National Screening Unit

Summary: Submissions from consultation on the Newborn Metabolic Screening Programme Policy Framework, February to March 2011

The Ministry of Health consulted on new policy requirements for the Newborn Metabolic Screening Programme (NMSP) during February and March 2011. Consultation time was extended for four key stakeholders due to the February earthquake in Christchurch, namely the Chief Coroner, Police, College of Midwives and Auckland District Health Board – LabPLUS.

Previous consultation stages were undertaken during 2007 and 2008, with ongoing consideration of feedback and expert advice from the NMSP Advisory Group to inform policy development.

29 submissions/responses were received in total. Appendix 1 lists the organisations and departments who were consulted on the draft Policy Framework in 2011, which was sent out as two documents:

- NMSP Policy documentation (general)
- NMSP Policy documentation (storage and use).

The key issues raised in submissions were around the:

- need for informed consent for both screening and storage of blood spot cards
- permanent retention of blood spot cards
- protection of privacy
- secondary uses of blood spot cards
- Programme reporting.

NMSP Policy documentation (general)

There were some minor wording, clarification and format changes recommended in feedback on the general NMSP Policy Framework. More significant recommendations and detailed comments were received on the Storage and Use of Blood Spot Samples document. Positive feedback included:

- *Very thorough and reasonable document and I appreciate the amount of work that would have gone into its creation.*
- *The documents provide clearly outlined processes for the management and ongoing evaluation of the programme, good protection for citizens and well defined provisions for other parties to access information should they require it.*
- *Overall, this draft framework does a good job of clarifying the processes around this important programme. For instance we are pleased to see a clear distinction between obtaining consent to participate in the programme on the one hand and consent to retain the cards in line with the stated primary and secondary purposes on the other*.

A number of organisations thanked the National Screening Unit (NSU) for the opportunity to review the Policy Framework and provided no comment. Detailed/specific feedback was received from the:

- Office of the Privacy Commissioner
- Office of the Health and Disability Commissioner
- Chief Coroner
- New Zealand Police
- New Zealand College of Midwives
- Women's Health Action Trust
- Federation of Women's Health Councils Aotearoa
- University of Auckland
- Royal New Zealand College of General Practitioners.

NMSP Policy documentation (storage and use)

Themes from submissions on the storage and uses of residual blood spot samples (cards) are summarised below.

- A number of positive suggestions were received to improve and clarify wording around governance and operational requirements. Submissions reinforced the need for a robust and transparent process for changes to possible future uses of residual blood spot cards and changes to the Policy Framework.
- Concern regarding a lack of public awareness/knowledge that blood spot cards have been stored and are available for secondary uses. This was supported by recommendations for additional information to support meaningful informed consent to screening, card storage and secondary use, along with the need to monitor and evaluate consent processes.
- The need for additional protections for any potential information that may be gained from the blood spot samples.
- Recognition that while there may be societal benefits from secondary uses, such as the potential value of blood spot cards for identification purposes in case of natural disasters, these must not undermine the primary purpose of the NMSP.
- A recommendation for an additional consumer member on the NMSP Advisory Group, especially when considering research applications.
- The need for public reporting on secondary uses of blood spot cards with strong support for written consent for research using residual blood spot samples collected prior to June 2011.
- A recommendation for processes to ensure requests for additional tests are appropriate and costs are managed.

All submissions have been carefully considered. Many points and suggested changes have been incorporated into the final Policy Framework and Programme governance arrangements. Formal responses have been provided to those organisations and departments who provided specific /detailed feedback and suggestions.

Appendix 1: Organisations/individuals consulted

Archives New Zealand
Chief Coroner
Clinical Director LabPLUS, Auckland DHB
Director of Public Health
District Health Board Maternity Managers
Environmental Science and Research
Federation of Womens Health Councils
Health and Disability Commissioner
Health Star Pacific
International Accreditation New Zealand
Law Commission
Manager LabPLUS, Auckland DHB
Maternity Services Consumer Council
Ministry of Consumer Affairs
Ministry of Health - Maori Health
Ministry of Health - National Screening Unit Clinical Governance Group
Ministry of Health - Pacific Policy
Ministry of Health - Strategy and System Performance (Policy Teams)
Ministry of Health - Maternity Services
Ministry of Social Development
National Ethics Advisory Committee
National Health Committee
New Zealand College of Midwives
New Zealand Midwifery Council
New Zealand Police
Newborn Metabolic Screening Programme Advisory Group (Governance Team)
Office of the Privacy Commissioner
University of Otago
Paediatric Society
Royal New Zealand College of General Practitioners
Royal New Zealand College of Obstetricians and Gynaecologists
Screening Educator LabPLUS, Auckland DHB
Treasury
University of Auckland
Women's Health Action