In Confidence

Office of the Minister of Health

Cabinet Social Policy Committee

The New Policy and Governance Arrangements for Newborn Metabolic Screening Programme Blood Spot Cards

Proposal

1. I propose that Cabinet notes the Ministry of Health's new policy and governance arrangements for Newborn Metabolic Screening Programme blood spot cards.

Executive Summary

2. In July 2010, the Cabinet Social Policy Committee (SOC) discussed the paper "Options for the Retention of Newborn Metabolic Screening Programme Blood Spot Cards" (SOC(10)73). In this meeting, SOC agreed to the permanent retention of blood spot cards and invited the Minister of Health to report back to them on the new policy and governance arrangements to support the permanent retention of blood spot cards in March 2011 (SOC Min(10)16/4). An extension for report back was agreed until May 2011, due to the adverse impact of the Christchurch Earthquake on key interested parties.

3. The new policy and governance arrangements to support the permanent retention of blood spot cards are within the Newborn Metabolic Screening Programme Policy Framework, which the Ministry of Health consulted on February – March 2011. Positive feedback was received on the comprehensive nature of the Programme documentation, which will help Newborn Metabolic Screening Programme policies and governance arrangements to be more transparent and widely known. The framework brings all Programme policies, governance and provider responsibilities together in one place for the first time in the Programme's history.

4. For the purpose of this SOC report back, the new policy and governance arrangements specific to the permanent retention of blood spot cards were consulted on separately. More than 20 submissions were received, and all were in general agreement with the proposed arrangements. In particular, the Office of the Health and Disability Commissioner, the Chief Coroner and New Zealand Police support the proposed arrangements. The Privacy Commissioner is also positive, however the Commissioner continues to advocate for the development of a Code under privacy law, to provide additional protections for the blood spot cards.

5. The new policy and governance arrangements to support the permanent retention of blood spot cards describe the:

- requirements for requesting and returning blood spot cards to parents/guardians and individuals
- governing provisions for storage and use of blood spot cards, including legislative/regulatory protections and guidance
- potential uses of stored blood spot cards, and
- requirements that must be met for any release of stored blood spot cards.

6. The two key changes to existing Programme policies and procedures are that:

- governance arrangements have been clearly documented, and the roles and responsibilities between the Ministry of Health, Newborn Metabolic Screening Programme operations and the Governance Team have been clarified
- a research applications pathway has been developed to clarify the requirements for requesting blood spot cards for research, and that written consent is required for population research on samples collected prior to the formal introduction of this policy, which is June 2011.
    - For cards collected prior to June 2011 individual written consent will always be required for cards to be released for research purposes.
    - For cards collected after June 2011, parents will be properly informed of the potential primary and secondary uses of the card (including possible future research) before consenting to long term storage of the card. Even if consent is given to long term storage of the card, individuals have the right to request the return of their cards at any time. Any proposal for research that will require release of cards collected after June 2011 must first be approved by an Ethics Committee and reviewed by the Governance Team.

Background to the Newborn Metabolic Screening Programme

7. The Newborn Metabolic Screening Programme was established in 1969, as a national programme to screen babies for certain metabolic disorders. Over time the range of disorders included in newborn metabolic screening has increased, and currently 28 disorders can be identified. The Programme has nearly 100% population coverage and approximately 45 babies each year are identified with one of the disorders screened for. Early detection and treatment of these disorders is important in reducing morbidity and mortality.

8. For newborn metabolic screening, a blood sample is collected from the baby's heel onto a blood spot card. The card is sent to the laboratory for testing, the results are provided to the Lead Maternity Carer to discuss with the family, and the residual blood spot sample (which is not used up by the screening process) is securely stored, or returned to families.

9. In 2005, responsibility for the Newborn Metabolic Screening Programme was transferred from a lead DHB model to a centralised national screening Programme managed by the Ministry of Health. Since this shift, the Ministry has comprehensively reviewed Programme operations, policies, governance and legislative protections. Improvements that have been made to the Programme include:

   - the introduction of new technology, to increase the capacity and scope of laboratory analysis
   - increased monitoring, audit and evaluation requirements, to enable public reporting about the Programme
   - the development and publication of practitioner guidelines, online learning, and disorder specific information, to support the provision of high quality screening services
   - new consumer resources and more accessible online information to support informed participation in the Newborn Metabolic Screening Programme.

Permanent Retention of Blood Spot Cards

10. One of the key Programme issues was the practice of permanent retention of blood spot cards. After screening is complete, blood spot cards have always been retained by the Programme in secure storage for quality assurance purposes. Internationally, there is no consensus on retention practices, however all programmes hold blood spot cards for a period of time after screening has been completed. Amongst stakeholders there will always be a spectrum of views on blood spot card retention.

11. Due to the differing views amongst stakeholders, and potential public interest, the review of permanent retention in New Zealand included online public consultation, consumer focus groups and stakeholder workshops, and expert advice from the Newborn Metabolic Screening Programme Advisory Group. To finalise this review process, endorsement of the policy of continued permanent retention was sought from Cabinet in 2010.

12. On 21 July 2010, the Cabinet Social Policy Committee (SOC) discussed the paper "Options for the Retention of Newborn Metabolic Screening Programme Blood Spot Cards" (SOC(10)73). In the paper it was presented that while there was overall stakeholder support for the permanent retention of blood spot cards, there were some differences in opinion about whether existing legislative mechanisms provide adequate protections. In particular the Privacy Commissioner advocated for additional legislative measures for the protection of genetic privacy.

13. On balance SOC agreed that the potential public benefits of permanent retention were significant and that the blood spot cards should continue to be retained. SOC agreed to the permanent retention of blood spot cards, with a strengthened policy framework, and improved Ministry of Health and Advisory Group governance arrangements. The Committee invited the Minister of Health to report back to them on the new policy and governance arrangements for blood spot cards, including protections and limitations, in March 2011 (SOC Min(10)16/4). An extension for report back was agreed until May 2011, due to the adverse impact of the Christchurch Earthquake on key interested parties, including the Chief Coroner, New Zealand Police, and the New Zealand College of Midwives.

Comment

14. The new policy and governance arrangements to support the permanent retention of blood spot cards are attached as Appendix A to this paper. The new arrangements are an integral part of the Newborn Metabolic Screening Programme Policy Framework. The framework brings all Programme policies, governance and provider responsibilities together in one place for the first time in the Programme's history. Positive feedback was received from stakeholders on the comprehensive nature of the documentation, which will help to make Newborn Metabolic Screening Programme policies and governance arrangements more transparent and widely known.

15. As the Newborn Metabolic Screening Programme Policy Framework is a new document, the key points of the new policy and governance arrangements to support the permanent retention of blood spot cards are summarised below.

Informed Consent for Newborn Metabolic Screening

16. Informed consent for newborn metabolic screening has always been required, however the policy documentation clearly defines the requirements for primary uses of blood spot samples which need to be discussed with the parents/guardians. These encompass:

    a. the initial screening test
    b. repeat confirmatory testing (including testing missed cases)
    c. investigation of initial screening test results that may have been a false positive or false negative
    d. quality assurance and audit of the programme
    e. assay improvement and validation of tests for disorders currently in the programme
    f. validation of assays for potential new disorders to be added to the newborn screening panel.

17. At the time of screening, parents/guardians consent to either return of the residual blood spot sample after testing is complete, or for it to be held in indefinite secure storage by the programme for potential secondary uses. Once in storage, parents/guardians or individuals can request return of the residual blood spot sample at any time.

Storage of Blood Spot Cards

18. Residual blood spot sample storage continues to be in a secured locked area with safeguards to prevent unauthorised use, disclosure, loss or other misuse. Access is:

- restricted to authorised personnel only
- restricted to the specific uses as outlined in the Policy Framework
- documented, reported and available for audit and laboratory accreditation assessments.

Governance Requirements for Laboratory Activities

19. Specific governance requirements have been put in place for those activities undertaken within the contracted laboratory, for instance regarding assay improvements and validation of assays for potential new disorders. An application must be made to the Newborn Metabolic Screening Programme Governance Team, prior to any authorisation by the Ministry of Health.

Secondary Uses of Stored Blood Spot Cards

20. Residual blood spot samples held in storage with consent currently have a number of authorised secondary uses, which are:

- those that benefit the individual and his/her family/whānau (for instance further blood testing not covered by the original consent)
- Forensic/Police investigations (governed by Memorandum of Understanding between the Ministry of Health and the New Zealand Police)
- Coroner investigations (governed by the Coroners Act 2006)
- Mortality review (governed by the New Zealand Public Health and Disability Act 2000)
- research (covered by Right 7(10) of the Code of Health and Disability Services Consumer Rights Regulation 1996)
- other requests, which may include requests for other testing, and come from third parties such as health providers, insurance companies or legal representatives.

21. All requests for secondary uses of residual blood spot samples have specific requirements that must be met, including written consent from the individual concerned, or those authorised to give consent on their behalf, a court order or legislative requirements.

Requests from the New Zealand Police

22. Requests from the New Zealand Police are required to be in accordance with the Memorandum of Understanding between the Ministry of Health and the New Zealand Police. The Memorandum was first developed in 2005, updated in 2009, and will continue to be consulted on and reviewed on a regular basis. The Memorandum is attached as Appendix B and is available online at www.nsu.govt.nz.

23. The purpose of the Memorandum is to:

- regulate requests from the Police to the Ministry for access to blood samples and other information relating to those samples, and
- clarify the circumstances in which such requests may be granted, with particular reference to the overarching interests of the individual concerned and the wider public interest in law enforcement and public safety.

24. The overriding principle enshrined in the Memorandum is that:

"The blood spot card and information associated with it is collected for health purposes only. Any use of the blood spot card for any non-health related purpose is exceptional. The Police should have recourse to the blood spot cards and associated Information only rarely, and as a last resort."

Requests for Research

25. Applications for residual blood spot samples to be used for research have strengthened requirements through a 'Research applications pathway', as detailed in Appendix A (page 20). Residual blood spots collected prior to June 2011 (the formal introduction of this policy) require written consent for research use for each individual blood spot from the person authorised to give consent.

26. For cards collected after June 2011, parents will be properly informed of the potential primary and secondary uses of the cards, including possible future research, before consenting to long term storage of the cards. Even if consent is given to long term storage of the card, individuals have right to request the return of the cards at any time.

27. Research proposals must also:

- have Ethics Committee approval prior to consideration by the Newborn Metabolic Screening Programme Governance Team and the Ministry of Health
- not use all of the residual blood from an individual blood spot sample.

28. It is acknowledged that the requirement for specific consent for samples taken prior to June 2011 will place limitations on large-scale population research. However, public consultation in 2007 highlighted that not all participants in newborn metabolic screening over the past 40 years are aware that their blood spot cards have been stored, and therefore may not have consented to research on their sample. While the release of identified cards for population research without further consent is permitted under right 7(10) of the Code of Health and Disability Services Consumers' Rights, most stakeholders consider that large-scale releases without consent would jeopardise public confidence and trust in the Programme. All stakeholders, except for some researchers, are comfortable with the requirement to seek consent before research is supported.

29. The results of a recent literature scan on the kinds of population research carried out on residual blood spot samples over the past 20 years indicate that this type of research is infrequent. Of the published studies:

- most are small in scope (between 10 and 800 samples) and use identified samples to examine disease prevalence or environmental toxin levels. In these studies, using identified samples is ethically essential in case a disease or high levels of toxin are identified, and require follow-up

- some examine the stability of various chemical components within the sample, which do not have a direct implication towards the health of the person the sample was collected from.

30. Since the Newborn Metabolic Screening Programme began in New Zealand, there have only been two research requests to access blood spot cards. One request was to carry out an HIV prevalence study on de-identified blood spot cards. This request was declined as it was believed that identified information should be used. If HIV was identified in any individuals as a result of the study, the people concerned should be informed, as HIV has serious consequences for their own health as well as for their families and the community. Around the time of this request, there was a medico-legal case in the United States about the ethical obligation to inform research participants of findings such as HIV infection.

31. The second research request was to search for links between Sudden Unexplained Death in Infancy and an inherited heart defect with a known genetic mutation. This request, which was based on using de-identified blood spot cards without further consent, was declined by an Ethics Committee as it was believed that families must be informed if a mutation was found. This research has since come under the auspice of the New Zealand Cot Death Association, which offers parents an opportunity to participate in research, with full informed consent, if their child has died unexpectedly.

Governance Arrangements: The Newborn Metabolic Screening Programme Governance Team

32. The Newborn Metabolic Screening Programme has always had an Advisory Group. The newly appointed Governance Team replaces the existing Advisory Group. In establishing the Governance Team, roles and responsibilities have been clarified between the Ministry of Health, Programme operations and the Governance Team.

33. The Newborn Metabolic Screening Programme Governance Team's primary function is to support the Ministry of Health to provide high quality and accessible screening for New Zealand babies and their families/whānau. The roles of the Governance Team include to:

- review, critique and interpret annual programme reports, and to make recommendations to the Ministry of Health on these reports
- make recommendations to the Ministry of Health on changes to screened disorders or the introduction of new technology
- make recommendations to the Ministry of Health on research proposals for blood spot cards
- provide advice on the strategic direction of the Newborn Metabolic Screening Programme
- provide advice from time to time on other areas of the Programme as agreed
- share responsibility for providing liaison back to members respective formal bodies and constituencies.

34. Members of the Governance Team are appointed by the National Screening Unit, Ministry of Health. Membership includes:

- International expert
- Midwife/Lead Maternity Carer (with endorsement from the New Zealand College of Midwives)
- Paediatrician
- Representative from the Commissioner for Children
- Legal advisor
- Newborn Metabolic Screening Programme representative(s)
- Maori advisor(s)
- Pacific advisor
- Public Health Physician
- Consumer advisor(s).

35. Any technical matters are reviewed by a smaller membership of the Governance Team. Recommendations are then made to the Ministry of Health.

Stakeholder Consultation on the New Policy and Governance Arrangements for the Permanent Retention of Blood Spot Cards

36. More than 20 submissions were received on the new policy and governance arrangements. In general, feedback was positive, and there was broad recognition that the documentation of the requirements that govern the storage and uses of blood spot samples is beneficial.

37. Specific feedback was received from the Office of the Privacy Commissioner, the Office of the Health and Disability Commissioner, the Chief Coroner, New Zealand Police and the New Zealand College of Midwives. Two consumer organisations, The Federation of Women's Health Councils Aotearoa and Women's Health Action Trust, also provided detailed feedback. The following paragraphs summarise the key points raised by these organisations.

38. The Office of the Privacy Commissioner provided a number of positive suggestions to improve the clarity of wording. The main concern of the Privacy Commissioner was stated as ensuring that any future changes in secondary uses for the collection are only introduced through a robust and transparent process. For this reason, the Privacy Commissioner continues to favour the development of a Code under privacy law to provide additional protections for any potential information that may be gained from the blood spot samples. The Ministry's legal advice is that this proposal is limited, as a Code made under section 46 of the Privacy Act would only apply to the part of the blood spot card that has information written on it, and the information derived from the sample. It would not apply to the blood spot sample itself.

39. The Office of the Health and Disability Commissioner noted that newborn blood spot cards may be of value for identification purposes in the event of a disaster. It was noted that while there may be societal benefits from secondary uses, these must not undermine the primary purpose of the Newborn Metabolic Screening Programme.

40. The Chief Coroner supports the permanent retention of newborn blood spot cards. He suggested that all coroner requests for blood spot cards should be channelled through the Chief Coroners Office. This would make the request process clear, and as many of the tests that may be requested are costly, this would ensure requests are appropriate. This suggestion has been incorporated into the Policy Framework.

41. The New Zealand Police acknowledged the potential value of blood spot cards for identification purposes in case of natural disasters. The Police continue to support the management of access to blood spot cards through the existing Memorandum of Understanding, and recommend a review of its provisions to ensure continued relevancy. Such review will occur on a regular basis and include consultation with relevant parties.

42. The New Zealand College of Midwives welcomed the policy development around the storage and uses of blood spot cards, which will assist midwives in their discussions with families. The College considered that the detailed documentation has provided clarity in relation to the storage and uses of blood spot cards. The Ministry will work with the College to ensure that the new policy is incorporated into ongoing education initiatives for midwives.

43. Feedback from the two consumer organisations acknowledged that the clear documentation of policy and governance arrangements is a positive step. Their feedback contained consistent key themes, which were centred on their strong support for more information for consumers, to support the informed consent process. These organisations continue to be concerned about the permanent retention of blood spot cards, and have reservations about future unspecified uses of blood spot cards.

44. All feedback received has been carefully considered and many suggestions have been incorporated into the new policy. The Ministry of Health will be responding formally to all organisations who provided feedback.

Consultation

45. The following departments and agencies have been consulted on this paper: Te Puni Kōkiri, State Services Commission, the Offices of the Children's Commissioner, the Health and Disability Commissioner and the Privacy Commissioner; Treasury; the Ministries of Justice, Science and Innovation, Social Development, Women's Affairs, Pacific Island Affairs and Consumer Affairs, the Office of Ethnic Affairs and the Department of Internal Affairs. The Department of Prime Minister and Cabinet has been informed.

46. The comments received from departments and agencies have been carefully considered. While this matter does not directly impact on the work of any department or agency, specific views expressed through the consultation process are reflected in the paragraphs below.

47. Te Puni Kōkiri supported the direction of the Cabinet Paper. Of particular note was the support for the current Memorandum of Understanding with the New Zealand Police and the protocol for requests by the Coroner. They noted that restrictions on access to blood spots for research need to be strong, with protection and monitoring at the governance level. Te Puni Kōkiri also recommended that the policy implications of the recently released report on the Wai 262 Claim be considered. Te Kēte Hauora is leading this work for the Ministry of Health.

48. The Ministry for Science and Innovation commented on membership of the Newborn Metabolic Screening Programme Governance Team, which they believe should include people with expertise in research (which is the case). They also commented on the need to ensure that there is minimal duplication between ethics committee and Programme Governance Team requirements.

49. The Office of Ethnic Affairs is supportive of the new policy. Comments raised on the consent process and the requirements for cultural competencies are covered within the overall Policy Framework, and other operational Programme documentation such as practitioner guidelines.

Privacy Commissioner's Comment for inclusion in the Cabinet Paper

50. The Privacy Commissioner comments requested for inclusion in this paper are as follows:

"I am keenly aware of the need to protect the bloodspot samples held in the Guthrie Card collection against potential future misuse. We need to safeguard the Newborn Metabolic Screening Programme's important work and to show good faith to all the parents who gave permission for their newborn babies to be tested.

The Ministry of Health's policy framework for governance of the collection, to which this paper refers, presents a good way to make the decisions that will need to be taken around the cards in the collection. I appreciate the work the Ministry has done, in consultation with my Office and other stakeholders, in developing this framework.

However, the collection is to be retained forever. *Policy frameworks can change. To protect the collection into the future, some form of additional protection is needed. While the blood spot samples themselves do not present a privacy concern, there will be the ongoing potential for information to be derived from those samples and used for purposes unrelated to the original screening programme.*

I therefore intend to begin development of a code regulating any information derived from the blood spot samples held on the collection. Such a code would reflect the existing acceptable uses outlined in the policy framework, while allowing new uses in the future by way of public consultation and formally notified amendment".

51. Ministry of Health legal advice notes that while the Commissioner can initiate development of a Code on her own initiative under section 47 of the Privacy Act 1993, such a Code will be inherently limited. It is limited to information derived from the sample, and cannot address broader requirements relating to storage and access to the blood samples. Health information contained in the cards is already subject to the Health Information Privacy Code 1994. The Ministry of Health considers that an additional Code is unlikely to significantly contribute to improved protection and regulation over use of the cards, compared to the Policy Framework requirements, which provide a comprehensive approach for maintenance and governance of the blood spot cards.

Financial Implications

52. There are no financial implications arising from this paper. All costs are being met from within existing baselines.

Human Rights

53. The Policy Framework for the storage and use of blood spot samples is not inconsistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Gender Implications

54. There are no gender implications arising from this paper.

Legislative Implications

55. There are no legislative implications from the recommendations in this paper.

Regulatory Impact Analysis

56. A regulatory impact analysis is not required for this paper because it does not involve the development of legislation or regulations.

Disability Perspective

57. This paper does not impact on disabled people.

58. The New Zealand Organisation for Rare Disorders (NZORD) has been involved in the development of the Newborn Metabolic Screening Programme Policy Framework, and NZORD supports potential research that will assist in furthering knowledge of rare disorders.

Publicity

59. The storage and uses of blood spot cards has attracted some media interest. To support the communications plan for the introduction of the new policy and governance arrangements, this paper will be made available on the Ministry of Health website.

Recommendations

60. The Minister of Health recommends that the Committee:

    1. note this report back on the new policy and governance arrangements to support the permanent retention of blood spot cards was requested by SOC in July 2010

    2. note the policy framework (Appendix A) brings all the policies, governance and provider responsibilities together in one place for the first time in the Programme's history, which will help to make the policy and governance arrangements more transparent and widely known

3. note the two key changes to existing Programme policies and procedures are:

- governance arrangements have been clearly documented, and the roles and responsibilities between the Ministry of Health, Newborn Metabolic Screening Programme operations and the Governance Team have been clarified

- a research applications pathway has been developed to clarify the requirements for requesting blood spot cards for research. Individual written consent is required for population research on samples collected prior to June 2011. For cards collected after June 2011, parents will be properly informed of the potential primary and secondary uses of the card before consenting to long term storage of the card. Any proposal for research that will require release of cards collected after June 2011 must first be approved by an Ethics Committee and reviewed by the Governance Team.

Ryall

Hon Tony Ryall
Minister of Health

Date: 9 / 7 / 11