Public Health England – Informed Choice Consultation

Christian Medical Fellowship (CMF) was founded in 1949 and is an interdenominational organisation with over 5,000 British doctor members in all branches of medicine. A registered charity, it is linked to about 75 similar bodies in other countries throughout the world.

CMF exists to unite Christian doctors to pursue the highest ethical standards in Christian and professional life and to increase faith in Christ and acceptance of his ethical teaching.

Introduction

We welcome the UK National Screening Committee's initiative, seeking to standardise the approach to information provision across all screening programmes and all four countries within the UK. We also appreciate the intention to produce an agreed definition of the meaning of informed choice and believe the introduction and use of 'personalised informed choice' as both a notion and a term would be a helpful step in the right direction.

Our concerns at CMF are around Non-Invasive Prenatal Testing (NIPT) that measures the level of circulating fetal DNA in maternal blood as a contingent test for those in whom initial screening has indicated a high chance of Down Syndrome (DS) or another trisomy.

Those concerns include:

1. The appropriateness of its inclusion as a screening test at all
2. The comprehensiveness of 'personalised informed choice' information, time and resources
3. The climate of 'presumed outcomes' to positive test results currently prevalent amongst healthcare professionals
4. The use of the test in private healthcare settings

1. NIPT – an inappropriate test for a screening programme

The **UK NSC's own criterion** (Number 3) for appraising the viability, effectiveness and appropriateness of a screening programme states that *'where there is no prospect of benefit for the individual screened then the screening programme shouldn't be further considered'*. The individual being screened with NIPT is the fetus. The screening conveys no benefit to the fetus – indeed, it could be said to put the continuation of his/her life in danger and, as such, is inappropriate in our view.

World Health Organisation criteria governing screening protocols include the requirement that: *'there should be treatment for the condition being screened'*.[1] In cases of trisomies, prenatal screening tests are carried out not to identify individuals with special needs, in order that they may be more effectively treated, but with the expectation of eliminating them from the population. This

[1] Wilson JMG, Jungner G. (1968) Principles and practice of screening for disease (large pdf). WHO Chronicle Geneva:World Health Organization. 22(11):473. Public Health Papers, #34.

type of screening offers no benefit to the fetus being screened and also results in collateral damage in that unaffected fetuses may also die as a result of inadvertent miscarriage. We submit that this is contrary to the Hippocratic Oath,[2] the Declaration of Geneva[3] and to the general strategy of medicine. There is no treatment on offer for Down Syndrome and in over 90% of cases the outcome is to terminate the life of the one screened.[4]

In our opinion, Down Syndrome should not be classed as a 'serious handicap' under Ground E of the Abortion Act, and screening for it **should only be offered to mothers in order better to prepare them and their families to be joined by a child with additional needs**.

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, in order to make personal and fully informed decisions. The culture in obstetric departments must be one where the woman and her partner can comfortably refuse screening without experiencing a negative attitude in response.

We are particularly concerned by reports that a 'reflex DNA system', trialled[5] by researchers at Queen Mary University of London across five NHS maternity wards, involves taking the pregnant woman's blood at the initial screening stage and *automatically* sending it to be analysed using NIPT if the woman is found to have at least a 1 in 800 chance of having a baby with a trisomy syndrome. This removes the opportunity for counselling and reflection before embarking on NIPT and in our opinion further undermines the notion of informed consent.

2. Personalised informed choice must be comprehensive

a) Counselling , resources and the opportunity for reflection

Whilst we agree with your definition of informed choice, we suggest that it is not sufficiently comprehensive when applied to NIPT. We suggest that qualified counselling and support, written and online resources and the opportunity to meet with parents of children with trisomies as well as the children themselves, should all be included[6] as part of 'the opportunity to reflect on what the test and its results might mean to the individual'.

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.

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[2] http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html
[3] http://www.wma.net/en/30publications/10policies/g1/
[4] Morris JK, Springett A. (December 2014) The National Down Syndrome Cytogenetic Register for England and Wales: 2013 Annual Report. http://www.binocar.org/content/annrep2013_FINAL.pdf
[5] http://www.lmsalpha.co.uk/content/papers/gim2017188a.pdf
[6] Parens E and Asch A. The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations. Hastings Center Report 1999; 29(5): S1-S22

b) Time and integrity

Screening tests come with the aura of medical authority and respectability; to decline them may feel like '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.[7] 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. Following Montgomery v Lanarkshire Health Board, doctors must now ensure that patients are aware of any 'material risks' involved in a proposed treatment, and of reasonable alternatives. The Supreme Court's ruling outlined the new test: *'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'*[8]

c) Interpretation and understanding

A clear understanding of the limitations of the test is also necessary. There is a 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 has found that in over half of discussions, health care providers did not clarify the fact that screening is not diagnostic.[9] How does UKNSC propose to audit the performance of healthcare providers?

Ambiguous results are not uncommon with NIPT and lead to increased anxiety and uncertainty for women confronted by them. Since a test outcome of Down Syndrome represents a spectrum of disability, it is almost impossible to predict the implications for a particular child.[10]

False-positive results present a particular challenge when it comes to explaining and understanding chance. We welcome the draft proposal commitment to explain the notion of positive predictive value but wonder if, in practice, its significance will be clearly understood by those already made anxious by the test result.

d) Morbidity and regret following abortion for fetal abnormality

Abortions for congenital abnormality often take place later in pregnancies. It is not surprising therefore that psychological morbidity is considerable. Morbidity following termination of pregnancy for fetal disability has been shown to be both prevalent and persistent,[11] and associated with long-

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

[8] www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf

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

[10] http://dontscreenusout.org/wp-content/uploads/2016/02/Abortion-and-Disability-Report-17-7-13.pdf Professor John Wyatt, Oral Evidence Session 4, page 60

[11] Davies V et al. Psychological outcome in women undergoing termination of pregnancy for ultrasound-detected fetal anomaly in the first and second trimesters: a pilot study. Ultrasound Obstet Gynecol 2005;25(4):389-92(April)

lasting consequences for a substantial number of women.[12] Rather than leading to psychological well-being, termination of pregnancy for fetal disability can be an emotionally traumatic major life event which leads to severe post-traumatic stress response and intense grief reactions that are still detectable some years later.[13] In fact women who terminate pregnancies for fetal anomalies experience grief as intense as those who experience spontaneous perinatal loss with approximately a fifth developing major depression and/or requiring psychiatric intervention.[14] Their families are also not immune with even very young children and those sheltered from knowledge of the event showing reactions to their parents' distress and maternal absence.[15] Awareness of the possibility of such outcomes must be included in the information provided if consent is to be truly informed.

There is evidence to suggest that some women make 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.'[16] We believe that such information is germane to achieving personalised informed consent.

e) Awareness of perinatal palliative care

The availability of perinatal palliative care has been shown to 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.[17] The comparative figure is US studies was between 75% and 85%.[18] These facts help to inform consent and should be included routinely in counselling in order to minimise the risk of later regret.

3. Personalised informed consent is incompatible with presumed outcomes

The very existence of screening tests designed to 'uncover' the presence of a child affected by a trisomy, and the subsequent offer to terminate the pregnancy if the abnormality is confirmed by amniocentesis, reinforces in the public mind set the notion that children with chromosomal abnormalities (and associated additional needs) should be 'screened out' and destroyed.

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[12] Kersting A et al. Grief after termination of pregnancy due to fetal malformation. J Psychosom Obstet Gynaecol 2004;25(2):163-9(June)

[13] Kersting A et al. Trauma and grief 2-7 years after termination of pregnancy because of fetal anomalies--a pilot study. J Psychosom Obstet Gynaecol 2005;26(1):9-14 (March)

[14] Zeanah CH et al. Do women grieve after terminating pregnancies because of fetal anomalies? A controlled investigation. ObstetGynecol 1993;82(2):270-5 (August)

[15] Furlong RM, Black RB. Pregnancy termination for genetic indications: the impact on families. Soc Work Health Care 1984;10(1):17-34(Autumn)

[16] http nddisability.org/resources/Abortion-and-Disability-Report-17-7-13.pdf

[17] Breeze AC et al. Palliative care for prenatally diagnosed lethal fetal abnormality. Arch Dis Child Fetal

[18] http://www.aaplog.org/wp-content/uploads/2015/07/AAPLOG-Practice-Bulletin-1.compressed.pdf

Evidence from the UK Parliamentary Inquiry into Abortion on the Grounds of Disability suggests that healthcare professionals tend to assume women will participate in screening and that after the discovery of a fetal disability, the presumption of the medical profession was that parents would opt for abortion'.[19] 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.[20] *'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.'*[21]

Such an environment threatens the notion of fully informed consent. 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'*.[22]

4. Personalised informed consent in private healthcare settings

As awareness of NIPT increases and its cost comes down, then many pregnant women will seek to access the test privately. In such settings, 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. We appeal to UK NSC to extend the new guidance by statute to include private providers.

The test can also be used to determine the sex of the baby. The International Bioethics Committee 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 to a selection based on sex, which is against ethical values of equality and non-discrimination.'*[23]

[19] 33http://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

[20] Marteau, T et al. Journal of Psychosomatic Research (1988), 32:403-408.

[21] Ibid: Section 3; para 51.

[22] Ibid: p5: 8,6.

[23] '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

Conclusions

We welcome the UK National Screening Committee's initiative in seeking to both clarify the definition and improve the application of 'personalised informed consent' across all screening procedures and all four UK countries.

Our concern relates to the particular case of NIPT and can be summarised as follows:

- **NIPT fails to meet both the UK NSC's own criterion (Number 3), and WHO criteria, as a valid screening test. We believe it should only be offered to mothers in order better to prepare them and their families to be joined by a child with additional needs;**
- **Where NIPT is made available, personalised informed choice will not be possible in the absence of comprehensive, skilled, pre- and post-test, non-directive counselling; adequate consultation time in a climate free of outcome presumption; understanding and awareness of the limitations of the test; awareness of possible negative consequences following abortion for fetal abnormality as well as the benefits afforded by perinatal palliative care;**
- **The use of the test in private healthcare settings where patients' best interests may play second fiddle to commercial interests; where necessary counselling and support may be lacking and where extended application of the test may uncover a confusing and frightening array of potential conditions; where test results may be used to inform sex-selection abortion.**

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