

**Draft Policy Options on the Secondary use and
Retention of Newborn Metabolic Screening
Programme Blood Spot Cards**

National Screening Unit

Ministry of Health

15 September 2008

1.1 Background

Current policy work by the Ministry of Health (the Ministry) on the retention and use of newborn metabolic screening blood spot cards continues a process that began in 1999. In that year the High Court ordered the release of a residual newborn blood spot card for a deceased child to determine the child's paternity.¹ This led to investigations by both the Privacy Commissioner and the Health and Disability Commissioner.

The mother of the child at the centre of the 1999 High Court case complained to the Health and Disability Commissioner that her child's blood had been collected and stored without her consent. In his report into the case, the Commissioner recommended development of policy to ensure informed consent is obtained from parents or legal guardians for neonatal blood tests before blood is taken and stored.²

The then Privacy Commissioner also began an investigation into the collection, retention, use and release of newborn metabolic screening blood spot cards after the 1999 case. The then Privacy Commissioner made the following recommendations in a 2003 report:³

- that the Ministry allocate clear responsibility and authority for the operation of the Newborn Metabolic Screening Programme (the Programme);
- that the body appointed move urgently to develop clear rules for retention of the samples and any further use or third party access to those samples, consulting widely with stakeholders and with the Privacy Commissioner; and
- that these rules, and any permission-granting structures they involve, be incorporated in legislation in such a way that they are clear, robust and enforceable.

¹ H v G (1999)

² Ron Paterson (Health and Disability Commissioner) 4 August 2000. "Report on Opinion: Case 99HDC09011."

³ Bruce Slane (Privacy Commissioner). Guthrie Tests. Wellington, 2003.

In order to address the first of these recommendations from the then Privacy Commissioner, the Ministry appointed responsibility for the funding, monitoring and strategic direction of the Programme to the National Screening Unit (NSU) in 2005.

Over the last two years, the Ministry has engaged in a consultation process to address the other recommendations from both the Health and Disability Commissioner and the Privacy Commissioner. This process has included public consultation in 2007 (through an on-line public consultation document and focus group analysis) and a first workshop with key stakeholders on 11 August 2008.

The first workshop was arranged by the Ministry in order to discuss recommendations made by the Newborn Metabolic Screening Programme Advisory Group (the Advisory Group) to the NSU on policy options for the use and retention of newborn blood spot cards collected by the Programme. At the first workshop, key stakeholders were invited to give their views on the use and retention of blood spot cards.

The public consultation process, the Advisory Group recommendations and the views of key stakeholders from the first workshop have informed the development of draft policy options by the Ministry on the use and retention of blood spot cards acquired by the Programme.

This paper outlines the Ministry's draft response to the recommendations of the Advisory Group, together with its response to the other recommendations made by the Health and Disability Commissioner and the Privacy Commissioner outlined above. Draft policy options in relation to the retention time of the cards are also presented in this paper.

The purpose of this paper is to inform key stakeholders of the Ministry's draft position and policy options in order that they may be considered at a second workshop on 15 September 2008. The Ministry welcomes feedback by key stakeholders as it will assist in the development of final policy options and recommendations that will be put to the Ministry's Executive Leadership Team

(ELT) and then to the Minister of Health for the Minister's consideration and final decision.

1.2 Summary of Advisory Group recommendations

The Advisory Group has provided the NSU with the following recommendations related to consent, storage and use of blood spot cards.

1. That consent for participation in the Programme and consent for storage be distinct processes, but obtained at the same time.
2. That verbal consent is adequate.
3. That consent/decline is recorded in clinical notes.
4. That the NSU fund an education programme targeted at lead maternity carers to raise awareness of the Programme and the importance of gaining informed consent.
5. That newborn blood spot cards are available for the primary use of the Programme.
6. That investigation of morbidity and mortality is acknowledged as a secondary use of newborn blood spot cards.
7. That victim identification is acknowledged as a secondary use of residual newborn blood spot cards.
8. That assay improvement and validation for disorders currently in the Screening Programme panel is acknowledged as a secondary use of de-identified newborn blood spot cards.
9. That validation of assays for potential new disorders to be added to the screening panel is acknowledged as a secondary use of de-identified newborn blood spot cards.
10. That research (with appropriate consents and approvals) is acknowledged as a secondary use of identified newborn blood spot cards.
11. That research (with appropriate consents and approvals) is acknowledged as a secondary use of de-identified newborn blood spot cards.
12. That following completion of testing, newborn blood spot cards are to be retained for a minimum of 16 years (for primary usage). The

Advisory Group recommends retention beyond 16 years for the identified secondary uses, but is unable to identify a maximum retention time.

13. That a guardianship group is established to control third party access to residual newborn blood spot cards.
14. That the Memorandum of Understanding with the Police be strengthened to ensure that Police access to the blood spot card collection is only possible with a court order or the requisite consent of a person legally entitled to give such consent.

2. Policy framework and evaluation criteria

The NSU is responsible for providing high quality, cost-effective screening programmes that are trusted by the public. This responsibility is the NSU's primary concern. In order to help ensure that this responsibility is met, the NSU has developed three principles to guide the development of policy for screening programmes. The principles are:

- maintaining a high quality screening programme;
- maintaining public trust and confidence in the programme; and
- ensuring value for money.

The primary aim of the Programme is very important to the evaluation of the various policy options, particularly in relation to retention time. While a range of views have been considered, representing diverse and legitimate interests, these views must be weighed against the primary aim of the Programme, which is to *ensure the early detection and appropriate treatment of newborns with congenital metabolic disorders*.

There are a number of additional criteria that can be used to determine appropriate policy for the Programme, which are specific to the issues at hand. These criteria include:

- maximisation of individual benefit to the child and whanau;
- public benefit;
- stakeholder support;
- compliance with existing legislative and regulatory frameworks applicable to blood spot cards, and;

- the Ministry of Economic Development's principle of "legislation as a last resort".

3.0 Response to the Advisory Group recommendations

3.1 Consent

The Ministry accepts the Advisory Group recommendations in relation to consent (Recommendations 1 to 4 inclusive).

There is general support amongst key stakeholders for these recommendations and although some stakeholders would prefer consent to be written, verbal consent with consent/decline recorded in clinical notes is consistent with other screening programmes and most other health services.

It is accepted that the consent process must include consent to participation in the Programme and consent for storage (by parents fully informed of all primary uses and potential secondary uses). In terms of implementation of the Advisory Group's recommendations on consent, the NSU will take further advice from the Office of the Health and Disability Commissioner as to how to best manage the consent process and will continue to work on an education programme targeted at lead maternity carers.

3.2 Use of cards

The Ministry accepts the Advisory Group recommendations in relation to the primary and secondary uses of cards (Recommendations 5 to 11 inclusive).

The purpose of collecting blood samples from newborn babies is for participation in the Programme. The Programme and the primary uses for the cards must have priority over potential secondary uses. These primary uses are:

1. the initial screening test;
2. occasional repeat confirmatory screening;
3. rare investigations of false negative results; and
4. quality assurance and audit of the Programme.

Even though the purpose of collecting blood samples from newborns is to meet the Programme's aim of ensuring the early detection and appropriate treatment of newborns with congenital metabolic disorders, it is acknowledged that cards are potentially available for secondary uses that are legally permitted, regardless of the retention period for the cards.

Apart from the secondary uses directly associated with the Programme (uses 3 and 4 below), nearly all secondary uses require specific consent from those legally authorised to give such consent at the time of secondary use. Consent for secondary uses directly associated with the Programme (uses 3 and 4 below) must be obtained at the time the baby's blood sample is collected.

Use of de-identified blood spots for population research (use 6 below) is a potential exception where specific consent may not be required. Use for research without specific consent is legally permitted under Right 7(10) of the Code of Health and Disability Services Consumers' Rights 1996 (the Code of Consumers' Rights), provided such research has been approved by an ethics committee. However, although specific consent may not be required by the law, it may be a condition of ethical approval by an ethics committee even when samples are de-identified.

The Ministry accepts the Advisory Group's categorisation of the following as secondary uses.

1. investigation of morbidity and mortality;
2. victim identification;
3. assay improvement and validation for disorders currently in the newborn metabolic screening programme;
4. validation of assays for potential new disorders to be added to the newborn metabolic screening panel;
5. research (with appropriate consents and approvals) using identified newborn blood spots; and
6. research (with appropriate consents and approvals) using de-identified newborn blood spots.

3.3 Retention period

The Ministry considers that the minimum retention period must align with the period the cards are required for their primary use by the Programme. The Ministry accepts that this period is difficult to determine with precision, but supports sixteen years as a minimum retention period as recommended by the Advisory Group.

The Ministry acknowledges that there is no clear consensus within the sector, or from the consultation process, on retaining blood spot cards beyond sixteen years for identified secondary uses. However, the Ministry has identified three policy options which it is currently evaluating. The comment and advice of key stakeholders on these options is welcomed and will assist with ongoing analysis in preparation of advice for the Minister's consideration.

Option one: retention for sixteen years

Under this option cards are not retained beyond the period the cards are required for the purpose of the Programme and would be routinely destroyed in batches after sixteen years. This is the NSU's preferred option. Any transition to this policy would need to be carefully managed in conjunction with Archives New Zealand to ensure compliance with the Public Records Act 2005. As the current collection has been held on the basis of indefinite retention any transition to this policy would also need to include public notification and a reasonable opportunity for individuals/families/whanau to request the return of blood spot cards prior to their being destroyed. This requirement is made mandatory by the Public Records Act and the Code of Consumers' Rights (Right 7(9)).

Benefits	Costs and risks
<ul style="list-style-type: none">• Is consistent with the stated purpose of collecting the blood samples and ensures the integrity of the Programme (cards are not retained beyond the period required for the purpose of maintaining a quality	<ul style="list-style-type: none">• Cards are not available for therapeutic research of benefit to individuals and whanau beyond 16 years unless their return has been requested.• Cards are not available beyond 16

<p>screening programme).</p> <ul style="list-style-type: none"> Existing legislative framework provides sufficient protection against risks. There is no additional cost to the Programme or wider health sector in storing cards for longer than they are needed by the programme, thus ensuring that the Programme continues to provide a service that meets the requirements of the primary aim. Less risk to public trust and confidence, this may be important in maintaining the very high participation in the programme. 	<p>years for population research of benefit to the public.</p> <ul style="list-style-type: none"> Cards are not available beyond 16 years for victim identification purposes. Cards are not available for as yet, undefined future benefit to individuals, whanau and the public.
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Option two: indefinite retention

This option confirms the status quo, with cards retained indefinitely beyond the period they are required for the purpose of the Programme and available for identified secondary uses. Consideration would need to be given to transferring cards (once no longer required by the Programme) to another agency for ongoing storage and to ensuring ongoing governance of any such collection.

Benefits	Costs and risks
<ul style="list-style-type: none"> Cards are available for therapeutic research of benefit to individuals and whanau. Cards are available for population research of benefit to the public. Cards are available for victim identification purposes. Cards are available for as yet, undefined future benefit to individuals, whanau and the public. 	<ul style="list-style-type: none"> Would require altering the stated purpose for the Programme collecting blood samples. Has the potential to compromise the integrity of the Programme. Resources required for long-term storage may be at the expense of the Programme itself and risk maintaining a high quality screening programme. Could lead to lower rates of

	<p>participation in the Programme if public trust is eroded (and possibly increased risk of avoidable morbidity and mortality).</p> <ul style="list-style-type: none"> • Possibly, increased costs if cards are to be stored in special storage. • May need identification of another agency to store cards beyond 16 years. • May need specific legislation to address all risks.
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Option three: retention after sixteen years with specific consent

Under this option there would be an opportunity for children at the age of sixteen years to decide on the disposition of their card once it is no longer required by the Programme. This option proposes that children turning 16 years be given three choices:

- request return of the card⁴;
- consent to its destruction; and
- consent to their card being archived for research, either in an identifiable or de-identified form.

One of these choices could be the default option (either destroy or archive). As with option two, consideration would need to be given to transferring cards (once no longer required by the Programme) to another agency for ongoing storage and to ensuring ongoing governance of any such collection.

Benefits	Costs and risks
<ul style="list-style-type: none"> • Some cards are available for therapeutic research of benefit to individuals and whanau. • Some cards are available for population research of benefit to the public. 	<ul style="list-style-type: none"> • Consideration of the default option compromising the integrity of the Programme needs to be made. • The practical implications of identifying individuals at the age of 16 are significant.

⁴ Individuals/whanau currently have the right to request the return of their cards at any time, and as set out in 5.1.1 it is proposed that more information on this right be included in Programme materials.

<ul style="list-style-type: none"> • Some cards are available for victim identification purposes. • Some cards are available for as yet, undefined future benefit to individuals, whanau and the public. 	<ul style="list-style-type: none"> • Identifying individuals through school attendance may lead to inequalities in exercising informed consent among some groups. • Likely to be significant costs to identifying individuals or running ongoing communication campaigns. • Possibly, increased costs if cards are to be stored in special storage. • May need identification of another agency to store cards beyond 16 years. • May need specific legislation to address all risks. • De-identified cards preclude use for therapeutic research of benefit to individuals and whanau or for victim identification. • Potential selection bias issues will affect the quality of the de-identified collection as a tool for population level research.
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3.4 Guardianship group

The Ministry accepts the need for strong and transparent governance arrangements to control third party access to residual newborn blood spot cards, but does not support the establishment of an independent guardianship group if option one is the preferred option.

The role of guardian is included in the responsibilities the Ministry assigned to the NSU in 2005. Under the current legislative framework, handing this decision-making authority to an independent third party during the period cards are required by the Programme is problematic, and would more than likely require specific legislation. As discussed below, if a decision is made to retain cards beyond sixteen years, the need for specific legislation to protect the card collection is more compelling and this legislation would need to address issues such as governance, storage and third party access.

Notwithstanding this, the Ministry accepts the intent behind the recommendation for a guardianship group. If option one for retention is chosen (and in the absence of programme specific legislation), the Ministry acting as guardian would take advice from the Advisory Group and LabPlus within Auckland District Health Board (which manages the National Testing Centre) in determining whether a request for third party access to residual cards for population research was appropriate.

Under option one (and in the absence of programme specific legislation) the Ministry also proposes developing clear and explicit protocols and decision-making criteria to govern third party access for research purposes. Decision-making criteria are likely to include the following.

- Does the request comply with relevant legislation?
- Have all appropriate ethical approvals been obtained?
- Is the release authorised by individual/parents/guardians, or does it comply with Right 7(10) of the Code of Consumer's Rights?
- Will the research use compromise the primary use of cards?
- Is the request supported by the Advisory Group and/or other relevant professional expertise?
- Can the costs of retrieval be met by the requestor?
- Will the requested blood samples (which are likely to be de-identified) be stored in a secure, locked area with appropriate safeguards to prevent unauthorised use, disclosure, loss or other misuse during the research period?
- Is the requestor guaranteeing the return or destruction of any residual blood sample used in research once the research is completed?

3.5 Police access

The Ministry accepts the Advisory Group's recommendation to strengthen the Memorandum of Understanding with the Police to ensure that Police access to the blood spot card collection is only possible with a court order or the requisite consent of a person legally entitled to give such consent. There was broad support for this recommendation at the first workshop, and changing

the Memorandum in this way will help maintain public trust and confidence in the Programme.

4.0 Response to the Privacy Commissioner's recommendations

4.1 Clear rules for blood spot card use and retention

The second workshop is a key step in the process to finalise policy for the use and retention of blood spot cards collected by the Programme. Once policy has been determined, this policy and all rules will be explicitly stated in all Programme documentation.

4.2 Legislation

The existing legislative and regulatory framework that applies to the Programme was outlined at the first workshop. Relevant legislation includes the Code of Consumers' Rights, the Health Information Privacy Code 1994, and possibly⁵ the Standard for Non-therapeutic Use of Human Tissue, which is soon to be released and will have the force of regulations under the newly enacted Human Tissue Act 2008. These provisions are all generic provisions.

The Programme does not have programme-specific legislation. While there are emerging areas of potential concern, such as those that relate to genetic privacy, the Ministry considers that they are not specific to the Programme and, if necessary, would be best dealt with by a wider public policy process and generic legislation.

The Ministry notes that since the then Privacy Commissioner made his 2003 recommendations, Parliament has passed a significant amendment to Right 7(10) of the Code of Consumers' Rights and the Human Tissue Act, both of which affect the storage of human tissue, including blood.

If the cards are to be retained for sixteen years only, the Ministry believes that clearly stated policy and protocols, along with existing legislation, is sufficient to ensure the safety and integrity of the collection. However, the Ministry acknowledges that generic legislation may not be appropriate in the situation where there is long term or indefinite retention of newborn blood spot cards. If

⁵ It is not yet confirmed whether or not this Standard will apply to newborn metabolic blood spot cards

it is decided to retain cards beyond sixteen years and make them available for secondary uses, the Ministry considers specific legislation governing the newborn blood spot card collection may be necessary.

5.0 Draft Ministry policy proposals

The proposals below, or as amended following today's workshop and further internal Ministry consultation, will form the basis of advice to ELT and the Minister of Health.

5.1 Consent and use

It is proposed that.

- 5.1.1 Programme materials, including the pamphlet for parents, are revised to include: the Programme's stated aim, acknowledgement of all primary and secondary uses of newborn blood spot cards, details of storage time, and information on the right to request the return of cards.
- 5.1.2 The consent process includes consent to participation in the Programme and consent to storage, with full knowledge of primary and secondary uses;
- 5.1.3 Where there is consent to participation in the Programme, but no consent for storage, the blood spot card will be returned to the family/whanau for safekeeping after the initial screening test.
- 5.1.4 Verbal consent is adequate, but consent/decline will be recorded in the mother and baby's clinical notes.
- 5.1.5 An education programme will be initiated to raise lead maternity carers' awareness of the Programme and the importance of gaining informed consent.

5.2. Retention period

It is proposed that.

- 5.2.1 Newborn blood spot cards are retained for a minimum of sixteen years for primary use by the Programme.
- 5.2.2 The Ministry gives further consideration to the benefits, costs and risks of the three options identified in Section 3.3 above before providing its advice to the Minister.

5.3. Access to cards for population research

It is proposed that.

- 5.3.1 In the absence of specific legislation (i.e. where the cards are only retained for sixteen years under option one identified in Section 3.3 above), the Ministry retains responsibility for access to newborn blood spot cards for population research where the specific consent of the individual/family/whanau has not been given.
- 5.3.2 In exercising this guardianship role, the Ministry's priority of use (in order) will be:
 - i. use for the benefit of individual/family/whanau;
 - ii. maintenance of a high quality screening programme; and
 - iii. gaining new knowledge through research and development.
- 5.3.3 The Ministry will consult with LabPlus within Auckland District Health Board and the Advisory Group in coming to any decision to release cards for population research.
- 5.3.4 The Ministry's criteria for decision-making will be explicit and transparent.

5.4 Police access

It is proposed that.

- 5.4.1 The Ministry's Memorandum of Understanding with the Police will be revised to ensure Police access to the cards is only possible with the consent of a person legally entitled to give such consent or pursuant to a court order.

6.0 Period for further comment

As well as the opportunity to comment on the Ministry's draft proposals at today's workshop, further comment from key stakeholders is invited over the next month. Views on issues related to the use and retention of newborn blood spot cards under the Programme can be emailed to: geoffrey_roche@moh.govt.nz and all emails will be considered if received prior to Friday 31 October 2008.

7.0 Next steps

Once the Minister has made a final determination on the Ministry's policy recommendations, actions for implementing the policy will be incorporated in the NSU's work plan. Actions are likely to include:

- incorporating policy changes in a revision of the current Programme national policy and quality standards;
- ensuring providers involved in delivering the Programme are required to comply with the national policy and quality standards;
- revising the pamphlet made available to parents, and other publicly available information about the Programme, to ensure all information is consistent with Programme policy on retention and use of the cards and consent practices; and
- an education programme targeted at lead maternity carers to raise awareness of changes in programme policy.