

Briefing Document for Stakeholder Workshops on the Secondary  
use and Retention of Newborn Metabolic Screening Programme  
Blood Spot Cards

**National Screening Unit**

**1 August 2008**

## 1 PURPOSE

Following public consultation in 2007, and having received recommendations from the Newborn Metabolic Screening Programme Advisory Group (the Advisory Group) this year, the National Screening Unit (NSU) now wishes to engage with key stakeholders to discuss policy options for the use and retention of newborn metabolic screening programme (NMSP) blood spot cards and to discuss whether current protective mechanisms ensure appropriate use of, and access to, the cards.

This document is intended to inform and facilitate discussion with stakeholders at workshops to be held on 11 August and 15 September 2008 on the use and retention of newborn blood spot cards. Also attached are:

- the agenda for the first workshop to be held on 11 August, and;
- a copy of the Advisory Group's recommendations to the NSU (workshop participants are encouraged to familiarise themselves with these recommendations prior to the first workshop).

Please note that the results of public consultation undertaken last year will be presented at the first workshop. The consultation reports are available on request for workshop participants who may wish to receive copies prior to 11 August.<sup>i</sup>

## 2 THE NEWBORN METABOLIC SCREENING PROGRAMME

The purpose of newborn metabolic screening is to identify specific metabolic disorders in newborn babies. The NMSP currently screens for 28 disorders. The main aim of screening is early identification and treatment of disorders which can be life-threatening. The programme began in New Zealand in the late 1960s with a test for a single condition (PKU) and currently screens around 60,000 children a year. Coverage is almost 100% and approximately 45 affected infants are identified annually.

Lead Maternity Carers (LMCs) are responsible for offering screening to parents, ensuring screening is performed if there is consent, and completing follow-up if required. The screening procedure is a blood sample, taken from the baby's heel (often

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<sup>i</sup> Send an email to [sarah\\_templeton@moh.govt.nz](mailto:sarah_templeton@moh.govt.nz) for a copy of the reports

called a 'heel prick'). Drops of blood are then collected on absorbent collection paper fixed to a cardboard card (commonly referred to as a "Guthrie" card, - after Dr. Robert Guthrie who developed blood on paper as an analytical specimen). The card records the baby's name, gender, weight, ethnicity, birth date and time, the name of the mother, the details of the LMC, sample date and time, and where the baby was born.

The samples are sent to the National Testing Centre (NTC) within LabPLUS at Auckland City Hospital, where they are tested. The tests detect elevated blood chemicals associated with the screened disorders. When screening is complete, the cards are stored at the NTC for six months before being moved to a secure storage facility.

The original newborn blood spot cards used in New Zealand were printed on a single sheet of collection paper, which also recorded the mother's name and ethnicity and the name of the baby, and attending doctor. The newborn blood spot card used since 1999 has two distinct components with a smaller portion of collection paper, separated by a perforation (see Figure 1). Above the perforation is the blood spot portion with the baby name and NHI. The LMC fills in the remainder of the card with demographic details as described above. Once received in the laboratory, a unique laboratory number is placed on both sections of the card.

### 3 HISTORICAL BACKGROUND

Newborn blood spot cards have been kept and stored on an indefinite basis since the programme commenced in the late 1960s. The primary purpose for retaining cards was to be able to ensure programme quality by reviewing missed cases. The NMSP and the National Testing Centre Advisory Group (a group in existence prior to the NSU taking responsibility for the programme) have reviewed the retention period several times in the last 15 years, and the decision has always been to continue to retain the cards indefinitely. As technology improvements have occurred (both in genetics and screening technology), and as access to newborn blood spot cards has been questioned, another review of uses and retention of the cards is appropriate.

One high profile example of access to a newborn blood spot card was the High Court case of *H v G* (1999), where the Court ordered the release of a residual newborn blood spot card for a dead child to determine the child's paternity. This led to investigations into the consent and storage of the cards by both the Privacy Commissioner and the Health and Disability Commissioner.<sup>ii</sup>

The then Privacy Commissioner made the following recommendations in his 2003 report:

- that the Ministry of Health allocate clear responsibility and authority for the operation of the newborn metabolic screening 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;

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<sup>ii</sup> Bruce Slane (Privacy Commissioner). *Guthrie Tests*. Wellington, 2003; Health and Disability Commissioner Wellington Opinion 99HDC09011.

- 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.

In response to these recommendations, the Ministry of Health appointed responsibility for the funding, monitoring and strategic direction of the NMSP to the NSU in 2005. Since this time the NSU has consulted with the public on consent, storage and use of the cards, and the wider focus of the programme. Public consultation involved two distinct processes; an on-line questionnaire and focus group discussions. Following this process, the Advisory Group has provided recommendations to the NSU regarding the retention period and secondary use of the cards.

#### **4 INTERNATIONAL PRACTICE**

Retention times for residual cards vary widely around the world. In Australia, cards are stored for eighteen years in New South Wales, two years in Western Australia, and indefinitely in Victoria and South Australia. Israel stores cards for one month, France stores them for six months, and Germany keeps them for five years. Retention times also vary widely within the United States and Canada.

The reason for the different approach in different jurisdictions may reflect different attitudes towards the risk and benefit of retaining the cards. For example some societies may place greater importance on the possible public benefit in retaining the cards, whereas others may have greater concerns about issues such as “genetic privacy”.

#### **5 LEGAL ISSUES**

There are a number of different laws in New Zealand that affect the collection and retention of newborn blood spot cards. An overview of applicable law will be provided at the first workshop. There is no programme specific legislation governing the NMSP, although the NSU is in discussion with the Privacy Commissioner and Health and Disability Commissioner about whether legislative or regulatory change is necessary.

The Code of Health and Disability Services Consumers' Rights 1996 (the Code of Consumers' Rights) and the Health Information Privacy Code 1994 are both applicable to the NMSP. Ensuring compliance with these codes is a key outcome for the NSU in developing its policy framework for the retention and use of newborn blood spot cards.

The newly enacted Human Tissue Act 2008 provides for the making of Standards for collection or use of human tissue for non-therapeutic purposes. Standards made under the Act apply to existing holdings of human tissue as well as future collection and use. A draft Standard for Non-Therapeutic Use of Human Tissue is currently out for public consultation.

## **6 USES OF NEWBORN BLOOD SPOT CARDS**

The attached Advisory Group paper identifies current and potential uses of the cards, categories them into primary and secondary uses, and makes recommendations which relate to transparency, consent issues and strengthening protective mechanisms around use of the cards.

### **Primary use**

The primary use of the cards is for the NMSP to operate safely and effectively in order to ensure the early detection and appropriate treatment of newborns with congenital metabolic disorders.

## Secondary uses

Current and potential uses of the cards as identified by the Advisory Group include:

- investigation of morbidity and mortality,
- victim identification,
- assay improvement and validation for disorders currently in the newborn metabolic screening programme,
- validation of assays for potential new disorders to be added to the newborn metabolic screening panel,
- research using identified newborn blood spots,
- research using de-identified newborn blood spots,<sup>iii</sup> and
- Police may have access to the cards pursuant to a Memorandum of Understanding between the Ministry and the New Zealand Police.<sup>iv</sup>

It should be noted that the Courts have an inherent jurisdiction to make orders granting Police or other third parties access to the cards. Families also have a right to request the return of cards without being required to give a reason. The NSU has not received any formal requests to date for newborn blood spot cards to be used for non-therapeutic research. The cards have also not been used to date for validation of assays for potential new disorders to be added to the screening programme. Advice from the Health and Disability Commissioner suggests such use requires specific consent, as it is not covered by the Code of Consumers' Rights exceptions under Right 7(10).

Workshop participants will be encouraged to express views and opinions about these uses, but the NSU is not of itself seeking to alter current legally permitted uses, particularly as the regulatory frameworks<sup>v</sup> involved have a wider scope than the NMSP.

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<sup>iii</sup> The Advisory Group is recommending a guardianship group is established to control access to the cards by researchers.

<sup>iv</sup> The Advisory Group is recommending this be strengthened so that the Police only have access if there is a court order or requisite consent

<sup>v</sup> For example, the Code of Consumers' Rights and the Health Information Privacy Code

## 7 DISCUSSION OPTIONS ON RETENTION TIME

From consultations to date, it is evident that there is a range of views on the period of time newborn blood spot cards should be retained in storage, and potentially be available for secondary uses. The NSU view is that the minimum retention period must align with the period the cards are required for their primary use (i.e. use by the NMSP). The Advisory Group considers this period to be sixteen years.

The workshops will provide participants an opportunity to express their views on this issue. Four initial options are suggested to facilitate discussion.

### **Option one: indefinite retention (status quo)**

Option one is to continue the existing policy of the NMSP and retain cards indefinitely. This option makes cards potentially available for all secondary uses. This option also allows for a final decision on retention time to be deferred until any new legislation resolves significant issues around genetic privacy, which extend beyond newborn blood spot cards.

### **Option two: retention for sixteen years**

Sixteen years is identified as the minimum period the cards are required by the NMSP for their primary use. This option allows for legally permitted secondary uses during the retention period unless families have requested the return of cards.

### **Option three: long term retention for a set period**

Option three requires a decision regarding the preferred time for long term retention. The Advisory Group report has identified a range of potential time periods. Options could be:

- 17 – 25 years
- 50 years
- 75 years
- 100 years

**Option four: permanent retention**

This option is similar to Option one, but involves a policy decision now to retain cards permanently rather than deferring a decision. Like Option one, cards would be available for secondary uses in line with advances in technology and regulatory frameworks.

Your views on these options will be welcomed at the workshops

**8 TIME FRAME AND PROCESS FOR FINALISING POLICY ON USE AND RETENTION OF NEWBORN METABOLIC BLOOD SPOT CARDS**

The stakeholder workshops are a key component in the process to inform policy development on secondary use and retention of newborn blood spot cards. Workshop one is designed to provide stakeholders with the opportunity to express their views on the issues and to comment on the Advisory Group recommendations.

The NSU, informed by the first workshop discussion, will present its policy proposals for comment and discussion at the second workshop on 15 September. These proposals, or as amended following the second workshop, will form the basis of advice to the Minister of Health. The advice will include any requirements for legislative change.

Once the policy is finalised, actions for its implementation will be incorporated in the NSU's work plan. Actions are likely to include:

- incorporating any policy changes in a revision of the current NMSP national policy and quality standards;
- ensuring providers involved in delivering the NMSP are required to comply with the national policy and quality standards;
- revising the pamphlet made available to parents, and other publicly available information on the NMSP, to ensure communication on uses and consent practices, and;
- an education programme targeted at LMCs to raise awareness of any changes.

