

DOWN SYNDROME AUSTRALIA

Submission to Medical Services Advisory Committee
Regarding Non-invasive Prenatal Screening (NIPS)

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ABOUT DOWN SYNDROME AUSTRALIA

Down Syndrome Australia was established in 2011 as the peak body for people with Down syndrome in Australia.

Our purpose is to influence social and policy change, and provide a national profile and voice for people living with Down syndrome. We work collaboratively with the state and territory Down syndrome associations to achieve our mission.

Our vision is an Australia where people living with Down syndrome are valued, reach their potential and enjoy social and economic inclusion.

Down syndrome is a genetic condition in which the person has an extra copy of some or all of chromosome 21. This additional chromosome results in a number of physical and developmental characteristics and some level of intellectual disability. There are more than 13,000 Australians who have Down syndrome and approximately 1 in every 1,100 babies in Australia are born with Down syndrome.¹

Down Syndrome Australia is making this submission to MSAC to ensure that the views of people with Down Syndrome and their families are considered in the consideration of the listing of non-invasive prenatal screening.

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¹ http://www.downsyndrome.org.au/down_syndrome_population_statistics.html

Executive Summary

Over the last few years the capacity to test for genetic conditions such as Down syndrome before birth has increased. It is now possible to detect various chromosomal conditions prenatally through a blood test also known as a non-invasive prenatal screening (NIPS). The Medical Services Advisory Committee (MSAC) received two applications in July 2016 to add NIPS to the Medicare Benefit Scheme.

Down Syndrome Australia believes that prenatal screening must be accompanied by appropriate information to support families in making informed decisions about screening and how to respond to the results. Providing a screening test without ensuring informed consent, adequate support and up-to-date information regarding the results is unethical.

The World Health Organisation has published guidelines regarding the implementation of screening tests which include:

- The programme should integrate education, testing, clinical services and programme management.
- The programme should ensure informed choice, confidentiality and respect for autonomy.²

We are concerned that the current screening programs and the proposed implementation of NIPS does not meet these criteria.

It is important to note that Down Syndrome Australia recognises the right of all women to choose to continue or to terminate a pregnancy. Making such decisions can be extremely difficult and our concern is regarding the accuracy of the information being provided to inform that choice.

Our submission will focus on the research evidence and feedback relating to Down syndrome as this is our area of expertise. It should be noted, however, that the same issues and concerns would apply in regards to other chromosomal conditions which can be detected through prenatal screening.

Evidence suggests that often women are not aware of what they are being screened for and are not aware they can opt out of prenatal screening³. After the screening is complete, women who have a result indicating a high chance of having a child with Down syndrome do not always get access to appropriate information and support. Feedback from the Down syndrome community suggests that in most cases the information provided to families is outdated or focused on a very negative portrayal of what it is like to have a child with Down syndrome rather than providing a current and balanced perspective.

The terminology used after receiving a high chance result can be problematic with parents being told that there is “bad news” or that they have a high-risk of having a child with Down syndrome. Advocates have challenged this language successfully with Tasmania's Anti-Discrimination Commissioner finding the use of negative language in a Down syndrome diagnosis could breach the Anti-Discrimination Act. This finding has prompted a change in the national guidelines for prenatal testing. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists guidelines now point to more neutral terminology like "chance" or "probability".

² Andermann, A, Blancquaert, I, Beauchamp S, Dery V. Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years. Bull World Health Organ. 2008 Apr;86(4):317-9.

³ Constantine M, Allyse M, Rockwood T, Wall M, De Vries R. Imperfect informed consent for prenatal screening: Lessons from the quad screen. Clinical Ethics. 2014;9(1):17–27.

Feedback from families suggests that negative language is still often used by the medical community and that some families who choose to continue their pregnancy after receiving a high chance result feel that they do not receive adequate support and information from health professionals.

Negative information about Down syndrome being provided by doctors is incongruent with the experience of most families who have a child with Down syndrome. For example, a survey of parents and siblings of people with Down syndrome indicate that most people have had a positive experience having a person with Down syndrome in their life. Very few (less than 5%) indicated any regret about their decision to have their child.⁴

There is also a range of ethical issues raised by the increased availability of NIPS including the potential of increased stigma and discrimination associated with Down syndrome or choosing to continue a pregnancy after having received an early result indicating a high chance for having a child with Down syndrome. For example, the Nuffield Council on Bioethics notes:

*“There is concern that NIPS could lead to higher uptake and the potential routinisation of screening, which may exacerbate difficulties that people with disabilities and their families already face, such as stigmatisation, lack of advocacy, and reluctance to provide places for children with Down Syndrome in mainstream schools. If earlier, easier and safer testing is available and a woman chooses to continue with an affected pregnancy or not have the test at all, there may be a perception that any problems she and her family encounter down the line are their fault and that society should not take any responsibility”.*⁵

Down Syndrome Australia does not support the listing of NIPS on MBS until further work is done to ensure that women are supported to make informed choices both pre- and post-screening, regardless of whether they choose to terminate or to continue the pregnancy. It is clearly unethical to implement a screening test in any population without providing the appropriate referrals and supports including up-to-date and accurate information.

It is imperative that MSAC consider the impact of the implementation of the screening program on consumers. There is now well established evidence regarding the importance of involving consumers in decision making about health policy.⁶ As the major consumer organisation for Down syndrome in Australia, the submission from Down Syndrome Australia should be given appropriate consideration. It is disappointing that neither application to MSAC has considered the issue of post-screening support and the ethical requirements in any depth.

Given the evidence of significant issues around informed consent and appropriate post-screening counselling, Down Syndrome Australia recommends that MSAC does not approve NIPS to be listed on the MBS until such time as appropriate information and supports are put in place. We make the following recommendations to the Australian Government:

1. The Government supports the development of national resources and a national training program for health professionals (including GP’s, midwives, Obstetricians etc.) who are involved in prenatal screening to ensure that they are skilled on providing informed consent and appropriate post screening counselling.

⁴ Skotko BG, Levine SP, Goldstein R. 2011. Having a son or daughter with Down syndrome: Perspectives from mothers and fathers. Am J Med Genet Part A 155:2335–2347.

⁵ Nuffield Council on Bioethics (2016) Report on Roundtable Meeting. Non-Invasive Prenatal Testing.

⁶ Consumer Focus Collaboration 2001. The Evidence Supporting Consumer Participation in Health , Commonwealth Department of Health and Aged Care, Canberra, Australia.

2. The Government ensures access to post-screening counselling by appropriate health professionals (e.g. genetic counsellors). As part of this counselling, families should be supported to be connect to other families through Down syndrome organisations. Access to counselling should be supported by creating a specific MBS item for provision of post-screening counselling.
3. Down Syndrome Australia recommends that the Government work closely with representative organisations and people with Down syndrome to develop a public awareness campaign to tackle the stigma associated with intellectual disability and raise public awareness around Down syndrome and other chromosomal disorders

After implementation and review of this approach, it would be appropriate to reconsider the listing of NIPS as a contingency screening approach to reduce the costs and risks associated with invasive testing. This approach should include a complaints process for women who do not receive appropriate information and support.

Background

Trisomy 21 (also known as Down syndrome) is the most common cause of intellectual disability and everyone who has Down syndrome will have some degree of intellectual disability. In the past, many people with Down syndrome have not had the same opportunities as their peers. Often, they have been separated from the rest of the community, living in segregated settings such as care institutions. Low expectations were placed on them and there were limited opportunities for learning and participation in inclusive activities.

With better early intervention and medical care, as well as the increased inclusion and integration of people with Down syndrome into society, the quality of life for people with Down syndrome has increased. Children with Down syndrome usually attend childcare settings, pre-schools and regular primary and high schools alongside other children of their age. Adults with Down syndrome are involved in their communities including through paid employment (open or supported) and voluntary work. An increasing number are living independently, with some level of support, within the community. The life expectancy of a person with Down syndrome has increased from only 25 years of age in 1983 to approximately 60 years in 2016 due to better support and health care, with one in 1 in 10 living to their seventies.⁷

People with Down syndrome report having a high quality of life, with one survey finding that 99% indicated that they were very happy.⁸ Similarly a survey of parents and siblings of people with Down syndrome indicate that most people have had a positive experience having a person with Down syndrome in their life. Very few (less than 5%) indicated any regret about their decision to have their child.⁹

Prenatal screening for Down syndrome is not a new phenomenon. Screening has been available since the late 1960s when women over the age of 35 were offered amniocentesis to test for Down syndrome. In the 1980s the association of Down syndrome with levels of certain biochemical markers was discovered, and blood tests were developed which further improved the detection rate. In the early 2000, ultrasounds were utilised to further enhance the reliability of the screening approach through examination of Nuchal Translucency thickness. These tests have identified women who are at a higher chance of having a child with Down syndrome. Currently the only way to determine a definitive diagnosis is to undergo a more invasive procedure (amniocentesis or Chorionic villus sampling (CVS)). These more invasive tests come with a potential risk of miscarriage (of around 1%).

⁷ Torr J, Strydom A, Patti P, Jokinen N. Aging in Down syndrome: Morbidity and mortality. *Journal of Policy and Practice in Intellectual Disabilities*. 2010;7(1):70-81.

⁸ Skotko BG, Levine SP, Goldstein R. 2011. Self-perceptions from people with Down syndrome. *Am J Med Genet Part A* 155:2360–2369.

⁹ Skotko BG, Levine SP, Goldstein R. 2011. Having a son or daughter with Down syndrome: Perspectives from mothers and fathers. *Am J Med Genet Part A* 155:2335–2347.

Informed Choices

Prenatal screening is becoming a more routine part of prenatal care. Screening can be beneficial in providing parents and health professionals with information in order to support the provision of the best care during pregnancy and immediately after the birth of the child. It also provides families with information which can be utilised to make a decision about whether to continue a pregnancy. These benefits, undergoing screening. Down Syndrome Australia is concerned that women are not being given appropriate information both prior to screening and after receiving their results.

The World Health Organisation has published a synthesis of screening criteria for genetic screening updating the gold standard Wilson and Jungner (1968)¹⁰ screening criteria. The updated criteria¹¹ are as follows:

- The screening programme should respond to a recognised need.
- The objectives of screening should be defined at the outset.
- There should be a defined target population.
- There should be scientific evidence of screening programme effectiveness.
- The programme should integrate education, testing, clinical services and programme management.
- There should be quality assurance, with mechanisms to minimize potential risks of screening.
- The programme should ensure informed choice, confidentiality and respect for autonomy.
- The programme should promote equity and access to screening for the entire target population.
- Programme evaluation should be planned from the outset.
- The overall benefits of screening should outweigh the harm.

Current supports are inadequate and the proposed NIPS listing will increase the number of women undergo screening. The current approach to screening does not meet the requirement to integrate education and clinical services into the screening program. There are also not sufficient safeguards to ensure informed choice and respect for autonomy. Without significant changes to the proposed approach to screening, there are serious concerns about the ethics of implementing this national approach.

Prior to undergoing any testing, women have a right to have information about the proposed test and the potential outcomes in order to make an informed decision about whether to go ahead with this testing. There are concerns that if the NIPS is listed on MBS and there is no cost to the individual woman to undertake this testing, there will be an assumption by health care providers that everyone wants to take part in this screening process.

It is important to acknowledge that various Australian Health Guidelines for prenatal care clearly state the need for pre-screening information and counselling including up to date information about Down syndrome.¹²

¹⁰ Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva: WHO; 1968. Available from: <http://www.who.int/bulletin/volumes/86/4/07-050112BP.pdf>

¹¹ Andermann, A, Blancquaert, I, Beauchamp S, Dery V. Revisiting Wilson and Jungner in the genomic age: a review of screening criteria over the past 40 years. Bull World Health Organ. 2008 Apr;86(4):317-9.

¹² <http://www.health.gov.au/antenatal>;

For example the Royal Australian and New Zealand College of Obstetrics and Gynaecologists recommends: "Information provided should include:

- The difference between screening and diagnostic testing.
- The relative advantages and disadvantages of the available screening tests.
- Details of the nature, purpose, limitations and consequences of screening.
- That the decision whether to undertake screening or not is entirely that of the woman.
- Practical aspects of screening including the conditions that are being screened for, the type of tests, the timing of tests and the approximate costs involved.
- The possibility of diagnosing fetal genetic or structural conditions other than those for which the screening programs are designed.
- The nature of results (often expressed as a numerical probability estimate) and the offer of a follow up diagnostic test if an 'increased' probability' result is obtained.
- That continuing or not continuing the pregnancy are both options in the event that a fetal genetic or structural condition is diagnosed.
- An assurance that continuation of the pregnancy is a valid option should a fetal genetic or structural condition be diagnosed, and that couples will receive appropriate counselling and care in preparation for birth"¹³

Research suggests that this level of information is not being provided in many cases and that often acceptance of screening is presumed. There are concerns that NIPS could become seen as a routine blood test as one of the many that pregnant women are asked to have as part of 'typical' prenatal care.¹⁴ If women are not given a clear choice about whether or not to undergo NIPS, they may not have an opportunity to consider whether they want the test results or the decisions they would have to make after receiving a high chance result.¹⁵ Issues around the information provided and the process of informed consent have also been identified in the more traditional screening approaches.¹⁶

For example, an Australian study found that only 37% of women were fully informed regarding a prenatal blood serum screen and only 62% were aware that termination of pregnancy would be offered if Down syndrome were to be diagnosed¹⁷. Similarly, a 2009 study found that approximately half of women surveyed who underwent both ultrasound and biochemical screening did not foresee that they might ultimately be confronted with the need to make the decision about whether or not to continue the pregnancy.¹⁸ Research suggests that the implementation of NIPS may further exacerbate the issue around access to informed consent as screening becomes more routine and available earlier in the pregnancy.¹⁹

¹³ The Royal Australian and New Zealand College of Obstetricians and Gynecologists (2015). C-Obs 25 Prenatal Screening for Genetic or Structural Conditions. Available: [https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women's%20Health/Statement%20and%20guidelines/Clinical-Obstetrics/Prenatal-Screening-for-Fetal-Genetic-or-Structural-Conditions-\(C-Obs-35\)-Review-March-2016.pdf?ext=.pdf](https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women's%20Health/Statement%20and%20guidelines/Clinical-Obstetrics/Prenatal-Screening-for-Fetal-Genetic-or-Structural-Conditions-(C-Obs-35)-Review-March-2016.pdf?ext=.pdf)

¹⁴ Deans Z, Newson AJ. Should non-invasiveness change informed consent procedures for prenatal diagnosis? *Health Care Anal.* 2011;19(2):122–132.

¹⁵ van Schendel RV, Kleinveld JH, Dondorp WJ, et al. Attitudes of pregnant women and male partners towards non-invasive prenatal testing and widening the scope of prenatal screening. *Eur J Hum Genet.* 2014 Mar 19;

¹⁶ Constantine M, Allyse M, Rockwood T, Wall M, De Vries R. Imperfect informed consent for prenatal screening: Lessons from the quad screen. *Clinical Ethics.* 2014;9(1):17–27.

¹⁷ ROWE, H. J., FISHER, J. R. W. and QUINLIVAN, J. A. (2006), Are pregnant Australian women well informed about prenatal genetic screening? A systematic investigation using the Multidimensional Measure of Informed Choice. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 46: 433–439. doi:10.1111/j.1479-828X.2006.00630.x

¹⁸ Seror V, Ville Y. Prenatal screening for Down syndrome: women's involvement in decision-making and their attitudes to screening. *Prenat Diagn.* 2009;29(2):120-128.

¹⁹ *J. Clin. Med.* 2014, 3(2), 614-631; doi:10.3390/jcm3020614

Down Syndrome Australia is also concerned about the information being provided to women after they receive a result which indicates a high chance of having a child with Down syndrome. A 2014 survey of women who had a child with Down syndrome found that nearly half (48%) believed that health professionals were giving biased or incorrect information about Down syndrome at the time of diagnosis. Approximately a quarter of women surveyed believed that this biased information was leading to more terminations of pregnancies of fetuses with Down syndrome²⁰.

These findings are consistent with the results of a survey published by Down Syndrome Tasmania of 58 Australian women who have a child with Down syndrome and received a high chance result during pregnancy. Amongst these women 62% indicated that negative language was used by health professionals when informing the women of the high probability result. One woman described her experience as *'They weren't just negative, they told us our baby would most probably die in utero but if she survived she would be in hospital for most of her "short" life, never walk, talk or have any quality of life'*.²¹

Some anecdotal reports have indicated that women are being told that a child with Down syndrome can never go to a mainstream school and that parents will have to give up their careers to support the child. A recent post to the parenting blog Mamamia.com.au told of a woman who decided to terminate her pregnancy to avoid pain for her child.²² "We ended little Dot's life because we didn't want her to endure a lifetime of pain. We knew that she would need constant medical attention, and we felt we couldn't stand by and watch her as she struggled physically and intellectually throughout her (possibly short) life, when we couldn't do anything to help her." This description of life with Down syndrome is at odds with research findings and the experience of most families.

As outlined above, the reality of life with Down syndrome has changed dramatically over the last three decades. There is an urgent need to ensure that health professionals (including GPs, specialists, radiographers, sonographers, midwives, nurses, counsellors) are providing women with up to date, accurate information about Down syndrome so that they can make an informed decision about whether or not to continue with their pregnancy. It is also important that women have access to supported-decision making as often the medical terminology and information can become overwhelming.

As discussed above there are a range of guidelines which provide advice indicating that there is a need to provide up to date information about the relevant conditions. However, this is not always put in practice. There are some good initiatives in some areas, for example University of Sydney is utilising the Down Syndrome International "Dear future mom" video (<https://youtu.be/Ju-q4OnBtNU>) to provide medical students with information about life with Down syndrome.

If NIPS is to be publicly funded through the MBS, the Australian Government has an obligation to ensure that accurate information and support is available. Health professionals should be required to provide up to date information as well as linking families to support organisations and other families who have had a child with Down syndrome. Manufacturers of the test must ensure that consumer information is accurate, up to date and uses appropriate language. Down Syndrome Australia recommends that a separate MBS item be created for post-testing counselling and information and that a complaints mechanism be put in place to support women who are not receiving the appropriate support regarding the testing.

²⁰ Kellogg, G., Slattery, L., Hudgins, L. et al. J Genet Counsel (2014) 23: 805. doi:10.1007/s10897-014-9694-7

²¹ Kelly, R. (2016). Carrying a baby with Down syndrome: Women's experiences of prenatal screening, diagnosis and pregnancy care. (published by Down Syndrome Tasmania).

²² <http://www.mamamia.com.au/terminate-down-syndrome-pregnancy/> (accessed 9/1/2017)

There are also concerns that in some cases terminations are being scheduled without the appropriate follow up tests after a positive result on NIPS. Although NIPS has a relatively high rate of accuracy, there are still some false positive results. The UN Committee on Bioethics notes “there is the risk that pregnant women with a positive result don’t await the validation of the result through invasive diagnostics, but immediately choose to abort the embryo or foetus, without adequate counselling about the relevance of the detected abnormality.”²³

Cost/Benefit Analysis

The United Nations International Bioethics Committee has noted in its 2015 report on the Human Genome and Human Rights that in relation to NIPS “*prevention as a social objective, focused, for example, on reducing care costs for people with congenital conditions or disabilities, cannot be the goal of such screening. That would imply a discriminatory practice that sends the message that these people are unwelcome in society.*”²⁴

We are concerned that the applications to MSAC are disregarding this advice and suggesting that MSAC consider the benefit of reductions in costs to the health or disability services due to terminations of pregnancies at high chance of Down syndrome. For example, The Roche application to MSAC makes the following comment in regards to this issue:

“A reduction in the birth incidence of trisomies would reduce the costs of such medical and supportive care as may have been required”²⁵

It is important that MSAC ensure that in the cost/benefit analysis of listing NIPS on the MBS that the costs are considered in relation to other screening approaches, rather than measuring potential costs to the disability/health system of a child being born with Down syndrome.

Primary Screen

The cost effectiveness of the use of NIPS as a primary screen has repeatedly been called into doubt by various economic analyses.²⁶ The current Roche application to have the Harmony test added to the MBS²⁷ estimates that under a primary screen model NIPS will be taken up by 230,000 of the 300,000 women that have babies each year²⁸. At an average cost of \$500 per test this represents a total annual cost of \$115 million, in addition to the existing prenatal screening program. This cost would be partially offset by a reduction in invasive testing (CVS and amniocentesis) but there is not a clear cost benefit to this approach.

Contingency Screen

The contingency screening approach would be significantly less costly as it would be targeted to women who had already been identified as having indicating a higher chance of having a child with Down syndrome. The Roche application suggests that under this approach approximately 29,000-39,000 women per year would utilise NIPS. At a reimbursement rate of \$500 this would be equivalent to a cost of \$14.5 million per year. A 2013 study which examined the potential economic case for implementation of NIPS in Australia did not find a contingency model to be cost effective

²³ <http://unesdoc.unesco.org/images/0023/002332/233258E.pdf>

²⁴ <http://unesdoc.unesco.org/images/0023/002332/233258E.pdf>

²⁵ <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1461-Public>

²⁶ Ayres AC, Whitty JA, Ellwood DA, 2014, ‘A cost-effectiveness analysis comparing different strategies to implement noninvasive prenatal testing into a Down syndrome screening program’, *Aust N Z J Obstet Gynaecol*; 54(5):412-417.

²⁷ <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1396-public>

²⁸ <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1396-public>

taking into account the impact of reduced invasive procedures. They estimated that the cost to identify a case of Down syndrome using a contingency model of NIPS would be 9.7% higher than the current testing approach.²⁹ There is, however, the additional benefit of a reduction in adverse outcomes from potentially unnecessarily invasive testing for those who would receive a high chance result under traditional screen but a low chance result under NIPS.

Ethical Issues

There are a range of ethical issues regarding prenatal screening which professional organisations such as the UN Committee on Bioethics³⁰ have identified including:

- Ensuring screening is not being utilised as a social objective to reduce the number of people with a disability and the potential subsequent health and support costs
- Stigma associated with refusal of the test or decision to continue a pregnancy
- Use of NIPS to analyse other genetic markers for other conditions and the potential impact on parents in making decisions about the gravity of those conditions.
- People making a decision to terminate based on the NIPS alone without undertaking the appropriate follow up testing.
- Impact on the community response and understanding of Down syndrome.

The latter issue of the impact on people living with Down syndrome today and their family members is often not explored in discussions around prenatal testing. The improvements in technology around screening for Down syndrome has meant that the community response to Down syndrome has changed to some extent. For example, as previously noted: the Nuffield Council on Bioethics notes *“The use of NIPT does, however, raise questions about how society views people with disabilities. There is concern that NIPT could lead to higher uptake and the potential routinisation of screening, which may exacerbate difficulties that people with disabilities and their families already face, such as stigmatisation, lack of advocacy, and reluctance to provide places for children with Down Syndrome in mainstream schools. If earlier, easier and safer testing is available and a woman chooses to continue with an affected pregnancy or not have the test at all, there may be a perception that any problems she and her family encounter down the line are their fault and that society should not take any responsibility”*.³¹

Research with parents of people with Down syndrome has found that they have concerns around the implementation of NIPS including issues around provision of information both pre- and post-testing as well as the potential implications in terms of the social stigma associated with having a child with Down syndrome and the availability of early intervention and other supports. Down syndrome Australia has received anecdotal reports of families being asked by people in the community “did you know when you were pregnant?” and feeling that they are being judged if they decided to continue with a pregnancy after receiving a screening result indicating a higher chance of having a child with Down syndrome.

As the use of NIPS becomes more prevalent it is going to be important to monitor and address the impact on the community understanding of Down syndrome and the potential stigma associated with having a child with Down syndrome.

²⁹ O’Leary, P., Maxwell, S., Murch, A. and Hendrie, D. (2013), Prenatal screening for Down syndrome in Australia: Costs and benefits of current and novel screening strategies. *Aust N Z J Obstet Gynaecol*, 53: 425–433. doi:10.1111/ajo.12136

³⁰ <http://unesdoc.unesco.org/images/0023/002332/233258E.pdf>

³¹ Nuffield Council on Bioethics (2016) Report on Roundtable Meeting. Non-Invasive Prenatal Testing.

Conclusion

There are currently a range of issues around informed consent and adequate and appropriate pre- and post-screening counselling which means that it would not be in the public interest to list NIPS on the MBS. In fact, implementing a national screening program without the appropriate supports and information is clearly unethical. It is essential that MSAC give serious weight to concerns being raised by one of the major national consumer groups which will be affected by implementation of this screening approach.

The Government has a responsibility to undertake further work to improve the current prenatal screening program before adding an additional costly test that is likely to have even greater issues around consent and information. Down Syndrome Australia acknowledges the potential future benefit of the NIPS in reducing the need for invasive testing for some women but further work needs to be done particularly in the provision of information and support before it can be implemented in an appropriate way that will lead to good outcomes for women undergoing screening.