Guideline title: Antenatal care for uncomplicated pregnancies update

NICE National Institute for Health and Care Excellence

Consultation on draft scope – deadline for comments by 5pm on 18 April 2018 **email**: Antenatal@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly or arrive after the deadline. We would like to hear your views on these questions: 1. Which interventions or forms of practice might result in cost saving recommendations if included in the guideline? 2. [Insert any specific questions you would like considered during consultation, or delete if not needed] 3. [Insert any specific questions you would like considered during consultation, or delete if not needed] Developing NICE guidance: how to get involved has a list of possible areas for comment on the draft scope.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Christian Medical Fellowship
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None**
Name of person completing form:	**Richard Thomas**
Type	[for office use only]

Comment No.	Page number or **'general'** for comments on the whole document	Line number or **'general'** for comments on the whole document	**Comments** Insert each comment in a new row. Do not paste other tables into this table, as your comments could get lost – type directly into this table.
Example	3	55	The draft scope currently excludes people who have already been diagnosed. We feel this group should be included because….

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

1	3	11	Antenatal care will signpost to UK NSC fetal anomaly screening programme. This will include non-invasive prenatal testing (NIPT) of maternal blood for those mothers deemed to be at significant risk of having a child affected by trisomy (Down, Edwards or Patau syndromes). A positive NIPT screening result, followed by a diagnostic invasive test that confirms trisomy, would enable parents to prepare for the arrival of a child with special needs. The availability of time for reflection, qualified counselling and support, written and online resources and the opportunity to meet with parents of children with trisomy-related disabilities, and the children themselves, have been shown to be helpful in this,[1] and we urge that this be reflected in the new guidelines. We do have a number of **concerns for mothers and their partners**: • Increased anxiety for those whose risk levels, following existing initial screening tests, are considered just below the threshold level and who would not therefore 'qualify' for the new, more sensitive test. • The public misconception that NIPT is a 'diagnostic' test, on a par with invasive testing, not a screening test that would need to be followed by a diagnostic invasive procedure. Research[2] has found that in over half of discussions, health care providers did not clarify the fact that screening is not diagnostic, and guidelines should emphasise the importance of clarity of communication in this. • Increased sense of 'tentativeness' in pregnancy – the mother is wary of committing, emotionally or relationally, to her unborn child lest the baby be shown by tests to carry an abnormality. The provision of sensitive, non-directive counselling, we suggest, should form part of standard procedure in the guidelines • Increased anxiety and uncertainty for women confronted by ambiguous results. Since an outcome of Down Syndrome represents a spectrum of disability, it is almost impossible to predict the implications for a particular child. The opportunity to meet with parents, siblings and the children themselves who are affected by trisomy syndromes, particularly Down Syndrome, we believe could go a long way towards reducing such fears and anxieties and provide an essential period of 'pause for thought' in place of rushing to a decision to terminate the pregnancy – a decision that might later be

[1] Parens E and Asch A. The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations. Hastings Center Report 1999; 29(5):S1-S22

[2] http://journals.lww.com/greenjournal/Abstract/2016/06000/Patient_Health_Care_Provider_Conversations_About.23.aspx

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

1			regretted. We are concerned about guidelines that might appear to reinforce the notion that children with chromosomal abnormalities (and thereby special needs) should be 'screened out' and destroyed. • Increased likelihood of some women making choices they later regret. A British Parliamentary Inquiry into abortion on the grounds of disability concluded that: '...the studies have all found that around 20% of women, between one and two years after an abortion for fetal abnormality, have a psychiatric condition, usually a complicated grief reaction, a depressive disorder or post-traumatic stress disorder.'[3] Signposting this possible long term outcome should be routine and included in guidelines. The availability of perinatal palliative care would encourage a higher proportion of pregnant women carrying a baby with a trisomy disorder to continue their pregnancies and avoid many of the mental disorders associated with regret. In one British study, when parents were offered perinatal hospice as an option, 40% chose to continue with their pregnancies.[4] The comparative figure in US studies was between 75% and 85%.[5] • Guidelines should extend to the private sphere. As awareness of the test increases, and its cost comes down, then many pregnant women will seek to access the test privately. As things stand, they may not receive pre-test information and counselling. They will receive results outlining all manner of variable predictive risks faced by their babies, but will not have the context in which to discuss, assess and weigh the relevance of those results. This will increase anxiety further and make abortion a more likely outcome, sometimes without evidence of trisomy. • The routinisation and ease of accessing the tests are likely to lead to the general perception that it is a 'duty' to test rather than an option. Evidence from the Parliamentary Inquiry reflected this concern.[6] The test can also be used to determine the sex of the baby. The International BioethicsCommittee of UNESCO (IBC), sounding their concerns over the test, has said that: *'Another risk lies in the cultural prejudices of preferring a child of the male sex, the sex of the baby being one of the characteristics that can obviously be discovered by NIPT. As this test can be carried out at a very early stage of the pregnancy it would be difficult, even impossible for doctors to forbid the communicating of sex to the parents, and especially at a time when many countries have liberalised abortion. This could lead*

[3] http://www.abortionanddisability.org/resources/Abortion-and-Disability-Report-17-7-13.pdf
[4] Breeze AC et al. Palliative care for prenatally diagnosed lethal fetal abnormality. Arch Dis Child FetalNeonatal Ed. 2007 Jan;92(1):F56-8
[5] http://www.aaplog.org/wp-content/uploads/2015/07/AAPLOG-Practice-Bulletin-1.compressed.pdf
[6] http://orca.cf.ac.uk/50207/1/Oral%20Evidence_Parliamentary%20Inquiry%20February%202013_DisCopy.pdf

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk
NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

1			*to a selection based on sex, which is against ethical values of equality and non-discrimination.*[7] Guidelines should encourage health professionals NOT to be drawn into giving information beyond the intention of the test. We are also **concerned about the implications for healthcare staff** of implementing NIPT: • The same technology that allows NIPT to detect trisomy also detects other genetic features, including gender, and will in time permit the detection of a wide range of genetic 'conditions' and predispositions. Increasingly widespread use of NIPT to analyse more and more genetic features up to the entire genome would mean the complexity of data would lead to a significant increase of false-positives, requiring confirmation by invasive tests of abnormalities whose relevance or significance is little known or not known at all. This uncertainty will lead many parents to not take any risk, with the resulting paradox: the number of invasive diagnostics would rise because of the use of the new test that should precisely be diminishing the use of invasive diagnostics. That increase in the number of invasive tests would also lead to an increase in the number of unintended miscarriages, often of normal fetuses. • Increased rate of discovery of babies affected by Down Syndrome and other trisomies and, if current trends continue, overall increase in abortion numbers leading to a projected decline of 13% reported live births of babies with Down, Patau and Edwards Syndromes.[8] Healthcare professionals would be enabling a kind of informal eugenics, which would raise issues of conscience for many. • Ground E of the Abortion Act does not specify what amounts to 'serious handicap'. In practice it is left to individual clinicians to 'interpret' the results of screening tests to parents and to inform them of likely implications. There will be many clinicians who do not believe that Down Syndrome represents a 'serious handicap'. There is potential for significant differences (and even conflict) between doctors as to which disabilities fall within the scope of the law and which do not. Clearer guidelines will be needed for doctors, particularly when they find themselves in such a situation late in a pregnancy, at a stage when the fetus is potentially viable. • A culture shift among healthcare professionals is required. At present, subtle or direct

[7] 'Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights', October 02nd 2015, http://unesdoc.unesco.org/images/0023/002332/233258e.pdf

[8] http://www.binocar.org/content/annrep2013_FINAL_nologo.pdf

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

1			pressure may be placed on parents who decide not to abort their child.[9] Some parents have already been made to feel that to bring into the world a child with known disability is somehow irresponsible and blameworthy,[10] a precedent that suggests that this trend will worsen. CMF supports the recommendations of the Parliamentary Inquiry into Abortion on the Grounds of Disability (2013)[11] that include: '*Guidelines for the medical profession should include training for obstetricians, fetal medicine specialists and midwives on the practical realities of the lives of children living with the different conditions which are screened for through ante-natal tests*.' • Following Montgomery v Lanarkshire Health Board[12] the requirement upon doctors, as part of the consent process, to inform patients about risk associated with any procedure, or its alternatives, has been enhanced. The risks of false positive and inconclusive outcomes must be explained. The information provided should, for example, include: '*an explanation of the investigation, diagnosis or treatment; an explanation of the probabilities of success, or the risk of failure; or harm associated with options for treatment. The patient should be given time to ask questions. The GMC and the courts expect patients to be given all information material to their decision, with the proviso that it would not cause the patient serious harm'*.[13] This sets the bar higher than the previous Bolam test and failure to comply risks legal action We are concerned that the **provision of information and counselling is presently unsatisfactory:** • Evidence from the Parliamentary Inquiry, already mentioned, suggests that healthcare professionals tend to assume women will participate in screening and that little attention is given to explaining the purpose or possible outcomes and options. In one study in a London teaching hospital, 27% of women did not know that they had received blood tests during pregnancy to detect spina bifida.[14]

[9] http://www.cmfblog.org.uk/2013/02/19/women-who-keep-their-disabled-babies-face-coercion-discrimination-and-disdain/
[10] Nuffield Council on Bioethics, Genetic Screening: Ethical Issues, London 1993, para 8.11.
[11] http://dontscreenusout.org/wp-content/uploads/2016/02/Abortion-and-Disability-Report-17-7-13.pdf
[12] https://www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf
[13] http://www.medicalprotection.org/uk/resources/factsheets/england/england-factsheets/uk-eng-consent-the-basics
[14] Marteau, T et al. Journal of Psychosomatic Research (1988), 32:403-408.

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk
NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

1			• As the number of available genetic tests increases, so does the problem of providing suitable and sufficient pre-test information and counselling. Yet this is surely essential if consent is to be fully informed. Screening tests come with the aura of medical authority and respectability; to decline them may seem to be 'going against medical advice'. • US Obstetrics and Gynaecology research found that the average time provided by healthcare providers to prenatal genetic screening counselling amounts to just 1.5 minutes, and does not adhere to College recommendations.[15] False-positive rates were seldom discussed and in half of the conversations between providers and parents, it was not made clear that prenatal genetic screening is not a diagnostic test. Cursory explanations and inadequate information undermine the integrity of consent in any healthcare setting. • In the UK Parliamentary Inquiry into Abortion on the Grounds of Disability, a '*considerable number of witnesses reported from their experience that after the discovery of a fetal disability, the presumption of the medical profession was that parents would opt for abortion'.*[16] *'Parents can find themselves given only a leaflet on abortion and plenty of support or advice on having an abortion rather than a support package and/or information specific to the condition diagnosed.'*[17] • We support the recommendations of the Parliamentary Inquiry that '*It should be best practice that parents are provided with practical and balanced information as soon as possible after discovery of a fetal disability and before leaving hospital so that they can make an informed choice. This should include leaflets or other information written by relevant disability groups. Parents should be offered contact with families with a child with a similar diagnosis without delay' and that 'following a prenatal discovery of a fetal disability, parents should be encouraged and supported to consider adoption for their child as one of the options available to them. Literature distributed by patient interest groups to couples should promote adoption as a positive option'.*[18]

[15] http://journals.lww.com/greenjournal/Abstract/2016/06000/Patient_Health_Care_Provider_Conversations_About.23.aspx
[16] http://dontscreenusout.org/wp-content/uploads/2016/02/Abortion-and-Disability-Report-17-7-13.pdf For instance, Written evidence, Q8, Respondent 8, parent; Written Evidence, Q11, Respondent 21; Written Evidence, Q5, Respondent 30
[17] Ibid: Section 3; para 51
[18] Ibid: p5: 8,6.

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk
NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

2	5	9	**Information and support for women and their families:** • When pregnancy is confirmed, non-directive information about all screening tests should be made available. The distinction should be drawn between those tests that carry treatment options and those where the only available 'treatment' would be the termination of the pregnancy. It should not be assumed that a woman wishes to undergo every test. Time and trained pre-natal counsellors must be available so that women and their partners can understand their options and related risks, and make fully informed decisions. The culture in obstetric departments must change to one where the woman and her partner can comfortably refuse screening without experiencing a negative attitude in response**.** • It must be made clear before taking the test that NIPT is not a diagnostic test, but a screening test and confirmatory invasive procedures may be necessary. If the result of any screening test, including NIPT (and any subsequent invasive test), suggests that the baby may have Down Syndrome or another trisomy, then parents should be offered the option to meet others who have first-hand experience of the condition or disability in question. This includes affected patients and their families, disability-specific support groups, healthcare professionals caring for babies, children and adults with the relevant condition. There should be counselling and support offered and available for those who choose an abortion on the grounds of disability both before and after abortion. For parents who choose to continue with their pregnancy, there needs to be improved, positive and consistent care and support from across the medical profession. • As stated above, over time it is likely that those purchasing NIPT privately will be given a mass of information outlining all manner of variable predictive risks faced by their babies. Anxiety levels are likely to rise and the experience of pregnancy become yet more tentative. Pregnant women and their partners will need help to understand, weigh and respond to the information they have been given and the burden of this is likely to be felt by NHS workers. • Whatever information, genetic or otherwise, that NIPT brings to light, should be used only to enable medical staff, parents and other family members to be better prepared for the arrival of the new baby or to enable therapeutic interventions (medical or surgical) to improve the baby's health before birth or in the perinatal period. • Waiting for a child, that is known to be impaired to be born can be a distressing and anxiety-ridden experience. There is much to be said for not knowing in advance, so that parents can give themselves to loving the mysterious gift that is not yet 'unwrapped'.

Add extra rows if needed

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.

Checklist for submitting comments

- Use this form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include page and line number (not section number) of the text each comment is about.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 response from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- For copyright reasons, do not include attachments such as research articles, letters or leaflets. We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.

Please add extra rows as needed

Please return to: Antenatal@nice.org.uk

NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.