Thank you. Whilst we recognise the importance of establishing the benefits of screening for chlamydial infection during pregnancy this was not the focus of this systematic review which was undertaken to answer the clinical question: "What is the diagnostic value and effectiveness of the following screening methods in identifying genital Chlamydia? Age; Urine testing; endocervical swabs; serum antibody testing; history." Unfortunately it was not possible within the time constraints and resource limitations of this guideline update to include further clinical questions.
SH	National Chlamydia Screening Programme	11	FULL	Section 10.3	pages 210-216	Diagnostic accuracy The laboratory methods for the diagnosis of C. trachomatis are well established and documented in the scientific literature. NAAT testing for C. trachomatis, which is the most sensitive and specific diagnostic method available for routine screening is the only testing strategy recommended by the National Chlamydia Screening Programme (NCSP) and is available through virtually all laboratories in England. This section and that on diagnostic accuracy should be removed as it does not add to the more important clinical question being addressed by the NICE guidelines which is: should pregnant women be screened for C. trachomatis infection?	Thank you. Currently NAAT testing has been shown to be the best, so if screening were to be undertaken it would be using NAATS. However it is important to establish the evidence base upon which this decision is made. In looking for evidence of the effectiveness of screening for Chlamydia during pregnancy the searching included other screening methods in an attempt to answer this question as comprehensively as possible. Even though this wide

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							search was undertaken there was still found to be no evidence to answer this part of the clinical question.
SH	National Chlamydia Screening Programme	12	FULL	Section 10.3	pages 216-218	<p>Literature quoted in NICE guidelines</p> <p>Only six papers were included in the revised NICE guidance: one RCT and five cohort studies1-6*. One of these publications should not have been included in the NICE guidance. This used Chlamydiazyme a notoriously insensitive, unspecific diagnostic test (Black-Payne, 1990) (Table: Relationship between C. trachomatis infection and pregnancy outcomes)</p> <div data-bbox="1176 721 1249 782" data-label="Image"> </div> <p>Relationship between C. trachoma'</p> <p>In case you cannot open the embedded file, it has been attached as Appendix 1</p> <p>Additional studies known to the NCSP HPA but not quoted in NICE draft guidance</p> <p>Whilst the NCSP HPA did not undertake a systematic literature review, an NCSP HPA assessment of the literature suggests that a further nine publications, seven cohort and two case-control studies, could have been included in the review table7-15*. With one exception (Rastogi, 2003) all the studies came from the US. Like those found by NICE, each study only considered a maximum of four adverse outcomes which were not consistent between investigations. Overall these showed that</p>	<p>Thank you for sending us the list of studies.</p> <p>The specific guideline question was to find evidence on the effectiveness of antenatal screening tests for Chlamydia in normal healthy pregnant women, that is, are these tests helpful in preventing maternal and neonatal adverse outcomes?</p> <p>As is evident from the NCSP HPA findings, none of the studies in the attached file had answered this question. Evidence for association between genital Chlamydia and adverse outcomes does not translate into evidence for the effectiveness of antenatal screening tests. At the same time it is evident that there is not enough robust evidence to show that treatment of Chlamydia improves perinatal outcomes.</p> <p>This is further reinforced by the CDC findings: "Screening during the first trimester might prevent the adverse effects of chlamydia during pregnancy, but supportive evidence for this is lacking".</p> <p>Regarding the question of inclusion or exclusion of certain studies, some of the studies had been conducted in high risk pregnant women while some others had been evaluated as EL 2- (poor quality rating). Three studies given in your list (Blas 2007, Harrison</p>

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						<p>there was generally an association between genital chlamydial infection and adverse pregnancy outcome. Some of the populations studied are high risk which accounts for the contradictory findings that were reported, for example in the two papers by Andrews et al. (see table).</p> <p>Overall interpretation of evidence-base</p> <p>There is limited evidence from RCTs and no cost-effectiveness studies. However, although the overall quality of the evidence-base is limited, the studies clearly demonstrate that: (i) genital chlamydial infection is associated with adverse outcomes in pregnancy, and (ii) that antenatal chlamydia screening during pregnancy does not do any harm. This is in line with the current CDC guidelines which state that "All pregnant women should be routinely tested for Chlamydia trachomatis at the first prenatal visit. Women aged <25 years and those at increased risk for chlamydia (ie., women who have a new or more than one sex partner) also should be retested during the third trimester to prevent maternal postnatal complications and chlamydial infection in the infant. Screening during the first trimester might prevent the adverse effects of chlamydia during pregnancy, but supportive evidence for this is lacking. If screening is performed only during the first trimester, a longer period exists for acquiring infection before delivery"¹⁶.*</p> <p>(iii) no evidence that treatment for chlamydia during pregnancy does harm.</p>	1983, Gravett 1986) were not identified from our literature search as these were looking for association between various pathogens and adverse maternal outcomes – thus are not related directly to the question.
SH	National Chlamydia Screening Programme	13	FULL	Section 10.3	Page 218 Lines 24 &	<p>GDG interpretation of evidence</p> <p>'There is no good quality evidence which would support routine antenatal screening for</p>	The specific guideline question was to find evidence on the effectiveness of antenatal screening tests for Chlamydia in normal healthy pregnant


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				Section 10.3	25 Page 218 Lines 26 & 27	<p>genital chlamydia'.</p> <p>Although the overall quality of the evidence-base is limited, the studies clearly demonstrate that: (i) genital chlamydial infection is associated with adverse outcomes in pregnancy, and (ii) that antenatal screening during pregnancy does not do any harm.</p> <p>'There are concerns regarding the practicality of undertaking adequate counselling, contact tracing, partner testing and follow-up in the antenatal care setting.'</p> <p>Experience from the implementation of the NCSP suggests that such concerns are unfounded. The usual management pathway for chlamydia antenatal screening is shown in the embedded file entitled 'Management pathway for NCSP screening in antenatal clinics'.</p> <p>The involvement of midwives within the NCSP can be limited to making the initial offer of screening to the patient. The rest of the procedures for the screening programme are undertaken by the local chlamydia screening office and the laboratory.</p> <div data-bbox="1176 1117 1243 1181" data-label="Image"> </div> <p>Management pathway for NCSP screening in antenatal clinics</p> <p>In case you cannot open the embedded file, it has been attached as Appendix 2</p> <p>The following examples show how four NCSP programme areas manage antenatal screening for genital chlamydial infection. All four stress</p>	<p>women, that is, are these tests helpful in preventing maternal and neonatal adverse outcomes?</p> <p>As is evident from the NCSP HPA findings, none of the studies in the attached file had answered this question. Evidence for association between genital Chlamydia and adverse outcomes does not translate into evidence for the effectiveness of antenatal screening tests. At the same time it is evident that there is not enough robust evidence to show that treatment of Chlamydia improves perinatal outcomes. This is further reinforced by the CDC findings:</p> <p>"Screening during the first trimester might prevent the adverse effects of chlamydia during pregnancy, but supportive evidence for this is lacking".</p> <p>Thank you. In order for the GDG to recommend screening for Chlamydia infection to be undertaken as part of antenatal care it would require a demonstration that screening is effective in terms of reducing negative outcomes. There is no evidence to show this.</p> <p>Thank you. Whilst acknowledging it may be possible to provide Chlamydia screening in the antenatal clinic following specialist training the GDG do not think it appropriate to recommend this as a national</p>

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						<p>that they undertake training for the midwives before the project starts. Training is ongoing for new staff and most NCSP programme areas also offer updating sessions, in addition to newsletters which are circulated to midwifery staff.</p> <p>Example 1 Hull NCSP request forms (RF) and patient information leaflets (PIL) are sent with the booking letter to all patients under 25s. Usually the patient has completed the RF by the time she attends the clinic. If she chooses not to take part at that stage, she is offered another opportunity at the 20 week scan. The result goes into the AN notes. The chlamydia screening office (CSO) arranges treatment for positives and partner management. Statement from a midwife: "I have spoken to a selection of midwives and the feeling is that it has become part of their routine questioning as everything is provided for them, although there is the feeling that we do have to go through so much with them at booking, we are currently reconfiguring our community services with a view to having pre booking information sessions to inform women of all the different screening options available."</p> <p>Example 2 Brent and Harrow The test offer is made at the booking visit using the NCSP PIL and RF. Self taken vaginal swabs are taken. The CSO sends a text message to all women who are negative and 'phones those who are positive. The CSO arranges all treatment and partner management and the result is written on the labour ward page.</p> <p>Example 3 Nottingham</p>	component of antenatal care given the lack of evidence of benefit in terms of improved perinatal outcomes.

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				Section 10.3	Page 218 Lines 28-30	<p>The availability of chlamydia testing is included in their hospital antenatal booklet which is sent to all pregnant women. The chlamydia test is offered at booking. All subsequent follow-up is done by the CSO.</p> <p>Example 4 South East Essex They have amended the NCSP leaflet to include a section on screening in pregnancy (see attached file: Patient Information leaflet, Southend).</p>  <p>Patient Information Leaflet- Southend.pdf</p> <p>In case you cannot open the embedded file, it has been attached as Appendix 3</p> <p>'In addition, it seems likely that the implementation of the NCSP should itself lead to reduction in the prevalence of chlamydia infection in women under the age of 25.'</p> <p>This statement assumes that antenatal testing is not required because the NCSP will control the infection. Antenatal screening is undertaken in some primary care organisations as part of the NCSP and accounted for 4640 screens, including those from obstetrics and gynaecology, in the financial year 2006/07. However, to work effectively the NCSP has to achieve a sustained, high level of coverage within the at target population, women under 25 years of age. The NCSP is an opportunistic screening programme undertaken in clinical and non-clinical settings outside genitourinary medicine clinics. The inclusion of women</p>	

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						attending antenatal services in the NCSP has two advantages. It is a very good opportunity to offer screening to sexually active women, and it will prevent complications associated with genital chlamydial infection in pregnancy.	
SH	National Chlamydia Screening Programme	14	FULL	Section 10.3	Page 218	<p>NCSP HPA Conclusions on data</p> <p>1 There is an association between genital chlamydial infection and adverse pregnancy outcome.</p> <p>2 Screening and treatment for genital chlamydial infection during pregnancy is not harmful.</p>	Thank you. What this does not show, however, is that screening in pregnancy is clinically and cost-effective.
SH	National Chlamydia Screening Programme	15	FULL	Section 10.3	Page 218	<p>NCSP proposed recommendations:</p> <p>1. Health professionals need to inform all pregnant women under the age of 25 about the high prevalence of chlamydia infection in their age group and offer the opportunity for screening. (The role of the midwife is noted in 3 and in embedded figure on page 3).</p> <p>Comment: Routine screening and treatment of <i>C. trachomatis</i> infection in the pregnant under 25s should be undertaken to reduce the adverse effects of obstetric outcome. With 167 000 live births amongst women under 25 years of age in 2005, national screening for <i>C. trachomatis</i> as part of antenatal care would be a major public health intervention and a welcomed development for the NCSP.</p> <p>2. Women aged 25 years and over should not routinely be offered chlamydia screening.</p>	Thank you. The GDG have considered all comments carefully, with the expert advice of sexual health specialist doctor. It is felt that it is not appropriate to recommend screening within the antenatal care setting for Chlamydia infection in pregnant women under the age of 25 due to the lack of evidence of its clinical effectiveness in terms of reducing negative outcomes for this population and concerns regarding the practicality of undertaking adequate counselling, contact tracing, partner testing and follow-up in the antenatal clinic setting..

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						<p>3. The management of a chlamydia positive pregnant woman and her partners will be the responsibility of the local NCSP screening office unless agreed differently.</p> <p>Comment: NCSP screening is part of antenatal care offered to patients in many primary care organisations. Experience in these centres provides a model for the roll out of screening to all antenatal clinics.</p>	
SH	National Chlamydia Screening Programme	16	NICE	1.2.7.3 First appoint ment		<p>Recommendations – first appointment: to add Inform all under 25s about chlamydia and offer screening At subsequent visits to add: Check re Chlamydia trachomatis screening</p>	Thank you for your comment, however given the lack of evidence of effectiveness of chlamydia screening and treatment in terms of pregnancy outcomes this is thought to be inappropriate.
SH	National Chlamydia Screening Programme	17		1.3.8 SI in pregna ncy		<p>Consider adding: Unprotected sexual intercourse can increase the risk of a sexually transmitted infection or HIV</p>	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	National Chlamydia Screening Programme	18		1.4.6.1 Vaginal Dischar ge		<p>Although C. trachomatis is usually asymptomatic, it can result in vaginal discharge. We feel Ct should be mentioned in this section.</p>	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	National Chlamydia Screening Programme	19		1.8.3.1		<p>Chlamydia screening should not be offered as part of routine antenatal care. NCSP HPA recommended statement Chlamydia screening should not be routinely offered as part of routine antenatal care to women aged 25 and over.</p>	Thank you. The GDG decided not to recommend that Chlamydia screening be carried out by midwives in antenatal clinics, even for women aged under 25, due to concerns regarding lack of evidence of effectiveness and difficulties associated with the practicality of undertaking adequate counselling, contact tracing, partner testing and follow-up in the antenatal clinic setting.
SH	National Chlamydia Screening Programme	20		1.8.3.2		<p>Health care professionals need to inform pregnant women under the age of 25 about the high prevalence of</p>	

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						<p>chlamydia infection in their age group, and give details of their local National Chlamydia Screening Programme provision</p> <p>NCSP HPA Recommendation: 1. Reworded as: Health professionals need to inform all pregnant women under the age of 25 about the high prevalence of chlamydia infection in their age group and offer the opportunity for screening.</p> <p>2. This sentence above should come first as 1.8.3.1</p>	<p>Thank you. The order of these recommendations has been reversed as you suggest. The GDG decided not to recommend that Chlamydia screening be carried out by midwives in antenatal clinics due to concerns regarding the practicality of undertaking adequate counselling, contact tracing, partner testing and follow-up in the antenatal clinic setting.</p>
SH	National Chlamydia Screening Programme	21		Section 3 Implementation		<p>NCSP HPA would be willing to assist in providing implementation tools. In particular, it is working on an AN Information leaflet.</p>	Noted with thanks.
SH	National Chlamydia Screening Programme	22		Section 4.2 Research Recommendations		<p>Further research needs to be undertaken to assess the effectiveness, practicality and acceptability of chlamydia screening in an antenatal setting.</p> <p>NCSP suggests the following: Research Recommendation The practicality of midwives being more involved in the management of screen positives and their partners.</p> <p>Why this is important Chlamydia is an important health care issue especially amongst the young, but the current level of evidence provides an insufficient basis for a recommendation. NCSP does not support the above sentence.</p>	<p>Thank you.</p> <p>This suggestion has been added to the research recommendation.</p> <p>Thank you. Despite the fact the CMO expert group decided in 2000 to set up a National Chlamydia Screening</p>

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						<p>The CMO Expert Advisory Group decided back in 2000 to set up a National Chlamydia Screening Programme with antenatal services as a screening venue.</p> <p>Of particular importance is the possibility that treatment might reduce the incidence of preterm birth and neonatal complications and studies should be directed to these areas. NCSP supports this further research.</p>	Programme with antenatal services as a screening venue, having reviewed the evidence the GDG still feel the evidence base is poor, especially in terms of evidence that screening in the antenatal period leads to improved outcomes, as you allude to in your next sentence. The research recommendation as it stands includes the effectiveness of screening which includes reduction of adverse outcomes such as preterm birth and neonatal complications.
SH	National Patient Safety Agency					This organisation was approached but did not respond.	
SH	National perinatal epidemiology unit	1	Full	5.1.2		<p>The recommendation on lines 31-32 of page 103 seems to run contrary to the advice recently issued by the four CMOs. This may be confusing to pregnant women. In addition, although the first three months of pregnancy may be a period of high risk for teratogenesis, animal experiments have also shown effects on brain development during the third trimester.</p>	<p>Thank you for your comment. The GDG have reconsidered the recommendations and have decided, as you suggest, to make the message more in keeping with DoH guidance in order to avoid the possibility of confusion and apparent contradiction. The 2 sets of recommendations are now very similar and, we believe, fairly reflect the evidence and its current state of uncertainty.</p> <p>The evidence from animal studies would not be considered as evidence for a NICE guideline. In the human research there is no evidence of harm at the low levels of alcohol consumption recommended as a maximum in the NICE guidance.</p>
SH	National perinatal epidemiology unit	2	Full	11.1		<p>The recommendations appear in agreement with the available evidence. Given the low grade of evidence presented, a recommendation to guide future research would be useful.</p>	<p>Thank you. The GDG felt it was not appropriate to make a research recommendation at this stage since the findings from the HAPO study have not yet been fully reported. Once those findings are</p>

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						Will the figures for Table X be completed? These cost-effectiveness figures are particularly useful to give an overall assessment of the different strategies.	known the direction for future research will be more evident. Table X (now table 6 in this chapter) has been completed.
SH	National perinatal epidemiology unit	3	FULL	8.2 general		It wasn't clear how the review and the recommendations fitted in with the views of the national screening committee – little mention was made of their work at any stage	Thank you. The National Screening Committee policy has already been mentioned in the introduction to this section and has now also been added to the GDG interpretation of evidence as it was a factor considered by the GDG when making recommendations for practice. It should be noted however, that the NSC's policy of screening for thalassaemias using red blood cell indices is not supported by the evidence thus in this area the NICE guidance differs.
SH	National perinatal epidemiology unit	4		8.3 recommendations		Final recommendation about consideration for partner testing if a woman is RhD-negative. This would open the whole minefield of non-paternity. A women may know her partner is not the father but may not wish to say so and so any result might not actually relate to the fetus and rhesus sensitisation result may follow a test effectively on the wrong person. Whilst this may not happen often it is of potential concern for those women affected.	Thank you. The section on rhesus factor testing was not included in the scope of this guideline update, but these recommendations will be reviewed shortly as the technology assessment underpinning this section is currently being updated.
SH	National perinatal epidemiology unit	5	FULL	9.1	p 151line 17,18	Strongly support recommendation re Regional Congenital Anomaly Registers (in line with those of the CMO). However these Registers need to be supported financially because funding is currently haphazard and short term.	Thank you. By making this one of our key recommendations this will get Implementation and Costing support from NICE which we hope will, in turn, lead to funds being made available.
SH	National perinatal epidemiology unit	6			P 140-lines 1-26	Difficult to understand, many errors – needs proof reading properly	Thank you, the full version of the guideline has now been copy-edited and so errors such as these should be at a minimum.
SH	National perinatal epidemiology unit	7			P151	Should be re-ordered to reflect frequency i.e. intrauterine therapy last	Thank you, we have re-ordered these bullet points as suggested.

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					lines 7-11		
SH	National perinatal epidemiology unit	8			P142 line 121	"poor spelling at school" is irrelevant to this discussion	Poor spelling at school is used by the authors as a proxy for impaired neurological development and is therefore reported as an outcome of the study.
SH	National perinatal epidemiology unit	9		9.2 General		Why is there no discussion on the handling of results concerning risk for Trisomies 18 and 13? There is a dilemma as to whether these should be reported and if so the risk cut off. Guidance is needed on this.	The scope related to screening for Down's syndrome thus only evidence for this screening was reviewed.
SH	National perinatal epidemiology unit	10		9.2 General		Why is there no discussion concerning the issue of rapid karyotyping and whether a full karyotype should always be carried out?	This guideline deals with screening rather than diagnosis.
SH	National perinatal epidemiology unit	11		9.2 General		Concerned about the age of the papers reviewed in relation to ultra-sound since the technology has improved greatly over time and some of the papers quoted are really quite old.	The papers used were considered the most appropriate and some were relatively "old" However some of the included papers did postdate the HTA report on ultrasound. In fact in general, they did not seem to offer any different results to the older ones
SH	National perinatal epidemiology unit	12		9.2 general		Again it was not clear how the review and the recommendations fitted in with the views and work of the national screening committee – little mention was made of their work at any stage.	Thank you. The National Screening Committee reports do not form part of the systematic review as the reviews in NICE guidance are research papers or systematic reviews of research. The work of the NSC is sometimes referred to in introductions or GDG interpretations in order to put the NICE recommendations in context with other guidance where the GDG feel this is appropriate.
SH	National Public Health Service - Wales					This organisation was approached but did not respond.	
SH	NHS Direct					This organisation was approached but did not respond.	
SH	NHS Quality Improvement Scotland					This organisation was approached but did not respond.	

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SH	NHS Sickle Cell and Thalassemia Screening Programme	1	Full			General comment about terminology: The UK National Screening Committee have moved away from using trimester, as there is some controversy on the precise timing particularly the first trimester. Removing this wording would also be consistent with the NICE Algorithm	Thank you. The GDG feel the term trimester is still widely used and well understood. However, to ensure clarity weeks of pregnancy are also included in all recommendations where appropriate.
SH	NHS Sickle Cell and Thalassemia Screening Programme	2	Full		pp4 line 10 pp39 line 7, line 9, line19 Section 8.2, Pp 126 line 15, line 41 Pp127 line 1, line 2, line 4, line 5,line 11, line 16, line 17, line 45, line 46, line 47, line 48, line 50, Pp128	Sickle cell disorders should be changed to sickle cell disease throughout the document to be consistent with the Screening Programme publications; specific pages that need amending highlighted below from page 4-418. The terminology has been changes as a result of a recent recommendation from the Screening Programmes Steering Group chaired by Lay Chair Archbishop of York and consisting of a mixture of health care professionals, users of services and Voluntary Organisations http://www.sickleandthal.org.uk/Membership.htm : Pp127 line 1, line 2, line 4, line 5,line 11, line 16, line 17, line 45, line 46, line 47, line 48, line 50, Pp128	Thank you for your comment. These have now been amended.

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					<p>line 5,</p> <p>pp136 line 29</p> <p>pp137, line 7, line 9, line19,</p> <p>Section 8.2 pp 417, line 1, line 3,</p> <p>Pp417 Line 10, line 11, line 22,line 27,</p> <p>Pp 418 line 7</p>	<p>Should read sickle cell disease includes a variety of haemoglobin variants</p> <p>Sickle cell disorders should be changed to sickle cell disease</p>	
SH	NHS Sickle Cell and Thalassemia Screening Programme	3			<p>Pp 126 line 19 Pp126 line 14</p> <p>Pp127 line 28</p>	<p>Sickle Cell carrier rather than Sickle Cell Trait is the preferred terminology to be used to be consistent with other recessive genetic conditions, specific pages that need amending are highlighted below pages 126-418:</p> <p>Should read sickle cell disease/ sickle cell carrier</p>	<p>Thank you. Trait has now been replaced by carrier throughout this section.</p> <p>Page 127 line 28: this sentence has now been amended to read as you</p>

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						Should read there are an estimated 240,000 health carriers of sickle cell (NHS Sickle.....	suggest.
					Pp133 line 37	Need to clarify should read: One Beta Thalassaemia gene may be inherited resulting in a carrier (sometimes called beta thalassaemia minor) or no Beta Thalassaemia genes are inherited this results in a severe disorder (Beta Thalassaemia major)	Pp133 line 37: amended.
					Pp134, line 3, line 20,		Pp134, line 3, line 20: amended.
					Pp134 line 32	Should read sickle cell disease/ sickle cell carrier	Pp135 , line 15, line 16 Line 17: amended.
					Pp135 , line 15, line 16 Line 17	Should read sickle cell disease/ sickle cell carrier	Section 8.2 introduction: amended.
					Section 8.2	Should read sickle cell carrier Should read Thalassaemia carrier Should read sickle cell carrier	Pg 417 & 418 are deleted material from the previous guideline and so it would not be appropriate to make amendments here.
					Pp 417, line 7	Should read sickle cell carrier	
					Pp 417, line 15	Should read thalassaemia carrier	
					Pp417, line 39	Should read sickle cell carrier	
					Pp417, line 40, line 50	Should read thalassaemia carrier	
					Pp417, line 52	Should read if both parents are carriers	
						Should read thalassaemia carrier	
						Should read haemoglobinopathy carriers	

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					Pp418, line 8 Pp418, line 29		
SH	NHS Sickle Cell and Thalassemia Screening Programme	4	Full	Section 2.1	Pp29, pp42	Family origin is preferable to ethnic group and more relevant to screening and antenatal care than the census categories	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	5	Full		pp7	Correct spelling of Allison (from Alison)	Amended, apologies.
SH	NHS Sickle Cell and Thalassemia Screening Programme	6	Full		pp 20	Areas outside the remit of the guideline – suggest you make it clear that pre-conceptual care was excluded in the general sense	Thank you. Added.
SH	NHS Sickle Cell and Thalassemia Screening Programme	7	Full Section 2	Section 2	p 29	Line 10 – need to be consistent with Down's and use term offered- also suggest you clarify that haemoglobinopathies means sickle cell and thalassaemia and other haemoglobin variants (re accessibility of your report) as many people don't join the two up.	Thank you, this has been added to the glossary and to the introduction to aid clarity.
SH	NHS Sickle Cell and Thalassemia Screening Programme	8		Section 2	p 30	Line 1 – suggest you list specifically what tests you mean and include infections, foetal anomaly and sickle and thal) don't assume everyone knows	Thank you. This recommendation is meant as a concise summary of information giving. More detail is provided as each area of screening is addressed and in the list of what to do at each antenatal appointment that appears in the full version and as an appendix to the Quick Reference Guide.
SH	NHS Sickle Cell and Thalassemia Screening Programme	9		Section 2	pp31	Line 41 onwards – despite supporting sickle and thal screening nowhere is it listed in the recommendations – this needs to be fixed or again SC&T seems marginal – an afterthought. It seems the section on haemoglobinopathy screening was developed separately from this section and is not fully integrated/throughout though as to the mainstream of antenatal care.	Thank you for your comment, haemoglobinopathy screening is now included in the list of screening to be carried out at the booking appointment. Preconceptual care is not included in this list which covers appointments

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						<p>We have had quite a few comments about this point from a range of our own stakeholders.</p> <p>Review of need to offer testing needs to be included at first appointment if not already offered/primary care or preconceptionally. Point that testing can be offered preconceptionally needs to be covered here. The process should link to the early antenatal assessment of needs – if a woman is a carrier and her partner needs testing this should start immediately.</p>	during pregnancy.
SH	NHS Sickle Cell and Thalassaemia Screening Programme	10		Section 2		<p>You refer to prior to 12 weeks here but this is not specific enough to be consistent with your helpful recommendation in the SC&T section on by 8-10 weeks some joining up and consistency is needed to make it explicit that maternity care pathway needs to be designed to ensure that this is achieved. However testing can be done at any time and there is no end point for testing like there is for Down's.</p> <p>In general it appears that on the ground Maternity matters modernisation initiatives are happening and that screening programme requirements are not well linked in here – for successful implementation some linkage to this is needed or could put elsewhere</p> <p>The SHIFT HTA funded trial now has run in baseline data published and this needs to be included in the detailed review section – it would be very useful in terms of making the comments about 8-10weeks more explicit and emphasising the practical problems. Dormandy E, Gulliford M, Reid EP, Brown K, Marteau TM, Delay between pregnancy confirmation and sickle cell and thalassaemia</p>	<p>Thank you. This has now been amended to say prior to 10 weeks to improve consistency.</p> <p>Thank you. We will flag this link for the NICE Implementation Team.</p> <p>Thank you but this study does not</p>

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						screening: a population-based cohort study, in press British Journal of General Practice, 2007	address the clinical question as posed for the systematic review. Since the recommendation has been made to carry out early screening and to bring forward booking appointments to before 10 weeks we feel this issue has been adequately address nonetheless.
SH	NHS Sickle Cell and Thalassemia Screening Programme	11		Section 2	Page 32 line 32-33	The offer of screening for sickle cell (other haemoglobin variants) and thalassaemia need to be included in the list to fit with the inclusion in section 8.2, emphasising the point that this should be offered as soon as possible in pregnancy, as a minimum by 10 weeks	Thank you, this has now been added.
SH	NHS Sickle Cell and Thalassemia Screening Programme	12		Section 2	pp 38–lines 1-23	<p>Section 8.2 Summary Heading appears to be missing Screening for haemoglobinopathies Overall we very much welcome these high level recommendations and the general direction they move things forward in. Our comments are to try and get the facts correct and to address inconsistencies within the report as a whole. They should not take away from the overall view that they are welcomed by the NHS Sickle Cell and Thalassaemia Programme.</p> <p>We would also ask the recommendations are incorporated within the general summary recommendations in a more inclusive way. We have had quite a few comments relating to the great emphasis on the Down's programme c.f. this area so there is a constituency comment rather than just a programme specific comment.</p>	<p>Thank you very much indeed, and thank you for all your help in developing this section of the guideline.</p> <p>We have strived to include recommendations on haemoglobinopathy screening throughout the summary sections and outline of appointments as appropriate.</p>
SH	NHS Sickle Cell and Thalassemia Screening Programme	13			Pp 39 line 2	Recommendation on pre-conceptual counselling and testing is welcome. This should of course be part of the national pre-conceptual policy and services of which there is none – would it be helpful to have a recommendation that such a policy and services should be formalised and this	<p>Thank you. It is outside the scope of NICE clinical guidance to establish national policy and services.</p> <p>Recommendations throughout the guideline emphasise undertaking screening early in order to allow for</p>

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						<p>recommendation would then have a "home". This would be a national requirement for DH to develop.</p> <p>The Programme recommends that the offers of screening includes the uptake of and reporting of results of pre natal diagnosis and any subsequent action by the end of 12 weeks of pregnancy. The timing and organisational requirements for the delivery of the main aims and objectives presents a considerable challenge to health care professionals, however there is some evidence to support this approach (see section 2.1 Antenatal Knowledge week: http://www.library.nhs.uk/screening/ViewResource.aspx?resID=269344&tabID=289&catID=1328</p> <p>You suggest for preconceptual policy that women at higher risk are offered testing (meaning as identified by an FOQ) but this is different to the antenatal policy which is based on policy for maternity units – being defined as high prevalence or low prevalence. Your recommendation doesn't have evidence behind it in the way the antenatal recommendations for high and low prevalence</p>	<p>further testing if desired and provide reproductive choice for women.</p> <p>Thank you for your comment about preconceptual care. The recommendation reflects the GDG's position that a woman should be screened using the FOQ and if she is found to be at higher risk then testing should be offered.</p>
SH	NHS Sickle Cell and Thalassemia Screening Programme	14			Pp 39 Line 5-6	<p>Terminology should be offered and carried out,</p> <p>Line 5-6 could be combined with line 9 – 11 or run consecutively as there is some repetition.eg</p> <ul style="list-style-type: none"> Screening for haemoglobinopathies (sickle cell, thalassaemia and other haemoglobin variants) should be offered to all pregnant women and should be carried out as soon as possible in pregnancy, or as a minimum by 10 weeks. To facilitate informed decision making for women/ couples, so that the offer of, uptake of 	<p>Thank you, this is now amended.</p> <p>These recommendations have been combined to avoid repetition as you suggest.</p>

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						<p>and reporting of results of prenatal diagnosis and any subsequent action by the end of 12 weeks of pregnancy. Practically this means early enough to allow a vacuum suction termination.</p> <ul style="list-style-type: none"> Screening should be in the context of primary or secondary care, and be preceded by counselling and accessible information. The type of screening depends upon the prevalence of sickle cell disease for each local unit. 	
SH	NHS Sickle Cell and Thalassemia Screening Programme	15			Pp 39 Line 7-8	Last word change to these as it is not the intention to discuss each of the different carrier statuses – more the implication of being a couple, being an at-risk couple and having an affected infant. Should also add accessible information: provided with accessible information	Thank you. Amended to these as the last word. The word accessible has not been added since recommendations about information-giving refer to good practice in this area in some detail.
SH	NHS Sickle Cell and Thalassemia Screening Programme	16			Pp 39 Line 9-11	Add for each local unit	Thank you. We have not added “for each unit” as the screening in some instances is being carried out in primary care settings where the word “unit” does not apply.
SH	NHS Sickle Cell and Thalassemia Screening Programme	17			Pp 39 Line 12	Should add 1.5 cases of sickle cell disease Change to areas served by high prevalence trusts	Thank you, we have added sickle cell disease and reworded the recommendation slightly which has removed the need to use the word “area”.
SH	NHS Sickle Cell and Thalassemia Screening Programme	18			Pp 39 Line 15	Change to areas served by low prevalence trusts Should add less than...of sickle cell disease	Thank you, we have added sickle cell disease and reworded the recommendation slightly which has removed the need to use the word “area”.
SH	NHS Sickle Cell and Thalassemia Screening Programme	19			Pp 39 Line 20	Very specific method specified – they don't have evidence to make such a specific recommendation. We suggest replace all	Thank you. We have amended the recommendation to reflect your concern, however there is evidence

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						three references to high performance liquid chromatography to simply read 'laboratory screening' Also P27.'	that high performance liquid chromatography performs well and our expert advisor also endorsed this as the most suitable method and so this remains in the recommendation as the preferred method.
SH	NHS Sickle Cell and Thalassemia Screening Programme	20			Pp 39 Lines 21-23	Suggest replace reference to high performance liquid chromatography to simple read 'laboratory screening' Second bullet format Should delete mention of family origin and read 'If the mean cell haemoglobin is less than 27pg...	Thank you. We have amended the recommendation to reflect your concern, however there is evidence that high performance liquid chromatography performs well and our expert advisor also endorsed this as the most suitable method and so this remains in the recommendation as the preferred method. We have also deleted the mention of the FOQ in screening for thalassaemias in low prevalence areas as you suggest.
SH	NHS Sickle Cell and Thalassemia Screening Programme	21			Pp 39 Line 24-25	This recommendation needs to be tightened up – we will pick up in the detailed section but we don't think all partners of identified carriers (of which there are about 800 variants) should be offered screening more partners of a woman identified as a carrier of a haemoglobin variant that could result in an significant disorder in the fetus. At present nowhere in the guideline do you specify which conditions and carrier status should be screened for and this needs to be covered in the detailed section or much unnecessary anxiety will be generated. Refer to page 13 to Programme Standards http://www.sickleandthal.org.uk/Documents/ProgrammeSTAN.pdf	Thank you. The GDG feel it is not appropriate to list all the potential variants of haemoglobinopathies in a general guideline for AN care. However we have included a link to the NHS Sickle Cell and Thalassemia Screening Programme.
SH	NHS Sickle Cell and Thalassemia Screening Programme	22			Pp 39 Lines 24-25	See comments relating to pp 125 line 13 & 14. Suggest you reword to say "partners should be offered timely testing without delay"	Thank you. "Without delay" has now been added to this recommendation.

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						<p>Suggest you use consider using term “father of the baby” rather than partner when referring to antenatal screening as it is the biological father who needs testing which may not be the same as the partner.</p> <p>Partner is appropriate term for pre-conceptual testing.</p>	The GDG has considered using the term “father of the baby” instead of partner, but since it is applicable in the minority of cases and the woman's partner may well be with her during the appointment it was felt inappropriate to include it here in the recommendation.
SH	NHS Sickle Cell and Thalassemia Screening Programme	23			Line 26	<p>We are disappointed to see no research recommendations made in relation to the sickle and thal programme despite the fact that this is a relatively poorly researched area. We think that the equity issue should be considered here.</p> <p>In terms of key areas for further research the more detailed review identifies many areas where there is limited research and these are all possible areas for further research. Firstly we suggest research to clarify the policy for screening for alpha thalassaemia, see section 8.2</p> <p>For a second area the potential application of MS to antenatal screening would allow much centralisation of screening (using dried blood cards) and reduce costs increasing cost-effectiveness – this could be considered as area for further research. ... Daniel YA, Turner C, Haynes RM, Hunt BJ, Dalton RN (2007) Quantification of Haemoglobin A2 by tandem mass spectrometry. Clinical Chemistry</p>	Thank you for your comment. The importance of haemoglobinopathy screening has been highlighted by the guideline by making this one of our key priorities for implementation. The GDG did not feel it appropriate to include a research recommendation in this section as the screening programme is already rolled out nationally. It would be hoped that the NHS Sickle Cell and Thalassemia Screening Programme itself would be responsible for auditing this.
SH	NHS Sickle Cell and Thalassemia Screening Programme	24			Pp 40 – lines 18-21	<p>We suggest that these general points be put as general recommendations – they are not specific to the Down's programme but should relate to all screening.</p> <p>In relation to the lines that follow if you are</p>	Thank you. The recommendations are now amended so as to cross refer to the information-giving section so that this specific information does not appear just in the Down's Syndrome

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						<p>specifying what should be covered for Down's you should be consistent and fair and give equal importance to other screening programmes and their requirements. For Sickle and Thal screening this would then allow the recommendation to spell out that screening is for significant maternal haemoglobinopathies as per other list pp 13 programme standard document) (b) maternal conditions requiring partner testing – see list on pp 13.</p> <p>The same applies to rapid access to adequately trained staff – the current recommendations could be seen as not focusing on equity between programmes or than NICE was not concerned with Equity. We are not specifying how you address these points in terms of layout just that it is important that you do so.</p>	screening recommendations.
SH	NHS Sickle Cell and Thalassemia Screening Programme	25		Section 2.3, pp45		Should amend to be consistent with the Sickle cell and thalassaemia screening programmes and say family (ethnic) origin	Thank you. This has been amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	26		Page 76 line 17		Information should be given about all antenatal screening, including the offer of screening test for haemoglobinopathies (sickle cell and thalassaemia and other haemoglobin variants)	Thank you, screening for haemoglobinopathies is included under all antenatal screening and it would be inappropriate to single it out here.
SH	NHS Sickle Cell and Thalassemia Screening Programme	27		Page 89 line 27		As suggested for Section 2 – pp32 line 22	Thank you, this has been amended to include ideally before 10 weeks.
SH	NHS Sickle Cell and Thalassemia Screening Programme	28		Page 89 line 30 - 43		Need to add offer screening for sickle cell and thalassaemia and other haemoglobin variants	Thank you, haemoglobinopathy screening has been added here too.
SH	NHS Sickle Cell and Thalassemia Screening Programme	29	Section 8.1	Pp 125 line 13 & 14		Please note that commonly iron deficiency may be suspected following haemoglobin screening. Partner testing should not be delayed whilst iron supplementation is offered	Thank you. Screening for anaemia was outside the scope for this update and the GDG believe the new recommendations for sickle cell and

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						without investigating the haemoglobinopathy carrier risk or using possible iron deficiency as a reason not to proceed with partner testing. Your guidance as it standard allows the old practice to continue – Identification of iron deficiency should not delay partner testing for haemoglobinopathy carrier status.	thalassaemia screening will ensure correct practice is followed.
SH	NHS Sickle Cell and Thalassemia Screening Programme	30					
SH	NHS Sickle Cell and Thalassemia Screening Programme	31	Section 8.2	Pp126, line 12		Omission to also add in self management: Includes antibiotics, self management, painkillers	This recommendation was made for the 2003 guideline and is outside the scope of this update.
SH	NHS Sickle Cell and Thalassemia Screening Programme	32	Section 8.2	Pp126 line 17		Heading for the clinical question needs to be clarified cf pp 129 where there is a heading saying thalassaemia screening and then on pp 133 a question on sickle cell disease/trait. We think this should be reframed to make it clear that this is what is covered subsequently as two separate sections. Our general comment on the approach to separating the two questions is given below.	Thank you. The introduction and background is meant to cover all haemoglobinopathy screening but the systematic reviewing was undertaken for the two separately, then together as this reflects how the clinical questions were asked. We think this is clear from the heading used. In order to make this clearer the clinical question has been removed from section 8.2.
SH	NHS Sickle Cell and Thalassemia Screening Programme	33				To separate thalassaemia screening for sickle cell /variant screening is not very helpful as the inheritance of the conditions interact and both need to be considered together in the round which is what the recommendations do. We understand you wish to consider how well the particular screening works but in practice the two operate together. This is especially relevant for identifying couples at risk a women who is a thalassaemia carrier is for example at risk of an affected baby if her partner is a sickle cell carrier (S-Beta Thal results in 1:4 cases and presents as a sickling condition) – the partner needs to be tested for both sickle and thalassaemia carrier status.	Thank you for your comment. We recognise this is a complex area and the two areas of screening interact. However, in terms of systematic reviewing it was felt more appropriate to separate the 2 types of conditions as this is how the subject has been researched.

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SH	NHS Sickle Cell and Thalassemia Screening Programme	34	Section 8.2	Pp126 Line 21, line 29		Amend to be consistent with Sickle Cell and Thalassaemia Screening publications – family origin, rather than ethnic background	The clinical question has now been removed from this section, but the amendments you suggest have been made later in the document where appropriate.
SH	NHS Sickle Cell and Thalassemia Screening Programme	35		Pp126, line 25		Sickledex is a trade name. The sickle solubility test' is generic equivalent and should be used	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	36		Pp 126 line 36		Facts wrong- should read: normal adult haemoglobin has four globin chains each associated with one haem part	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	37		Pp126-129 – omission See also pp 148 lines 5-9 consistency needed between section 8.2 and this section		<p>General comment on what is missing from the background section on pp 126-129. Overall point is that we recommend that aims of the programme are outlined in a way that is consistent with the other sections of the document</p> <p>There is no mention of what the aim of the antenatal and pre-conceptual screening is. Aims are specified, for example in the foetal anomaly section, so there should be consistency in approach across the guideline.</p> <p>Due to the lack of aims outlined in this section it is unclear what the specific question is focusing on. For aims of the NHS Sickle Cell and Thalassaemia programme (see standards doc pp18-20 http://www.sickleandthal.org.uk/Documents/ProgrammeSTAN.pdf). The aim is stated as "to offer* timely antenatal sickle cell and thalassaemia screening to all women (and couples) to facilitate informed decision making (the offer* includes: the offer of, uptake of, and reporting of results of prenatal diagnosis and any subsequent action by the end of 12 weeks of pregnancy).</p>	Thank you. The overall aims of the screening programme have now been added, along with a reference to the NHS Sickle Cell and Thalassaemia Screening Programme where the reader can find more information. It is not possible to include all this detail here as the guideline has to provide a balance between useful information and clinical utility.

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						<p>Specific objectives include: -</p> <ul style="list-style-type: none"> (i) To accurately diagnose women and couples with genotypes specified as requiring further investigation (ii) To accurately diagnose specified conditions where prenatal diagnosis is undertaken [and by implication not others which are not clinically significant]. <p>From this follows that specific significant conditions (HbSS, HbSC, HbSD Punjab, HbSE, HbSO Arab, HbS Lepore, HbS beta Thalassaemia, Beta Thalassaemia Intermedia, HbSH, Beta thalassaemia major) are identified in the mother so that the women is given specialist obstetric care and specific carrier states in the mother are to be screened for page 13 Programme Standards http://www.sickleandthal.org.uk/Documents/ProgrammeSTAN.pdf) and not all carrier states. This should be covered in the introduction as the guideline stands it is not clear if you are recommending identifying all carrier states or only ones which are likely to be clinically important. This leaves the guideline open to misinterpretation and needs tightening up</p> <p>Pre-conceptual testing is preferable, as it offers further choices not available in pregnancy, which include selection of partner who is not a carrier, not having children, opting for PIGD etc. We support this recommendation but suggest that somewhere in the introduction section this information could be added to make the guidelines clearer as to what they are about – in particular about individual women's choice and not just testing.</p>	<p>The importance of pre-conceptual counselling is acknowledged and demonstrated by the fact that the GDG felt it important to recommend that it be available, even though this is outside the scope of the guideline.</p> <p>The importance of early screening and testing is highlighted in the recommendations following review of evidence which shows that early termination of pregnancy is more acceptable to women, including those from certain ethnic and religious groups who may find later termination unacceptable.</p> <p>Findings relating to women's views of late termination of pregnancy is derived from evidence relating to screening for structural anomalies hence it appears in this systematic review and can't be repeated under a different clinical question.</p>

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						<p>The reason testing needs to be offered by 8-10 weeks of pregnancy at the latest to be “timely” is to ensure informed decision making including the option of a suction termination of pregnancy which is a much more acceptable option, particularly for certain ethnic and religious groups, than termination at a later stage of pregnancy. This means that it is very important if equity in an underlying concern.</p> <p>The evidence that women are less likely to take up the option of prenatal diagnosis in the second trimester than in the first trimester, suggesting that they find the option of TOP more difficult with advancing gestation is given in two papers: (Modell et al, (1997) Audit of prenatal diagnosis for haemoglobin disorders in the UK; the first twenty years. BMJ 315, 779-784; Petrou et al (1992) Factors affecting uptake of prenatal diagnosis for sickle cell disease. J Med Genet 29, 820-823).</p> <p>Both practitioners and women find late termination, especially if feticide is involved (after 21+6 weeks), difficult. An unpublished survey of fetal medicine specialists showed wide variation in their views regarding late termination for both sickle and thal, which may mean that this service would not be available in certain parts of the country.</p> <p>See pg 148 lines 5-8 the same points about difficulties in termination after 20 weeks are relevant here and should for consistency be included here</p>	
SH	NHS Sickle Cell and Thalassemia Screening Programme	38		Pp 127 line 21		Facts wrong – should read- amount of alpha-globin, causing a reduction in MCV & MCH, and in some cases anaemia and a	Thank you, this has been amended.

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						characteristic blood film	
SH	NHS Sickle Cell and Thalassemia Screening Programme	39		Pp 127 line 26/7		Not very clear Should read Inheritance of one alpha thalassaemia gene gives rise to an alpha thalassaemia carrier who will have a reduced production of alpha globin, resulting in the person having anaemia and a characteristic blood film. Inaccurate – should read: an unborn child inherits no healthy genes for alpha-globin production, this typically results in a lethal disorder known as alpha-thalassaemia major or haemoglobin or Haemoglobin Bart's hydrops.	Thank you. This section has been amended following suggestions from the Royal College of Paediatrics and Child Health.
SH	NHS Sickle Cell and Thalassemia Screening Programme	40		Pp 127 –line 16-18		Factual errors: figures quoted are very out of date. About 8,500 sickle cell carriers are identified by the programme each year and about 300 babies are detected with sickle cell disease (NHS Sickle Cell and Thalassemia Screening Programme 2007)	Thank you for these figures, these have been amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	41		Pp 127, line 34- 35		Most patients have life long treatments of blood transfusions and iron chelation...	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	42		Pp 127 line 36		Error. Appropriately treated patients are now expected to live much longer, at least 50 years and probably for a 'normal' lifespan	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	43		Pp 127 line 36/37		Inaccurate –should read: bone marrow transplantation is an option if a suitable donor is available, and gene therapy may become an option in the future.	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	44		Pp 128 line 25		Incorrect – should read: Mean corpuscular haemoglobin (MCH)	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	45		Pp 128 line 28		Add investigating ferritin level outcomes should not delay partner testing for haemoglobin disorders here, but investigation for anaemia should occur at the same time.	Thank you for your comment. Whilst we acknowledge your concern about the issue of delayed partner testing was not looked at as part of this update, and does not fit here within the definition for additional tests.
SH	NHS Sickle Cell and Thalassemia Screening Programme	46		Pp128 line 29		Suggest delete this line as people may have, and often do have, both iron deficiency and	Thank you. We have deleted this as you suggest.

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						thalassaemia	
SH	NHS Sickle Cell and Thalassemia Screening Programme	47		Pp128, line 36-39		Screening process paragraph talks about DNA analysis may be undertaken to confirm before prenatal diagnosis - in practice this is done at the same time as it reads suggests that PND may be delayed	Thank you. This has been amended to improve clarity and accuracy.
SH	NHS Sickle Cell and Thalassemia Screening Programme	48		Pp 128 line 45-46		States 4 papers then says 1 Canadian + 1 USA + 3 UK but then describes only 2 UK	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	49		Pp 128 – line 5		<p>Inaccurate: use condition not disorders — we are not recommending using term disorders for sickle cell disease.</p> <p>Definitions that may be helpful:</p> <ul style="list-style-type: none"> ▪ Disease Literally dis-ease, the opposite of ease, when something is wrong with a bodily function. The words disease, illness, and sickness are loosely interchangeable, but are better regarded as synonymous. Disease is a physiological/ psychological dysfunction ▪ Illness is a subjective state of the person who feels aware of not being well ▪ Sickness is a state of social dysfunction, i.e. a role that the individual assumes when ill <p>Disorder, Disease, Syndrome. These word often loosely used have a precise meanings. A disorder is a disturbance or departure from normal healthy function, e.g. of an organ or body system, i.e. Impairment. A disease is a disorder that can be assigned to a diagnostic category; it usually has a distinct clinical course and often a distinct aetiology. A syndrome is a group of symptoms and signs that tend to appear together and collectively characterise a disorder (J Last Dictionary of</p>	Thank you. Amended.

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						Epidemiology)	
SH	NHS Sickle Cell and Thalassemia Screening Programme	50		Pp 128 – line 6 and elsewhere in this section		<p>Factual errors: Please do not use the term selective screening this is WRONG. See Wald J. All screening is universal. Medical Screening 2001:8:169.</p> <p>To be consistent with the section on Down's screening you should be able to incorporate the "package that is screening" rather than just an individual screening test such as a lab index/cut-off or a family origin questionnaire.</p> <p>Our recommendations for your approach to this are as follows: "screening using family origin question" or "screening using laboratory methods". If you are quoting a study which erroneously uses the term put the terms in italics. On review of the Wald paper you may decide on your own style to make it clear that screening is not selective.</p>	Thank you for your comment. We have now amended this paragraph to reflect the screening as a "package of screening" as you suggest, and removed the term "selective" which is, as you imply, widespread throughout the literature.
SH	NHS Sickle Cell and Thalassemia Screening Programme	51		Pp 128 –line 8		Factual error: delete Wales. Wales have developed their own approach and do not use the Family Origin Questionnaire but a separate question.	Thank you. We haven't changed this since we have a stakeholder comment from Antenatal Screening Wales stating that they wish to follow the same screening programme as recommended in the NICE guidance ie. the NHS Sickle Cell and Thalassemia Screening Programme.
SH	NHS Sickle Cell and Thalassemia Screening Programme	52		Pp 128 –line 13		Factual error: Correct title = NHS Sickle Cell and Thalassemia Screening Programme.	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	53		Pp 128 – lines 12-13		Update: 70% have implemented by September and all except one with no confirmed date are due to implement by end of December	Thank you for these figures. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	54		Pp 128 – line 28		Factual inaccuracies: reword to "Ferritin – this is a test performed on patients with a low haemoglobin to detect iron deficiency"	Thank you. Amended.

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						(Don't mention haemoglobinopathy as there is some overlap)	
SH	NHS Sickle Cell and Thalassemia Screening Programme	55		Pp 129 line 49 –50 & pp 133 line 39- 40		The questions on pp 129 lines 49-50 and pp 133 lines 39-40 could be rephrased to read "...methods.... Clinically significant thalassaemia and maternal conditions requiring offer of partner testing"	Thank you. It is not possible to alter the clinical question at this stage as the searching and systematic reviewing is specific to the question as written.
SH	NHS Sickle Cell and Thalassemia Screening Programme	56		Pp 129 – line 40-46		To avoid misinterpretation in the media NICE should make it clear that it supports "informed choice" – the statements could be read by the Minority Press as implying NICE supports termination more than choice.	This paragraph begins with the statement "All the published economic evidence in this clinical area" In order to make it clear it is the published evidence we are referring to rather than it being a reflection of NICE's or theGDG's viewpoint. NICE's statement regarding woman-centred care and the chapter on informed decision making make it clear that informed choice is supported by NICE and the GDG.
SH	NHS Sickle Cell and Thalassemia Screening Programme	57		Pp 129 – lines 49-50		The real question for the antenatal programme is about "identifying conditions where prenatal diagnosis is undertaken" (i.e. foetus at risk rather than woman affected- as in the case of thalassaemia beta thal will already be obvious and this is not the main aim). See earlier comments about lack of specification of aims of the programme, which is why you have a problem here.	Thank you. The aims of the screening programme have now been included, they do not however, form the basis of the systematic review which is based upon the clinical question as stated.
SH	NHS Sickle Cell and Thalassemia Screening Programme	58		Pp129, line 52		Amend to be consistent with Sickle Cell and Thalassaemia Screening publications – family origin, rather than ethnic background	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	59		Pp 130, line 3		Suggest add: g) Mean Cell Haemoglobin	Thank you. MCH was in fact included in the specified review outcomes and so has been added to this list.
SH	NHS Sickle Cell and Thalassemia Screening Programme	60		Pp 133 – lines 19-20		Omission of important evidence point: a key point you report is that Pakistani women are much more likely to take up PND if offered in	Thank you, this evidence point has now been added.

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						the first trimester (pp 132 lines 10-13) – this supports your recommendation on timing and is a key requirement if we are to offer a service that is more acceptable to all of the English population.	
SH	NHS Sickle Cell and Thalassemia Screening Programme	61		Pp133, line 42		Amend to be consistent with Sickle cell and Thalassemia Screening publications – family origin, rather than ethnic background	Thank you. Amended.
SH	NHS Sickle Cell and Thalassemia Screening Programme	62		Pp 134 – lines 4-19		Delete these lines. This reference is not useful as we do not recommend solubility testing in the UK (unreliable). It will not detect some of the carrier states, which should be detected in pregnancy: - C, D, E.	Thank you but we do not wish to delete this section of the review since sickle solubility testing was identified at the outset of the guideline update for inclusion in this clinical question. Furthermore the study provides evidence that electrophoresis is more accurate than sickle solubility testing thereby giving the evidence base to underpin your own recommendation that it should not be used.
SH	NHS Sickle Cell and Thalassemia Screening Programme	63		Pp134 line 37-38		Add “subsequent” termination of an affected pregnancy is acceptable	Thank you. This has been added.
SH	NHS Sickle Cell and Thalassemia Screening Programme	64		Pp134, line 41		Sentence is unclear, it should read: “sickle cell carriers are less likely to be offered and receive screening in a timely manner”	Thank you. This has been clarified.
SH	NHS Sickle Cell and Thalassemia Screening Programme	65		Pp 135 – lines 34 onwards		The Sickle cell and Thalassemia Screening Programme commissioned the initial study from which this paper is derived. In our opinion unfortunately the paper and initial EQUANS study presents limited information in relation to the original intended purpose of informing national policy. In relation to the analysis of data the main areas of concern, it has been reported to us by a co-applicant of the original study that it is possible to estimate the rates for each carrier state, for each site for both question A and B and identify where the problems lie with the question. This has not been done and makes the presentation of the results limited. In addition, the precision of the	Thank you for this extensive comment. This information has formed the basis of an on-going discussion between the GDG/NCC-WCH technical team and the NHS Sickle Cell and Thalassemia Screening Programme, however our guideline development process allows us to use published material only. Whilst acknowledging the shortfalls you describe the overall conclusion reached is that a fixed response questionnaire seems preferable and the NHS Sickle Cell and Thalassemia Screening Programme FOQ is recommended for use, a

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						<p>estimates, there is evidence of between – centre variations in time taken. Under these circumstances estimates of the average time taken, sensitivity and specificity should have been derived from random effect (multi-level) models and not ruled out. The use of only 4 centres results in estimates with much greater uncertainty than is implied by the fixed effect model assumed in the analysis. As a result the SC & T Programme are unable to come to the same conclusions, as it is hard to know whether the time taken for question A and B are realistic.</p> <p>With respect to the missed cases; it's reported that 7/122 for question A and 10/103 for question B, no information about the types of carriers and the types of errors concerned. The analysis should have described how the question works but this is not covered. E.g. all women have routine blood indices inspected, beta thalassaemia carriers should be identified and therefore the key carrier states to be identified and therefore the key carrier states to be identified by the family origin questionnaire are most importantly S,C,D and E. The paper gives none of this analysis, which is what is really needed to understand what the likely implication of the finding would be.</p> <p>The main conclusion to be drawn from the study as reported was that ensuring the test was offered is the most important indicator of whether this type of screening tool would work. Due to limitations described above it is not possible to conclude that the questions did not work, as there were significant problems in the implementation of the study and engagement of staff.</p>	recommendation that you endorse.

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						<p>In particular the clinically relevant haemoglobinopathies definition is loose and includes a number of results which the programme would not consider to be clinically significant – mainly alpha thalassaemia + results. As far as we are aware only one HbAS result was missed</p> <p>The programme has commissioned an independent study of the family origin questionnaire within the first phase of the low prevalence roll out. ETHNOS. Evaluation of the "family origin questionnaire". March 2006.</p>	
SH	NHS Sickle Cell and Thalassemia Screening Programme	66		Pp 136 – lines 6-7		Define term: please specify what “early” in pregnancy means here.	“Early” pregnancy in this research paper referred to prior to booking, usually prior to 12 weeks.
SH	NHS Sickle Cell and Thalassemia Screening Programme	67		Pp 136 – lines 36-37		Factual error: replace thalassaemia with word “variant” DN – Joan/David do these lines make sense – the thal “screen” is surely the routine indices. This is the variant screen	Thank you. This has been amended to improve accuracy.
SH	NHS Sickle Cell and Thalassemia Screening Programme	68		Pp 137 – lines 1-25		Comments on recommendations covered earlier in response to the summary section	Thank you.
SH	NHS Sickle Cell and Thalassemia Screening Programme	69		Pp 137 lines 15-17		<p>In low prevalence areas (foetal prevalence of sickle cell disease of <1.5 per 10,000 births) all women should be offered screening for thalassaemia and the offer of screening for sickle cell and other haemoglobin variants should be based on an assessment of risk using the family origin questionnaire</p> <p>Also need to add within recommendation section to screen as early as possible in pregnancy and as a minimum by 10 weeks gestation to ensure the offer of, uptake of and reporting of prenatal diagnosis and any subsequent action (termination where requested) is complete by the end of 12 weeks</p>	Thank you. We have amended this recommendation slightly but the GDG prefer not to use the word “risk” in recommendations as it is felt this word has negative connotations and is used to frequently in association with pregnancy.

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SH	NHS Sickle Cell and Thalassemia Screening Programme	70	Full section 8.2	Omission		<p>No specific consideration of alpha thalassaemia screening policy in this guideline – suggest you recommend further research to clarify the policy on this if you are not covering this here or cover it in the guideline otherwise this section is incomplete. Specifically you have not mentioned or reviewed laboratory methods or the use of ultrasound to identify hydrops fetuses c.f. laboratory methods. Our guidelines – see laboratory handbook pp 42 http://www.sickleandthal.org.uk/Documents/LabHandbook2006.pdf state “foetuses thought to be at risk for these rare cases of Hb Bart’s hydrops fetalis can be examined by ultrasound for signs of anaemia and hydrops fetalis. These women should be referred for ultrasound assessment of fetal anaemia using middle cerebral artery Doppler peak systolic velocities, which will become abnormal before clinically apparent hydrops”.</p> <p>The recent paper by Josh Wright et al J Medical Screening Wright J, Rati N, Kennefick A, et al. A pilot study of ‘fast track’ antenatal screening for haemoglobinopathies. J Med Screen 2003, 10(4):169–171 [PubMed abstract]– supports the approach we have taken to alpha thalassaemia screening is relevant to this area. The findings from the study suggest that using a family origin question is a sensible way to reduce the false positive rate regarding alpha + thalassaemia (and we think by up to 95% in low prevalence areas). See our recent literature review for national knowledge week http://www.library.nhs.uk/screening/ViewResource.aspx?resID=268964 [In clinical practice now women who are thought to be at risk of an affected pregnancy are now being scanned for this rather than</p>	<p>Thank you. Within the resources of the guideline update we had to prioritise by focussing on the more common conditions. The fetal conditions you mention are extremely rare and it was felt therefore to be inappropriate to include them in a national guideline concerned with usual care of a healthy pregnant women.</p> <p>Thank you. The clinical question lists the included thalassaemias and we have removed alpha thalassaemia as you suggest.</p>

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						<p>having a prenatal diagnosis, which risks the loss of a potential normal baby. We recommend that if this is not covered in the ultrasound section under foetal anomalies –as at present- you acknowledge the gap in the guideline and recommend a review of the evidence to date and possible further research. Hydrops foetalis is invariably fatal or very severe. It also is a significant risk to mother's health during pregnancy so usually a termination is offered. As the prevalence of the condition is low in the UK, evidence from SE Asia is most relevant.</p> <p>Assuming you are not covering alpha thal here we suggest that you tighten up the definition of the clinical question on pp 129 line 49 so its clear that thalassaemia excludes alpha thal unless you want to review the evidence as well as laboratory methods or do a section on the evidence around alpha thalassaemia.</p>	
SH	NHS Sickle Cell and Thalassemia Screening Programme	71		Up to date review of literature on this subject		Further evidence supporting the Programmes policies can be found in the National Knowledge week for Antenatal Care http://www.library.nhs.uk/screening/ViewResource.aspx?resID=268964	Thank you.
SH	NHS Sickle Cell and Thalassemia Screening Programme	72		Important publication now "in press"		A cohort study of all pregnancies (n=1441) reported in 25 general practices in two UK inner city Primary Care Trusts offering universal screening reported the median (inter-quartile range) gestational age at pregnancy confirmation was 7.6 weeks (6.0-10.7 weeks) and 74% presented before ten weeks. The median gestational age at screening was 15.3 weeks (IQR 12.6-18.0 weeks), with only 4.4% being screened before 10 weeks. The median delay between pregnancy confirmation and	Thank you for this reference. The evidence you quote further supports the recommendations, particularly the need to carry out screening earlier in pregnancy to provide women with real choice.

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						screening was 6.9 weeks (4.7-9.3 weeks). Dormandy E, Gulliford M, Reid EP, Brown K, Marteau TM, Delay between pregnancy confirmation and sickle cell and thalassaemia screening: a population-based cohort study, in press, British Journal of General Practice, 2007	
SH	NHS Sickle Cell and Thalassaemia Screening Programme	73		Omission – appendix B		We note that no economic modelling has been applied to the haemoglobinopathy screening section. This should be made clear in the section 8.2	Thank you. We feel this is clear from the text.
SH	NHS Sickle Cell and Thalassaemia Screening Programme	74		Omission on Refs (2008 update)		Refs 718 & 719 have no author names – need to correct	These refs are by Sin, Ghosh, Tang et al and Yeo, Tan & Liu respectively – these names appear in the reference list in the full version of the guideline (p. 604).
SH	NHS Sickle Cell and Thalassaemia Screening Programme	75				See also recent knowledge week review for more recent list of references	Thank you. All references have been checked and none add to the evidence for this clinical question.
SH	NHS Sickle Cell and Thalassaemia Screening Programme	76	Algorithm			To clarify and emphasise the importance of screening early for haemoglobinopathies, the box on page 2 of the algorithm could read To be arranged early in pregnancy by 10 weeks gestation: Blood tests to screen for: Thalassaemia Sickle cell and other haemoglobin variants To be arranged by 16 weeks of gestation: To emphasise the importance of specialist care for pregnant women living with a haemoglobinopathy add to the box leading from Women who may need additional care, Should add sickle cell disease, thalassaemia to the conditions as haematological conditions	Thank you. This algorithm will be replaced by the new NICE Quick Reference Guide (QRG). We will ensure early screening is included in this. Thank you. This has now been added.

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						is a term commonly used to describe these conditions	
SH	NHS Sickle Cell and Thalassemia Screening Programme	77	NICE	1.1.1.1 pp 7		At first contact with a health care professional provide information about all antenatal screening and offer screening for thalassaemia, sickle cell and other haemoglobin variants as per local policy to facilitate informed reproductive choice	Thank you for these comments. All antenatal screening includes screening for sickle cell and thalassaemia and it would be inappropriate to single these out here.
				1.1.1.1, pp 8		Before or at 36 weeks discuss newborn screening including bloodspot test for sickle cell, Medium Chain Acyl Co –A Dehydrogenase, Cystic Fibrosis, Congenital Hypothyroidism, Phenylketonuria, Hearing, and Newborn physical tests in line with NSC standards and guidance	Information about newborn screening is outside the scope of this antenatal care update.
				1.6.2.7			Preconceptual screening and early screening are both included in our recommendations.
				1.2.7.3 pp 13		Screening should be offered ideally preconceptually and before 10 weeks gestation to facilitate reproductive choice (see NSC Guidance)	Screening for haemoglobinopathies has its own heading in the full version and this will be carried over in to the NICE version.
				1.2.7.3 pp16		First appointment needs to be earlier in pregnancy (prior to 10 weeks) to aide informed choice for genetic conditions Omission at first appointment offer screening for thalassaemia, sickle cell and other haemoglobin variants	Whilst other national screening programmes and policies are considered when the GDG are interpreting the evidence the NICE process demands that recommendations are based on evidence rather than other forms of guidance, many of which are not evidence-based.
				1.6.2 pp26		Omission add give information on newborn screening including bloodspot test for sickle cell, Medium Chain Acyl Co-A Dehydrogenase, Cystic Fibrosis, Congenital Hypothyroidism, Phenylketonuria, Hearing, and Newborn physical tests in line with NSC standards and guidance	
				1.6.2.6			

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				1.6.2.8, 1.6.2.9, 1.6.2.1 1		<p>Sickle Cell and Thalassaemia should have own heading with sections for 1.6.2.6 – 1.6.2.12</p> <p>Section should be amended to make it more consistent with the antenatal screening policy:</p> <p>Preconceptual counselling and carrier testing should be available for all women to fit with the antenatal screening policy</p> <p>Sickle cell disorders should be changed to sickle cell disease throughout the document to be consistent with the Screening Programme publications</p>	
SH	North Tees and Hartlepool Acute Trust					This organisation was approached but did not respond.	
SH	Northumbria Healthcare NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Nutrition Society	1	Full	Section 1.4 and 1.5	page 21-22	Whilst the Nutrition Society is pleased that Dietitian is listed amongst the consulted external advisers, it is suggested that a nutrition health professional, such as a Dietitian, Registered Nutritionist or Registered Public Health Nutritionist, be considered for membership of Guideline Development Groups when producing guidelines that include nutritional recommendations.	The dietician who acted as an external advisor received all meeting papers (including summaries of evidence) and attended the Guideline Development Group when nutritional recommendations were being made, playing an active part in the drawing up of those recommendations.
SH	Nutrition Society	2	Full	Section 1.2	page 20-21	Most birthweight references in current paediatric use do not display the 5th and 95th centiles. Thus babies in categories <5th and >95th will not be identified. Better to use <0.4th or <2nd centile, depending on the risk being sought. Of course, some babies of normal birthweight may also have experienced intrauterine growth restriction.	Thank you for your comment. Whilst paediatric birthweight charts may no longer use 5 th and 95 th centiles, these are still used by obstetricians and midwives when referring to measurements relating to unborn babies. Part of the reason for this is the margin of error associated with ultrasound measurement (approx. 10%).

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SH	Nutrition Society	3	Full	Section 2.1	page 29	The Nutrition Society supports the idea of offering vitamin D supplements although some of the criteria here are less objective than is desirable. How dark does skin have to be to qualify? Women in Northern climes in the UK may be more 'at risk' than those in Southern climes particularly for pregnancies over the winter months. What does the panel mean by 'at risk of deficiency'? Does it accept the consensus definition based on a plasma 25-OHD concentration below 25 nmol /l? If so, what proportion of women in the UK with low plasma 25-OHD will be identified by the listed criteria, and what proportion will not? The prevalence of this condition (NDNS) in (non pregnant, not breastfeeding) women aged 19-24 is 28%, and it is 13 - 15% in women aged 25-49. If the Panel think it unimportant for this group to meet the RNI through use of supplements, how will they ensure that the fetus has adequate vitamin D stores to meet demands through 6 months of exclusive breastfeeding? A broader range of criteria for offering vitamin D supplements may be desirable. The Nutrition Society supports the call for more research on vitamin D supplementation and there ought to be funding provided for this.	Thank you. We have amended the criteria for risk status so as to improve clarity. The ANCu GDG does accept the consensus definition of plasma 25-OHD concentration below 25 nmol /l. It is believed the list of risk factors will identify the vast majority of women at risk. The recommendation has been substantially revised and now ensures all women are informed of the importance of vitamin D and that women are told about the Healthy Start vitamin supplement. Women in high risk groups are encouraged to take this supplement.
SH	Nutrition Society	4	Full	Section 2.2 First contact with a health professional.	page 29-30	The Nutrition Society welcomes the provision of information on nutrition, diet and food hygiene being included in a pregnant woman's first meeting with a healthcare professional. The Nutrition Society does, however, suggest minimum training requirements be introduced for this person to advise on nutrition. Later in the guidance (page 13) it is stated that this first appointment should be before 12 weeks of pregnancy, meaning that information about folic acid supplementation is still valid,	Minimum training standards are outside the scope of this NICE clinical guideline.

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						however the Society would encourage healthcare professionals to provide this information to all women who could become pregnant as benefit is shown in women taking folic acid supplements before conception.	
SH	Nutrition Society	5	Full	Section 5.3 Working in Pregnancy.	page 92-93	The importance of ensuring that eligible women are informed about 'Healthy Start' and enabled to register with the scheme should be specifically mentioned because encouraging continued contact with health professionals through pregnancy and beyond is a core principle of the scheme.	Thank you. Healthy Start is now mentioned in the guideline recommendations (Chapter 3).
SH	Nutrition Society	6	Full	Section 5.5 Supplements	page 94-97	Mention of prescribing 5 mg folic acid is required. Whilst women who have previously had an NTD-affected pregnancy will be captured by the list in 1.2, those whose partners have a family history, or who have other risk factors will not be.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Nutrition Society	7	Full	Section 5.6	page 97	The Nutrition Society supports the advice for the avoidance of food-acquired infections.	Thank you
SH	Nutrition Society	8	Full	Section 5.12 Alcohol	page 100-5	The Nutrition Society supports advice to avoid alcohol during pregnancy. It is questionable that a woman can consume up to 10 units of alcohol per week without risk. Whilst the evidence is mixed (possibly due to confounding) there is some evidence of harm even at this level. A precautionary approach should be adopted in the absence of sufficient evidence to establish a safe threshold. Indeed, the concept that a 'safe' threshold exists may itself be flawed. There is no section or comment relating to caffeine use during pregnancy but there is some evidence of adverse effects in experimental studies. While there may not be enough evidence to advise limiting use during pregnancy, there is enough to recommend that more research is needed on the effects of caffeine.	Thank you. Following stakeholder consultation the GDG have now decided to reduce the recommended maximum in order to be more cautious and to avoid giving confusing messages to women. Thus the NICE recommendation now states no more than 1-2 UK units once or twice a week, the same level as recommended by the DoH, 2007.

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SH	Nutrition Society	9	Full	7.2 Breast examination	page 120	Should not this be actively discouraged rather than just described as 'not recommended'? One of the best RCTs (Alexander 1992) found that many women positively decided before birth not to breastfeed when told they may have a problem as the result of breast examination.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Nutrition Society	10	NICE	1.9.1 Gestational diabetes	page 32-33	<p>The Nutrition Society is concerned that the NICE guidelines do not contain advice about recognising the symptoms of gestational diabetes. Women to whom the specified risk factors do not apply may also develop diabetes during pregnancy, and the Society is of the opinion that this should be highlighted.</p> <p>The Nutrition Society would welcome the provision for all women with newly diagnosed gestational diabetes to meet privately with a nutrition health professional, and be given individualised dietary advice and the opportunity to ask any questions about the practicalities of controlling the diabetes through alteration to diet.</p>	<p>Thank you. Pregnant women rarely report symptoms of gestational diabetes so this was not felt to be a necessary inclusion.</p> <p>Thank you. Please see recommendations made in the Diabetes in Pregnancy clinical guideline for recommendations relating to care and treatment of women with gestational diabetes, where this is included.</p>
SH	Obstetric Anaesthetists Association	1	Full			Surveys ref ~ 670 – 672 have extremely low response rates ? representative/ (responses rates between 47 – 12%)	Thank you for your comment. The low response rate is unfortunately typical for this kind of longitudinal survey. The survey with the lowest response rate has been removed from the review as it is recognised the findings may not be generalisable. The other study has been retained as the response rate of 159/400 is considered adequate for a prospective longitudinal study of this nature.
SH	Obstetric Anaesthetists Association	2	Full	3.1.12		All studies considered looked at information provision to influence behaviour rather than primarily to enable informed decisions/ consent	Thank you. The evidence base is, as you note, looking at information-giving in relation to supporting change in

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						(see recommendation, page 76, lines 47-49)	behaviour. In this respect the evidence supports all recommendations relating to giving information in the antenatal period in order to encourage healthy behaviour. The recommendation on p.76 lines 47-49 refers to informed decision-making and is a good practice point extrapolated from the evidence.
SH	Obstetric Anaesthetists Association	3	Full	3.1		There is no mention of the need to inform women about pain/ pain relief options. What about potential complications/ need for emergency intervention: see Fortescue C Is preparation for emergency obstetric anaesthesia adequate? International Journal of Obstetric Anaesthesia 2007; 16: 336.	Thank you. Pain relief for labour has now been added to preparation for labour and birth.
SH	Obstetric Anaesthetists Association	4	Full	3.2		There is no mention of how to identify those needing referral to other specialities eg obstetric medicine/ Obstetric anaesthesia clinics,, See final Scope 4.3.a	Identification of women needing referral for additional specialist care is covered by the antenatal assessment tool which is currently under development.
SH	Office for National Statistics	1	NICE	General		1.7.1.5 Participation in regional congenital anomaly registers is strongly recommended to facilitate the audit of detection rates. The Office for National Statistics strongly supports the recommendation for participation in regional congenital anomaly registers, in line with those of the Chief Medical Officer ¹ . ONS is part of the British Isles Network of Congenital Anomaly Registers (BINOCAR). The local registers, which ascertain cases of congenital anomalies from multiple sources, submit data to the National Congenital Anomaly System (NCAS) which is maintained by ONS. NCAS cannot assist with the audit of detection rates because it only records notifications resulting in a live or stillbirth. However it is used for public health surveillance to monitor changes in the number of notifications for specific causes in different	Thank you very much for your comment.

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						<p>parts of England and Wales. It also provides the only national data on the number of children born with congenital anomalies. Reporting to the system is voluntary. Some areas of England and Wales are not covered by local registers; notifications from these areas are submitted on paper SD56 forms by health service practitioners. There is evidence of under-reporting in NCAS, particularly in areas not covered by local registers². ONS would like the guidelines to encourage NHS Trusts which are not covered by local registers to report cases direct to NCAS to improve statistics on congenital anomalies in these areas.</p> <p>A possible amendment to the guideline might be:</p> <p>1.7.1.5 Participation in regional congenital anomaly registers is strongly recommended to facilitate the audit of detection rates. If there is no local register, NHS Trusts are asked to report details of any live or stillbirth affected by a congenital anomaly to the National Congenital Anomaly System at the Office for National Statistics.</p> <p>¹ Department of Health (2004). On the state of the public health: Annual report of the Chief Medical Officer of the Department of Health.</p> <p>² Boyd PA, Armstrong B, Dolk H, Botting B, Pattenden S, Abramsky L, Rankin J, Vrijheid M and Wellesley D (2005) Congenital anomaly surveillance in England – ascertainment deficiencies in the national system. British Medical Journal 330,27.</p>	<p>Thank you. We have now amended this recommendation to also include NSC approved audit systems as a way of collecting this important data.</p>
SH	Partnerships for Children, Families, Women and Maternity			1.7.1.5		This organisation was approached but did not respond.	

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SH	PERIGON Healthcare Ltd					This organisation was approached but did not respond.	
SH	Perinatal Institute	1	Full & NICE	General		<p>GENERAL COMMENT</p> <p>1. We have a number of grave reservations about the proposed Draft Guideline. The Perinatal Institute has sought to address the shortcomings of the current review and recommendation but we are particularly concerned that there is currently only one round of consultation. As our comments are fairly fundamental, we would like to ask that another round of consultation be agreed to ensure that the substantive changes which we believe are necessary can be commented upon once more, before publication of the final Guideline.</p> <p>2. It would be appropriate to make the evidence base more comprehensive, to account for the fact that prospective studies in antenatal care are often lacking or difficult to obtain because of</p> <ul style="list-style-type: none"> ➤ general ethical considerations ➤ difficulty in 'blinding' ➤ information obtained antenatally will influence management and outcome ➤ relatively rare outcomes require large studies to prove effectiveness <p>3. A substantial amount of evidence has been gleaned from careful audit studies and reviews of adverse outcome, such as confidential case reviews undertaken with rigorous methodology and against well defined criteria and standards.</p>	<p>1. Thank you. All comments received for the Antenatal Care Guideline update have been carefully considered and recommendations amended where the GDG felt this was necessary. All comments have been responded to individually. We hope that following our post-consultation review of the guideline update the Perinatal Institute will be assured that we have been rigorous as possible in reviewing and considering the relevant evidence base for all areas addressed.</p> <p>2. The evidence base for this guideline has been very far-reaching, including non-randomised studies where randomised studies are not available or do not address all relevant outcomes. The systematic reviewers for the guideline assess quality of included studies according to NICE methodology and all studies which meet these criteria and address the posed clinical question are included.</p> <p>3. At present audit and case studies do not meet NICE criteria for inclusion in clinical guidelines.</p>
SH	Perinatal Institute	2	Full &	9.2		DOWN'S SCREENING	

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			NICE	1.7.2.3		<p>1. We welcome the inclusion and reference to 'new models' of screening that take into account the service limitations of providing nuchal translucency measurements in all cases (page 192).</p> <p>2. Findings state that selection of cut offs is complex and difficult to practise. The NSC funded pilot in Stafford, West Midlands has demonstrated that implementing a '3 stage Contingency Screening Policy' [1] is no more difficult than implementing any screening policy beginning in the 1st trimester. 94% of the screened population received a result in the 1st trimester. It offers improved levels of safety over the combined test (7.8 cases detected per procedure related loss compared to 6.2 cases).</p> <p>3. Radiology departments are facing a national staffing crisis [2]. In the NSC Survey of Ultrasound Services [3], 45% of units were noted as having sonographer vacancies.</p> <p>4. Ultrasound resources in parts of the NHS including the Midlands and North of England are severely limited and will restrict the introduction of a combined screening test within the timeframe of the NSC Model of Best Practice [4]. The new guidance will also impact on ultrasound services with the new requirement for fetal echocardiography with four chamber and outflow tract view recommended.</p> <p>5. Combined screening is not a feasible screening programme within current ultrasound and maternity services. The Contingent Screening Model offers an</p>	<p>1. Thank you.</p> <p>2. Thank you for your comments on contingency screening. It is known that a number of different approaches are being explored for Down's screening. The best evidence is for combined screening although it is accepted that there are implications for implementation. The Stafford study was a pilot study and so although the results are interesting further work is clearly needed.</p> <p>3. Thank you. The issues of staffing are acknowledged</p> <p>4. As above</p> <p>5 See comments under 2</p> <p>6 This will be dealt with by the implementation team at NICE</p> <p>7 See 2</p>

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						<p>alternative interim solution to offering women an early test without impacting significantly on already compromised ultrasound, midwifery and diagnostic services.</p> <p>6. We suggest that the recommendations on combined screening should be made conditional on the availability of adequate ultrasound resources.</p> <p>7. We also suggest that the guideline include a provision for contingent methods of 1st trimester screening, if they can demonstrate that they can meet the NSC's criteria for detection- and false positive rates.</p> <p>References</p> <p>1. Three Stage Contingency Screening for Down's Syndrome. Results of the Stafford Pilot. The Perinatal Institute: Nov 2006. http://www.pi.nhs.uk/screening/downs/index_downscreeningreport.htm</p> <p>2 Extending the Provision of Ultrasound Services in the UK. British Medical Ultrasound Society: Sep 2003 http://www.bmus.org/about/ab-strategy.asp</p> <p>3. Antenatal Ultrasound Screening. Ultrasound Survey of England: 2002. National Screening Committee: April 2005.</p> <p>4. Model of Best Practice: Nov 2003. Department of Health. http://www.screening.nhs.uk/downs/model_bestpractice.pdf</p>	
SH	Perinatal Institute	3	Full & NICE	5.5 1.3.2.4		<p>VITAMIN D SUPPLEMENTS</p> <p>The guidance recommends normal healthy women should not be routinely offered vitamin</p>	Thank you we are aware of this.

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						<p>D supplementation during pregnancy. This conflicts with recommendations from other national groups such as the food standards agency and the Scientific Advisory Committee on Nutrition. These recommend that all pregnant women should take supplements http://www.sacn.gov.uk/reports/# http://www.eatwell.gov.uk/agesandstages/pregnancy/whenyrepregnant/</p> <p>We believe that having different recommendations is unhelpful and confusing for both expectant mothers and their care providers.</p>	
SH	Perinatal Institute	4	Full & NICE	5.12 1.3.9.1		<p>ALCOHOL IN PREGNANCY</p> <p>The guidance recommends less than 1 drink (1.5 UK units of alcohol) per day. This would allow for up to 10 units per week. This contradicts the recommendations from the Department of Health which states: Women who do choose to drink, before and during pregnancy, should drink no more than one to two units of alcohol once or twice a week. http://www.dh.gov.uk/en/News/DH_074968</p> <p>The BMA Board of Science in the Fetal alcohol spectrum disorders- a guide for health professionals publication recommend women who are pregnant, or who are considering a pregnancy, should be advised not to consume any alcohol. http://www.nofasuk.org/PDF/BMA%20REPORT%204%20JUNE%202007.pdf</p> <p>We believe that having different recommendations is unhelpful and confusing for both expectant mothers and their care</p>	<p>Thank you.</p> <p>Following stakeholder consultation the GDG have now decided to reduce the recommended maximum in order to be more cautious and to avoid giving confusing messages to women. Thus the NICE recommendation now states no more than 1-2 UK units once or twice a week, the same level as recommended by the DoH, 2007.</p>

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						providers.	
SH	Perinatal Institute	5	Full & NICE	12		<p>FETAL GROWTH AND WELLBEING</p> <p>General Comments</p> <p>1. Screening or surveillance? The guideline frequently confuses, and needs to distinguish, between spot- check of size and serial assessment of growth. It has been established for some time that the former are less predictive than the latter.</p> <p>[1] Chang TC, Robson SC, Spencer JA, Gallivan S. Prediction of perinatal morbidity at term in small fetuses: comparison of fetal growth and Doppler ultrasound. Br J Obstet Gynaecol 1994;101:422-427.</p> <p>This raises the question whether serial assessment can be regarded as 'screening': it could be also considered to be 'surveillance'.</p> <p>2. This being a guide for healthy pregnancy, it would be appropriate to state within the section for fetal growth and well-being that there is in fact no agreed UK population standard to define normal ranges for estimated fetal weight, fetal growth, and birthweight.</p>	<p>Thank you for your comments.</p> <p>1. As you point out serial assessment of growth could be regarded as screening or surveillance. Following the NSC's definition of screening as included in the introductory chapter screening is the term used to detect something, surveillance suggests monitoring in an ongoing way. We have amended this section to clarify its meaning in relation to these terms.</p> <p>2. Thank you. This has been added to the introductory text.</p>
SH	Perinatal Institute	6	Full & NICE	1.2.7.3 pp 15-17		<p>3. As concerns fundal height, the Draft Guideline currently states as good practice points that 'symphysis-fundal height should be 'measured and plotted', at each antenatal visit from 25 weeks. There is however no single accepted / agreed fundal height chart in use in the UK.</p> <p>4. If there were such a standard, it would be challenged on the basis of evidence that an</p>	<p>3. Noted with thanks.</p> <p>4. Thank you.</p>

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						individually adjustable, 'customised' standard is better in detecting abnormal growth and more accurately reflects normality.	
SH	Perinatal Institute	7	Full & NICE	12 1.10.1. 2		<p>5. Specifically, the Draft Guidelines now suggest +/- 3 cm as action points for fundal height. Firstly, even though serial measurements are recommended, no consideration is given to longitudinal assessment of growth and related action points - i.e. changes evident over time such as slow growth or no growth. Action points for longitudinal assessment have been defined (www.pi.nhs.uk/growth) and have been used in the evaluation of fundal height measurements in the controlled study in Nottingham [your ref #567].</p> <p>6. Defining +/- 3 cm as normal boundaries would furthermore result in a wide up-and-down variation of fundal height across the third trimester gestational age range being considered acceptable. Expressed as coefficient of variation, this 'normal' range, would be relatively even wider in the early weeks of the third trimester, as 3 cm would represent a larger proportion of the mean fundal height expected at these gestations.</p> <p>7. The NICE proposal would imply a ? new chart which in essence has the 50th centile line running at 45 degrees, making gestational age (weeks) equivalent to fundal height (cms), and action lines running in parallel at 3 cm distance above and below. We are not aware of (m)any units where such a standard is applied today. Furthermore, we are not aware of any significant study supporting its effectiveness for detecting 'SGA'.</p>	<p>5. Thank you. Following stakeholder consultation this recommendation has been removed.</p> <p>6. Thank you. The GDG have considered your valuable comments, and those from other stakeholders regarding the issue of a 3 cm difference and have now removed this recommendation.</p> <p>7. Thank you. The GDG have considered your valuable comments, and those from other stakeholders regarding the issue of a 3 cm difference and have now removed this recommendation. The need for a chart such as the one you describe is obviously not supported by evidence and would be unlikely to be useful in clinical practice.</p>

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						<p>8. At this point, the most commonly used standard for fundal height, EFW and birthweight measurements is likely to be the customised charts, implemented following RCOG recommendations (Guideline 31, 2002) in about 70 maternity units in England, Wales and Northern Ireland. In total, these units look after approximately 200,000 pregnancies per annum. A list of these units is available on request.</p> <p>[2] Royal College of Obstetricians and Gynaecologists. The investigation and management of the small-for-gestational age fetus. RCOG Green Top Guideline 2002(No.31).</p> <p>9. The customised growth chart is the term used for an individually adjustable standard called 'Gestation Related Optimum Weight' (GROW), available as free software from www.gestation.net. The website is administered by the Perinatal Institute, an NHS organisation.</p> <p>10. The GROW - customised standard for fundal height, EFW and birthweight has been developed on the principles that it is a.) appropriately dated, b.) individually adjusted, c.) free from pathology (e.g. smoking, diabetes) and d.) fetal weight based.</p> <p>[3] Gardosi J, Chang A, Kalyan B, Sahota D, Symonds EM. Customised antenatal growth charts. The Lancet 1992;339:283-287.</p> <p>[4] Gardosi J, Mongelli M, Wilcox M, Chang A. An adjustable fetal weight standard. Ultrasound Obstet Gynecol 1995;6:168-174.</p> <p>11. In contrast, population based charts</p>	<p>8. We recognise that the customised growth charts are being used in a number of UK units. To this end we have now removed the recommendation saying they are not recommended as we do not intend these units having to change their practice.</p> <p>9. Thank you for this definition. We have added it to this section of the guideline and to the glossary.</p> <p>10. Thank you. We have now referred to customised growth charts in the glossary and main body of the text. We feel it inappropriate to refer to one specific chart in the guideline given that a number are currently in use and there is no evidence that one is better than another in terms of improving pregnancy outcomes.</p>

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						include a sizeable proportion of pathological factors due to smoking and prematurity, and fail to adjust for constitutional variation.	11. Thank you, noted.
SH	Perinatal Institute	8	Full	12.6		<p>Fetal Growth</p> <p>12. The study by Owen et al 2003 [your ref: 933] was designed to compare two strategies for predicting low neonatal morphometry characteristics – customised estimated fetal weight from the last scan and growth velocity using fetal abdominal area. In calculating fetal growth velocity, a generous time difference between the last and the third last scan measurement was allowed – which would make this parameter of doubtful relevance clinically. Furthermore and without explanation, three different cut-off values (Z scores) were selected for growth velocity for each of the outcome measures studied: – 2 for prediction of low skinfold thickness, -1.55 for low ponderal index, and –1.5 for low mid-arm circumference to occipito-frontal circumference ratio.</p> <p>13. Despite this questionable methodology, the authors (who are published proponents of the growth velocity method) could show no significant difference in positive likelihood ratios between their varied Z score cut-off limits and a customised centile <5th. When relaxing the customised centile cut-off to 10th centile (but still maintaining their chosen, and</p>	<p>12. Thank you.</p> <p>The researchers were aware of the study comparing two strategies and limitations of the methodology (like the last EFW prior to delivery used for customized fetal weight centile and ponderal index < 25th centile as the outcome). At the same time it is important to note that this was the only published study identified which provided sufficient data to calculate the diagnostic value (sensitivity/spec./PPV/NPV and +/- LR's) of CFGC.</p> <p>13. Thank you. The text summary in the guideline reports the poor performance of this growth chart, and this is again reported in the evidence summary.</p>

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						<p>presumably best cut-offs for abdominal circumference growth), they could still only find a significant difference in one of the three outcome measures (Ponderal Index <25th centile).</p> <p>14. The performance of this test (low customised EFW) cannot be compared with the results quoted from other biometry studies listed in Section 12.3, as the latter had SGA as outcome. In this study, a more stringent outcome (IUGR defined by neonatal morphometry) was used. We suggest that this study shows in fact good predictive values of a normal customised EFW centile. This is even more so the case if a similarly more stringent cut-off (5th customised centile) is used, with a –ve LR of 0.84, which compares favourably with the quoted biometry studies for predicting 'SGA' (Section 12.3).</p> <p>15. There is additional evidence supporting the use of customised fetal growth limits during pregnancy:</p> <p>16. Fetal weight SGA by customised percentile was examined in a prospective study of serial ultrasound assessment in 215 pregnancies. Various limits were studied; for the 10th customised centile, the results showed ST 68, SP 89, PPV 72 NPV 86.</p> <p>[5] De Jong CLD, Francis A, Van Geijn HP, Gardosi J. Customized fetal weight limits for antenatal detection of fetal growth restriction. Ultrasound Obstet Gynecol 2000;15:36-40.</p> <p>17. Individualised fetal growth limits resulted in a reduction of false positive diagnoses of 'IUGR' in a cohort of pregnancies with normal</p>	<p>14. Agreed that the outcomes were different and appropriate changes have been made in the evidence summary for this study.</p> <p>Nevertheless we disagree with your suggestion that this study shows CFGC to have good diagnostic value for predicting SGA. Your suggestion is contradictory – if this study is not to be used for comparing with other biometry studies (because of different outcomes), then it cannot be used to interpret the results for SGA babies.</p> <p>15. The identification of 3 other studies is mentioned in this section but as they do not provide data to answer the clinical question they can not be included.</p> <p>Response for 16, 17, 18, 19 Thank you for sending the list of studies. As is evident from their results, the studies had shown CFGC either to reduce the false positive rate of IUGR pregnancies or showed a correlation of the curve with maternal characteristics. These results do not translate into evidence for the effectiveness of CFGC, that is, are these charts effective in improving</p>

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						<p>outcome.</p> <p>[6] Mongelli M, Gardosi J. Reduction of false-positive diagnosis of fetal growth restriction by application of customized fetal growth standards. <i>Obstet Gynecol</i> 1996;88:844-848.</p> <p>18. Fetal growth curves were found to vary according to maternal characteristics used for customising the normal limits, in low as well as high risk populations</p> <p>[7] Mongelli M, Gardosi J. Longitudinal study of fetal growth in subgroups of a low risk population. <i>Ultrasound in Obstetrics & Gynecology</i> 1995;6:340-344.</p> <p>[8] de Jong CLD, Gardosi J, Baldwin C, Francis A, Dekker GA, van Geijn HP. Fetal weight gain in a serially scanned high-risk population. <i>Ultrasound Obstet Gynecol</i> 1998;11:39-43</p> <p>19. These studies dealt mainly with estimated fetal weight, plotted on customised charts for EFW. It is important to note that individual ultrasound parameters cannot be customised but are population averages only. They may therefore be inaccurate in demonstrating fetal growth restriction and may be responsible for avoidable adverse outcome. This has been illustrated in a recently completed confidential enquiry into stillbirths with fetal growth restriction conducted by the Perinatal Institute in Birmingham and the Black Country (www.pi.nhs.uk/pnm/ce)</p>	<p>adverse perinatal outcomes associated with SGA babies? In the absence of prospective evidence on its effectiveness, the GDG decided to recommend further research to inform future practice.</p> <p>19. Thank you for this information.</p>
SH	Perinatal Institute	9	Full	12.15		<p>BIRTHWEIGHT</p> <p>20. In the guideline draft, two studies (your refs: 940, 941) were summarised, both based</p>	<p>Thank you.</p> <p>The list of additional studies was reviewed by the GDG and two of the</p>

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						<p>on a Swedish cohort, the second one being an extension of the former with more cases. Both studies agreed that there was a strong association between smallness for gestational age, as defined by customised centile <10, and adverse outcome. The second of the studies highlighted an observed increase in OR for adverse outcome in the customised SGA-only group compared to the group which was SGA by both customised and population methods, and suggested that this was an artefact due to the SGA (cust only) group having more preterm babies.</p> <p>21. These claims have been refuted in recently published correspondence [9] Gardosi J, Clausson B, Francis A. The use of customised versus population-based birthweight standards in predicting perinatal mortality. BJOG 2007;114(10):1301-2.</p> <p>Firstly, differences in gestational age are not a confounder for stillbirth as an outcome. Secondly, such differences should not be surprising to anyone familiar with the way customised growth charts are constituted. They predict an optimal weight, which includes a fetal weight based curve derived from a normal population, rather than a birthweight curve. The latter represent an inappropriate standard, as birth weights are negatively skewed in the preterm period due to the association between preterm delivery and growth restriction. In addition, CGCs exclude known pathological factors such as smoking, and adjust only within a normal BMI range of the population. As a result, the SGA by customised centile-only includes more pathological pregnancies in general – including</p>	<p>studies have been included in the evidence text (Ego et al, Figueras et al). It is important to note that most of the studies (McCowan, Ego, Figueras, Clausson) were retrospective studies. These studies have indicated that CFGC helps in detection of SGA babies who are at higher risk from adverse outcomes, but the results have not been consistent for the same outcomes. Moreover none of the studies published so far as shown CFGC to be effective or helpful in reducing adverse perinatal outcomes. In the absence of good prospective evidence on its effectiveness, the GDG decided to recommend further research to inform future practice.</p>

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						<p>more preterm deliveries as well as more smokers and more obese women, than the other SGA subgroups. In addition, it includes women who are taller and heavier but with a normal BMI, in whom SGA is less likely to be recognised using a population standard. (Ref 9).</p> <p>22. There is additional evidence of the improved ability of customised centiles to identify pathologically abnormal growth status / birthweight, based on studies from The Netherlands, New Zealand, France and Spain:</p> <p>23. In the study by deJong et al (1998), 31 of 217 babies had SGA birthweights by the standard Dutch population weight standard. Application of customised centiles identified an additional 37 SGA pregnancies which were significantly more likely to have had pre-eclampsia, absent or reduced end diastolic flow, caesarean section for fetal distress, admission to neonatal intensive care, and artificial ventilation</p> <p>[10] de Jong CLD, Gardosi J, Dekker GA, Colenbrander GJ, van Geijn HP. Application of a customised birthweight standard in the assessment of perinatal outcome in a high risk population. BJOG 1998;105:531-35.</p> <p>24. McCowan et al (2005) compared customised and New Zealand population centiles in an antenatal SGA cohort (n=374) and a general obstetric population (12,879). She found that customised centiles were more likely to detect babies with perinatal morbidity and mortality than general population centiles.</p>	

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						<p>This applied to caesarean section for fetal distress, a variety of perinatal morbidity indices, and abnormal uterine artery Doppler indices which are independent of gestational age.</p> <p>[11] McCowan L, Harding JE, Stewart AW. Customised birthweight centiles predict SGA pregnancies with perinatal morbidity. Br J Obstet Gynaecol 2005;112:1026-1033.</p> <p>25. Ego and colleagues (2006) looked at 56,606 births in 5 tertiary maternity hospitals in France. Once again, customised centiles identified a group of SGA babies which were not small by population centiles. This group had a similar mean gestational age as the group which was designated small by the population standard only, but a fourfold higher risk of stillbirths, while the group small by population centiles- only did not have an increased risk.</p> <p>[12] Ego A, Subtil D, Grange G, Thiebaugeorges O, Senat MV, Vayssiere C, et al. Customized versus population-based birth weight standards for identifying growth restricted infants: a French multicenter study. Am J Obstet Gynecol. 2006;194(4):1042-9.</p> <p>26. A study by Figueras et al (2007) compared Spanish population-based centiles and customised centiles in 13,661 singleton deliveries. Customised assessment identified an additional group which had an increased risk of perinatal mortality and morbidity. Once again, this was in part because most SGA preterm babies are not recognised by population centiles. However, unlike the</p>	

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						<p>population SGA group, customised SGA remained an important risk factor for neonatal morbidity even after adjusting for gestational age at delivery.</p> <p>[13] Figueras F, Figueras J, Meier E, Eixarch E, Coll O, Gratacos E, et al. Customised birthweight percentiles accurately predict perinatal morbidity. Arch Dis Child Fetal Neonatal Ed. 2007;92(4):277-80.</p> <p>False positives</p> <p>27. The GDG did not comment on another important feature of customisation apparent in the analyses of the Swedish data: that the method identifies a proportion of cases (29% in the Swedish study- your ref # 940) which are small by population centiles only, and NOT by customised centiles; and that this group had no increased risk of adverse outcome when compared to the population which was not SGA by either method. This means that almost a third of cases considered to be small by population charts are in fact not pathological, but have only constitutional smallness. The same principle was observed in each the other studies (McCowan et al 2005; Ego et al, 2006; Figueras et al, 2007).</p> <p>28. This high false positive rate when using population charts is expected to translate into unnecessary maternal anxiety, investigations, and interventions. One example of the clinical implication was demonstrated in a study from Blackburn (Dua & Schram, 2006): Retrospective application of customised charts in 109 women induced for suspected intrauterine growth restriction found that the majority of cases (58%) induced for IUGR had</p>	

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						<p>in fact babies within the normal range when assessed by CGCs. Furthermore, had CGCs been used, 54% of growth scans and 53% of antenatal day unit appointments would have been unnecessary. In a multi-ethnic population, Indian and Pakistani women were in fact greatly over-represented. This suggests that population standards are unable to provide a fair and equitable means to assess fetal size and growth in a heterogeneous population.</p> <p>[14] Dua A, Schram C. An investigation into the applicability of customised charts for the assessment of fetal growth in antenatal population at Blackburn, Lancashire, UK. J Obstet Gynaecol 2006;26(5):411-413.</p> <p>FUNDAL HEIGHT</p> <p>28. Fundal height measurements vary with maternal characteristics and do not follow any 'cm per week' rule. The average measurement at 40 weeks was 38 cm (Mongelli 1999)</p> <p>[15] Mongelli M, Gardosi J. Symphysis-Fundus Height and Pregnancy Characteristics in Ultrasound-Dated Pregnancies. Obstetrics & Gynecology 1999;94:591-4</p> <p>If the -3 cm rule proposed by GDG were to be followed, there would be many unnecessary referrals for ultrasound.</p> <p>29. Customised charts for fundal height are individually adjusted for maternal variables. The study referred to in your draft (your ref #: 567) was accurately summarised in that it</p>	

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						<p>showed significantly increased detection of SGA and reduced referrals for unnecessary investigations where the baby was not SGA. The study was not powered to assess obstetric intervention or adverse outcome. Its main objective was to assess diagnostic value, in terms of antenatal detection of SGA, and the resultant number of referrals for investigations. In the light of evidence that the use of biometry and Doppler in high risk pregnancy reduces perinatal mortality, the antenatal detection of SGA is a valid objective and good practice point in itself. The findings in fact showed increased detection as well as reduced referrals. The latter was considered to be due to fewer false positive assessments of SGA, typically in cases where the mother was constitutionally small and was carrying a baby which was of normal size for her.</p> <p>30. A longitudinal study in Birmingham (City Hospital NHS Trust) has since confirmed these findings, observing significantly higher detection rates of SGA in combination with significantly reduced referrals and ultrasound scans when customised growth charts were used. However, the importance of ongoing training was emphasised to further improve the antenatal detection of SGA.</p> <p>[16] Wright J, Morse K, Kady S et al. Audit of fundal height measurement plotted on customised growth charts MIDIRS Midwifery Digest 2006; 16:341-45</p>	
SH	Perinatal Institute	10	Full	12.16		<p>HEALTH ECONOMICS IMPLICATIONS</p> <p>31. Surprisingly, there is no consideration of the health economical implications of customised growth charts in light of the</p>	In the absence of evidence of clinical effectiveness in terms of outcomes it would not be possible to carry out work looking at cost-effectiveness. In addition, it is as yet uncertain whether

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						<p>evidence available. For a policy of fundal height measurement supplemented with fetal biometry where indicated, the use of customised charts will result not only in increased detection but reduced costs of investigations.</p> <p>32. The value of increased detection is not easy to quantify and is obviously not only a benefit in terms of costs, but will result in reduced morbidity and mortality with the application of the appropriate protocols for further investigations. However the reduction of referrals for further investigation and reduced interventions will translate into savings. This is supported by evidence from each of these studies:</p> <p>33.</p> <ul style="list-style-type: none"> • Mongelli (1996; ref [6]): customised charts reduce false positives • Clausson (2001, your ref # 940): customised standards identify 29% false positive by population standard – these have no increased risk • Further false positives (small by population centile, not at increased risk) identified in studies by McCowan et al (2005; ref [11]) and Ego et al (2006; ref [12]) • Dua 2006 (ref [14]): over 50% of inductions for IUGR could be saved • Gardosi (your ref 567): Customised fundal height charts reduce referrals and admissions for falsely suspected SGA. <p>34. Customised growth charts are freely available, require little effort to print out at the beginning of each pregnancy and are easily</p>	<p>the increased identification of SGA babies improves outcomes although it is likely it will increase surveillance (scans), and thus costs. Until improved outcomes can be demonstrated this is an additional cost for no extra gain.</p>

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						implemented with the appropriate training, available from the Perinatal Institute.	
SH	Perinatal Institute	11	NICE	1.10		<p>Recommendations</p> <p>35. In the light of this consistent and overwhelming evidence, we maintain that continued use of 'population charts' is no longer tenable and should be replaced by individually adjusted, 'customised' charts. We suggest that the recommendations should be altered as follows:</p> <p>1.10.1.1. Fundal height should be measured at each antenatal visit from 25 weeks gestation.</p> <p>1.10.1.2. The measurement should be plotted on customised growth charts adjusted for maternal height, weight in early pregnancy, parity and ethnic origin. [NEW]</p> <p>1.10.1.3 A fetal growth scan to detect SGA unborn babies should be offered if</p> <ul style="list-style-type: none"> - the first fundal height measurement is below the 10th centile on the customised chart or - serial measurements have shown a slowing of growth [NEW] <p>1.10.1.4. The results of the ultrasound biometry, expressed as estimated fetal weight, should be plotted on the customised growth chart to assess relative size-for gestation, (or growth if a previous EFW has been plotted). [NEW]</p> <p>1.10.1.5. An EFW below the 10th centile on the customised chart, or slow EFW growth, is an indication to consider further investigations such as the assessment of umbilical artery</p>	<p>Thank you for your comment. Following stakeholder consultation the GDG have amended the recommendations in this section. The recommendation stating the customised fetal growth charts are not recommended has now been removed in recognition of the fact that they are at least as useful as non-customised charts and are in use in a number of units across the UK. The GDG felt it was inappropriate at present to recommend these charts above any other since, although there is some evidence to suggest they lead to better detection of unborn babies with restricted growth there is no evidence that this then leads to improved pregnancy outcomes.</p>

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						Doppler flow. [NEW] 1.10.1.6 NEW - as current 1.10.1.3 1.10.1.7 NEW – as in current 1.10.1.4	
SH	Perinatal Institute	12	Algorithm			Algorithm - should be amended accordingly	See above.
SH	Perinatal Institute	13	Full	12.16		Full report – Recommendations (following section 12.16): As above.	See above.
SH	PNI ORG UK					This organisation was approached but did not respond.	
SH	Positively Women					This organisation was approached but did not respond.	
SH	Post Natal Illness Organisation (PNI)					This organisation was approached but did not respond.	
SH	Primary Care Pharmacists' Association					This organisation was approached but did not respond.	
SH	PRIMIS+					This organisation was approached but did not respond.	
SH	Princess Alexandra Hospital NHS Trust					This organisation was approached but did not respond.	
SH	Queen Mary's Hospital NHS Trust (Sidcup)					This organisation was approached but did not respond.	
SH	RCM Consultant Midwives Group					This organisation was approached but did not respond.	
SH	Regional Maternity Survey Office					This organisation was approached but did not respond.	
SH	Royal College of General Practitioners					This organisation was approached but did not respond.	
SH	Royal College of Midwives	1	NICE Antenatal Care Routine Care for healthy pregnant woman	1.1 Woman centred care and informed decision		Statutory supervision of midwives requires that supervisors support midwives who are supporting women in making care choices and provide additional advice to women who are experiencing difficulty in achieving their care choices (NMC Standards for the preparation and practice of supervisors of midwives 19/2007 NMC Circular). The College would like to see specific reference to the role of the	Making reference to specific midwifery roles is outside the scope of NICE clinical guidance.

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				n making		<p>supervisor of midwives within the guideline. Supervisors of midwives can be influential in ensuring maternity services are responsive to the needs of women and advocating for the rights of all women to make informed choices and to contribute decision making related to their care. How local supervisors of midwives can be accessed and contacted should be made public.</p> <p>Maternity Matters April 2007 appendix A, identifies the following as key elements that commissioners and providers will want to have in place in order to deliver woman-focused, family-centred maternity care.</p> <ol style="list-style-type: none"> 1. Visible, self-referral midwifery services available in easily accessible settings including Sure Start Children's Centres 2. Publicly available information e.g. in local pharmacies, community centres and in pregnancy testing kits, about the need to seek care as early as possible including self referral to a midwife 3. Contact details of midwifery services published in local PCT prospectuses and Your Guide to Local Health Services 4. GP receptionists, NHS Direct and pharmacists knowledgeable about the availability of direct access midwifery services and how to direct women to this service 	
				1.1.1.1 Bullet point 1			
				Last paragraph		This partial update provides opportunity to promote the midwife as the first point of contact and to reinforce this message. This will help facilitate early access and initiate NICE recommendations early in pregnancy and have	

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						<p>optimum impact Please replace the generic term healthcare professional with midwife.</p> <p>The Pregnancy Book is only available for primigravid women.</p>	
SH	Royal College of Midwives	2	NICE Antenatal Care Routine Care for healthy pregnant woman	1.1.1.10		<p>Please add provide the NSC booklet 'Screening tests for you and your baby'. This is available to maternity units free of charge and can be accessed on http://www.screening.nhs.uk/anpublications/index.htm</p>	Thank you, reference to NSC publications has now been added.
SH	Royal College of Midwives	3	NICE Antenatal Care Routine Care for healthy pregnant woman	1.2.5.1		<p>Total number of appointments should reflect the option for 2 appointments prior to 12 weeks (P46 logarithm full guidelines) otherwise there is a risk of appointments being omitted later in the pregnancy to keep within recommended total of 10 for nulliparous and 7 for parous women.</p>	Thank you, this has now been clarified.
SH	Royal College of Midwives	4	Full version		P46	<p>Omit 'including haemoglobinopathy' from the line offer screening tests and add haemoglobinopathy to the list of blood tests to screen for on P47.</p> <p>Total number of appointments should reflect the option for 2 appointments prior to 12 weeks otherwise there is a risk of appointments being omitted later in the pregnancy to keep within recommended total of 10 for nulliparous and 7 for parous women.</p> <p>Where measure SFH is stated add record</p>	<p>Thank you. This has now been added.</p> <p>Thank you, this has been amended to give clarity as you suggest.</p>
SH	Royal College of Midwives	5	NICE Antenatal Care Routine		P13 First appointment	<p>Add complete family origin questionnaire and offer haemoglobinopathy screening. The full guidance recommends this is done at 10 weeks gestation.</p>	Thank you, haemoglobinopathy screening has been added to this section.

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			Care for healthy pregnant woman				
SH	Royal College of Midwives	6	Full version		P19	Add reference to Maternity Matters April 2007 in addition to Changing Childbirth	Thank you. This has been added.
SH	Royal College of Midwives	7	NICE Antenatal Care Routine Care for healthy pregnant woman	1.3.2.4 and 1.3.2.5	P18	<p>The College support the view that vitamin D supplementation should be offered to women at risk of vitamin D deficiency. However these statements as made are unhelpful in identifying at risk groups.</p> <p>Referring to women with dark skin is reminiscent of the derogatory term 'darkie'. If it refers to ethnic minority groups then it should say so as in page 32, 1.9.1.1.</p> <p>The term 'women who usually cover up' is meaningless and it is unclear why all women in age group 19-24 years are at risk and by inference that women outside of the 19-24 years age group are not at risk.</p> <p>There is inconsistency with the target population identified in recommendation 5 of the draft guidance to improve the nutrition of pregnant women and breastfeeding mothers and children in low income households and no reference to the Healthy Start benefit.</p> <p>Advice on healthy eating should be tailored to meet assessed and individual needs and reference to exploring dietary intake and discussing what constitutes a healthy diet needs to be included in the recommendation.</p>	Thank you for your comments we are clarifying these issues We are mentioning the Healthy Start programme.
SH	Royal College of Midwives	8		1.5.6.1	P24	There is no reference to the recently published mental health guidelines. These guidelines recommend the 'Whooley questions' as a relatively quick and convenient way of case finding.	Thank you. The recommendations made in the NICE mental health guidelines have now been reproduced in the ANC update.

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SH	Royal College of Midwives	9		1.7.1.5		The College supports this recommendation and the importance of monitoring the performance of the antenatal screening programmes.	Thank you.
SH	Royal College of Midwives	10		1.6.2.6		The College welcomes the inclusion of pre-conceptual counseling and carrier testing for women at risk of haemoglobinopathies but this should be extended to the wider population and include rubella screening, advice on healthy diet, folic acid, smoking cessation etc.	Thank you. We agree but these other areas were outside the scope of this update.
SH	Royal College of Midwives	11	NICE Antenatal Care Routine Care for healthy pregnant woman	1.8.3.1 -	Page 30	Is there an optimum time for Chlamydia screening to take place? Should this go a step further and say what the guideline should be if screening is carried out and found to be positive - what the treatment should be? This would bring it in line with some of the other points where further information is given about what to do if tests are positive.	Thank you. Since the guideline recommends that the screening be undertaken at the antenatal clinic it was not felt necessary to outline the treatment required as this too would be undertaken as part of the NCSP provision.
SH	Royal College of Midwives	12	Full version		P29 Lines 16-18	The College support this research recommendation.	Thank you.
SH	Royal College of Midwives	13	Full version		P30 no. 7 No.11 P30 In section 3	<p>This would read better if said" Lifestyle advice including smoking cessation and the implications of recreational drug use and alcohol consumption in pregnancy.</p> <p>Call it pregnancy care pathway</p> <p>At or before 36 weeks add another bullet point to include newborn screening tests Bullet point 24, 25 only nulliparous women are given the pregnancy book. Add provide the NSC Screening tests for you and your baby http://www.screening.nhs.uk/anpublications/index.htm</p>	<p>Thank you. This has been amended.</p> <p>Added.</p> <p>Thank you, this has now been included.</p>

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							Thank you we have expanded this to now include NSC publications and others.
SH	Royal College of Midwives	14	Full version		P36 Line 12 & 13	Code evidence for statement re: binge drinking and pregnancy	Thank you for your comment. Getting drunk has now been added to this recommendation to improve clarity of what we mean by binge drinking.
SH	Royal College of Midwives	15	Full version		P40 Line 18	Add provide the NSC Screening tests for you and your baby http://www.screening.nhs.uk/anpublications/index.htm	Thank you. The GDG considered referring specifically to this information but have decided to broaden the recommendation in chapter 3 to include all other "relevant information" as a number of good sources were identified. To avoid repetition sources of information are not included in this section.
SH	Royal College of Midwives	16		1.3.9.1	P20	Pregnancy is a time when women are receptive and potentially more open to change. The College recommends an additional bullet point recommending that an objective history should be undertaken at the earliest opportunity to explore with women their current alcohol intake and their understanding of alcohol units. Appropriate support for women at high risk should be available following this assessment. The recommendations differ to those in draft guidance to improve the nutrition of pregnant women and breastfeeding mothers and children in low income households.	Thank you. History-taking was not part of the scope for this update, however women's history of alcohol consumption will be included in the antenatal assessment tool currently under development. Following stakeholder consultation the GDG have now decided to reduce the recommended maximum in order to be more cautious and to avoid giving confusing messages to women. Thus the NICE recommendation now states no more than 1-2 UK units once or twice a week, the same level as recommended by the DoH, 2007
SH	Royal College of Midwives	17	Full version		P44 Lines 6-8	This advice is clear and helpful. It would be of benefit to describe how to measure.	Thank you. Following stakeholder consultation the reference to a 3cm difference has been removed due to a very strong feeling among a number of stakeholders that it was inappropriate.
SH	Royal College of Midwives	18	Full version		P48 Line 36	This sentence refers to Standard 3 of NSF. Should this read part 3 of standard 11 as	Thank you. Amended.

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						Standard 3 relates to Children not women	
SH	Royal College of Midwives	19	Full version		P68 L17	Spelling error - face not fae	Thank you. Amended.
SH	Royal College of Midwives	20	Full version		P88 Line 40	Spelling error - error not rror	Thank you. Amended.
SH	Royal College of Midwives	21	Full version		P76 Line Section 3	At or before 36 weeks add another bullet point to include newborn screening tests and recommend Screening tests for your baby available from Add provide the NSC Screening tests for you and your baby http://www.screening.nhs.uk/anpublications/index.htm	Thank you, this has now been included. Thank you we have expanded this to now include NSC publications and others.
SH	Royal College of Midwives	22	Full version		P77	Add line to promote the use of NSC information	Thank you we have expanded this to now include NSC publications and others.
SH	Royal College of Midwives	23	Full version		P89 Line 27 Line 38 Line 48	Some conflict between advice for HBO screening at < 10 weeks gestation. Suggest state 10 for consistency Add screening for HBO Add screening for HBO	Thank you. These amendments have been made as you suggest.
SH	Royal College of Midwives	24	Full version		P261- 264	To reduce confusion for the reader it would be helpful to be consistent throughout these pages and use either SPTB (spontaneous preterm birth) or SPTD (spontaneous preterm delivery) not mixing the two abbreviations.	Thank you. We have amended all references to SPTB for consistency.
SH	Royal College of Midwives	25	Full version	General		Need mention of Healthy start in dietary advice	Thank you. Healthy Start is now included.
SH	Royal College of Midwives	26	Both	General		The College is pleased that women are seen as partners in their care and that the emphasis is on women taking control of their own health. Women, midwives and obstetricians should record the plan of care in the maternity hand held notes.	Thank you. We agree, however this component of care did not form part of the guideline

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						1.5.4.1. Although comments were not sought on this topic the College would recommend that women who have been identified with FGM are treated sensitively and referred for appropriate specialist advice and counselling.	update. Thank you, but as you rightly identify FGM is outside the scope of this update.
SH	Royal College of Nursing	2	Full		P 43 L 19-20	Greater clarification is requested regarding the appropriate device for measuring blood pressure. Semi automatic is not a term in common use in maternity care for sphygmomanometers.	Thank you. The term is meant to describe devices where inflating and deflating of the cuff are automated but the practitioner listens to the sounds him/herself. No alternative term could be found for this type of device.
SH	Royal College of Nursing	3	Full		P245 L 25-27	Does the guideline development group consider the recommendation relating to standardised equipment in the antenatal period is achievable when women present at a number of clinics? This concern relates particularly to the difficulty of requesting standardised equipment in a variety of GP and health clinics. Midwives working from these clinics have reported difficulties with checking that the equipment has been properly calibrated.	Thank you for your comment. The GDG recognise this may be difficult to achieve in the short term, however it is a goal that is worth pursuing given the known inaccuracies and unreliability of some currently used devices.
SH	Royal College of Nursing	4	Full		P251 L37	Spelling error for 'identify'	Thank you. Amended.
SH	Royal College of Nursing	5	Full		P252 L22-23	Advice regarding automatic and semi automatic machines for blood pressure estimation would be welcome. For instance, we are aware of one organisation providing care for more than 5,000 births, where mercury sphygmomanometers were removed because of the risk of spilling a hazardous liquid. The manual sphygs are not of the mercury type. The replacement in a hospital setting with dynamap machines also led to lower than expected diastolic recordings. The community referrals for hypertension (raised diastolic) to a hospital setting, often found no evidence of a raised diastolic – this	Thank you for your comment. We have amended this recommendation so now neither mercury sphygmomanometers not fully automate devices are included.

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						was felt to be related to the type of machine used. The medical device department explained that the model of dynamap machine was not designed for one-off readings of diastolic and systolic (because of estimated averages) – it was intended to be used for general trends over a period of time (such as post operative recovery).	
SH	Royal College of Nursing	6	Full	General		The advice regarding estimation of fetal growth is very welcome and addresses inequalities across service provision.	Thank you for your comment.
SH	Royal College of Nursing	7	Full	General		The advice regarding antenatal screening is very comprehensive and will be of great assistance in providing informed choice to women. ³	Thank you.
SH	Royal College of Nursing	8	Full	3.1.1		The evidence review regarding counselling in the antenatal period is very helpful particularly the inclusion of the evidence summary supporting the use of a face to face discussion.	Thank you.
SH	Royal College of Obstetricians & Gynaecologists	1				The algorithm says that women with the placenta covering os at 20 weeks should have scan at 32 and 36 if placenta within 2cm of os. The 32 week scan is not mentioned in the GL.	Thank you. This section has been updated due to the GDG noting a change in practice since publication of the first ANC guideline and the recommendation is now that the second scan should be performed at 32 weeks.
SH	Royal College of Obstetricians & Gynaecologists	3				Providing the Combined Test should be done for women who choose to have first trimester screening but should not be the principal screening test offered. This is because screening and diagnostic programmes based on the Combined Test are materially less effective and safe than programmes based on the Integrated Test; the Combined Test has a false-positive rate 5 times greater for the same 85% detection rate (see attached Table based on the HTA SURUSS Report ¹). These differences in health benefits are substantial, and should not be ignored when providing clinical recommendations. Trusts should	Thank you for your comments about the integrated test (IT). The GDG has reviewed the available literature, including additional papers suggested by stakeholders but still feel that although the IT performs well it would be too early to recommend it as the preferred national test. Of course those units who feel that they have the capacity to undertake the IT should not be discouraged and we have altered our recommendation to reflect this. The major areas of concern are as follows.

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						<p>therefore be in a position to provide both the Integrated Test and the Combined Test.</p> <p>Recommendations regarding second trimester screening should state a preference for the Quadruple Test because of the associated improvement in efficacy and safety. The Triple Test fails to meet the target set by the National Screening Committee (75% detection rate for a 3% or lower false-positive rate).</p>	<p>Implementation: The single report provided by you does show that the test can be implemented but this needs to be confirmed using a multicentred approach. It was of concern that 25% of women did not come for the second phase of the test and had to be chased up. This could have considerable implications for the service</p> <p>Women's preference: The evidence we have largely points to women wishing an early test. In fact the quality of studies in this area are poor and again should be the subject of further research</p> <p>Cost: The costing studies reviewed give conflicting information</p> <p>A prior requirement for the IT to work is first trimester NT and serum testing (the combined test). This in itself will be challenging to implement but it could be seen as a way to the eventual use of the IT if appropriate studies, into the feasibility of implementation, to establish women's views and to determine more clearly costs, can be completed and shown to be favourable.</p>
SH	Royal College of Obstetricians & Gynaecologists	5	NICE	1.7.2.4.		We urge NICE to reconsider these recommendations and revise them in accordance with the above comments.	The GDG has considered all stakeholder comments carefully and revised the recommendations regarding Down's screening as outlined in the above response.
SH	Royal College of Obstetricians and Gynaecologists	1	NICE	general		The Integrated Test should be the recommended test because of the greater	Thank you for your comments about the integrated test (IT). The GDG has

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						<p>efficacy and safety associated with this method of screening. Public bodies such as NICE should, I believe, regard efficacy and safety as the first priority in making their judgements. The Combined Test should only be offered as an alternative to the Integrated Test when there is a pressing need for an earlier diagnosis.</p> <p>A conference on the Integrated Test held at Brown University, Rhode Island, USA in March 2007, drew the same conclusion. There were contributions from many groups, a large number of whom had already introduced routine Integrated Testing into antenatal care. These groups all demonstrated high levels of acceptance of the test, and concluded that such screening was ethical in routine antenatal care. Contributions included those from representatives of the American and Canadian Colleges of Obstetrics and Gynecology, which support use of the Integrated Test. The American College of Gynecologists' guidelines are available on the web¹</p> <p>The UCH experience of the Integrated Test showed that 97% of women who wanted screening and attended for antenatal care in the first trimester accepted the Integrated Test; only 3% opted for the first trimester Combined Test².</p> <p>It therefore seems clear that NICE should recommend the Integrated Test as the preferred antenatal screen for Down's syndrome; this recommendation would reflect an evidence-based approach, as this method of screening has been shown to be acceptable to women, and is achieving a high positive predictive value, with high detection rates and</p>	<p>reviewed the available literature, including additional papers suggested by stakeholders but still feel that although the IT performs well it would be too early to recommend it as the preferred national test. Of course those units who feel that they have the capacity to undertake the IT should not be discouraged and we have altered our recommendation to reflect this. The major areas of concern are as follows.</p> <p>Implementation:</p> <p>The single report provided does show that the test can be implemented but this needs to be confirmed using a multicentred approach. It was of concern that 25% of women did not come for the second phase of the test and had to be chased up. This could have considerable implications for the service</p> <p>Women's preference:</p> <p>The evidence we have largely points to women wishing an early test. In fact the quality of studies in this area are poor and again should be the subject of further research</p> <p>Cost:</p> <p>The costing studies reviewed give conflicting information</p> <p>A prior requirement for the IT to work is first trimester NT and serum testing (the combined test). This in itself will be challenging to implement but it could be seen as a way to the eventual use of the IT if appropriate studies, into the feasibility of implementation, to establish women's</p>

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						fewer women requiring an invasive diagnostic test.	views and to determine more clearly costs, can be completed and shown to be favourable.
SH	Royal College of Obstetricians and Gynaecologists	2				This recommendation fails to offer the most effective and safe method of screening for Down's syndrome. The evidence shows that the most effective and safe method of screening is to offer the Integrated Test which uses information from both the first and second trimester of pregnancy to provide a single estimate of risk (either with or without nuchal translucency depending on the availability of ultrasound facilities) with the provision made for first trimester screening for those women who are willing to forgo the extra efficacy and safety of integrated screening in order to have an earlier result.	Please refer to our full explanation above as to why the integrated test has not been recommended.
SH	Royal College of Obstetricians and Gynaecologists	4	NICE			<p>The recommendation not to offer the Integrated Test is wrong. As already stated, integrated screening has substantially better screening performance and associated safety than first trimester screening, through fewer women requiring invasive diagnostic testing. There is no disagreement or professional uncertainty on this. In addition, integrated screening is cost effective: the cost per Down's syndrome pregnancy identified is less than with the Combined Test (see Table), as established in the SURUSS study and confirmed by the American NIH supported FASTER study²</p> <p>There is therefore no medical, scientific or economic justification for this recommendation against offering the Integrated Test routinely. Moreover, this recommendation is at variance with guidelines produced in the United States,³ Canada⁴ and New Zealand⁵ and the 2003</p>	<p>Thank you for your comments about the integrated test (IT). The GDG has reviewed the available literature, including additional papers suggested by stakeholders but still feels that although the IT performs well it would be too early to recommend it as the preferred national test. Of course those units who feel that they have the capacity to undertake the IT should not be discouraged and we have altered our recommendation to reflect this. The major areas of concern are as follows.</p> <p>Implementation: A single report provided by stakeholders does show that the test can be implemented but this needs to be confirmed using a multicentred approach. It was of concern that 25% of women did not come for the second</p>

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						<p>NICE report entitled "Routine Care for Healthy Pregnant Women".</p> <p>The recommendation for first trimester screening alone seems to ignore the fact that amniocentesis is a preferred method of diagnostic testing compared with chorionic villus sampling CVS, and is more widely available in the UK. Amniocentesis, because it samples fetal cells, is diagnostically more accurate than CVS, which samples placental cells; accuracy and interpretation of the results from CVS are compromised by the phenomenon of confined placental mosaicism, whereby the genetic constitution of the placenta may differ from that of the fetus. In addition amniocentesis may cause fewer losses of healthy fetuses than CVS; there is a body of medical opinion which believes that CVS is less safe than amniocentesis, while others believe the risks are similar. The wide use of PCR as a rapid diagnostic test now means that amniocentesis results can be available early in the second trimester ie in the 15th or 16th week of pregnancy.</p> <p>An issue that is of considerable importance to the emotional welfare of the women screened is the fact that one in 5 terminations would not be needed if integrated screening were carried out, as these pregnancies would be lost naturally between 11 and 15 weeks. While any loss of a wanted pregnancy is distressing to the parents, the decision to terminate an affected pregnancy often leads to a sense of persistent guilt that would not arise following a miscarriage.</p> <p>Concerns over potential difficulties in the implementation of integrated screening, and</p>	<p>phase of the test and had to be chased up. This could have considerable implications for the service</p> <p>Women's preference: The evidence we have largely points to women wishing an early test. In fact the quality of studies in this area are poor and again should be the subject of further research</p> <p>Cost: The costing studies reviewed give conflicting information</p> <p>A prior requirement for the IT to work is first trimester NT and serum testing (the combined test). This in itself will be challenging to implement but it could be seen as a way to the eventual use of the IT if appropriate studies, into the feasibility of implementation, to establish women's views and to determine more clearly costs, can be completed and shown to be favourable.</p>

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						<p>uncertainty over whether women would prefer an earlier albeit less effective screening test, have been dispelled by evidence from recent practice and publications. Two London teaching hospitals (University College Hospital and St Mary's Hospital) have offered integrated screening on a routine NHS basis for over three years and found it to have been highly successful and well accepted by women and staff. The UCH experience has been published⁶ and presented at the annual meeting of the International Society of Ultrasound in Obstetrics and Gynaecology in October 2007 (where it was awarded the prize for the best oral presentation⁷). An international demonstration project (including centres in Britain, Canada, Portugal and Italy) confirmed that integrated screening was a significant improvement over previous methods of screening and was well accepted by staff and patients⁸. The method has now been adopted on a routine basis in the centres involved. Research has been conducted into the acceptability of integrated screening and into the views of women on different methods of screening. The results show that women prefer the safety and accuracy of the Integrated Test over the earlier screening result from first trimester screening alone^{9,10}.</p>	
SH	Royal College of Obstetricians and Gynaecologists	6	NICE	General		<p>References:</p> <p>1 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). Journal of Medical Screening 2003;10(2)</p> <p>2 Malone FD, Canick JA, Ball RH,</p>	Thank you for these additional references – these have all been considered and, where appropriate, reviewed.

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						<p>Nyberg DA, Comstock CH, Bukowski R, Berkowitz RL, Gross SJ, Dugoff L, Craigo SD, Timor-Tritsch IE, Carr SR, Wolfe HM, Dukes K, Bianchi DW, Rudnicka AR, Hackshaw AK, Lambert-Messerlian G, Wald NJ, D'Alton ME, First- and Second-Trimester Evaluation of Risk (FASTER) Research Consortium. First-trimester or second-trimester screening, or both, for Down's syndrome. N Engl J Med 2005;353:2001-11</p> <p>3 American College of Obstetrics and Gynaecology, ACOG Practice Bulletin No. 77: screening for fetal chromosomal abnormalities. Obstet Gynecol. 2007 Jan;109(1):217-27</p> <p>4 Society of Obstetricians and Gynaecologists of Canada. Prenatal Screening for Fetal Aneuploidy. J Obstet Gynaecol Can 2007;29(2):146–161</p> <p>5 New Zealand Screening Committee, Antenatal Down Syndrome Screening in New Zealand 2007: A report of the Antenatal Down Syndrome Screening Advisory Group to the National Screening Unit</p> <p>6 Weisz B, Pandya P, Chitty L, Jones P, Huttly W, Rodeck C. Practical issues drawn from the implementation of the integrated test for Down syndrome screening into routine clinical practice. BJOG 2007;114:493-7</p> <p>7 Pandya P, Huttly W, Jones P, Wald N, Rodeck C. Effectiveness of the integrated test in Down Syndrome screening. 17th World Congress on Ultrasound in Obstetrics and Gynecology 2007</p>	

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						<p>8 Wald NH, Rudnicka AR. Antenatal screening for Down syndrome using the Integrated test. In Prenatal Medicine. Van Vugt JMG, Shulman LP (Eds). Taylor and Francis, New York, 2006. (79-102)</p> <p>9 Bishop AJ, Marteau TM, Armstrong D, Chitty LS, Longworth L, Buxton MJ, Berlin C. Women and health care professionals' preferences for Down's syndrome screening tests: a conjoint analysis study. BJOG 2004;111:775-9</p> <p>10 Palomaki GE, Kloza EM, Haddow JE, Williams J, Knight GJ. Patient and Health Professional Acceptance of Integrated Serum Screening for Down Syndrome. Semin Perinatol 2005;29:247-251</p> <p>Please see table A at the end of this document which didn't fit in this table</p>	
SH	Royal College of Paediatrics and Child Health	1		General		At the first antenatal appointment, risk factors should be highlighted and this may warrant the transfer to a consultant obstetrician. There is no mention in the guideline of this, or that the woman can be referred back to midwifery care.	The identification of women who may need additional care (including care from an obstetrician) is outlined in the recommendations under the heading "What should happen at antenatal appointments" and in the algorithm. This issue will also be covered comprehensively by the antenatal assessment tool which is currently under development.
SH	Royal College of Paediatrics and Child Health	2		General		We note that fetal movement counting is not included as a sign of fetal well-being, however, this is commonly used in clinical practice. We are aware of the evidence or lack of evidence, however, if it is suggested that we should not use a reduction of fetal movements as an indicator why do hundreds of units around the	Thank you. The sections you mention were not included in the scope of this update which concentrated on assessment of fetal growth – the recommendations on assessment of fetal wellbeing remain unchanged for the time being. The sections were

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						country continue to undertake cardiotocograph monitoring on women who call with a reduction of movements? Is NICE suggesting that this practice cease?	mistakenly omitted from the consultation version and have been reinstated for the final draft. Thank you for spotting this.
SH	Royal College of Paediatrics and Child Health	3		General		We are disappointed that there is very little mention of the booking process, risk assessment, referral etc.	Risk assessment at booking will be covered comprehensively by the antenatal assessment tool which is currently under development prior to validation.
SH	Royal College of Paediatrics and Child Health	4	NICE	General		This section reads well and supports all new / amended recommendations	Thank you.
SH	Royal College of Paediatrics and Child Health	5	NICE	1.1.1		This section should also include information on newborn screening and prevention of cot death.	Thank you, this has now been included.
SH	Royal College of Paediatrics and Child Health	6	NICE	1.1.1.1		The phrase 'providing a book' can be misinterpreted as meaning you don't need to discuss the issues.	Thank you, this is a useful point. We have now altered the wording of this part of the recommendation to make it clear this is not what we mean.
SH	Royal College of Paediatrics and Child Health	7	NICE	1.1.1.1		At the first contact with a midwife, the midwife should assess the mental health of the woman by asking the questions as recommended in the NICE guideline on ANPNMH. This may be a good place to reinforce this message and cross reference the guideline. Although this is included later in the guideline, it would be helpful if it was mentioned in both places.	Thank you. We acknowledge the importance of this issue but this recommendation is looking at information giving rather than screening and so are not able to add this here. However the list which details what to do at each antenatal appointment does include the need to identify women who may need additional care and this would include women who need additional care due to mental health problems.
SH	Royal College of Paediatrics and Child Health	8	NICE	1.1.1.2		This is excellent. However, a minor point is that some women do speak English but do not understand the jargon used. Where possible, all literature for women and their partners should be jargon free.	Thank you. We agree and this is what we meant by the term "accessible" ie both physically and cognitively accessible. To make this clearer we have added "easily understood".
SH	Royal College of Paediatrics and Child Health	9	NICE	1.1.1.5		This is a very good inclusion. However, it will mean extending the length of appointments. It	Thank you. We recognise the service constraints but feel this aspect of

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						is understood that it is anticipated that visits will be reduced due to the schedule, however, the reduced schedule of visits is already in place and at the present time many clinics are overbooked and run late.	antenatal care is vitally important and so needs to be highlighted.
SH	Royal College of Paediatrics and Child Health	10	NICE	1.1.1.6		Although it is a good idea to have participant led classes during the antenatal period, we would like more information on what these look like. We value the work of the NCT and trust that they agree with this?	Thank you. The NCT run participant-led classes. These may take a variety of formats but the key feature is that the agenda for the sessions is decided by the participants rather than the group leader.
SH	Royal College of Paediatrics and Child Health	11	NICE	1.1.1.8		'Sufficient time' should be defined.	Sufficient here means enough time for that individual woman (and her partner where appropriate) to feel she has considered the information and its implications and made a choice. This time will vary from woman to woman and so cannot be specified here.
SH	Royal College of Paediatrics and Child Health	12	NICE	1.3.9.1		This is too vague and open to misinterpretation. There should be some reference to not drinking.	Thank you. The recommendation now states clearly that women should be advised not to drink alcohol in the first 3 months of pregnancy.
SH	Royal College of Paediatrics and Child Health	13	NICE	1.3.9.4		We note that there was no reference to nicotine replacement therapy as an alternative. Also the recommendation on alcohol use during pregnancy conflicts with that of the government's in that no alcohol should be consumed whilst pregnant.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Royal College of Paediatrics and Child Health	14	NICE	1.4.6.2		There is no recommendation that the partner should be treated for candidiasis.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Royal College of Paediatrics and Child Health	15	NICE	1.5.4.1		Women should be informed that FGM is illegal in this country and it is illegal for any female child to undergo this procedure. This should be documented.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Royal College of Paediatrics and Child Health	16	NICE	1.7.1		Details of whom parents should be seen by following the discovery of anomalies should be	Thank you for your comment. It is not possible to specify which health care

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						provided. E.g. paediatrician for Down's Syndrome, paediatric cardiologist for severe cardiac anomalies or paediatric surgeon for diaphragmatic hernia/gastroschisis as well as a midwife/obstetrician.	professional women should be referred to following detection of an anomaly since this is outside the remit of NICE clinical guidance.
SH	Royal College of Paediatrics and Child Health	17	NICE	1.7.1.4		It should be made clearer that the discussion for termination would only be had in appropriate cases, not all normal 20 week scans.	Thank you, this recommendation has now been amended to improve its clarity.
SH	Royal College of Paediatrics and Child Health	18	NICE	1.7.2.3		Combined testing means that there must be ready access to CVS and information about the interpretation and availability of PCR & Karyotype results.	Thank you – we agree.
SH	Royal College of Paediatrics and Child Health	19	NICE	1.7.2.4		Integrated testing as the evidence shows is the most effective screening with the fewest fetal losses. UCH have successfully implemented this since 2003. If women prefer a one stage test they have the option of combined testing whilst allowing second trimester screening for late booking women. From the practical side of the screening integrated testing fits in with the pattern of antenatal care as recommended by NSF & NICE.	Thank you for your comments about the integrated test (IT). The GDG has reviewed the available literature, including additional papers suggested by stakeholders but still feels that although the IT performs well it would be too early to recommend it as the preferred national test. Of course those units who feel that they have the capacity to undertake the IT should not be discouraged and we have altered our recommendation to reflect this. The major areas of concern are as follows. Implementation: A single report provided by stakeholders does show that the test can be implemented but this needs to be confirmed using a multicentred approach. It was of concern that 25% of women did not come for the second phase of the test and had to be chased up. This could have considerable implications for the

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							<p>service</p> <p>Women's preference: The evidence we have largely points to women wishing an early test. In fact the quality of studies in this area are poor and again should be the subject of further research</p> <p>Cost: The costing studies reviewed give conflicting information</p> <p>A prior requirement for the IT to work is first trimester NT and serum testing (the combined test). This in itself will be challenging to implement but it could be seen as a way to the eventual use of the IT if appropriate studies, into the feasibility of implementation, to establish women's views and to determine more clearly costs, can be completed and shown to be favourable.</p>
SH	Royal College of Paediatrics and Child Health	20	NICE	1.2.6		<p>Should EDD based on scan replace LMP dates as stated in previous guidelines? It should be made clear that LMP is not used. How reliable is HC after 14 weeks? What about late bookers - should a repeat scan be offered to estimate EDD?</p> <p>A comment should be added about using the date of egg retrieval in IVF/ICSI pregnancies.</p>	Yes, thank you. The recommendation has been amended to make this clear.
SH	Royal College of Paediatrics and Child Health	21	NICE	1.10.1.4		<p>We think it should be re-worded that 'Doppler ultrasound should not be used to monitor fetal growth in a low risk pregnancy' rather than just the statement that it should not be used to monitor fetal growth. It does have a role in some pregnancies where there are abnormalities of fetal growth although we accept that a normal Doppler in the third trimester does not exclude a problem with</p>	Thank you. The recommendation has been amended as you suggest.

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						growth.	
SH	Royal College of Paediatrics and Child Health	22	Full	1.2		Most birthweight references in current paediatric use do not display the 5th and 95th centiles. Thus babies in categories <5th and >95th will not be identified. It is better to use <0.4th or <2nd centile, depending on the risk being sought. Of course, some babies of normal birthweight may also have experienced intrauterine growth restriction.	Thank you for your comment. Although paediatricians now use the 0.4 th and 2 nd centiles, in obstetrics the 5 th and 95 th centiles are still used.
SH	Royal College of Paediatrics and Child Health	23	Full	1.4 & 1.5		Do the Committee consider it advisable when making nutritional recommendations to include in their membership a dietitian, registered nutritionist or registered public health nutritionist?	Thank you. The Guideline had a dietician as an external expert advisor who received all meeting papers and attended GDG meetings playing an active part in making nutritional recommendations.
SH	Royal College of Paediatrics and Child Health	24	Full	1.6		The scope was included in the 2006 version, therefore we have no comment for the 2008 version. We agree with the process, and results, on review and grading of the evidence.	Thank you
SH	Royal College of Paediatrics and Child Health	25	Full	2.1		It is unclear what is meant by "at risk of deficiency"? Does NICE accept the consensus definition based on a plasma 25-OHD concentration below 25 nmol /l? If so, what proportion of women in the UK with plasma 25OHD will be identified by the listed criteria, and what proportion will not? The prevalence of this condition (NDNS) in (non pregnant, not breastfeeding) women aged 19-24 is 28%, and it is 13 - 15% in women aged 25-49. If NICE think it unimportant for this group to meet RNI through use of supplements, how will they ensure that the fetus has adequate vitamin D stores to meet demands through 6-months of exclusive breastfeeding?	Thank you. The ANCu GDG does accept the consensus definition of plasma 25-OHD concentration below 25 nmol /l. It is believed the list of risk factors will identify the vast majority of women at risk. The recommendation has now been reworded to ensure that all women are informed of the importance of vitamin D and that women are told about the Healthy Start vitamin supplement. Women in high risk groups are encouraged to take this supplement.

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SH	Royal College of Paediatrics and Child Health	26	Full	2.2		Information on "nutrition and diet" should be given by a "health professional" at first contact. What are the minimum training requirements for this person to advise on nutrition?	Minimum training requirements are outside the scope of this NICE clinical guideline.
SH	Royal College of Paediatrics and Child Health	27	Full	5.3		The importance of ensuring that eligible women are informed about "Healthy Start" and enabled to register with the Scheme should be specifically mentioned because encouraging continued contact with health professionals through pregnancy and beyond is core principle of the Scheme.	Thank you. Healthy Start has now been included.
SH	Royal College of Paediatrics and Child Health	28	Full	5.5		Mention of prescribing 5mg folic acid is required. Whilst women who have previously had an NTD-affected pregnancy will be captured by the list in 1.2, those whose partners have a family history, or who have other risk factors will not be.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Royal College of Paediatrics and Child Health	29	Full	5.12		It is unwarranted to suggest that women can consume up to 10 units of alcohol per week without risk. Whilst the evidence is mixed (principally due to confounding) there is some evidence of harm even at this level. A precautionary approach should be adopted in the absence of sufficient evidence to establish a safe threshold. Indeed, the concept that a "safe" threshold exists may itself be flawed. Experience with breast cancer suggests that risk is linearly related to alcohol consumption. For example a meta-analytic review in this area demonstrated a significant increase in risk associated with consuming 10g alcohol /d (RR 1.09; 1.04-1.13, Smith-Warner et al, JAMA 1998; 279: 535-40).	Thank you. Following stakeholder consultation the GDG have now decided to reduce the recommended maximum in order to be more cautious and to avoid giving confusing messages to women. Thus the NICE recommendation now states no more than 1-2 UK units once or twice a week, the same level as recommended by the DoH, 2007.
SH	Royal College of Paediatrics and Child Health	30	Full	7.2		This should be actively discouraged rather than just described as "not recommended"? One of the best RCTs (Alexander 1992) found	Thank you for this comment however breast examination was not within the scope of this update.

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						that many women positively decided before birth not to breastfeed when told they may have a problem as the result of breast examination.	
SH	Royal College of Paediatrics and Child Health	31	Full	8.2		This section does not appear to have been written or read by a haematologist and there are many points that are incorrect or subtly misleading. Below are some suggestions.	Thank you. This section was extensively reviewed prior to consultation both by members of the Sick Cell and Thalassaemia Screening Programme.
SH	Royal College of Paediatrics and Child Health	32	Full	8.2		There is no mention of haemoglobin variants and we are unclear if this was intended.	The scope of this review is Sick cell disease and thalassaemia, focussing on the most common variants of these. Other rare variants and less common haemoglobinopathies were not included in the scope for this update.
SH	Royal College of Paediatrics and Child Health	33	Full	8.2	P126 line 17	This clinical question appears to be repeated on p133 with different screening methods and this is confusing.	Thank you. This error has now been corrected.
SH	Royal College of Paediatrics and Child Health	34	Full	8.2	P127 line 24/5	'In alpha thalassaemia, trait inheritance of mutations in one or two of the four alpha genes results in the production of a reduced amount of alpha globin. Carriers usually have a mild anaemia with microcytic hypochromic indices (reduced MCV and MCH) and sometimes a characteristic blood film. If three abnormal alpha genes are inherited this is known as HbH disease which is a clinically mild disorder commonly characterised by anaemia, a characteristic blood film and splenomegaly ' is more accurate	Thank you. This section has been amended as you suggest.
SH	Royal College of Paediatrics and Child Health	35	Full	8.2	P127 line 26	This should read 'if an unborn child inherits no functioning alpha genes then no alpha globin is produced, this is alpha thalassaemia major and is not compatible with life'.	Thank you. This section has been amended as you suggest.
SH	Royal College of Paediatrics and Child Health	36	Full	8.2	P127 line 32	'Lead to death of children between one and two years of age without treatment'. - otherwise the next sentence doesn't make sense.	Thank you. This has now been added.

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SH	Royal College of Paediatrics and Child Health	37	Full	8.2	P127 line 36	'Bone marrow transplant is available to those children with an HLA matched sibling donor'. It is commonly performed in these patients in this country.	Thank you, this sentence has been amended.
SH	Royal College of Paediatrics and Child Health	38	Full	8.2	P 130 line 1	'Electrophoresis' should read 'Haemoglobin electrophoresis' - and HbA2 estimation should also be included here.	These amendments have been made, HbA2 estimation was in fact included as a screening method for review.
SH	Royal College of Paediatrics and Child Health	39	Full	8.2	P 130 line 3	Mean cell volume is part of the FBC and is less relevant than the MCH. We suggest that this is removed.	It is not possible to remove an item from this list as it was identified by the GDG as topics to be included in the review and was used to develop the search strategy for this clinical question.
SH	Royal College of Paediatrics and Child Health	40	Full	8.2 P 130 line 4		HbS/b-thalassaemia is a sickling disorder not a thalassaemia. Thalassaemias include: beta thalassaemia major and beta thalassaemia intermedia (this includes beta thalassaemia/HbE, beta thalassaemia/Hb Lepore and other rarer combinations).	Thank you. We acknowledge this discrepancy but feel it is not appropriate to remove this item from here as it was identified as a topic for reviewing when deciding this clinical question.
SH	Royal College of Paediatrics and Child Health	41	Full	8.2	P 130 line 5	Thalassaemia carrier status (trait) includes: beta thalassaemia trait, alpha thalassaemia trait, delta-beta thalassaemia trait, Hb Lepore trait. HbE trait could also be included here although it is technically a haemoglobin variant but is relevant.	Thank you. We have added HbE carrier status as this was included in the review. The other less common variants were not included in the review and therefore cannot be added.
SH	Royal College of Paediatrics and Child Health	42	Full	8.2	P 133 line 44	We suggest replacing 'Electrophoresis' with 'Haemoglobin electrophoresis' and /or HPLC should also be included here.	Thank you. These have been added since HPLC was also included in the review.
SH	Royal College of Paediatrics and Child Health	43	Full	8.2	P 133 line 46	Mean cell volume is part of the FBC and is not relevant for diagnosing sickle cell disease. We suggest that this is removed.	It is not possible to remove an item from this list as it was identified by the GDG as topics to be included in the review and was used to develop the search strategy for this clinical question.
SH	Royal College of Paediatrics and Child Health	44	Full	8.2	P 133 line 47	'Sickle cell disease includes: HbSS, HbSC, HbS/ beta thalassaemia, HbS/Hb lepore,	Thank you. We have included the first 2 most important variants and the third

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						HbS/delta beta thalassaemia, HbS/HPFH, HbS/D punjab and HbS/O arab'. The first three are the most important.	has been covered in the thalassaemia section.
SH	Royal College of Paediatrics and Child Health	45	Full	8.2	P 133 line 48	'Carrier status includes: HbAS, HbAC' – HbD and HbE etc are variant haemoglobins. HbD Punjab and HbO arab could also be included here but Hb E is not relevant.	Thank you. It is not possible to remove an item from this list as it was identified by the GDG as topics to be included in the review and was used to develop the search strategy for this clinical question. Since only one relevant study was identified it can be seen that the inclusion of HbAD and HbAE did not impact on the searching and subsequently the systematic review.
SH	Royal College of Paediatrics and Child Health	46	Full	8.2	P 134 line 30	Should 'phenotype' read 'genotype' here?	Thank you. This has been amended.
SH	Royal College of Paediatrics and Child Health	47	Full	15		Auditable standards include congenital infections and Down syndrome. They should also include management on fetal growth (IUGR), Preterm birth and Gestational Diabetes.	NICE audit criteria are based upon the key recommendations as identified by the guideline development group.
SH	Royal College of Paediatrics and Child Health	48	Algorithm	General		This is well-presented and clear	Thank you.
SH	Royal College of Pathologists	1		Cytogenetic prenatal diagnosis		This might normally follow the sections of screening for Down's syndrome - the diagnostic test being offered to women whose pregnancies are at high risk. There is however only minimal referral to diagnostic testing of Down's syndrome in the full version - remaining unchanged from the preceding version, and I can find nothing in the NICE guidelines.	Diagnostic testing for Down's syndrome was outside the scope for this Antenatal Care guideline update.
SH	Royal College of Psychiatrists					This organisation was approached but did not respond.	
SH	Royal College of Psychiatrists					This organisation was approached but did not respond.	
SH	Royal College of Radiologists					This organisation was approached but did not respond.	

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SH	Royal Liverpool Children's Hospital					This organisation was approached but did not respond.	
SH	Royal Society of Medicine					This organisation was approached but did not respond.	
SH	Royal Society of Medicine					This organisation was approached but did not respond.	
SH	Salford Royal Hospitals Foundation NHS Trust					This organisation was approached but did not respond.	
SH	Salisbury NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Sandwell & West Birmingham Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Sandwell PCT					This organisation was approached but did not respond.	
SH	Sanofi Pasteur MSD					This organisation was approached but did not respond.	
SH	Scottish Executive Health Department					This organisation was approached but did not respond.	
SH	Scottish Intercollegiate Guidelines Network (SIGN)					This organisation was approached but did not respond.	
SH	Sefton PCT					This organisation was approached but did not respond.	
SH	Sheffield PCT					This organisation was approached but did not respond.	
SH	Sheffield Teaching Hospitals NHS Foundation Trust	1	Full	General		There is no mention in the guideline of screening at booking for a personnel or family history of thromboembolic disease. In the last confidential enquiry into maternal deaths, thromboembolism was the leading cause of maternal death in the UK. Screening women in early pregnancy for increased risk by virtue of history is a method of reducing the risk.	The antenatal assessment tool which is currently under development will include a comprehensive list of all conditions to be screened for at booking, including thromboembolism.
SH	Sickle & Thalassaemia Association of Counsellors	1	NICE	Key Priorities	Page 6	Bullet point 2 – in view of the high risk pregnancy and health care requirements of women with disease states and the urgency of offering options for prenatal diagnosis and possible first trimester termination for couples at risk we suggest that 'as soon as possible' is too vague and advice adding - 'ideally before	Thank you, this has been added as you suggest.

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						ten weeks of pregnancy'	
SH	Sickle & Thalassaemia Association of Counsellors	2	NICE	1.1.1.1	Page 8	In order to achieve offer of prenatal diagnosis and if desired termination of an affected pregnancy need to consider adding <ul style="list-style-type: none"> At booking - Offer screening for haemoglobinopathies ideally by ten weeks of pregnancy	Thank you. This has been added.
SH	Sickle & Thalassaemia Association of Counsellors	3	NICE	1.2.7.3	Page 13	First appointment – having said earlier that screening for haemoglobinopathies need to be offered ideally before 10/ 40 gestation need to maintain consistency and suggest change (prior to 12 weeks) to (prior to 10 weeks) this will be in keeping with the Human Genetics Commission's position (2006) Making Babies, which recommend performing screening / testing as early as possible in pregnancy to enable women/ couples to make informed genetic choices as early as possible.	Thank you. This amendment has been made as you suggest.
SH	Sickle & Thalassaemia Association of Counsellors	4	NICE	1.2.7.3	Page 13	The Fourth bullet point we suggest adding <ul style="list-style-type: none"> offer screening for haemoglobinopathies 	Thank you. This has been added.
SH	Sickle & Thalassaemia Association of Counsellors	5	NICE	1.2.7.3	Page 14	First paragraph after the bullet points is confusing, is the sentence relating to screening or diagnostic testing, if testing is it to be 'arranged' or 'offered' at this stage? In respect of haemoglobinopathies this should be done ideally <12/40 weeks gestation and not 16. Also we suggest adding a bullet point for haemoglobinopathies screening.	Thank you. We agree this is confusing and has been amended.
SH	Sickle & Thalassaemia Association of Counsellors	6	NICE	1.2.7.3	Page 14	The first two bullet points after the sentence: After the first (and possibly)... relate to compulsory elements of antenatal care which we suggest should be done ideally at the first appointment as indicated in the early part of	Thank you. This section has been amended to improve clarity and to reflect the earlier gestation at which screening is recommended.

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						this section. It is usually explained to women that these tests are a necessary requirement and that it would be difficult to offer them care if this information is not made available to their health carer	
SH	Sickle & Thalassaemia Association of Counsellors	7	NICE	1.2.7.3	Page 14	We suggest adding another sentence as a prelude to the next two of four bullet points in the middle of the page to reflect the later gestation that these tests can and in some cases should be performed.	Thank you. This section has been amended to improve clarity and to reflect the earlier gestation at which screening is recommended.
SH	Sickle & Thalassaemia Association of Counsellors	8	NICE	1.2.7.3	Page 14	We suggest adding another bullet point to the four in the middle of the page to read: <ul style="list-style-type: none"> women at-risk of having a child with a serious genetic condition should be offered the option of partner testing, if required prenatal diagnosis and if selected the termination of an affected pregnancy ideally by 12 to 16 weeks gestation. 	This is included in the section on screening for haemoglobinopathies and does not sit comfortably here with the list of routine screening tests.
SH	Sickle & Thalassaemia Association of Counsellors	9	NICE	1.6.2.6	Page 26	Suggest adding bold heading to this section 1.6.3 Haemoglobinopathies and thalassaemias	Headings are formatted by our editors in accordance with the NICE house style.
SH	Sickle & Thalassaemia Association of Counsellors	10	NICE	1.6.2.6	Page 26	Suggest excluding first part of the sentence since it relates to preconception perhaps put somewhere else in the document i.e. Pre-conception counselling and carrier testing should be available to all women. Suggest use the following or similar sentence as an introduction to this section to be headed haemoglobinopathies and thalassaemias: Screening and pre test counselling should be made available to all women who are identified as being at higher	Thank you for your comment. This document is a list of all the recommendations as they appear in the full version of the guideline. It is not possible to move recommendations therefore. Introductions such as you suggest are not included in this version of the guidance.

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						risk of haemoglobinopathies using the Family Origin Questionnaire (NHS Antenatal and Newborn Screening Programmes) (See Appendix F of the full guideline).	
SH	Sickle & Thalassaemia Association of Counsellors	11	NICE	1.6.2.7	Page 26	Suggest omit 1.6.2.7 (tautological)	Thank you. The recommendations have been amended and combined to reduce repetition.
SH	Sickle & Thalassaemia Association of Counsellors	12	NICE	1.6.2.8	Page 26	Change to 1.6.3.1	The order of these recommendations has been altered so all references to preconception counselling and screening come first.
SH	Sickle & Thalassaemia Association of Counsellors	13	NICE	1.6.2.9/ 1.6.2.1 0/ 1.6.2.1 1	Page 26 to 27	<p>Change to 1.6.3.2 suggest amend sentence:</p> <p>Screening for sickle cell disorders and thalassaemia should be offered and performed for all pregnant women (ideally by 10 weeks), and be preceded by counselling ideally in primary care but can be done in secondary care settings. The type of screening depends upon the prevalence.</p> <ul style="list-style-type: none"> - In high prevalence areas (more than 1.5 cases per 10 000 pregnancies) screening should be offered to all women in order to identify carriers and those with a disorder - In low prevalence areas (less than or equal to 1.5 cases per 10 000 pregnancies) the Family Origin Questionnaire (NHS Antenatal and Newborn Screening Programme) should be used to identify women who are in the at risk group and offered screening for haemoglobinopathies (See Appendix F of the full guideline) 	<p>Thank you.</p> <p>These recommendations have been altered to make the flow more logical (preconception screening first) and to avoid repetition. The final version is similar to that you suggest.</p>

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SH	Sickle & Thalassaemia Association of Counsellors	14	NICE	1.6.2.1 0	Page 26	We felt this section contains unnecessary detail about laboratory techniques and will be confusing for generalist practitioners. In view of this we suggest omitting 'using high performance liquid chromatography'.	Thank you. At the suggestion of stakeholders this recommendation has been amended to say "laboratory testing" (preferably HPLC) which we hope will be easy to understand but still reflect the best test as shown by the evidence.
SH	Sickle & Thalassaemia Association of Counsellors	15	NICE	1.6.2.1 1	Page 27	In the first bullet point we suggest omitting 'using high performance liquid chromatography'.	Thank you. At the suggestion of stakeholders this recommendation has been amended to say "laboratory testing" (preferably HPLC) which we hope will be easy to understand but still reflect the best test as shown by the evidence.
SH	Sickle & Thalassaemia Association of Counsellors	16	NICE	1.6.2.1 1	Page 27	Second bullet point we suggest amend to read: If the Family Origin Questionnaire (NHS Antenatal and Newborn Screening Programme) indicates high risk of thalassaemia and mean Corpuscular haemoglobin (MCH) is less than 27pg screening should be offered	Thank you. At the suggestion of stakeholders this recommendation has been amended to say "laboratory testing" (preferably HPLC) which we hope will be easy to understand but still reflect the best test as shown by the evidence.
SH	Sickle & Thalassaemia Association of Counsellors	17	NICE	1.6.2.1 2	Page 27	Change to 1.6.3.5 We suggest amending sentence to read: Women identified as a carrier or those who have a disorder (disease) should be offered partner testing in order to identify those at risk of having a child with a serious disorder	Thank you, the GDG have decided to alter this recommendation slightly following a suggestion from another stakeholder also with vast experience in this field.
SH	Sickle & Thalassaemia Association of Counsellors	18	NICE	1.6.3.6	Page 27	We suggest adding 1.6.3.6	Thank you. We have not gone this far with our recommendations as fetal diagnosis is beyond the scope of our clinical question.

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						Women identified as being at-risk of having a child with a serious disorder should be offered genetic counselling and the option of prenatal (fetal) diagnosis and where selected termination of an affected pregnancy	
SH	Sickle & Thalassaemia Association of Counsellors	19	NICE	1.6.3.7	Page 27	<p>We suggest adding</p> <p>1.6.3.7</p> <p>It should be noted that women with a haemoglobinopathy or thalassaemia disorder (disease) are high risk of medical and obstetric complications and need specialist haematological and obstetric care</p>	Thank you. It was not felt necessary to add this recommendation as we have identified women with a haemoglobinopathy as women who require additional obstetric care during pregnancy.
SH	Society and College of Radiographers	1	full			The society and College of Radiographers welcome the opportunity to make comments on this document. These are very timely and comprehensive guidelines. We are very pleased that the role of ultrasound screening in fetal assessment of gestational age and screening has been explored in depth and useful recommendations are made to guide the sonography workforce involved with obstetric ultrasound examinations.	Thank you.
SH	Society and College of Radiographers	2	full	general	Page 90 Line 4	There is a discrepancy in the document in terms of the gestational age threshold for Nuchal translucency scans- stated as between 11-14 weeks instead of 13 weeks and 6 days. All NT packages available for Downs risk assessment have a cut off gestation of 13 weeks and 6 days.	Thank you. This has been amended to refer to a cut-off of 13 weeks and 6 days.
SH	Society and College of Radiographers	3	NICE	4.7		There should be a statement that says when the NT isn't possible due to fetal position or raised BMI then the women should be offered serum screening (triple or quadruple) at 14-20 weeks. There are occasions when an NT	Thank you. We have added a recommendation to reflect this.

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						measurement is not always possible.	
SH	Society and College of Radiographers	4	NICE	1.7.2.2		It would be ideal to offer a routine anomaly scan between 18-20 or (18-20+6 weeks, as recommended by the NSC) however there is no mention of "bariatric" patients or the increase in average weight of the population. There is also a potential for an increase in RSI related problems if all sonographers are expected to complete the anomaly scan by 20 weeks. Suggest the word "normally" be inserted to allow a certain leeway. e.g US screening for fetal abnormalities should normally be routinely offered between 18 and 20 weeks."	Thank you for your comment. We agree and this has been added to the recommendation as you suggest.
SH	Society and College of Radiographers	5	NICE	1.7.1		Ultrasound for Small for Gestational Age in women with Symphysis-fundal height of 3 cm less than gestational age is accepted, but the recommendation also suggests a growth scan for Small for Gestational Age even if the Symphysis-fundal height is 3 cms more than gestational age, This is confusing- is the scan checking for Large for gestational age?	Thank you. This recommendation has now been amended to include only women where the symphysis-fundal height is 3 cm or more below that expected for gestational age.
SH	South Asian Health Foundation	1	NICE	1.10.1.1 to 1.10.1.5		<p>In order to adequately address inequalities from a perinatal perspective, we are conscious that the one-size-fits all approach to growth charts is perhaps not the most appropriate approach. Not only would this fuel inequalities but also result in inappropriate use of healthcare resources.</p> <p>Customised growth charts have been widely used in the West Midlands and the evidence suggests their utilisation is beneficial and results in improved outcomes. Indeed, even the World health Organisation has accepted that conventional growth charts are inappropriate for all ethnic groups. More customised growth charts would accommodate individual variation within a multi-ethnic</p>	<p>Thank you for your comment.</p> <p>Whilst there is some evidence that use of customised fetal growth charts may improve detection of small for gestational age babies there is at present no evidence that this leads to improved outcomes. However, we do accept your point and have now removed the recommendation stating</p>

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						population. Even if widespread use is not advocated by the guideline, we feel that specific exclusion or discouragement is non-progressive and perhaps risks being regressive. In light of this, we strongly encourage reconsideration of this specific issue in what is otherwise a reasonable guideline.	that customised growth charts are not recommended, recognising that where they are in use there is no reason to discourage this.
SH	Southampton University Hospital Trust					This organisation was approached but did not respond.	
SH	Syner-Med Pharmaceutical Products Ltd	1	Full	11.1	line 27	Screening women from high risk ethnic groups for gestational diabetes should include additional iron status markers as these women are also at increased risk of developing iron deficiency and anaemia. Ferritin levels in these women may be elevated irrespective of iron stores and should be cross referenced with markers of inflammation. Anaemia, reduced haemoglobin levels, can affect the accuracy of HbA1c measurements. This factor may help account for the poor predictive accuracy of foetal overgrowth using HbA1c. (Lapolla Diabetes Res Clin Pract 2007 Sept;77(3):465-70.	Thank you for your comments. All women have a haemoglobin check at 28 weeks which will be at or after the time of their GD being identified.
SH	Syner-Med Pharmaceutical Products Ltd	2	Full	11.1	line 38	GD responds to dietary changes but those changes may exacerbate the development of iron deficiency if additional phytase containing foods are consumed. These compounds act as chelating agents even in iron replete subjects. (Bach Kristensen M, Eur J Nutr . 2005 Sep;44(6):334-40). Cultural dietary constraints, such as vegetarianism, common in high risk groups for gestational diabetes also increase the risk of developing iron deficiency (Obeid Eur J. Haematol 2002 Nov-Dec 69 (5-6):275-9). Accurate assessment of iron stores using serum transferrin receptor is independent of the inflammatory factors influencing ferritin as a marker and responds to iron	Thank you for your comments. The haemoglobin is checked in all women at 28 weeks. If this was found to be low follow up would be indicated by the present guideline.

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						supplementation even when ferritin shows no change. (Madhevan Nair K, Nutrition 2004 Oct;20(10):896-9).	
SH	Syner-Med Pharmaceutical Products Ltd	3	Full	11.3		Using ferritin as a generalized marker of inflammation may provide a cheaper predictive tool for preterm birth. This measure could provide a cost effective screening tool when used in conjunction with symphysis-fundal height at 24 weeks as it will also give an indication of iron deficiency if the value is low. High cervical ferritin levels are associated with spontaneous preterm birth in asymptomatic women at 22-24 weeks (Ramsey Am J Obstet Gynecol 2002 Mar;186(3):458-63). High plasma ferritin levels at 26 weeks is correlated to preterm delivery (Goldenberg Am J Obstet Gynecol 1996 Nov;175(5):1356-9).	Thank you for your comment. Ferritin was not identified by the guideline development group as a component of the clinical question on pre-term birth.
SH	Syner-Med Pharmaceutical Products Ltd	4	Full	12	line 6	If the fetal growth scan at 24 weeks indicates retarded growth, screening for iron deficiency should be performed to eliminate this factor as the causative or a contributing factor before other treatments are initiated. The next routine screening is 4 weeks after this time and only includes haemoglobin. There appears to be a strong correlation between high ferritin levels at 26 weeks and low birth weight, but this is in the context of ferritin as an inflammatory marker (Goldenberg Am J Obstet Gynecol 1996 Nov;175(5):1356-9). Low iron levels are also associated with growth restriction but a more sophisticated measure of iron stores than ferritin alone is obviously needed (Hou Obstet Gynecol 2000 Mar;96(3):447-52).	Thank you. Screening for iron deficiency is outside the scope of this guideline update.
SH	Syner-Med Pharmaceutical Products Ltd	5	Full	General		Current routine screening for anaemia does not include a serum ferritin measurement or other parameters to determine iron deficiency. A ferritin test is regarded necessary only to confirm suspected iron deficiency after symptomatic anaemia is established.	Screening for anaemia was outside the scope of this update and therefore not considered at this time.

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						<p>The prevalence of iron deficiency during pregnancy in the UK is higher in certain social, cultural and economic groups, comparable to that in other industrialised countries. These groups are also generally prone to present with or develop diabetes and have a higher risk of haemoglobinopathy. The influences on pregnancy of iron deficiency and of anaemia are not synonymous even in low income minority groups (Scholl TO, Am J Nutr 2005 May;85(5):1218S-1222S) nor do they appear to be moderated by the residence period of immigrant groups in developed countries (Nybo M, Ann Hematol 2007 Sep;86(9):647-51).</p> <p>An additional measurement of iron status at the two scheduled screening visits would be valuable in a significant percentage of all women tested. Using serum ferritin as the measure has diagnostic benefits when used in conjunction with routine screening already recommended. Symptomatic presentations associated with iron deficiency, such as restless leg syndrome, (Aul EA Neurology 1998;51:912), could be more easily diagnosed and treated as such if a baseline measurement was taken at the first visit. Development of anaemia in those women at high risk later in pregnancy could be avoided.</p> <p>Studies by Milman et al, have demonstrated the fall in ferritin level as pregnancy progresses. (Milman N, Acta Obstet Gynaecol Scand 1999; 78(9):749-757). The group followed this work with a study examining individually tailored iron prophylaxis based on ferritin measures taken early in pregnancy (Milman Ann Hematol 2006 Sep;85(9):567-73) indicating that a screen here for those with a</p>	

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						<p>low or relatively low ferritin would enable appropriate prophylactic treatment to be initiated. This would allow the standard approach of oral iron therapy to be successful at a relatively low dose and give better compliance. As a result fewer patients will progress to iron deficiency and anaemia later in pregnancy where standard oral therapy will be less likely to succeed (Breymann C, Fetal and Maternal Medicine Review 2002; 13:1 1-29) .</p> <p>Initial assessment of iron status and more frequent monitoring throughout the course of pregnancy would help ameliorate the morbidity to mother and foetus associated with iron deficiency. It would also be a valuable reference level against which inflammatory status could be compared if needed later in the course of the pregnancy.</p>	
SH	The British Psychological Society	1	Full	General		<p>While the Antenatal Care Guideline includes recommendations on serious psychiatric illness and antenatal screening for postnatal depression, it neglects to address the wider spectrum of psychological and mental health needs of women during pregnancy. This perpetuates the risk of missing less severe psychological problems and especially those other than depression, and consequently risks losing a valuable opportunity for psychological intervention and planning appropriate coordinated care.</p> <p>From clinical experience women are often all the more distressed by low mood during pregnancy because it is not generally recognised as is postnatal depression.</p>	Consideration of psychological and mental health issues during pregnancy has been comprehensively addressed in NICE clinical guideline number 45 "Antenatal and Postnatal Mental Health".

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SH	The British Psychological Society	2	NICE	Chap 3 Recom mendat ions		<p>Regarding the recommendation that “awareness of baby blues and postnatal depression” is addressed at or before 36 weeks. This is late to introduce mental health issues and inconsistent with the Guideline on Antenatal and Postnatal Mental Health recognising the importance of early and repeated assessment.</p> <p>There is good evidence that at least 15 per cent of pregnant women experience mild to moderate mental illness with some findings suggesting higher rates of depression in the last trimester of pregnancy than postnatally (Evans et al, 2001).</p> <p>Antenatal depression has been associated with prematurity, low birth weight and less optimal neurobehavioural profiles in the newborn (Field et al, 2004).</p> <p>High levels of anxiety are also relevant, especially as a number of research findings have demonstrated that they may contribute to preterm labour. Maternal antenatal stress has been associated with negative neonatal outcomes (Gitau et al, 2001; Huizink et al, 2003) and in the longer term with adverse emotional and behavioural outcomes for children (O'Connor et al, 2003).</p> <p>Raising awareness of antenatal depression and anxiety early in pregnancy would be helpful.</p> <p>It would also be helpful for women to be made aware that they should have priority for access to psychological therapies during pregnancy and the perinatal period as recommended in the Guideline for Antenatal and Postnatal Mental Health.</p>	Thank you. Discussion of mental health issues has now been included and cross reference made to the NICE Guideline for Antenatal and Postnatal Mental Health.
SH	The Chartered Society of Physiotherapy					This organisation was approached but did not respond.	

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SH	The Confidential Enquiry into Maternal & Child Health (CEMACH)					This organisation was approached but did not respond.	
SH	The Pelvic Partnership					This organisation was approached but did not respond.	
SH	The Phoenix Partnership					This organisation was approached but did not respond.	
SH	The Survivors Trust					This organisation was approached but did not respond.	
SH	Tiny Tickers					This organisation was approached but did not respond.	
SH	TIPS Limited	1	NICE	1.1.1.		<p>Information on the avoidance of certain skincare/food products that have the potential to sensitise the unborn infant should be given at the first antenatal visit. This could reduce the chances of the baby going on to develop skin and/or allergic conditions in the future. This could include the following statement:</p> <ul style="list-style-type: none"> Care should also be taken when using household (detergent residues can be absorbed into the bloodstream through the skin) or personal care products as these too can pose a risk to your unborn child. <p>Even during the antenatal period it is important to introduce the subject of safe skincare guidelines for infants during their early weeks of life. This is when many parents start buying baby products and this should be discouraged. This would complement the new advice in the recent postnatal care guidelines (July 2006) which recommends that bathing products are not necessary during the neonatal period.</p>	Thank you for your comment. Skin care, food avoidance and prevention of allergies were outside the scope of this update.
SH	TIPS Limited	2	NICE	1.3.3.		<p>Although Food acquired infections and Nutritional supplements are mentioned, it would be useful to include a section called 'Avoidance of allergies' which could include the latest advice:</p> <ul style="list-style-type: none"> 'Encouraging the pregnant woman to eat fresh foods containing as few 	Thank you for your comment, however this was outside the scope of this current guideline update.

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						<p>additives and preservatives as possible' or</p> <ul style="list-style-type: none"> • 'A previous history of allergic symptoms would make it sensible for a pregnant woman to avoid those substances that she knew she was sensitive to [i.e. nut allergies]'. This is based on information submitted to the House of Lords Science and Technology Sub-Committee on allergies by TIPS Ltd, on behalf of the RCM – I would be happy to provide this for you to read. 	
SH	TIPS Limited	3	NICE	1.3.5.1.		Over the counter (OTC) personal care products should be included here alongside OTC medicines (see above for reasons).	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	Twins & Multiple Births Association (Tamba)					This organisation was approached but did not respond.	
SH	UCLH NHS Foundation Trust					This organisation was approached but did not respond.	
SH	UK Coalition of People Living with HIV & AIDS					This organisation was approached but did not respond.	
SH	UK Forum on Haemoglobin Disorders	1	Full	8.2		Although there is comprehensive cover of haemoglobinopathy screening in terms of identifying pregnancy with a risk of a child with haemoglobin disorder there is no discussion of the implications of pregnancy in an individual with sickle cell disease or thalassaemia major. Both of these conditions should be regarded as high risk for mother and foetus & require care in a specialised centre with appropriate experience and access to a multidisciplinary team of experts. More detail is required on this area.	Thank you. Women with high-risk pregnancy requiring specialist care are outside the scope of this guideline.
SH	UK Forum on Haemoglobin Disorders	2	NICE	1.6		As above	Thank you. Women with high-risk pregnancy requiring specialist care are outside the scope of this guideline.
SH	UK National Screening Committee	1	Full		Page 17: Glossa	'Screening' – The current usage of the term 'screening'	Thank you. We have used your (much

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					ry of terms	<p>seems to be derived from the US Commission on Chronic Disease which reported in 1957. There seems to be no recognition of patient choice in the process or of screening as a systematically applied service.</p> <p>The NSC usage of the term retains the emphasis on unrecognised signs or symptoms and the need to differentiate screening from diagnosis but, as it was developed in 2000, it is more in keeping with current UK thinking on the above mentioned issues.</p> <p>‘Screening is a public health service in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications.’</p> <p>The distinction between screening and diagnosis could be assimilated more systematically eg in some of the reviewed sections the question is ‘what is the diagnostic value of screening methods to ...’. This is the case in the section on preterm birth, pre-eclampsia and gestational diabetes.</p>	<p>better) definition of screening in the glossary now.</p> <p>Thank you. It is too late to alter the clinical questions at this late stage but we acknowledge your useful comment and will be guided by it when developing guidelines in the future.</p>

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SH	UK National Screening Committee	2				'Sensitivity' – at present the glossary refers to diagnostic tests, does the definition fit screening tests ?	Thank you. The definition of sensitivity has been amended and now can be applied to screening tests as well as diagnostic tests.
SH	UK National Screening Committee	3				'Specificity' - at present the glossary refers to diagnostic tests, does the definition fit screening tests ?	Thank you. The definition of specificity has been amended and now can be applied to screening tests as well as diagnostic tests.
SH	UK National Screening Committee	5		Page 20, line 7		<p>It is stated on line 2 – 3 that 'the individual components and composite package of antenatal care should conform to the criteria for a successful screening programme'. The NSC welcomes this as the guideline's aim as much of the guidance concerns screening. However if this is the guiding thread there might be a case for expanding the number of bullet points or summarising them more closely to the full criteria eg to state explicitly that treatments or interventions should be 'effective'.</p> <p>The criteria could also be used as a framework for presenting the discussion on each condition eg see the comments on chlamydia and preterm labour.</p>	<p>Thank you. That treatments should be effective has now been added.</p> <p>Thank you for this. It is not possible due to severe time constraints to make this suggested change but we will bear it in mind for future work.</p>

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SH	UK National Screening Committee	6	Sickle Cell and Thalassaemia	General comments		<p>The NSC notes that the Sickle Cell and Thalassaemia Screening Programme has submitted a response. We would like to generally endorse the points made in this response and would like to draw particular attention to the following:</p> <ul style="list-style-type: none"> • screening for sickle cell and thalassaemia needs to be referenced consistently throughout the document as part of the antenatal and newborn screening programme • consistency about the timing of screening is necessary throughout the guidance's references to sickle cell and thalassaemia. The early offer of screening is essential for the delivery of high quality service and the optimal timing of screening is 8 – 10 weeks gestation • in keeping with other programmes screening for sickle cell and thalassaemia is 'offered' and this should be the preferred term used in the guidance, (see the comment the glossary definition of screening above) 	<p>Thank you.</p> <p>We have mentioned the antenatal and newborn screening programme consistently throughout this section. We have recommended that information-giving and screening is carried out by 10 weeks. Thank you. We have amended the guideline to ensure screening is "offered" as you rightly point out.</p>
SH	UK National Screening Committee	7	Chlamydia: Pages 210 - 218	general comments		<p>The discussion of the evidence relating to testing and treatment is divorced from the wider considerations identified by the NSC criteria and this results in a circumscribed discussion of the issues.</p> <p>A broader discussion relating to the condition, structured around the NSC criteria for evaluating screening programmes, could be</p>	<p>Thank you. The discussion as presented in the guideline answers the clinical question as stated. It is not the purpose of the guideline to give an in-depth discussion surrounding other issues of Chlamydia screening and the impact of Chlamydia infection in pregnancy. In order to address the issues you refer to eg. timing of</p>

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						<p>introduced into the 'Introduction and background' section. This might include:</p> <ul style="list-style-type: none"> the burden of disease not only in terms of its incidence but also of its impact on adverse outcomes of pregnancy and neonatal morbidities, consideration of the timing of testing as it relates to the stated purpose of screening eg (i) to reduce neonatal morbidities eg conjunctivitis, respiratory tract infections middle ear infections and the long term effects of these conditions in their more severe manifestations and / or (ii) to reduce adverse outcomes of pregnancy eg low birth weight, prematurity, stillbirth, intrauterine growth restriction, the current programme provision eg the NCSP which, in contrast to the above, aims to reduce the incidence of sexually transmitted Chlamydia infection and the related sexual and reproductive health morbidities eg infertility and ectopic pregnancy. The programme has employed an opportunistic strategy amongst high risk populations which has no inherent link to screening in pregnancy. The NICE Public Health Interventions Advisory Committee recently undertook a review of the NCSP and this might inform the discussion of the programme, evidence which informed the current policy not to screen in pregnancy. The NSC's assumptions were grounded in the work of Preece et al in the late 1980's.^{5, 6} These studies were based on an analysis of the UK's largest 	<p>testing, an underlying systematic review would need to be undertaken, driven by the relevant clinical questions. Within the time scale and resources available for this guideline update such a broad and detailed investigation of the evidence was not possible.</p>

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						<p>prospective study of Chlamydia screening and provided a firm steer away from screening during pregnancy. At present the NCSP's roll out in antenatal clinics has stimulated interest in the evidence base for screening in pregnancy and this provides the background to the current review.</p> <p>A discussion of this type would provide a structured context for the evidence summaries and recommendations.</p> <p>¹ Chlamydia trachomatis infection in late pregnancy: a prospective study; Preece, PM, Ades, A, Thompson, RG, Brookes, JH: Paediatric and Perinatal Epidemiology, 1989, 268 - 277</p> <p>² Chlamydia trachomatis infection in infants: a prospective study; Preece, PM, Ades, A, Thompson, RG: Archives of Disease in Childhood, 1989, 64, 525 – 529</p>	
SH	UK National Screening Committee	8			Page 210, line 26	<p>The accuracy of the stated rate of incidence of asymptomatic Chlamydia infection would be improved if the discussion was extended beyond the under 25 year old population as a whole.</p> <p>In terms of numbers, the burden of disease is currently stated as 10% of men and women under 25 years of age testing positive for asymptomatic carriage of Chlamydia.</p> <p>However the pregnant population, to which this guideline refers, may have a lower rate of incidence than the under 25 population as a whole.</p> <p>For example, the NCSP annual report 2005 / 6</p>	<p>Since screening for Chlamydia infection is only being suggested for women age 25 and under it is relevant to quote the incidence in this section of the population.</p> <p>We agree, as stated on page 210, line 26.</p> <p>This is also true, but we have no figures to support this.</p>

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						<p>states that 8.5% of all tests undertaken amongst women under 25 years of age in obstetrics and gynaecology, antenatal, infertility and colposcopy clinics were positive. (New Frontiers; National Chlamydia Screening Programme Annual Report 2005/6)</p> <p>Unfortunately the rate of incidence for different clinics are not separated. However, a personal communication from Dr Sarah Randall states that for antenatal clinics alone the proportion of positive tests was 7.5%. This can be supplied if required.</p>	Thank you, we have added these figures to the introduction.
SH	UK National Screening Committee	9			Page 210, lines 30 – 31	<p>The final sentence should be amended to read: 'Asymptomatic Chlamydia infection during pregnancy has been associated with adverse outcomes of pregnancy (low birth weight, premature delivery, preterm rupture of the membranes) and neonatal morbidities (respiratory tract infection and conjunctivitis). However a causal link between the organism and adverse outcomes of pregnancy has not been established and the evidence remains difficult to evaluate. In relation to neonatal morbidities, where a causal link between organism and outcome has been established, rapid identification and good management of affected neonates was thought to be a clinical and cost effective alternative to screening.'</p>	Thank you for this helpful comment. This has been added to the full text of the guideline to clarify the GDG interpretation of the evidence.
SH	UK National Screening Committee	10			Page 218, lines 26 – 27	<p>When read alongside the second recommendation, the current wording of this sentence could be interpreted as a justification for screening for Chlamydia carriage outside antenatal care settings during pregnancy. The current wording should be amended to read:</p> <p>'There are concerns regarding the practicality of undertaking adequate counselling, contact</p>	Thank you, the wording has been amended to aid clarity.

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						<p>tracing, partner testing and follow-up in the antenatal period.'</p> <p>These are key elements of effective opportunistic Chlamydia testing and should be discussed in the body of the text rather than being raised in isolation as new points at the end of the discussion.</p>	<p>It is not possible to include these points in the text summary as they are not addressed in the evidence reviewed. Hence they appear here in the GDG interpretation of the evidence in order to explain why the GDG has made the recommendations as they stand.</p>
SH	UK National Screening Committee	11			Page 218: recommendation 1	<p>The evidence summary states that there is only poor evidence to indicate that treating asymptomatic Chlamydia is effective in preventing adverse outcomes of pregnancy. The evidence summary also states that there is no significant evidence that treating asymptomatic Chlamydia is effective in reducing the incidence of neonatal morbidities.</p> <p>The NSC welcomes the reaffirmation of the policy not to offer screening in pregnancy. However the current wording, 'Chlamydia screening should not be offered as part of routine antenatal care', implies that there may be circumstances in which it should be offered.</p> <p>The recommendation should be amended to read: 'Antenatal screening for Chlamydia carriage should not be offered until there is firm evidence that screening and contact tracing is a clinical and cost effective means of reducing the sequelae of asymptomatic infection in pregnancy.'</p>	<p>Thank you.</p> <p>Thank you. The wording has been chosen to allow for some exceptional circumstances where screening for Chlamydia may be undertaken in the antenatal clinic – eg. at a woman's specific request.</p>
SH	UK National Screening Committee	12			Page 218: recommendation 2	<p>The evidence summary states that there is only poor evidence to indicate that treating asymptomatic Chlamydia is effective in preventing adverse outcomes of pregnancy. The evidence summary also states that there is no significant evidence that treating</p>	<p>Thank you for your comment. The reason for informing pregnant women of the national programme for chlamydia screening is to improve knowledge of and uptake of this programme and thus improve the</p>

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						<p>asymptomatic Chlamydia is effective in reducing the incidence of neonatal morbidities.</p> <p>As such, there is a poor correlation between the evidence summary and the recommendation that women under 25 years of age should be informed of the high prevalence of Chlamydia in their age group and be given details of their local NCSP provision.</p> <p>Given the conclusions of the evidence summary, the benefit to pregnant women arising from this recommendation is unclear and is likely to cause confusion. Given the aims of the NCSP there are two possibilities.</p> <p>A stated aim of the NCSP is to 'reduce the prevalence of costly sequelae of chlamydial infection in England'. The evidence indicates that treatment in pregnancy would be unlikely to contribute to this aim and the NSC is concerned that this recommendation could:</p> <ul style="list-style-type: none"> • lend tacit approval to antenatal screening where the evidence does not support it and also approval to remove antenatal care from an appropriate setting, • result in an expansion of antibiotic usage in pregnancy where there little evidence of benefit combined with the potential for antibiotic resistance to develop, • result in an unnecessary medicalisation of pregnancy (in terms of an increased number tests, anxiety and potential stigma), • put health professionals in a very difficult position when counselling 	<p>sexual health of women in this age group generally. As you rightly point out it would be appropriate to do this during the early booking appointment when other sexual health issues are being discussed.</p>

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						<p>women regarding the provision of screening via the NCSP,</p> <ul style="list-style-type: none"> • add to the workload of midwifery staff in return for no improvement in health outcomes, • undermine the value of screening as a means of managing risk in pregnancy. <p>Another stated aim of the NCSP is 'to improve general sexual health awareness'. The NSC agrees that sexual health awareness should be raised during pregnancy. If the recommendation is intended to direct women to the NCSP for this purpose then this should be made explicit in the guideline to avoid confusion.</p> <p>However there is already a recommendation to discuss sexual health matters with all pregnant women during the consultation on screening for the four infectious diseases (Hepatitis B, HIV, Rubella antibody and syphilis) early in pregnancy. If it is appropriate to raise awareness of Chlamydia during pregnancy this would be a more appropriate setting in which to do so.</p> <p>The NSC considers that recommendation 2 of the consultation document should be either removed or amended to read:</p> <p>'Appropriate information about Chlamydia infection should be transferred to pregnant women as part of the consultation around the Infectious Diseases in Pregnancy Screening Programme. This might focus on its association with neonatal morbidities, sexual and reproductive health morbidities relating to future pregnancies and prevention strategies given the absence of effective treatments.'</p>	

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						<p>The NSC would be happy to work with the NCSP to develop materials to support this recommendation.</p> <p>(Aims of the NCSP taken from: New Frontiers; National Chlamydia Screening Programme Annual Report 2005/6)</p>	
SH	UK National Screening Committee	13			Page 218: Research recommendation	<p>The NSC agrees that research is needed to examine the effectiveness of screening, its practicality and acceptability.</p> <p>However given that there is currently a Chlamydia screening programme the aims of which emphasise the prevention of sexual and reproductive health morbidities (eg infertility, ectopic pregnancy) it might be appropriate to consider research in the preconceptual and postnatal periods rather than the antenatal period. Consideration of these issues should be included in the research recommendation.</p>	Thank you for your comment. The GDG believe it not appropriate to make this research recommendation as it may be that treatment in pregnancy does have some positive effect.
SH	UK National Screening Committee	14	Gestational diabetes		P230 – 245	<p>This is an important update as it reverses the current policy which is not to offer screening. It is important that all the relevant evidence should inform this step. We have been advised that the HAPO trial, to which the 2003 guidance referred, will report in Spring 2008 and this may be a more appropriate time to update the previous HTA review. This pointed to a range of issues which prevented screening for GDM meeting the NSC criteria and a more direct engagement with these criteria and the previous HTA report would be valuable.</p> <p>For example, it is implied (p230, line 17 – 20)</p>	<p>Thank you. The ACHOIS study has been used as the best evidence on which to reverse the previous advice. The HAPO study has not reported but some preliminary information indicates the same direction of travel as ACHOIS although so far that extends only to biochemical evidence.</p> <p>This is not what is meant here, rather</p>

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						<p>that screening for, and intervening on, GDM can reduce the risk of developing type 2 diabetes in later life. However the HTA report suggests that this is not the case and that the mechanism of progression to type 2 diabetes is poorly understood.</p> <p>The HTA report also suggests that there is a great deal of uncertainty around OGTT as the diagnostic test and the HAPO trial is examining uniform standards for detection and diagnosis.</p> <p>The range of risk factors seem broadly in keeping with the HTA 2002 review but their interim status could be emphasised. Indeed the risk factors are said to be 'more practical and less disruptive for women.' (p 244 line 23-4) than other tests but the evidence supporting their use is said to be 'unclear'. We are concerned that policy for systematically offering screening should be made on this basis.</p> <p>We also received the following detailed comments:</p> <p>There are lots of American studies cited in the document with blood glucose given in mg/dl; I think it would be useful to give conversion in mmol/dl in parenthesis, as not everybody knows the conversion units on their fingertips.</p> <p>Page 232, line 24: The issue about recurrence of GDM in subsequent pregnancies is clearly very important. What is not addressed is the timing of OGTT in subsequent pregnancies i.e. should it still be 24-28 weeks or should it be earlier. There are no studies I know of which have addressed this issue. This is particularly important in Asian women who may have</p>	<p>that early detection of diabetes in pregnancy can lead to increased surveillance and early detection of Type II diabetes later on.</p> <p>We reviewed the data on screening and diagnostic tests and it was felt that the OGTT was the best.</p> <p>Thank you. The word unclear is a poor choice and has been removed.</p> <p>Thank you we have provided figures in both mmol/l and mg/dl now.</p> <p>Thank you, this is an important point which is dealt with in Diabetes in pregnancy guideline – they suggest 16 to 18 weeks ANC guideline deals with normal women.</p>

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						<p>multiple pregnancies. A totally pragmatic and common sense based approach used in York is to perform an earlier OGTT and we have picked up frank Diabetes on number of occasions. If the OGTT is normal we repeat it at 24-28 weeks. The advantage is thought to be picking GDM early and intervening early rather than late.</p> <p>Page 244 line 30:</p> <p>The recommendation to use BMI of >30 is not clear as >27 defines the obesity cut off in women at present.</p> <p>Line 41: In addition to stating that a diagnosis should be made using 75 gm OGTT and applying WHO criteria, a short reference needs to be made that all recommendation for performing OGTT should apply, i.e. patient should be rested during OGTT and not smoking etc</p>	<p>Thank you, the 30 cutoff was the preferred figure and is one in use in pregnancy to define obesity.</p>
SH	UK National Screening Committee	15	Pre – eclampsia			<p>A HTA report (from the team based in Birmingham) is due for publication. The team consider that review to have a far more comprehensive summary of the data on the issue of screening/prediction/prevention.</p> <p>We have also been advised that simply assessing accuracy of tests is not sufficient to reach a conclusion about this issue. The level of accuracy at which the test is likely to be worthwhile depends on what treatments are available and what the associated costs are. It appears that testing is not worthwhile to make decisions about preventative therapies like calcium or aspirin, which are far more cost effective when employed universally.</p>	<p>Thank you for this. We were in contact with the team in Birmingham and they were very helpful in providing us with an indication of the literature they were using. We have not seen the final report and it will be a pity if their conclusions are very different to ours. They certainly have not responded as stakeholders.</p> <p>The review presented to the guideline group was of course based on accuracy but the guideline group offered expert opinion to allow the clinical interpretation of the reviews undertaken.</p> <p>The fact that the GDG found no test to be particularly better than another</p>

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							does suggest the results were similar to the HTA review. The issue of intervention sat outside our scope.
SH	UK National Screening Committee	16				The HTA review team have advised us that the research recommendation should encourage investments in tests that are inexpensive. Further that testing should focus on prediction of early onset pre-eclampsia.	The research recommendation has been expanded to include cost-effectiveness of potential tests. Cost alone is not the issue, cost-effectiveness is what needs to be investigated.
SH	UK National Screening Committee	17	Pre-term Birth		260 - 305	<p>A HTA report (from the team based in Birmingham) is due for publication. The team consider that review to have a far more comprehensive summary of the data on the issue of screening/prediction.</p> <p>Again we have been advised that simply assessing accuracy of tests is not sufficient to reach a conclusion about this issue. The level of accuracy at which the test is likely to be worthwhile depends on what treatments are available and what the associated costs are.</p> <p>The approach to summarising data using RRs is inadequate for accuracy data.</p>	<p>Thank you for this. We were in contact with the team in Birmingham and they were very helpful in providing us with an indication of the literature they were using. We have not seen the final report and it will be a pity if their conclusions are very different to ours. They certainly have not responded as stakeholders.</p> <p>The review presented to the guideline group was of course based on accuracy but the guideline group offered expert opinion to allow the clinical interpretation of the reviews undertaken.</p> <p>The fact that the GDG found no test to be particularly better than another does suggest the results were similar to the HTA review. The issue of intervention sat outside our scope</p>
SH	UK National Screening Committee	18				The HTA review team have advised us that the research recommendation focusing on cervical ultrasound is not appropriate. The research recommendation should encourage investments in tests that are inexpensive.	Thank you. We agree that it is important to focus on less expensive tests, however many are of doubtful diagnostic value. We have amended the research recommendation to include those we feel most warrant further investigation. However, since they don't look very promising the need for further research into

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							ultrasound remains we believe, although may be at a lower priority.
SH	UK National Screening Committee	19				<p>We would like to add the following in relation to asymptomatic bacteriuria (p 289).</p> <p>If the test has poor predictive value for preterm labour this could lead to unnecessary treatment for many women.</p> <p>The overall recommendation (p 305), not to screen for predictors of pre – term labour, would imply that the current policy for Asymptomatic bacteriuria should be changed.</p> <p>We could find no references in the draft document to pyelonephritis and wonder whether this should be explored as an appropriate target for testing and intervention rather than pre-term labour. However the RCOG's 'Infection and Pregnancy' (2001) suggests that testing in early pregnancy would reduce risk in only a minority of cases and that close attention to and management of symptomatic cases of pyelonephritis could be a more appropriate strategy than screening the whole population. But this is based on old evidence and a review of the area might be necessary.</p>	Thank you for your comment. During the course of the guideline development process the GDG highlighted the problem you describe here in relation to screening for asymptomatic bacteriuria. For this reason this recommendation had been amended and the findings from the updated Cochrane review included in the guideline in order to address this change in evidence and the reason behind current screening for asymptomatic bacteriuria. Thus now this screening is recommended as it reduces the risk of pyelonephritis in pregnancy but is no longer linked with a reduction in pre-term birth.
SH	UK National Screening Committee	20				<p>We would also like to add that the wording of the final recommendation is confusing from a screening perspective eg 'Routine screening of low risk women for preterm labour should not be offered'.</p> <p>This refers to asymptomatic pregnancies but if symptoms indicative of preterm labour are identified then further tests etc are not 'screening' (see earlier definition of screening).</p>	Thank you for your comment. The reference to women being at low risk of preterm labour has now been removed from this recommendation to improve clarity.

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						Also, presumably, symptomatic pregnancies are outside the scope of the guideline. It might be simpler if this was amended to 'screening for predictors of preterm labour should not be offered'.	
SH	UK National Screening Committee	21	Off specific ation issues	Glossary – 'Screening'		See first comment above. This could be amended as an editorial change.	Thank you. Your definition for screening has now been included in the glossary.
SH	UK National Screening Committee	22			HIV p220 - 1	The recommendation remains valid but some of the statistical background is now out of date. We understand that the National Study of HIV in Pregnancy and Childhood has more recent data. We would be happy to help update the section if it was considered appropriate to do so.	Thank you for your comment, however this was outside the scope of this current guideline update.
SH	UK National Screening Committee	23			Group B streptococcus p223 - 225	A major HTA study, 'Prenatal screening and treatment strategies to prevent group B streptococcal and other bacterial infections in early infancy: cost effectiveness and expected value of information analyses' by R. Gilbert et al, has now reported. GBS is out of the scope of the current review and we would like to flag this study up for the next review.	Thank you for your comment, this has been noted.
SH	UK National Screening Committee – Fetal Anomaly Screening Programme Steering Group	1	NICE	General		We welcome the NICE draft guidelines and think you have considered the issues relevant to our area of work carefully and accurately. In response to the recommendations we wish to comment on the recommendations in section 9 (so especially pages 151 and 204) which directly relate to the National Screening program which we guide. In general we concur with the recommendations and wish to support them in the strongest terms and do not wish	Thank you very much.

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						the key aspects to be changed.	
SH	UK National Screening Committee – Fetal Anomaly Screening Programme Steering Group	2		Fetal anomal y scanni ng (page 151):		<p>Line 4. Since the literature reviewed was published, we have provided information designed for women both in England and Wales so please consider referring to these. Please consider mentioning not only the giving of information but the more difficult issue of checking that it has been understood.</p> <p>Line 14. This might read better as “Following the confirmation of an anomaly</p> <p>Line 17. Not all regions of the country have a congenital anomaly registry. Perhaps this should say “Participation in regional congenital anomaly registers and/or National Screening Committee approved audit systems.....”</p> <p>Line 21: We think it would be clearer to say “Nuchal translucency should not be used as the primary screen for cardiac anomalies.....”</p> <p>For clarity we think the gestational age of the scan is 18weeks and 0 days to 20 weeks 6 days rather than 20 weeks.</p>	<p>Thank you. Line 4: The GDG considered referring specifically to this information but have decided to broaden the recommendation in chapter 3 to include all other “relevant information” as a number of good sources were identified. To avoid repetition sources of information are not included in this section.</p> <p>Line 14: Thank you, the wording has now been amended.</p> <p>Line 17: Thank you, this recommendation is now amended as you suggest.</p> <p>Line 21: Thank you. The GDG reconsidered the wording of this recommendation and are happy with it slightly amended form.</p> <p>Thank you. We have added 20 weeks and 6 days to make this clearer.</p>
SH	UK National Screening Committee – Fetal Anomaly Screening Programme Steering Group	3		Downs screeni ng (page 204):		<p>Line 15. Since the available literature reviewed highlighted the problems, we have provided information for women in both England and Wales so please consider referring to these.</p> <p>Line 24. This would be clearer if it stated “Other screening tests (such as integrated).....”</p> <p>Line 39. In our statement about soft markers we said “The presence or absence of a soft marker of less predictive power than increased</p>	<p>Thank you for your comments. Line 15: The GDG considered referring specifically to this information but have decided to broaden the recommendation in chapter 3 to include all other “relevant information” as a number of good sources were identified. To avoid repetition sources of information are not included in this section.</p> <p>Line 24: In light of stakeholder</p>

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						<p>nuchal fold” Please consider if you would like to use the same words to avoid confusion.</p> <p>Line 46. In the research recommendation we suggest “The practicality and acceptability of other testing modalities (such as the integrated test).....” might be better. We make this suggestion because early repeated measures (ie 8 weeks and 11 weeks) may be worth considering and the word integrated could limit the research focus and also risks over-highlighting a patented test.</p> <p>Further research: We suggest that further research into the views and understanding of women going through the screening should be undertaken.</p>	<p>comments this recommendation has been removed.</p> <p>Line 39: Thank you. We agree this is very important and have added this to our research recommendations.</p>
SH	UK National Screening Committee – Fetal Anomaly Screening Programme Steering Group	4		Terminology In general		<p>Somewhere the readers should be reminded that Down's screening and ultrasound screening for fetal anomalies are part of an integrated screening programme and that all staff involved should know the care pathways and their role within them.</p> <p>On page 201 line 31 the word “failure” used in relation to women declining screening. On page 139 line 35 it is stated that the overall aim of fetal anomaly screening includes “preventing disability”. Both of these terms seem to us inappropriate and incorrect. They would be better replaced by “declined” and or “increasing choices in pregnancy” terminology. We hope the text can be proof read again for similar implied value-judgements</p>	<p>Thank you we have added this to the introduction.</p> <p>Thank you. Both phrases have been amended as you suggest in order to remove implied value-judgements as you rightly indicate.</p>
SH	UK Thalassaemia Society	1	NICE			<p>First contact with a healthcare professional – health professionals in primary care should be aware that screening for haemoglobinopathies must be done by 10 weeks or pregnancy and must ensure that pregnant women are booked</p>	<p>Thank you. Information about screening , including screening for haemoglobinopathies is now recommended at first contact with a health professional which is usually</p>

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						in immediately and screened. Many women are not screened until 17 weeks.	between 6 and 10 weeks of pregnancy. We also recommend that screening is carried out ideally by 10 weeks of pregnancy.
SH	UK Thalassaemia Society	2	NICE	1.1.1.1		Time to make an informed decision – in the case of haemoglobinopathies this is only possible if the point above has been addressed.	Thank you. We endorse this view.
SH	UK Thalassaemia Society	3	NICE	1.1.1.8		“Preconceptual counselling and carrier testing should be available” – presumably this would be initiated by the patient? It would be better if GPs screened all new patients for haemoglobinopathies using the FOQ as a matter of course.	Thank you. Screening of new patients by GPs is not within the scope of this Antenatal Care guideline update.
SH	UK Thalassaemia Society	4	NICE	1.6.2.6		While these recommendations are excellent, again they are worthless without the requirement for pregnant women to be booked in immediately on first contact with a health professional. Until this is a priority screening for haemoglobinopathies will not be done in time to give women an informed choice in reality.	Thank you, we agree. We have now extended the nature of the first contact appointment to include detailed information-giving, including information about screening for haemoglobinopathies. We have also recommended that booking takes place before 10 weeks in order to ensure real informed choice is given to women.
SH	UNICEF Baby Friendly Initiative		Full	1.6.2.7 – 1.6.2.1 2	76	The guidance recommends that breastfeeding is discussed early in pregnancy and breastfeeding technique discussed before 36 weeks gestation. The Baby Friendly criteria specifically state that the benefits of breastfeeding are discussed and good management practices which would help a woman succeed. These management practices include technique but also discussion on skin contact, rooming-in, demand feeding, avoiding teats and dummies and supplements. As the postnatal care guidelines has as a key recommendation the implementation of Baby Friendly and the draft Maternal and Child nutrition guideline includes a strong endorsement of this it would be good to see	Thank you. We have extended slightly this recommendation but feel it not appropriate to be too detailed here. We have referenced the UNICEF Baby Friendly Initiative and added a link to the Baby Friendly website.

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						continuity in this document. The Baby Friendly Initiative believes that provision of good antenatal information has a positive impact on postnatal success and therefore would like to see this reflected in the antenatal care guideline.	
SH	United Lincolnshire Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	University College London Hospitals (UCLH) Acute Trust					This organisation was approached but did not respond.	
SH	University Hospitals of Leicester					This organisation was approached but did not respond.	
SH	University of Leicester (The Infant Mortality & Morbidity Studies)	1	NICE	1.7.1.5		TIMMS strongly support the recommendation for participation in regional congenital anomaly registers. This is in line with those of the Chief Medical Officer [CMO Annual Report 2004].	Thank you.
SH	University of Leicester (The Infant Mortality & Morbidity Studies)	2	NICE	1.7.1.2		The order of this list does not reflect the frequency of each purpose. TIMMS think it would be better to change the ordering of the list to do so: i.e. intrauterine therapy to be at the bottom of the list.	Thank you, the order has been amended.
SH	Victim Support					This organisation was approached but did not respond.	
SH	Welsh Assembly Government					Thank you for giving the Welsh Assembly Government the opportunity to comment on the above guideline. We are content with the technical detail of the evidence supporting the guideline and have no further comments to make at this stage.	Thank you.
SH	Welsh Scientific Advisory Committee (WSAC)			General		This organisation was approached but did not respond.	
SH	West Herts Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	West Middlesex University NHS Trust	1			Page 35 line 13/4	reword 'Vitamin supplementation should not be offered routinely in pregnancy.'	Thank you. The recommendation has been reworded to ensure that all women are informed of the importance of vitamin D and that women are told about the Healthy Start vitamin supplement. Women in high risk

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							groups are encouraged to take this supplement.
SH	West Middlesex University NHS Trust	2		11.1,	pg 42 line 23 Line 39 Line 41	'macrosomic' would be better clarified with 'previous baby weighing >4.5kg' 'small number of' does not represent all populations. In fact about 50% of our population with GDM require insulin. change to 'controlling GD may improve perinatal outcome'	Thank you. The word "weighing" has been added to the recommendation for clarity. Due to the variation in proportion of women who fall in to this category the recommendation has now been amended to say "some women", and an approximate range given as 20-50%? The GDG did not feel any other changes were necessary.
SH	West Middlesex University NHS Trust	3			Page 43 line 19	Mercury sphygmomanometers have been removed from many work places; aneroid devices are suitable alternative manual devices which have been validated in pregnancy; many semi-automated devices are not validated against British Society Hypertension or other suitable standards, and should not be used. So consider reword 'Bp should be measured by standard mercury or aneroid sphygmomanometer, or a semi automated device validated for use in pregnancy'.	Thank you for your comment. We have now removed reference to mercury sphygmomanometers and added "validated for use in pregnancy" as you suggest.
SH	West Middlesex University NHS Trust	4			Chapter 12 Line 4 and onwards	Replace 'symphysio-..' with symphyseal-..'	Thank you. In fact for consistency we have now replaced symphysio with symphysis.
SH	West Middlesex University NHS Trust	5	Algorithm		page 47, box for 'planning care assessment'	: change to 'previous pre eclampsia, HELLP or eclampsia' and delete line above referring apparently to current severe pre eclampsia, HELLP or eclampsia	This algorithm is now replaced by the updated NICE Quick Reference Guide (QRG).

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SH	West Midlands Regional Ultrasound Group	1	NICE		First Appointment Page 15	Use of biparietal diameter in first appointment schedule needs to be removed and HC left in place to be consistent with BMUS recommendations and section 1.2.6.2.	Thank you, this has been amended.
SH	West Midlands Regional Ultrasound Group	2	NICE		16 weeks pages 14/46	Need to use this opportunity to discuss 18-20 week scan. Suggest: "To discuss the purpose and process of the 18-20 week scan"	Thank you, this has now been added.
SH	West Midlands Regional Ultrasound Group	3	NICE			Should be ordered as for frequency and remove preparation for TOP , suggest: <ul style="list-style-type: none"> • to identify fetal abnormalities and allow: - reproductive choice (Termination of pregnancy: TOP) - parents to prepare (for possible IUD/postnatal palliative care/Rx/disability) - managed delivery in specialist centre - intrauterine therapy Also would add an additional purpose at the bottom: <ul style="list-style-type: none"> - Implications for maternal health (e.g. risk for severe early PET or chorioamnionitis) 	Thank you. The list has been re-ordered.
SH	West Midlands Regional Ultrasound Group	4	NICE	1.7.1.2		Strongly support this recommendation.	Thank you.
SH	West Midlands Regional Ultrasound Group	5	NICE	1.7.1.5		Regarding cardiac scanning of outflow tracts: will be difficult to fulfil this with current scanning service. This would require additional scanning resources and training.	This recommendation is being included in the Costing work undertaken by NICE and any extra resources required will be identified.
SH	West Midlands Regional Ultrasound Group	6	NICE	1.7.1.6		Additional scanning resources are required for NT to be included in routine screening.	This recommendation is being included in the Costing work undertaken by NICE and any extra resources required will be identified.
SH	West Midlands Regional Ultrasound Group	7	NICE	1.7.2.:		Suggest not using referral to fetal medicine as this implies a tertiary referral to another	Diagnosis is outside the scope of this guideline update. The fetal medicine

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						<p>hospital – these issues should be dealt with “in house” for most hospitals.</p> <p>Suggest:</p> <p>“The presence of an increased nuchal fold (>6mm) or two or more soft markers should prompt fetal medicine input and the offer of karyotyping”</p>	<p>referral may not recommend karyotyping.</p> <p>We have added to the recommendation to be more explicit that the nuchal fold measurement should be equal to or greater than 6 mm.</p>
SH	West Midlands Regional Ultrasound Group	8	NICE	1.7.2.9		<p>Customised growth charts have been introduced regionally with the approval and support of the West Midlands Regional Ultrasound Group in 2003, following extensive review of the evidence and wide ranging consultation. All units have implemented the use of the charts for both screening of Symphysio-fundal height (SFH) and interpretation of estimated fetal weight (EFW). This means that the 65,000 births per annum in the West Midlands are being managed using customised growth charts.</p> <p>Their introduction was accompanied by some initial teething problems, which mainly related to uncertainty about how to deal with antenatal suspicion, based on SFH, of large-for-gestational age babies. These problems have been overcome through refinements in the referral protocol. The system is now well implemented and well in place.</p> <p>Staff at the Perinatal Institute have instituted a training programme within the region as well for an increasing number of units in other NHS regions, who either send senior representatives for ‘train the trainers’ workshops, or alternatively arrange to invite a team from the Institute to hold workshops for staff within their unit. A total of about 70 units have already implemented the customised charts in this way.</p> <p>An audit of the use of the charts was</p>	<p>Thank you for your helpful comments. You indicate that these charts have been successfully implemented in the West Midlands. You also state that they have been associated with increased detection of SFD babies but unfortunately we were unable to find peer reviewed literature to support this. The MIDIRS reference has been reviewed.</p> <p>Whilst it may well be that the customised charts are useful for plotting growth (and certainly as good as any other chart) it is not at all clear that their use would produce an improved outcome ie in SFD babies saved from intrauterine death. It is disappointing that some indication of effectiveness has not emerged from the West Midlands given that customised growth charts have been in place there for so long. Your comments about the recent review to not indicate the extent to which they have been successfully implemented.</p> <p>1 We really need objective evidence of effectiveness.</p> <p>2 We recognise the potential weakness of current plotting methods.</p> <p>3 If customised charts are working that is a matter for local agreement in the</p>

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						<p>undertaken in the City Hospital, Birmingham, and presented at RUG. It showed a significant increase in the antenatal detection of small babies, accompanied by a decrease in the number of unnecessary referrals for further investigations. [ref – MIDIRS]. This finding has added significance as understaffing and under-resourcing in maternity ultrasound services in the WM are endemic.</p> <p>Earlier this year, a confidential enquiry into stillbirths with fetal growth restriction was undertaken on behalf of the BBC – PCT Accord. The panel assessments were conducted by consultant obstetricians and midwives from outside the BBC. The panels identified potentially avoidable deaths associated with inappropriate use of customised growth charts to assess fetal growth (by fundal height or ultrasound). This included several instances where population charts for ultrasound biometry were used, and falsely suggested normality while a customised chart would have highlighted the potential problem of fetal growth restriction.</p> <p>Customised charts have a number of advantages for the assessment of fetal growth, and form a central role in our attempts to improve antenatal care. They are able to represent individual variation and are particularly important in our heterogeneous, multi-ethnic populations.</p> <p>They allow for a centile to be generated for previous babies giving a precise standard for further scan based on “previous IUGR”.</p> <p>We ask you to consider:</p> <ol style="list-style-type: none"> 1. Is customisation of SFH possible? We would say it is and is now in place across the West Midlands as well as many other areas. 2. Interpreting and plotting fetal biometry does not allow for individual measurement to be 	<p>West Midlands.</p> <p>4 The effectiveness of customised charts needs to be demonstrated for all ethnic groups.</p> <p>5. We agree with your comments about 3cm.</p>

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						<p>customised. EFW can be customised and therefore can be used to take management decisions being a single quantitative measurement which can be used in algorithms.</p> <p>3. We examined evidence and moved forward. It would now be retrograde step for us to stop using this method as the service is built on it.</p> <p>4. Areas with a high PNM are often inner city populations with a high rate of ethnic minorities who are diverse in maternal size, the customised charts allow for equitable provision of service to women from different cultures.</p> <p>5. SFH at term – 3 cm is equivalent to 37cm, this criterion for biometry will lead to a massive increase in referrals for ultrasound at the end of the pregnancy in hospitals with large numbers of small women, and potentially miss at risk cases in larger women, both situations being undesirable.</p> <p>The regional ultrasound group consider that the use of customised charts for screening of SFH and interpretation of EFW is beneficial for targeting ultrasound resources at those with highest need, and is the most effective method of managing cases at high risk based on screening. Withdrawal of this facility within the West Midlands would leave a large gap in the centre of obstetric ultrasound which the draft guideline does not fill.</p> <p>It is not clear from the guideline whether the NICE group do not believe that customisation of SFH and or EFW are desirable or are not doable. We consider they that they are both and recommend, especially in areas of diverse maternity populations the use of such methods.</p> <p>We suggest:</p> <p>“1.10.1.5 Customized fetal growth charts are</p>	

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						the best means of screening for small-for-gestational-age babies in populations from diverse ethnic backgrounds.” “1.10.1.6 Customised fetal growth charts are the best means of interpreting ultrasound based estimated fetal weight, especially in populations from a diverse ethnic background”	
SH	Western Cheshire Primary Care Trust			1.10.1.1-5		This organisation was approached but did not respond.	
SH	Wiltshire PCT					This organisation was approached but did not respond.	
SH	Wirral University Teaching Hospital NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Womens Health Research Group					This organisation was approached but did not respond.	
SH	Worcestershire Acute NHS Trust					This organisation was approached but did not respond.	
SH	Worthing and Southlands Hospital					This organisation was approached but did not respond.	
SH	Worthing Hospital					This organisation was approached but did not respond.	
SH	Wyre Forest Primary Care Trust					This organisation was approached but did not respond.	
SH	York NHS Trust					This organisation was approached but did not respond.	
SH	Yorkshire and Humber Local Supervising Authorities (LSA)					This organisation was approached but did not respond.	
Ex per t	NCCHTA1	1	Full			1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)	N/a
Ex per t	NCCHTA1	2		4.3e of scope		“What is an appropriate clinically and cost effective method of screening for women at risk of pre-eclampsia and preterm labour?” “ This does not appear to have been specifically addressed in the guideline nor was there a statement about why this might be appropriate/the need for future research.	We feel this area has been comprehensively addressed. Screening for pre-eclampsia is covered in section 11.2 of the full version of the guideline and includes systematic reviews of 10 possible screening methods. 8 recommendations are made

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							concerning appropriate screening for pre-eclampsia plus a research recommendation. We have re-ordered the recommendations to clarify what actions are being recommended.
Ex per t	NCCHTA1	3				2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).	N/a
Ex per t	NCCHTA1	4		Appendix B		Extensive health economics work has been undertaken in the guideline, which is pleasing, but in places it lacks clarity in the reporting of results and none of the economic models undertake probabilistic modeling as recommended in NICE guidance on appraisal techniques. It is not explicitly stated why probability distributions were not used to characterize the uncertainty surrounding input parameters in the models.	Unlike, NICE technology appraisals, probabilistic modelling is not a requirement for NICE Guidelines. http://www.nice.org.uk/niceMedia/pdf/GuidelinesManualAllChapters.pdf We will address any lack of clarity in results where a specific reference is made to this.
Ex per t	NCCHTA1	5				2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.	N/a
Ex per t	NCCHTA1	6		1.6 health economics		Did the answer 'yes' have to be to just one or all of the questions for the topic to be selected for a health economic analysis? (P25 line 46-47)	See 8.1.3.1 of the Nice Guideline Development Methods.
Ex per t	NCCHTA1	7		1.6 health economics		More detail is needed about the consensus methods used to derive cost data. Why could the same methods not be employed to fill in gaps of missing effectiveness data?	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	8		1.6 health economics		The definition of cost consequence on page 26, 2nd paragraph is wrong. Furthermore it is not included in the glossary of terms.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	9		1.6 health economics		There is some evidence about some of the issues raised at the bottom of page 26, for instance:	This section of the guideline is not part of the update and hence is outside of the scope.

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				mics		<p>Ryan M, Diack J, Watson V, Smith N. Rapid prenatal diagnostic testing for Down syndrome only or longer wait for full karyotype: the views of pregnant women. Prenat Diagn. 2005;25(13):1206-11.</p> <p>Shackley P, Cairns J. Evaluating the benefits of antenatal screening: an alternative approach. Health Policy. 1996;36(2):103-15.</p> <p>Donaldson C, Shackley P, Abdalla M, Miedzybrodzka Z. Willingness to pay for antenatal carrier screening for cystic fibrosis. Health Econ. 1995;4(6):439-52.</p> <p>The report reads as if nothing is known whereas what is meant is that it was beyond the scope of this report in part because of the focus on the health and social care perspective?</p>	
Ex per t	NCCHTA1	10		9.1, page 149 and append ix B.4		<p>Cannot 5 view chamber be consistently referred to as 4 view chamber view plus outflow tracts?</p> <p>p.149 could usefully refer to Appendix b.4 rather than B alone.</p>	Thank you we have now amended references to the 5 chamber view to 4 chamber view plus outflow tracts.
Ex per t	NCCHTA1	11		p.195		Price/Cost year?	See response in Health Economics comments table.
Ex per t	NCCHTA1	12		Genera l		<p>When appendix B is referred to in the main body of the text it would be useful to refer to specific bit of appendix B that is relevant e.g. Replace "(see Appendix B)" with "(see Appendix B.1)" p.207 and "Appendix B.2 on page 224, Appendix B.3 on page 227, Appendix B.5 p.243 etc...</p>	Agreed and changed in accordance with the suggestion.
Ex per t	NCCHTA1	13		Genera l		Last sentence of economic bit on p.208 a future research recommendation so should be moved to shaded box.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per	NCCHTA1	14		10.3		Need for economic evaluation needs adding to research recommendations.	Thank you, this has been added to the research recommendation.

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Ex per t	NCCHTA1	15		General		Even where economic models have not been developed it may be useful to point out the potential impact of economic considerations e.g. in areas such as HIV 10.7 and rubella 10.8 etc.	This examples cited are not part of the update and hence outside of the scope.
Ex per t	NCCHTA1	16		10.9 economic considerations		Appendix B2 states 43 papers of which 19 used. The text ere states 26 articles found, 25 of which studied in detail. Seems inconsistent.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	17		11.1 Health economics summary		Appendix B.5 states 6 rather than 7 papers identified examining cost-effectiveness of screening only. Presumably "XX" should read zero.	Thank you. 11.1 should read '6' not '7' XX should read one
Ex per t	NCCHTA1	18		11.1		Table X different to Table X given on p.391.	Thank you for this observation. This has now been corrected.
Ex per t	NCCHTA1	19		12.6		Line 2 "decision analytical model". Remove apostrophe at end of paragraph.	Unable to find this term in this section.
Ex per t	NCCHTA1	20		B.1		Reference 601 is stated in the text as the source of the cost of preterm birth whilst in Table B.1 source 45 is given. Source 601 is a systematic review article so if this is used it would be better to quote the original article.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	21		B.1		There is also a need to breakdown what exactly is included in the costs given in table B.1 e.g. what does the cost of preterm birth include? E.g. short and long term health care, education etc costs? What timeframe is the cost for?	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	22		B.1		Table B.1 needs "e" adding to the word Table.	Thank you.

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Ex per t	NCCHTA1	23		B.2		"None of the economic papers were conducted in a UK setting..."	This section of the guideline is not part of the update and hence is outside of the scope. Thank you for this comment. We've amended the wording to read; "None of the identified economic studies were undertaken in the UK".
Ex per t	NCCHTA1	24		B.3		Table B.2 includes a different range for the cost of preterm birth and quotes 601 as the source, see comment under B.1.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	25		B.3		What is the price year?	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	26		B.3		Need to state what the mean cost and benefit were under baseline results of model.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA1	27		B.4		Price year? How were costs in Table 2 adjusted?	Costs were not adjusted to a common price year. The year for the source data is given in the table and most values are taken from either 2005/06 or 2006/07 sources. Therefore, it was felt that such adjustment would make little difference to the results. The cost of birth was a 'rounding' of a cost derived by the author of this section as part of a previous private consultancy (unpublished). Given the number of variables that went into the estimate, the author felt that the cost given to the nearest thousand pounds was reasonable. Furthermore, sensitivity analysis shows that it has a negligible impact on results (as the no. of births is almost identical across the two interventions – e.g. at baseline there

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							are just 0.445 less births with the '4 chamber' view plus outflow tract strategy, largely as a result of a higher termination rate as a result of increased detection of anomalies).
Ex per t	NCCHTA1	28		B.4		Figure B.2, 3, 4, 5, 6 and 7 - No value in having a y-axis that goes much beyond £100,000 per QALY. It would be consistent to show all figures using the same scale on the y-Axis. Last para on p.367 – hard to see what is being described in the text because of the chosen Y-Axis scale.	The scale reflects the extent to which the ICER is sensitive to the parameter value – with a wider range generally indicating increased sensitivity. Where the relationship is non-linear it may also indicate ranges where the ICER is and isn't sensitive to parameter values. Therefore, we think that the range of scales used is appropriate.
Ex per t	NCCHTA1	29		B.4		Discussion p.367 – reference 6 needs formatting into superscript. Ditto ref 9 last paragraph.	Thank you - done.
Ex per t	NCCHTA1	30		B.4		p.367 2nd para – figure 2 is should be figure 3 and 3rd para figure 3 should be figure 2.	Agreed.
Ex per t	NCCHTA1	31		General		In places the report talks about a £20,000 per QALY threshold. In other places in the report a £30,000 per QALY presented as acceptable. Clarity on this issue is needed, since the NICE methods manual states anything up to a maximum of £30,000 per QALY is likely to be considered cost-effective maybe this should be taken as the maximum WTP rather than £20,000 per QALY?	This is addressed in footnote 5 of p.367 of the draft for consultation. The NICE Guideline Manual states; "The consensus among NICE's economic advisers is that NICE should, generally, accept as cost effective those interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY and that there should be increasingly strong reasons for accepting as cost effective interventions with an incremental cost-effectiveness ratio of over £30,000 per QALY"
Ex per t	NCCHTA1	32		B.5		Price year?	Generally it is 2006. However, where some sourced estimates are available for a couple of years earlier these are

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							used instead, especially as those parameter values are not important drivers of the model output. The price year of any parameter values is contained within the table.
Ex per t	NCCHTA1	33		B.5		State what is the exchange rate for Euros into pounds?	We have added this as a footnote.
Ex per t	NCCHTA1	34		B.5		p.369 "undertaken" 1st para line 8.	Thank you – corrected.
Ex per t	NCCHTA1	35		B.5		"compared" 2nd para line 17 p. 369.	Thank you – corrected.
Ex per t	NCCHTA1	36		B.5		p.370 line 15 "figure ??"	Thank you. A reference to another figure will be added.
Ex per t	NCCHTA1	37		B.5		p.371 women with false positives may have lower outcomes than had they been told they were negative – even if only psychologically.	Accepted. The wording is changed to; "The outcomes for women without GD (true negatives and false positives) in the screening arms were not considered as the perinatal outcomes for these pregnancies do not differ from those in the population of otherwise healthy pregnant women" We've also added a footnote elsewhere in the text which acknowledges; "It isn't explicitly addressed in the model but an undesirable consequence of screening may be the unnecessary inconvenience and worry for false positives."
Ex per t	NCCHTA1	38		B.5		Figure 2 – need to be clearer about which sub-trees connect to the [+]	We've amended the figures and notes accompanying them and hope that this makes them clearer. However, there are real logistical difficulties in accurately representing large decision trees in an A4 format.

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Ex per t	NCCHTA1	39		B.5		p.382 "outlined" line 8	Thank you – corrected.
Ex per t	NCCHTA1	40		B.5		The use of the retail price index to update the cost of induction of labour is inappropriate. (table 8).	We accept the methodological point being made here. However, the cost of IoL only contributes to approximately 0.4% of total screening/treatment/downstream costs. Furthermore, the difference between in IoL interventions and controls is not statistically significant. Interventions and controls is not statistically significant. For a cohort of 10,000 women IoL.
Ex per t	NCCHTA1	41		B.5		Minor point but why was the exact QALYs from averted death not used in the model (Table 11)? Small differences can have a big impact on the cost per QALY.	The 'exact' discounted QALY of 75 years lived in full health would be 27.33. Additionally, it might be noted that 75 years slightly underestimates current life expectancy. However, most lives are not lived in perfect health for their entirety and therefore 25 QALYs seems a reasonable 'rounded' estimate. It is the opinion of the authors that an alternative might suggest spurious precision. Using 27.33 QALYs reduces the baseline ICER for strategy 6 from £21,739 to £19,987 per QALY
Ex per t	NCCHTA1	42		B.5		Baseline result section needs more discussion and detail about how Table X on page 387 led to table X on page 388 for the non-economic expert particularly around the notion of extended dominance. Was zero used as the origin or the lowest mean cost?	Agreed. We have added further discussion.
Ex per t	NCCHTA1	43		B.5		Why was the sensitivity analysis only conducted on strategy 21 and 6? It is technically more appropriate to undertake SA on all strategies, rank, remove dominated, calculate ICER, remove extended dominated,	The sensitivity analysis was not only conducted on strategy 21 and 6, but they were the ones that remained after dominated and extended dominated had been removed.

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						re-estimate ICERs again as rankings may change.	
Ex per t	NCCHTA1	44		B.5		p.389 last para a few blank spaces and “...” need attending to.	Thank you, this has been changed.
Ex per t	NCCHTA1	45		B.5		p.391 line 6 “as well as putting strain on the local service.”	Changed as suggested.
Ex per t	NCCHTA1	46		B.5		p.391 line 20 “other than age is applied alone,”	Changed as suggested.
Ex per t	NCCHTA1	47		B.5		p.392 line 9 “p-values in this” and line 15 “women with GD”	Changed as suggested.
Ex per t	NCCHTA1	48		B.5		p.394 line 14 “it is important” and reference “Langer??” in table 1	Reference is Crowther et al. (ACHOIS).
Ex per t	NCCHTA1	49		B.5		The same y-axis scale should be used in figures 1-3.	We will make sure this is done at the copy editing stage.
Ex per t	NCCHTA1	50		B.5		p.397 line 6 “(insulin analogue or oral hypoglycaemic) used.”	Thank you – changed and slight re-ordering of text.
Ex per t	NCCHTA1	51		Genera l		Number of tables and figures throughout appendix B inconsistent. Many labeled “Table X”.	This will be addressed at the copy editing stage.
Ex per t	NCCHTA1	52		B.6		p.398 line 11 “and an economic”	Changed as suggested.
Ex per t	NCCHTA1	53		B.6		That chance nodes are represented by circles needs stating for the noon-expert.	“denoted by blue circles” added in parenthesis.
Ex per t	NCCHTA1	54		B.6		p.399 line 14 remove the first “the”.	Done.
Ex per t	NCCHTA1	55		B.6		No strategy 3 is shown in figure 1.	We've amended the decision tree figure so that all 3 strategies are shown.
Ex	NCCHTA1	56		B.6		Price year?	We accept the methodological point

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per t							being made here. However, the price year for individual unit costs is given in the table and they only differ from each other by one year (reflecting when data from the different sources becomes available). Adjusting some unit costs for a single year's inflation would make no meaningful to the results.
Ex per t	NCCHTA1	57		B.6		What does cc mean in table 2?	cc = complications. We've amended the text to make this clear.
Ex per t	NCCHTA1	58		B.6		Line 26 p.400 "assumed to be £20,000"	Done.
Ex per t	NCCHTA1	59		B.6		Need a discussion of the results.	Thank you, added.
Ex per t	NCCHTA1	60				3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?	N/a
Ex per t	NCCHTA1	61				Where health economics was undertaken the results appear to have informed appropriately the recommendations although see comment below about being more circumspect.	Thank you.
Ex per t	NCCHTA1	62				3.2 Are any important limitations of the evidence clearly described and discussed?	N/a
Ex per t	NCCHTA1	63		General		The section on Health economics in chapter 1 needs to be more circumspect in that it reports that many of the studies identified were of poor quality and yet it is this poor quality evidence the models are based upon in this report. The areas for future health economics research were not fully included in 2.3 p.45 even where they had been raised elsewhere in the report	These comments relate to a section of the guideline is not part of the update and hence is outside of the scope.

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						e.g. long term costs of preterm birth etc	
Ex per t	NCCHTA1	64				4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	N/a
Ex per t	NCCHTA1	65		Genera l		The health economics is not well integrated into the report, reads more as an add on.	This may reflect that this is a partial update rather than a complete rewriting of the guideline. We were constrained not to change those parts of the original guideline that were not part of the scope for the update.
Ex per t	NCCHTA1	66				4.2 Please comment on whether the research recommendations, if included, are clear and justified.	N/a
Ex per t	NCCHTA1	67				It would be useful if future research recommendations were prioritised in 2.3 on page 45.	Thank you. The key research recommendations have been identified and listed in chapter 2.
Ex per t	NCCHTA1	68				Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.	N/a
Ex per t	NCCHTA1	69		1.6		First line refers to National Institute for Clinical Excellence – Health needs adding in.	Thank you. Amended.
Ex per t	NCCHTA1	70		1.6 literatur e search strateg y for the 2008 update		www.ohe-heed.com is on the same line as a link to NHS CRD website.	Thank you. This has been amended for clarity.
Ex per	NCCHTA1	71		4.7		References 58 and 59 need formatting into superscript	Thank you. Amended.

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Ex per t	NCCHTA2			8.2		Screening – health economics summary. States 4 papers but 5 listed. Presumably should be 2 rather than 3 in UK? Each seems to focus on ability to detect cases without mention of possible false positives. If these do not occur it would be helpful to state this explicitly.	This section of the guideline is not part of the update and hence is outside of the scope.
Ex per t	NCCHTA2	1	Full			1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)	N/a
Ex per t	NCCHTA2	2				2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).	N/a
Ex per t	NCCHTA2	3		General		Although I am not familiar with much of the published work in this field, it appears to me that the appraisal of published work is not rigorously critical. For example, the findings reported by studies (usually those selected for their statistical 'significance') are repeated without consideration of reporting bias. Evidence level 2 appears to be used for all non-randomised experimental studies, whether or not they are "well-designed" to answer the review question.	Thank you for your comment. Evidence level 2 is the appropriate NICE grading for non-randomised experimental studies. If a study does not answer the clinical question it is usually not included in the review, unless there is a paucity of relevant evidence in which case studies may be included if they are felt to provide useful clinical information that needs to be considered by the GDG. Perhaps the relevance of studies to clinical questions in terms of considered outcomes will be more accurately reflected in the evidence grading when the GRADE system comes into use.
Ex per t	NCCHTA2	4		3.1.8		The evidence summary fails to cover the lack of evidence described in sections 3.1.7 and 3.1.8. Selective focus on 'significant' or interesting findings by reviewers can be a	Thank you. Sorry for this omission, all evidence statements have now been added.

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						potent source of bias	
Ex per t	NCCHTA2	5		3.1.9		And subsequent sections. There are references to 'improving' uptake rates of screening when it appears that 'increasing' is meant. This suggests prejudice on the part of the reviewers that an informed decision not to undergo screening is less valuable.	Thank you. This has been amended, it certainly was not the intention of the guideline developers to suggest an increased uptake was necessarily a desired outcome – that women understand the screening fully is the important issue here.
Ex per t	NCCHTA2	6		3.2.1		This may show my ignorance of NICE methods guidelines, but there is an issue with the levels of evidence. I understand the need to resort to lower level evidence in the absence of level 1 evidence, but here there are 5 RCT's providing level 1 evidence. The combined results of these are afforded a single paragraph, whereas the six level 3 studies' findings receive one paragraph each. The reviewers' conclusions (Evidence summary for section 3.2) ignore their earlier statement "Amongst the 5 RCTs no consistent results were seen" and focus instead on the 'positive' findings from lower level evidence. The purpose of an evidence hierarchy is surely that we know that lower grade evidence often suggests benefits that do not accrue in practice. However, the reviewers appear to be ignoring the evidence at level 1 in favour of the more palatable conclusions from lower levels.	The issue here is reporting relevant outcomes. The RCTs are small, quite old and look at knowledge acquisition. If we used just the 5 RCTs we would be none the wiser regarding any other outcomes. The inclusion of lower grade evidence sheds light on the processes and include the outcomes of interest ie. impact on experience of labour and birth and preparation for parenthood. Evidence of lower quality is more relevant to this area of the guideline and is often more complex to report – hence more space given to it.
Ex per t	NCCHTA2	7				2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.	N/a
Ex per t	NCCHTA2	8		Glossary		Negative likelihood ratio. There is a typo in the formula at the end of this paragraph. It should read: " $((1-\text{sensitivity})/\text{specificity})$ ". Note the brackets.	Thank you. Amended.
Ex per	NCCHTA2	9		General		There is misinterpretation of 'lack of statistical significance' that implies confusion between	Thank you for pointing this out. All uses of the term "statistically

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t						'significance' and 'importance'. "Not statistically significant" is not synonymous with "not statistically important". It is wrong to refer to a finding as statistically "insignificant". All such references throughout the text should be sought and re-worded. Care should be taken to ensure clear distinction between "lack of evidence of effect" and "evidence of lack of effect".	insignificant" have been amended.
Ex per t	NCCHTA2	10		3.1.4		First paragraph contains "not truly representative as available only from one trial with very narrow confidence intervals". There are two issues here. First, representativeness is not measured by the width of the confidence interval. Secondly, narrow confidence intervals are usually interpreted as a good sign of precision whereas here they sound like a negative feature. Was it meant to be "wide" rather than "narrow"?	Thank you for your comment. This is an error and should state that the confidence intervals were wide, thus the reliability of the findings is low.
Ex per t	NCCHTA2	11		3.1.5		First paragraph, sentence 3. This implies that a meta-analysis has been performed of only the trials that reported statistically significant results. That would be such a bad thing to do that I assume the sentence needs re-phrasing.	Thank you. This means that 48 trials out of 64 total found a significant reduction in smoking in the intervention groups. Other trials that did not report any statistically significant results have also been reported.
Ex per t	NCCHTA2	12		3.1.7		Final sentence contains "There were significantly more mothers in both arms". There were 4 rather than two arms, and "more" than what?	Thank you. The wording of this sentence has been amended to improve clarity.
Ex per t	NCCHTA2	13		3.1.9		Several studies examine group interventions (e.g. classes) where there would be expectation of a benefit from group dynamics. I suspect that few of the original reports considered clustering due to group effects when randomising individual participants. Uncritical repetition of flawed analyses should	Thank you for your comment. It is inevitable in studies of this nature that group effects as well as individual differences will influence the findings. This is acknowledged and reflected in the low evidence level given to all research of this type (EL 3). It might be

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						be avoided. It would be re-assuring if the reviewers showed some awareness of this issue.	<p>worth reflecting also that RCTs conducted in clinical settings often bear little relation to “normal” clinical practice, these differences often having a marked impact on how an intervention will influence outcomes in practice yet this evidence is still graded as 1+.</p> <p>I would like to assure you that the reviewers are well aware of the limitations of varying types of research. The style of reporting for clinical guidelines, however, is to report an evidence level based on assessment of quality and impact on bias rather than to discuss all issues separately.</p>
Ex per t	NCCHTA2	14		3.1.9		<p>The subsection on Down's screening shows a lower level of methodological insight than other sections. The study (reference 664) allocating by odd and even unit number is therefore not a randomised trial, should not be described as “RCT” and does not constitute evidence level 1. Level 2 might be too generous as it is clearly seriously flawed in design. The explanation offered as to why it was not subject to bias is naïve.</p> <p>Similarly, the following paragraph contains misinterpretation of subgroup analyses.</p>	<p>Thank you.</p> <p>We disagree with your comment. All the included studies under this section were RCT's and appraised of their quality using the criterion given in the NICE manual. The study reference 664 has been given an evidence level of EL 1-, which indicates its poor methodology. The details of grading the evidence can be seen in Chapter 7 of the NICE guidelines manual.</p> <p>Nevertheless we agree with your comment on the ‘explanation being naïve’ and have deleted the sentence.</p>
Ex per t	NCCHTA2	15		3.1.9		The study on pre-term delivery, comparing results in women who took up an offer with those who did not is a very good example of the general point above regarding validity.	We agree that it is a badly designed study and that is why it has been ascribed an evidence level of EL 2-. It is a cohort study and quality has been

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						This is a very badly designed study that should not be interpreted as Level 2 evidence.	graded according to the NICE guideline methodology. We would like to draw your attention to the use of minus signs in grading evidence levels – the minus indicates that the study is subject to serious bias that undermines the reliability of the findings. These have been correctly allocated throughout this section.
Ex per t	NCCHTA2	16		3.1.9		HIV study, final sentence. Does this study not just suggest that direct offer of a test increases uptake compared with 'availability on request'?	Thank you, you are right. We have amended the evidence statement to reflect this.
Ex per t	NCCHTA2	17		4.6		All these studies are based on predicting delivery date rather than "determining gestational age". Since there is a distribution of natural gestation times, the two are by no means the same, although this appears to be a common logical flaw. "Expected" delivery date is the expectation (statistical jargon for arithmetic mean) of the distribution, and is not synonymous with "anticipated". This may sound pedantic, but has immense clinical implications when inductions are encouraged for those "overdue" and diagnoses of SGA and LGA depend on this misunderstanding. Either the clinical question has been mis-worded, or none of these studies is "well designed" (evidence level 2) to answer it.	Thank you for your comment. We agree, most of the studies have looked at predicted date of birth rather than gestational age assessment. In practice it is not possible to accurately determine gestation of a baby until s/he is born – until then we can only measure and estimate. Therefore, as you point out it may have been better to rephrase the clinical question in terms of predicting date of birth. Despite this discrepancy, the evidence points firmly to the benefits of using ultrasound measurements to predict date of birth rather than LMP, one of the main benefits being in the reduction of unnecessary interventions for prolonged pregnancy. To this end we are happy that the recommendation is the correct one based on the appropriate evidence.
Ex per t	NCCHTA2	18		4.6		It is hard to imagine that ultrasound techniques have not developed over the period of time covered by included studies (1983 to 2006). It would be reassuring if the text mentioned this issue and how it may influence interpretation of the findings for current NHS practice.	Thank you. You are right. Text has been added to acknowledge this fact.

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Ex per t	NCCHTA2	19		5.12		IUGR evidence. I would have thought that recall bias would tend to make alcohol consumption look bad. That low to moderate intake looks protective despite the presence of recall bias should be noted. This is not my field, but I thought there was a theory that low alcohol consumption is generally good for cardiovascular system. This would seem consistent with the low-grade evidence presented here, yet the recommendations are worded such that they imply "less equals better, zero preferable". Given the lack of evidence of harm (and hint of benefit) with moderate drinking, this looks like a political rather than evidence-based recommendation. Perhaps the emotive word 'particularly' should be deleted from the recommendation regarding binge drinking?	Thank you for your comment. We agree that the evidence of harm is not there in the current evidence, hence our recommendation that if a woman chooses to drink alcohol she should be advised of a "safe" maximum. We agree this is cautious (even more so now that we have made amendments following stakeholder consultation) but this reflects the evidence of harm at higher levels and a concern that lower levels may be associated with a lower level of harm that is more difficult to detect in research studies. We have deleted the word "particularly" as you suggest.
Ex per t	NCCHTA2	21		9.2		"Detection rate" (DR) and "False positive rate" (FPR) are introduced without definition but these are not universally defined terms. If DR is '100% minus sensitivity' and FPR is '100% minus specificity', which makes sense, then this should be stated here for clarity and the terms added to the glossary.	Thank you, these terms have been added to the glossary so they can be referred to in relation to any section of the guideline.
Ex per t	NCCHTA2	22		9.2		There is a typo in the table of summary measures for second trimester screening for Downs. The confidence interval for sensitivity of thickened nuchal fold cannot be correct.	Thank you. Agreed and changed.
Ex per t	NCCHTA2	23		9.2		There is frequent uncritical repetition of studies' conclusions without apparent recognition of statistical flaws. In particular, lack of evidence is interpreted as evidence of no effect (e.g. "increasing knowledge does not raise anxiety levels"), associations are wrongly concluded to prove cause and effect (e.g. "Serum screening can have a detrimental effect on women's attachment"), and conclusions are believed from comparisons of significance levels between different	Thank you for your comment. It is important to note that the limitations of the studies included in this review (HTA) have already been given at the beginning. It is outside our domain to change the results of this review, and they have been presented here as given in the HTA.

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						subgroups.	
Ex per t	NCCHTA2	24		10.3		With most of the cited screening studies there is a circularity of logic, with definition of 'truth' including the 'test' results under study. Even if there is no better way to perform the studies, this presumably exaggerates the merit of the methods. It would be reassuring if there were some recognition or discussion of this before drawing conclusions that appear to accept all published results at face value.	Agreed. A few sentences have been added in the introduction to explain the issues surrounding the reference test in Chlamydia screening.
Ex per t	NCCHTA2	25		11.1		Many of the threshold values used to define sensitivity and specificity appear to be derived from the study's own data. No recognition of the inherent bias is apparent.	We agree - Studies only identify own thresholds and this does undermine the robustness of the evidence in this area.
Ex per t	NCCHTA2	26		12.11		This may be a Cochrane review, but how is it 'evidence level 1+'? There is only one 'randomised' trial, and this has doubtful allocation concealment (envelopes "unnumbered").	The evidence level refers to the rigour of the systematic review rather than the included studies. This I agree is somewhat misleading and is something research fellows often debate but as current NICE methodology stands this evidence level 1+ is correct. When we adopt the new GRADE system it may be that these inconsistencies will be ironed out.
Ex per t	NCCHTA2	27		12.12 (for exampl e)		The evidence summary wrongly interprets lack of evidence of difference as evidence of similarity.	Thank you for your comment. We agree, and the evidence summary has been changed.
Ex per t	NCCHTA2	28		14		Presumably the methods were somewhat more sophisticated than what can be described in limited space. For example, was 'important' interpreted by survey respondents as 'common' or as 'serious implication if missed regardless of how rare'?	The survey respondents were asked how important they felt it was that the particular question was included in the assessment tool ie. how strongly they felt that it should be included.
Ex per t	NCCHTA2	29		Genera l		The report varies throughout as to which aspects of screening tools merit reporting. Obviously individual studies may report	Thank you for your comment. We agree that it would be preferable to be able to report study findings in a

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						sensitivity/specificity, ROC curve, likelihood ratio, diagnostic odds ratio, predictive values and various other statistics. The review team appears to make little or no effort to convert these into a standard format to facilitate comparison, or to use a standard meta-analytic format for screening studies when averaging study results.	consistent manner. Unfortunately there are a number of reasons why this is not possible: <ol style="list-style-type: none"> 1. Many studies do not report sufficient data to enable these calculations to be made. 2. There is currently no standard meta-analytic format or software available to enable reviewers to meta-analyse diagnostic accuracy studies (although this is work in progress both at Cochrane and at the NCC-WCH). 3. The enormous volume of reviewing the NCC systematic reviewers have to undertake during the course of a guideline and the very tight timeframes this is set in unfortunately do not allow opportunity for extra work to be undertaken in order to try and improve the consistency of reported findings (eg. time to contact original authors for additional data).
Ex per t	NCCHTA2	30				3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?	N/a
Ex per t	NCCHTA2	31		3.2		GDG interpretation and recommendations. These are appended to section 3.2 but refer in equal measure to 3.1. It would be clearer if they were given their own section number.	Thank you. The GDG interpretation of evidence and recommendations refer to all evidence relating to antenatal information giving. The heading for both has been amended to make this clearer.

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Ex per t	NCCHTA2	32		3.2		It is not clear how these recommendations are derived from the preceding review. Some are no doubt justified, whereas others have had no preceding discussion but may be assumed to be seen as generally good clinical process. It would be helpful to give each an 'evidence level' label and some reference back to the page/section used in justification. This applies to every subsequent set of recommendations.	Thank you. We have added to the GDG interpretation of evidence to clarify how recommendations have been arrived at. It is no longer NICE policy to grade recommendations so it is not possible to distinguish between those based on evidence and those based solely on GDG expertise and experience.
Ex per t	NCCHTA2	33		9.2		There is surprisingly little consideration of the utility of outcomes rather than simply the probabilities. In particular, the risk of fetal death from CVS and amniocentesis appears to be unconsidered unless identified studies commented on it directly. The perception of that risk and 'cost' of the outcome is substantially underplayed.	See response in Health Economics comments table.
Ex per t	NCCHTA2	34				3.2 Are any important limitations of the evidence clearly described and discussed?	N/a
Ex per t	NCCHTA2	35				4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.	N/a
Ex per t	NCCHTA2	36				4.2 Please comment on whether the research recommendations, if included, are clear and justified.	N/a
Ex per t	NCCHTA2	37				Section five – additional comments Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.	N/a

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Ex per t	NCCHTA2	38		General		There does not appear, either from the list of names or from reading the chapters, to be senior statistical input to the critical appraisal process. My (non-evidence based) suspicion is that this has led to an overstatement of the quality and strength of evidence, particularly when interpreting subsidiary and multiple analyses in published work, and concluding 'evidence of no effect' rather than 'no evidence of effect'. Whilst possibly having less influence on the recommendations for practice, this may have serious implications for where further research should be prioritised.	Thank you. The senior research fellow has a good understanding of most statistical methods and is supported by a member of the NCC senior management team who has a high level of expertise in statistical methods. Your comment about subgroup analyses is valid. In deciding recommendations for future research the GDG tends to consider clinical appropriateness as well as gaps in evidence and prioritising of research has been based on these principles so we feel the key recommendations for further research are appropriate.