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| **National Screening Advisory Committee (NSAC)**  **National Screening Unit (NSU)** | | |
| **Minutes Wednesday 6 July 2016** | | |
| Venue | Ministry of Health (MOH), Freyberg Building, Aitken St, Wellington | |
| Start time | 1000hrs | |
| NSAC members  present | Professor Ross Lawrenson (Chair)  Dr Jane O’Hallahan (Deputy Chair)  Professor Jackie Cumming  Dr Joanne Dixon  John Forman  Dr Bryn Jones  Astrid Koornneef  Professor John Potter  Dr Deborah Rowe  Professor Diana Sarfati  Dr Andrew Simpson  Dr Pat Tuohy | |
| Other attendees | **NSU: All items**  Anne McNicholas  Dr Bronwyn Rendle  **Item 6: Primary HPV screening**  Helen Colebrook, *Programme Manager, National Cervical Screening Programme*  Dr Gary Fentiman*, Clinical Leader,*  **Item 7: Rheumatic heart disease**  Dr Craig Thornley, Medical Officer of Health, Regional Public Health | **Item 9: Non-invasive prenatal testing (NIPT)**  Dianne Callinicos, *Programme Manager, Antenatal & Newborn Screening*  Sian Burgess, *Programme Leader Antenatal Screening*  Dr Gary Jackson, *Ernst & Young* |
| Apologies | Professor John McMillan  Dr Carol Atmore | |

| **Item** | **Subject and summary** |
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| **1.** | **Welcome, apologies and introductions**  Ross Lawrenson welcomed the NSAC members, noting that Professor John Potter is attending for the first time. |
| **2.** | **Declaration of conflicts of interest (COI)**  John Potter advised he had recently received HRC funding to study HPV self-sampling in Maori and Pacific women. The Chair advised this research brought insight into an area rather than acting as a conflict of interest.  COI register tabled with no additions. |
| **3.** | **Conduct of meetings and terms of reference**  In committee discussion. |
| **4.** | **Minutes of 16 March 2016**  Confirmed as a true and accurate record. Moved by Deb Rowe. Seconded by Di Sarfati. |
| **5.** | **Actions from previous meetings**  NSAC considered non-invasive prenatal testing (NIPT) at its March 2016 meeting and discussed whether NSAC should review the NHC screening criteria in light of increased genetic screening. The NSU agreed to table the UK National Screening Committee screening criteria at the next meeting as these have recently been amended with some changes made to better account for genetic screening.  The UK Screening Criteria were tabled. Discussion included:   * regarding the UK’s 9th screening criteria “*where evidence relating to wider benefits of screening are taken into account, eg.those relating to family members…”*   + consideration needs to be given as to who is being screened – the mother or the foetus – when reviewing the acceptability/applicability of this criteria * regarding the UK’s 11th criteria “*There should be evidence from high quality randomised controlled trials that the screening programme is effective…. Where screening is aimed solely at providing information to allow the person being screened to make an “informed choice” (eg. Down’s syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk…”*    + It is not always possible to provide comprehensive evidence such as through a randomised control trial eg for rare diseases. The evidence may only become available through monitoring the performance of the screening programme.   + Many tests for genetic conditions do not measure risk directly as test results may be included and applied through an algorithm * it is important to consider value for money/cost effectiveness, however it should be balanced against the right to health and equity between disease groups * New Zealand’s current screening criteria do not address a cultural component or equitable access to screening * New Zealand’s screening criteria should be compared with those used within publicly funded health systems/screening programmes such as in Canada, Australia and the UK.   A review of the New Zealand criteria may be included in next year’s work plan. |

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| **6.** | **Cervical cancer screening in women aged 20-24 years**  At the 18 November 2015 meeting NSAC agreed that the NSU would undertake additional analyses to assist consideration of maintaining cytology screening in the 20-24 year age group for a transitional period when primary human papillomavirus (HPV) screening is introduced.  The NSU provided an analysis of the incidence of cervical cancer in New Zealand women aged 20 to 24 years undertaken by Drs Megan Smith and Karen Canfell from the New South Wales (NSW) Cancer Council, and also a NSU paper summarising the evidence about cervical screening in younger women, including an assessment of the harms and benefits of such screening.  The NSU believes the balance of evidence is in favour of not screening women aged 20-24 years**.** There is good evidence that screening women under the age of 25 is not effective and has the potential to cause more harm than good. In summary, the NSU provided evidence that:   * cervical cancer in young women is rare (in both HPV vaccinated and unvaccinated women) * screening women aged 20 to 24 years has had little or no impact on the number of cases of cervical cancer or deaths in this age group or up to age 30 internationally, and in New Zealand * investigating and treating common cervical abnormalities in young women, where the majority resolve without treatment, leads to substantial over-treatment with associated anxiety and trauma of treatment, and an increased risk of subsequent premature births * the falling prevalence of cervical abnormalities due to HPV vaccination is predicted to decrease the performance of cytology screening, reducing its sensitivity and positive predictive value so that a larger proportion of women who screen positive will prove to be false positives * HPV vaccination has already been shown internationally to reduce the prevalence of high grade cervical abnormalities in young women, even in countries with low HPV vaccine coverage * with NZ’s cohort of young women vaccinated since 2009 entering the screening programme, the balance of harms and benefit will move further away from screening women aged 20 to 24 years (in 2018, 11 and 12 year old girls vaccinated as part of the routine cohort in 2009 will reach 20 and 21 years of age).   Discussion included:   * the National Cervical Screening Programme’s clinical leaders have discussed the proposal widely with European and Australian colleagues and they are supportive of New Zealand’s approach * the UK is not revisiting its screen start age of 25 years and many European countries start screening at 30 years of age * all evidence points to screening not helping the 20-24 year age group, with the harms outweighing the benefits. For example, it was noted that a UK research paper reported that a high number (300-900) of women aged 20-24 years are treated for cervical intraepithelial neoplasia, with associated complications, to prevent one case of cancer * a work programme over the next 18 months will identify safeguards to help ensure women are engaged in screening at age 25 years * the clinical guidelines will include provision to screen 20-24 year olds on a case-by-case basis where there is potential early exposure to HPV eg, sexual abuse or early consensual sex * high uptake of the 9-valent vaccine (proposed for introduction in New Zealand in 2017) is critical to further cervical cancer protection, with combined messaging/promotion by the NSU and the Ministry’s immunisation programme expected * the NSW Cancer Council analysis indicates that screening has had no effect on cancer incidence in Māori and non-Māori women aged 20-24 years * the National Cervical Screening Programme HPV Technical Reference Group have reviewed the NSW Cancer Council analysis and the NSU paper summarising the evidence about cervical screening in younger women. They believe that the evidence is robust and are confident in the recommendation to stop cytology screening women aged 20-24 years * the NSU’s Māori Monitoring and Equity Group agrees in principle to the recommendation to stop screening women aged 20-24 years. However, they have requested clarification around aspects of the NSW Cancer Council analysis so that they have confidence the authors have considered the complexity of ethnicity related data issues, such as changes in ethnicity coding over time * NSAC endorsed the recommendations proposed by the NSU, noting the expectation that issues raised by the Māori Monitoring and Equity Group regarding the complexity of ethnicity data will be clarified. |

**NSAC endorsements**

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| 1. | Noted | The analysis of trends in cervical cancer in New Zealand since the inception of the National Cervical Screening Programme shows no reduction in cervical cancer incidence in Māori and non-Māori women aged 20 to 24 years. |
| 2. | Noted | Evidence indicates that the harms of screening women aged 20 to 24 years for cervical cancer outweighs the benefits. |
| 3. | Noted | Improvements in cervical cancer prevention and control in women aged 20 to 24 years can be best achieved by improving HPV vaccination uptake and the prompt investigation of women with symptoms. |
| 4. | Agreed | The National Cervical Screening Programme will cease cervical screening in women aged 20 to 24 years when primary HPV screening is introduced. |

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| **7.** | **Rheumatic Heart Disease (RHD)**  NSAC had previously considered RHD screening in 2013. At that time, the committee reviewed the 2011 New Zealand Guideline Group’s Research Report and concluded there was insufficient evidence to support echocardiography (echo) screening.  In May 2016, Capital Coast District Health Board (CCDHB) held a workshop to consider the introduction of RHD screening using echo. Regional Public Health provided a briefing paper to CCDHB on RHD screening. Drs Jane O’Hallahan and Craig Thornley attended the CCDHB workshop and provided a verbal update to NSAC.  The CCDHB briefing paper was provided to NSAC. The paper considers the practical implications of implementing a RHD screening programme targeting year 7 and 8 students in low decile schools. It’s conclusions included:   * the accuracy of portable echo and protocols are not clear within the literature, making it difficult to determine how many screening participants will be diagnosed incorrectly * there is uncertainty about the applicability of diagnostic criteria for RHD to the screening context; and that echo screening will also inadvertently screen for many non-RHD cardiac abnormalities, the impact of which has yet to be determined * there is no clear evidence that preventive antibiotic treatment given to asymptomatic patients with screen-detected RHD, who may not recall an episode of acute rheumatic fever, offers benefit, hence the potential benefit from echo screening cannot be calculated * that potential harms may include allergic reactions to preventive penicillin treatment, psychological harms, and self-imposed lifestyle restrictions that might follow the unexpected diagnosis of chronic heart disease * the requirement for quality monitoring so that it is possible to evaluate programme effectiveness, ensure benefits are maximised and risks mitigated * compared to current practice, all echo screening scenarios are considerably more costly   Discussion included:   * acknowledgment that clinicians clearly want to help prevent RHD, however a consideration of the harms as well as the benefits of echo screening was important, including other effective interventions * that while NZ research is currently being undertaken with the intention of reducing areas of uncertainty, it is thought unlikely it will provide sufficient information to answer a number of major questions related to the assessment of harms and benefits. It was noted there are issues related to the study design of current research initiatives, for example, much of the data is descriptive, there are low numbers of children in the studies and the data appears to be of variable quality * it is difficult for research studies to provide definitive findings regarding the harms of echo screening from over-diagnosis (disease being detected that would not benefit from screening) or false positives. However, a recent overseas paper indicates there are adverse changes in behaviour and uptake of physical activity for around a third of children following a positive screening result. There is also recent overseas evidence that screen detected RHD is likely to remain stable or resolve (not withstanding treatment) * the greatest gain is seen through primary prevention of RHD with the identification and treatment of group A streptococcus infections, and preventing serial cases of rheumatic fever * a recent substantial decrease in RHD incidence is evident in New Zealand, likely associated the introduction of sore throat screening for Group A streptococcus in a number of high risk populations. * realistic dollar costs of a screening programme need to be factored into considerations, including health promotion activities supporting informed consent, clinicians’ time, ongoing surveillance of screen detected cases, and comprehensive quality assurance and fail safe procedures .   **Conclusion**  NSAC acknowledged that the evidence base for echo screening is incomplete. However they agreed that based on the current evidence the harms of echo screening for RHD appear to outweigh the benefits. NSAC believes that resources would be better directed to primary prevention through identifying and treating group A streptococcus throat infections. |
| **8.** | **National Bowel Screening Programme Update**  The Bowel Screening Programme provided an update on progress towards implementation of a national programme, with the Budget 2014 providing $39.3 million over four years to begin implementation.   * The programme will be progressively rolled out across the country beginning in mid-2017, with all DHBs expected to have started screening by the end of 2019. * Hutt Valley and Wairarapa DHBs will begin screening the eligible 60 to 74 year age group from mid-2017. The age range differs to the Waitemata pilot where the 50 to 74 year age group were included. In the pilot more than 80 percent of cancers were detected in people aged 60 to 74 years. * There will be equity planning at a national, regional and local level.   The Bowel Screening Programme noted NSAC’s previous recommendation that they consider forwarding the iFOB haemoglobin level to GPs (rather than reporting the result as screen positive or negative). They advise that:   * NSAC’s suggested approach is a departure from standard practice internationally for iFOB testing in a population screening programme * they will seek the views of the Bowel Screening Advisory Group and their international advisers, Professor Stephen Halloran (Professor Emeritus, Clinical Biochemistry, at the University of Surrey) who has an active role in supporting colorectal cancer screening activities worldwide; and Professor Ernst Kuipers (Professor of Medicine and CEO of Erasmus MC University Medical Centre, Rotterdam).   NSAC discussed the concerns raised at their 18 November 2016 meeting, noting in particular the risks of:   * GPs and patients ignoring symptoms where the screening indicates a negative test, whereas using the pilot threshold, a positive result would have been reported * using a higher threshold than the pilot could be regarded as being akin to increasing the screening starting age compared with the pilot, which also results in fewer cases being detected * these approaches place a continued reliance on GPs applying clinical acumen to detect cancer in those with a negative screen because of the higher threshold; and those aged 50 to 60 years who are not eligible for screening. * the cut off used in the Waitemata pilot was intentionally set low to give quantitative data to inform consideration of threshold options, so the issue is one of communication, with perception important if altering the cut off means actionable information is potentially withheld * public statements are not clear as to what threshold is being used * the issue relates to understanding risk eg, high, intermediate or low risk with the option perhaps of an intermediate risk signalling recall at 12 months (not 24 months) if there are no clinical signs ie. having a clear pathway to follow * overseas programmes do not look at or report results just below their chosen thresholds * the importance of involving patient in decision making and their right to full information, acknowledging this creates issues with different pathways being followed eg private uptake of colonoscopy for lower risk results * the importance of explicitly addressing inequity, given it is likely to increase with screening.   **Conclusion**  NSAC thanked the Bowel Screening Programme for their report. NSAC noted its interest in the programme’s governance around equity and looked forward to receiving further feedback regarding decisions around setting the screening threshold. |
| **9.** | **Non invasive prenatal testing (NIPT)**  At the March 2016 meeting, NSAC considered current antenatal screening and options for inclusion of NIPT as a screening test. The NSU proposed further policy development and modelling of various pathways and thresholds for offering NIPT as a contingent screen.  Ernst Young has now completed additional economic evaluations of potential cost effectiveness of introducing NIPT. Their report was provided for NSAC’s consideration and Dr Gary Jackson presented the reports key findings at the meeting.  The NSU outlined the rationale for its support for introducing NIPT as a contingent screen within the current screening pathway, including that:   * invasive diagnostic testing with the associated risk of miscarriage would reduce, with modelling indicating a reduction from approximately 1,100 to between 538 and 635 procedures, depending on the screening risk threshold * more reliable information about the pregnancy will be provided to women and the number of false negative cases would reduce * compared to the current combined screening an additional 13 to 22 more pregnancies with Down syndrome (T21), Edwards syndrome (T18) or Patou syndrome (T13) are likely to be identified annually, depending on the screen risk threshold * the addition of NIPT to the antenatal screening pathway as a contingent screen could improve cost-effectiveness due the substantial decrease in the number of diagnostic amniocentesis tests, while detecting more cases of trisomy.     The NSU does not support the introduction of NIPT as a universal screen at this stage with the rational including that:   * universal use is not sufficiently proven internationally, with no country currently providing universal NIPT screening * there are unresolved concerns regarding test failures (especially in women with a higher body mass) and implementation issues related to specimen transportation and laboratory capacity * test costs are currently too high.   The NSU proposes offering NIPT as a contingent screen for women with an increased risk of trisomy identified through the current combined screening. NIPT would be offered following a risk result set at one of two cut off levels, the current threshold of 1:300 or a lower threshold of 1:1000, noting that based on the results of the cost evaluation the 1:1000 threshold appears the preferred option.  The NSU plans to undertake public consultation on offering NIPT as a contingent screen. The consultation will be over a six week period between August and October 2016. Participants will be invited to comment on any aspect of the proposal including its likely impact on workforce, service accessibility, training and education requirements, as well as cultural and/or ethical considerations. Consultation will commence subject to Ministerial approval.  The NSU anticipates providing the consultation findings and final recommendations for NSAC’s consideration at the November 2016 meeting.  Discussion included:   * the extent of concern regarding blood samples being tested offshore, with experience indicating objections are rarely raised as long as a robust consent process is in place, with the option to destroy or repatriate a sample offered * concerns around data sovereignty for indigenous samples that go off shore * the risk of women regarding NIPT as a diagnostic test and choosing to terminate a pregnancy without confirming a positive result through amniocentesis * New Zealand uptake of screening is low by international standards, and there is the potential for NIPT to reduce inequities in access * the NSU is establishing a workstream to consider equitable access to screening and diagnostic tests, and the potential impact of NIPT on screening uptake * understanding of and consent to NIPT screening will need to be robust (especially given potential of microarray testing for a large number of conditions) * increased access of midwifery and obstetric workforce to genetic services support will likely be required * anticipating workforce / lead maternity carer educational requirements including, for example, understanding the importance of the fetal fraction being included in laboratory reports * technology improvements will likely see a wider array of conditions available through NIPT, however this move is at least 5 years away and would require agreement on which conditions were included within a public funded screening programme * the name “Antenatal screening for Down syndrome and other conditions” is regarded by some as unhelpful - with a perception that more conditions are being tested for than actually occurs   + it was suggested that no condition should be included in the title   + the title “early pregnancy screening” was suggested. Such a change would provide future proofing when screening conditions are added or removed * the current cost of NIPT tests puts universal testing out of reach, however costs are expected to fall in the long term * the introduction of contingent testing is regarded as a step towards universal NIPT, allowing a managed introduction while volumes are lower * beyond the 1:1000 risk threshold, the number of additional trisomy cases detected isn’t as great as you might expect as it is a much lower risk group * the introduction of NIPT also creates the opportunity to move towards rationalisation of ultrasound provision within a broader fetal anomaly programme. |

# NSAC endorsements

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| 1. | Agreed | That the NSU will undertake consultation on the proposal to add NIPT to the current antenatal screening pathway as a contingent screen after a women’s combined screening indicates an increased risk for Down syndrome, trisomy 18, and trisomy 13. |
| 2. | Noted | That the NSU will identify the preferred risk threshold (1:300 or 1:1,000) following further consideration of cost-effectiveness analyses, feedback from public consultation, and advice from the Technical Working Group. |
| 3. | Noted | That the NSU will bring a final recommendation to NSAC in November 2016 identifying the preferred risk threshold. |

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| **10.** | **Terms of Reference – Annual Review**  The NSAC terms of reference include the requirement that they be reviewed annually. NSAC reviewed and agreed amended terms of reference for the next 12 month period. |
| **11.** | **Other business**  Topics NSAC will likely consider at the November 2016 meeting:   * NIPT: update and recommendations regarding implementation following public consultation * Abdominal Aortic Aneurysm (AAA) screening: review of report originally prepared for the National Health Committee * Breast cancer age extension.   Next meeting date: Wed 9 November 2016 |
|  | The meeting closed at 1530hrs |