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| **National Screening Advisory Committee (NSAC)** **National Screening Unit (NSU)** |
| **Minutes Wednesday 26 July 2017**  |
| Venue | Ministry of Health, 133 Molesworth St, Wellington  |
| Start time | 1000hrs |
| NSAC members present  | Dr Joanne Dixon (Chair)Dr Jane O’Hallahan (Deputy Chair) Dr Karen Bartholomew Professor Jackie Cumming Professor Mark Elwood John Forman Astrid KoornneefProfessor John McMillan Dr Deborah Rowe Dr Caroline Shaw Dr Pat Tuohy (10.30-12.30) |
| Other attendees | **NSU** Anne McNicholas Dr Bronwyn Rendle Dr Kerry Sexton  | **Item 7. Critical Congenital Heart Disease screening with pulse oximetry** Dr Elza Cloete*, Liggins Institute* Professor Frank Bloomfield, *Liggins Institute*   |
| Apologies | Dr Carol AtmoreDr Caroline McElnayProfessor John Potter |

| **Item** | **Subject and summary** |
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| **1.** | **Welcome, apologies and introductions** Jo Dixon welcomed new NSAC members Drs Caroline Shaw and Karen Bartholomew.  |
| **2.** | **Declaration of conflicts of interest (COI)**COI register tabled.  |
| **3.** | **Minutes of 22 March 2017** Amended and confirmed as a true and accurate record.  |
| **4.** | **Correspondence tabled**NSAC Chair’s 27 April 2017 letter to the Director of National Bowel Screening Programme regarding considerations at NSAC’s March 2017 meeting.  |
| **5.** | **Annual review of NSAC terms of Reference** The updated terms of reference were tabled. The Ministry of Health’s Director of Public Health position holder has been added as a committee member. No other substantive changes were made.  |
| **6.** | **International Cancer Screening Conference Bethesda Washington DC**Jane O’Hallahan reported back on this conference. * A key aim of this annual conference/network meeting is to support low resource countries implement evidence based screening programmes in a planned and systematic manner. The conference considerations included:
	+ use of screening criteria when considering introduction of screening programmes, with moves towards using fewer criteria alongside a requirement to better quantify where health benefits are substantial, harms limited and cost-benefit ratios reasonable.
	+ improvements in information for the public with more use of visual aids/pictograms to help with health literacy around screening
	+ moves towards increased risk stratification and individually tailored screening.

*Discussion included:** concerns regarding move to use of genomics in screening while many health professionals have limited understanding of this area
* a proposal that during the year NSAC should workshop considerations around genomics and changes in screening, including for example epi-genetic markers for tailored screening, more targeted screening programmes using predictive data and increased risk stratification
* over-diagnosis remains an important and complex issue in screening and consideration of this area in a future workshop would also be useful.
* advantages of visual aids as these can be used to more clearly articulate downsides of screening
* importance of differentiating symptomatic/diagnostic testing versus asymptomatic/screening tests.

**Actions** * NSU to maintain watch of international reviews of screening criteria and bring information back for NSAC’s consideration, noting UK review of their screening criteria recently completed.
* Karen Bartholomew will share slides she has on screening criteria.
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| **7.**  | **Critical Congenital Heart Disease (CCHD) and pulse oximetry screening (POS)**In July 2015 NSAC considered a preliminary assessment of POS of newborns for CCHD. Dr Elza Cloete attended the 2015 meeting and outlined plans for three year pilot/feasability study in the Auckland region. NSAC was supportive of POS for CCHD but was undecided as to which implementation approach would work best, with options including:* a nationally led screening programme, with all aspects of the screening pathway implemented and monitored by the NSU (as proposed by the Paediatric and Congenital Cardiac Service at Starship Children’s Hospital)
* a nationally led quality improvement programme with for example the development of national guidelines alongside DHB led implementation and monitoring
* sector led implementation with screening framed as being part of improvements in routine care, with a focus also on raising the quality of foetal anomaly screening by incorporating improvements in the 18-20 week antenatal ultrasound scan and the newborn clinical examination

**Dr Elza Cloete and Professor Frank Bloomfield (Liggins Institute) attended the 26 July 2017 meeting to present preliminary results from the first 12 months from their POS feasibility study.** The study will provide information on test accuracy (particularly the burden of investigating false positives) the impact on workload, resource implications, acceptability and equity. The study is underway at: * Auckland District Health Board (ADHB): Auckland City Hospital and Birthcare
* Lakes DHB: Rotorua and Taupo Hospitals, and Turangi Maternity Unit
* Counties Manukau DHB: Pukekohe, Papakura and Botany Maternity Units (not Middlemore hospital).

Approximately 5,400 newborns were screened at ADHB over the initial 12 month, with 18 respiratory related cases (false positives) and 1 CCHD case detected. Data collection will conclude in April 2018 with future work to include assessing acceptability of the test with consumers and midwives and cost-effective analyses. *Discussion included:* * the detection of newborns with respiratory related conditions can be seen as an additional benefit of POS for CCHD. Or, POS could be viewed more broadly as a screen for hypoxia, with the respiratory cases not categorised as false positives. However, the largest magnitude of benefit lies with early detection of CCHD, and it can be viewed as problematic applying screening criteria if there is not a single clear condition or outcome.
* it is difficult internationally to demonstrate an improvement in long term survival outcomes when the condition is rare but numbers needed to confidently show benefit is high. Demonstrating morbidity reduction is arguably easier. Scandinavian POS programmes are now in a position to assess these areas as they have been operating for around 10 years, with Sweden understood to be currently looking at longer term outcomes.
* feedback from health professionals and consumers involved in the pilot has been generally positive, with surveys of participants indicating that the benefits outweigh the burden of time and resources of screening. Midwives at birthing centres viewed POS as a useful safety net in addition to the newborn physical examination. Survey results also indicated some more information and awareness raising is required.
* the pilot is recording how long it takes to screen each baby and any additional services required to investigate a result so it will have good quality data to assess the impact of findings, especially false positives which is the area of most concern.
* there are plans to assess impact of late vs early diagnoses through a review of nine years of NZ paediatric cardiac data (approximately 1,300 patients and includes 40,000 outpatient events).
* POS acts as an adjunct to the 18-20 week antenatal ultrasound scan and the newborn physical examination but could be regarded as the “gatekeeper” to better ensure more babies with CCHD are detected given variable provision of the 18-20 week ultrasound scan.
* quality improvements in maternity ultrasounds are likely to improve the antenatal detection of CCHD (with the NSU at the preliminary stages of assessing how it can contribute to this area given its experience in quality improvement work around the 12 week antenatal scan).
* improvements in ultrasounds are dominated by the largest urban centres, with equity related issues for smaller DHBs and rural areas where there is less access to such ultrasound services. Universal POS would be expected to improve equity in early detection of CCHD in these areas.
* inherent difficulties of assessing rare conditions against established screening criteria and that a broad perspective is required where full information is not likely to become available. Such information may only become available through programme implementation *eg.,* impact of POS on improving equity.
* Wellington and Dunedin hospitals are understood to have adopted POS but the presenters were not aware of the level uptake, and to date there have been no reports of findings in the New Zealand literature.
* The Auckland research team have recently been awarded HRC funding which will go towards aspects of the pilot including focus groups, supporting DHB communications, economic analyses and providing POS equipment for midwives providing homebirth services.

The UK National Screening Committee (NSC) considerations re POS were also noted particularly in relation to the resources required to investigate what turn out to be false positives. * In 2014 the UK NSC found there was value in adding POS as an adjunct to the existing screening programmes for CHD (Newborn and Infant Physical Examination and Antenatal Fetal Anomaly Ultrasound Screening) and supported a POS pilot which was completed in December 2015.
* In July 2016 the NSC considered findings from their POS pilot but did not come to a decision as to whether screening did more harm than good. There were concerns that staff would be diverted to look after screen positive babies, the majority of whom would not have CCHD.
* The UK NSC decision is pending completion of further work to better understand these issues.

**Jackie Cumming gave a presentation and led a discussion on the use of economic evaluations in screening including a summary of findings from international economic evaluations of POS.** *Discussion included:* * high sensitivity (few false negatives/fewer cases missed) and high specificity (few false positives) of the screening tests are important considerations in the cost–effectiveness of screening programmes as well as defining what is being screened for
* economic evaluations are not the only decision making criteria with additional factors including consideration of equity (gender, ethnicity, alternative options to treat conditions); and that not all benefits are easily measured eg value of information to parents will be missing from POS cost/effectiveness studies
* cost-effectiveness is not the same as affordability and the total budget spend required is also important to assess as are the availability of trained staff and key infrastructure
* POS international studies have tended to look at the additional costs related to the timely detection of a CCHD case
* NZ needs its own POS economic evaluations to take into account the local context, service delivery models, as well as costs and likely benefits, especially give the variation in POS costs and benefits shown in international studies. A key area is the need to know the costs of additional services that may be offered if POS was implemented as a screening programme.

**Conclusion** NSAC felt the POS feasibility study results to date were very encouraging. It was noted that:* an economic analysis within the NZ context is required
* the wider pathway of the 18-20 week antenatal ultrasound screen, newborn physical examination and POS could potentially be brought together under the NSU, particularly as an overall quality improvement initiative
* NSU programmes systematically collect comprehensive data so are more able to more readily undertake formal analyses and to identify and address issues of equity
* in the meantime efforts should be made to encourage the sector to implement POS as part of routine clinical care.

**Actions** * NSU to contact Wellington and Dunedin hospitals to obtain information about how their POS programme operates.
* NSU to consider its potential role in supporting quality improvements related to the 18-20 week ultrasound screen.
* NSU to further consider options for a national POS screening programme on completion of the current pilot and an economic evaluation.
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| **8.**  | **Duty of Candour** **Professor John McMillan and Dr Jane O’Hallahan led discussion on the concept and practical application of Duty of Candour, including consideration of the following areas.** * Inherent to screening programmes is the expectation that false negatives and false positives will occur. However programmes need to differentiate false positives or negatives that have occurred because of limitations of the screening from false negatives or positives that have occurred because something has gone wrong.
* Public Health England’s 2016 guidance document on how screening programmes should apply duty of candour and disclose audit results. This guidance was prepared in response to the UK duty of candour legislation which set out requirements that providers must follow when things go wrong. The legislation extended duty of candour requirements to institutions (previously it was confined to clinicians). The guidance document advises organisations how to:
	+ ensure they are open and transparent with users of screening programmes
	+ ensure compliance with duty of candour regulations in these circumstances
	+ disclose results of audits undertaken following a diagnosis for a screened condition (positive) after a screening result that was reported as normal (negative).
* New Zealand’s Health and Disability (HDC) Code of Rights has been taken to imply providers have a duty of candour. NSAC noted a 2007 HDC decision that stated “hospital management and clinicians owe families a duty of candour...to openly discuss and honestly disclose what has happened and to apologise for any shortcomings in care”.
* The NSU is committed to open disclosure of missed cases (cases that could or should have been picked up in a screen) to all individuals who participate in its programmes.
* Freedom from bias, fairness, openness are crucial for screening programmes so they nurture trust and thereby equity; nurture understanding and thereby benefits (which makes screening more ethical because of harms); avoid the loss of trust, and thereby avoid harms; and because it is ethically important to be open and honest.

**Actions** NSU is looking to develop policies for each of its screening programmes in relation to duty of candour and will consult with HDC, ACC and relevant health professional colleges during this process.  |
| **9.**  | **NSU updates**Brief updates were provided on the: * Antenatal Screening for Down syndrome and Other Conditions Quality Improvement Programme and its ongoing consideration of non-invasive prenatal testing (NIPT), including assessment of inequity in uptake of current screening across ethnic groups; and the potential to bring the routine 18-20 week antenatal scan under NSU oversight so as to support quality improvements (similar to the UK approach).
	+ NSAC believes that the name of this antenatal screening should be changed, especially given the increasing range of conditions that can be screened for and that will likely come under the NSU oversight. Similar views were expressed at a previous NSAC meeting (16 March 2016).
* Neonatal Hearing Programme and its successful completion of a desktop audit.
* Newborn Metabolic Screening Programme and its process for assessing conditions that do not meet accepted screening criteria. The formal process for the removal of a screening condition is detailed in the programme’s Quality and Monitoring Framework.
* Breastscreen Aotearoa and its ongoing assessment of the impact on the programme if the eligible age range was extended to 74 years.
* National Cervical Screening Programme and ongoing preparation for introduction of primary HPV screening, including the recent completion of the Clinical Guidelines.
* National Bowel Screening Programme and progress implementing its rollout across DHBs.

**Actions** The NSU is to progress consideration of options for changing the name of “Antenatal screening for Down syndrome and Other Conditions”.  |
| **10.**  | **New Zealand Health Strategy and National Screening for Healthier Futures 2017-2022**Astrid Koornneef provided an update on progress with development of the National Screening for Healthier Futures 2017-2022 document whichis now in its final version. NSAC members had provided feedback on the document at their 22 March 2017 meeting.* The plan aligns with the New Zealand Health Strategy’s five central themes: people-powered, closer to home, value and high performance, one team and smart system.
* The underlying guiding principles include acknowledging the special relationship between Māori and the Crown under Te Tiriti o Waitangi, and the need for equitable access and active partnership and collaboration.
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| **11.**  | **NSAC 2017/18 work programme** The priorities for the NSAC work programme were reviewed. Within the next 12 months further consideration will be likely be given to of Abdominal Aortic Aneurysm (AAA) screening, non- invasive prenatal testing (NIPT), and aspects of wider maternal /foetal screening such as the potential to develop a quality improvement programme related to the 18-20 week antenatal ultrasound screen as well as pulse oximetry screening for CCHD.  |
| **12.** | **Other business** Next NSAC meeting date is Wednesday 15 Nov 2017. The meeting closed at 1500hrs. |