
Newborn Blood Spot Cards:
Consent Storage and Use
A Public Consultation

March 2007

Acknowledgements

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1 Introduction

This consultation document seeks public opinion on consent for screening newborn babies for metabolic conditions and storing and using the New Zealand collection of newborn blood spot cards (commonly known as 'Guthrie cards').

Over the last few years, some concerns have been expressed regarding the privacy, storage and future use of blood spot cards. As part of improvements to the programme, the Ministry of Health seeks public views through public consultation on these issues. The National Screening Unit (a unit of the Ministry of Health that governs the Newborn Metabolic Screening Programme) and the Newborn Metabolic Screening Programme (NMSP) Advisory Group regard the integrity of the NMSP as critical and wish to ensure participation in the programme is not compromised. The consultation is being conducted by the National Screening Unit.

Public opinion will be sought via:

- a web-based questionnaire (printed copies are also be available)
- public focus group discussions

The results of this consultation will be reported to the National Screening Unit and the NMSP Advisory Group. These groups will then make recommendations about the information that should be provided to parents/caregivers on the screening programme, the process for documenting consent for the screening, what the newborn blood spots should be used for and how the screening programme should be managed.

Section 1 of this document explains the background to newborn metabolic screening and describes current storage practices for newborn blood spot cards. Section 2 seeks feedback on the New Zealand programme and the consent process for obtaining newborn blood samples. Section 3 asks for opinions on storage and current and future uses of newborn blood spot cards. The document ends with a request for demographics information of respondents in Section 4.

Returning feedback

Your feedback is appreciated on this consultation document. You can respond on line through the Ministry of Health website: www.moh.govt.nz/newbornscreening or you may email your responses to: nsu_webmaster@moh.govt.nz

If you wish to respond by post or by fax, you may send your completed response to:

Sharon Scheffers
National Screening Unit
P O Box 5013
Wellington
Fax: 04 495 4484

If you would like to receive more copies of the questionnaire, please ring Sharon Scheffers at the National Screening Unit on 04 816 4385.

Closing date for responses: Wednesday 20 June 2007

2 Background

2.1 The Newborn Metabolic Screening Programme

What are metabolic conditions?

Metabolic disorders are rare, inherited disorders in which the pathways that produce certain proteins in a human malfunction. These pathways are like assembly lines in a human cell. A blockage at any point along the assembly line can lead to a build-up of toxic chemicals in the cell or a lack of an important protein or enzyme in the body. This can lead to an illness that is often irreversible – many of the chemicals that build up in a cell as a result of a metabolic condition can cause ill health, learning disabilities or death.

We can diagnose and treat many metabolic disorders. Treatment often takes the form of a special diet to reduce the amount of chemicals building up in the body.

What metabolic conditions are covered in the New Zealand screening programme?

The Newborn Metabolic Screening Programme (NMSP), which has been running in New Zealand since the 1960s, currently tests newborns for 28 metabolic disorders. These are:

1. Phenylketonuria (PKU)
2. Congenital hypothyroidism
3. Cystic fibrosis (CF)
4. Galactosaemia
5. Maple syrup urine disease (MSUD)
6. Congenital adrenal hyperplasia (CAH)
7. Biotinidase deficiency
8. a group of fatty acid oxidation disorders
9. a group of other amino acid disorders.

As a group, these conditions affect about 45 New Zealand babies per year out of approximately 59,000 babies born every year.

More information on these disorders can be found on www.moh.govt.nz/newbornscreening

What is screening?

‘Screening is a health service in which members of a defined population, who either do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications’.

(National Health Committee 2003)

The aim of screening is to reduce the number of people suffering and/or dying from a specified health condition. It reduces the risk of developing or dying from a disease, but is not a guarantee of prevention, or of diagnosis and cure. As screening has benefits, costs, and harms, there is an ethical obligation to minimise harm and the overall benefits should outweigh any harms that result from screening.

Screening for metabolic disorders leads to less newborns getting sick or dying from one of the disorders. Without screening approximately 45 newborns per year will die or be potentially severely affected by their metabolic disorder. In order for a screening programme to be successful, a co-ordinated approach is required. The essentials of such an approach include:

- clear lines of accountability
- high quality service provision
- effective monitoring of defined policy and quality standards
- the timely availability and appropriate integration of screening services with diagnostic and treatment services
- high levels of programme enrolment and participation.

What does the screening process involve?

Screening is offered for every baby born in New Zealand. It is highly recommended but is not compulsory. The screening takes the form of a blood sample, with blood obtained through a heel prick to the baby as soon after 48 hours of age as possible. The blood is placed on a blood spot card that also includes information about the baby, such as:

- the baby's name
- sex
- date and time of birth
- National Health Index (NHI) number
- the mother's name
- contact details for the family's Lead Maternity Carer (commonly known as LMC).

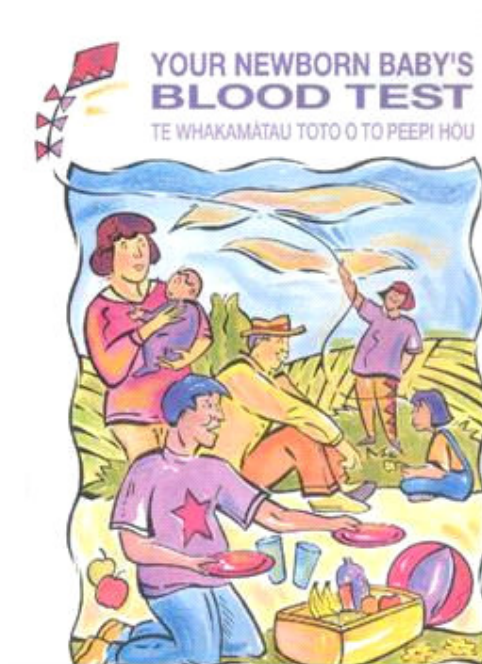
The Lead Maternity Carer is responsible for offering newborn metabolic screening to parents/caregivers, obtaining informed consent from the parents/caregivers, ensuring the blood sample is taken and all details on the sample card are completed and sending off the card to be tested at the National Testing Centre (a laboratory unit within LabPlus at Auckland City Hospital). The National Testing Centre reports back information to the NMSP.

The Lead Maternity Carer is also responsible for taking a second blood sample or for referring the family to specialist medical services if required.

At present, the NMSP screens about 59,000 New Zealand babies per year for these metabolic conditions – the programme covers nearly 100 percent of the New Zealand newborn population.

In 2006, the Starship Foundation gifted a new tandem mass spectrometer machine to the National Testing Centre. This machine allows more metabolic conditions to be tested and will increase the level of service in New Zealand to equal that currently available in countries such as Australia and the United States.

The NMSP has produced a brochure explaining the blood spot test and laboratory analysis process for parents/caregivers.



Example of the front cover of parent/caregiver information brochure

More information on the programme including the parent/caregiver information brochure can be found on the website: www.moh.govt.nz/newbornscreening.

2.2 International perspective on newborn metabolic screening

It is estimated that over its 40-year history, newborn metabolic screening has ensured that many thousands of children around the world have been protected from intellectual disability, a range of other disorders and death.

Most developed countries screen for metabolic disorders. In many states of America, newborn metabolic screening is mandatory for all babies. For most other countries, New Zealand and Australia included, newborn metabolic screening is performed with the consent of the parents/caregivers.

The number of conditions screened by each country varies due to cultural mix (incidence of disease varies for different cultures/races), expert advisory group recommendations, the way the number of disorders are counted (for instance some disorders can be classified with sub-groups), funding and service provision (for instance, the service's ability to follow up positive results).

2.3 Storing and using blood spot cards

Blood spot cards contain four small dried blood spots each about the size of a 10 cent piece. Information on the newborn, the mother and the Lead Maternity Carer is recorded on the card. Completed cards are stored and can be used in a number of ways, each of which is described in more detail in Section 3.1 below.

The image shows a yellow blood spot card form. At the top, there are four circular spots for blood collection. Below these are two boxes labeled 'NTC USE ONLY'. The main form is divided into sections: 'BABY INFORMATION - FILL OUT OR USE LABEL', 'MOTHER INFORMATION - if not on label', and 'LMC INFORMATION'. It includes fields for Baby Name, NHI #, Baby Number, Surname, First Name, Sex, Date and Time of Birth, Mother's Surname, First Name, LMC Name, Register No, Address, Mobile, Pager or Phone No, Birth Wt (g), Gestation age (wk), Collection Time, and Collection Date. There are also checkboxes for 'Baby 48h old' and '1st sample', and a note at the bottom: 'Only for NICU/SCBU: Sufficient Feeding for Screen. Y N'.

The parent/caregiver information brochure describes storage and future uses of the blood spot cards:

When the testing of your baby's blood is completed, the sample card is stored so that if a baby has one of the conditions tested for, but does not have a positive test result, we can find out why the mistake occurred and try to ensure the same mistake does not happen again. Some of the blood might be used to set up new screening tests; if a leftover scrap of your baby's blood is used for this, all the information about your baby will be disconnected from the blood so any results cannot be traced back to you and your baby. If you would like your baby's card returned to you after screening tests, write and ask for this and send the letter with the test card. Alternatively, a form is available from the National Testing Centre for this purpose.

2.4 Legislation and policies currently governing the Newborn Metabolic Screening Programme

Legislation

In New Zealand, legislation covers the obtaining, storage and use of blood spot cards. In particular, legislation is encompassed in the Health and Disability Commissioner Act

1994, the Code of Health and Disability Services Consumers' Rights 1996, the Privacy Act 1993 and the Health Information Privacy Code (HIPC) 1994.

The Health and Disability Commissioner Act 1994 outlines the role of the Commissioner and the process for submitting and resolving complaints about health and disability services.

The Code of Health and Disability Services Consumers' Rights 1996 confers a number of rights on all consumers of health and disability services in New Zealand and places corresponding obligations on providers of those services. Newborn metabolic screening is a health service that is covered by the Code. Consumers (or, in this case, their parents/caregivers/guardians) must be fully informed (right 6) and give their informed consent (right 7) before they receive the screening service. Right 7 also outlines the use of residual material as follows:

- 7(9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
- 7(10) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than –
 - (a) with the informed consent of the consumer; or
 - (b) for the purposes of research that has received the approval of an ethics committee; or
 - (c) for the purpose of one or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:
 - (i) a professionally recognised quality assurance programme;
 - (ii) an external audit of services;
 - (iii) an external evaluation of services.

Further information on these acts can be viewed at:

- www.privacy.org.nz/legislation/legislation.html
- www.hdc.org.nz/
- www.legislation.govt.nz/

Note

The Code of Health and Disability Services Consumers' Rights 1996 confers rights on consumers who receive health services. In the case of newborn metabolic screening, the consumer is the newborn baby. However, as a baby is not capable of giving consent, consent to blood tests, screening and storage must be given by the parents or caregivers entitled to provide consent on behalf of the baby. Later, when the consumer (baby) becomes competent to consent, he or she will be entitled to exercise his or her rights directly.

In September 2003, the then Privacy Commissioner, Bruce Slane, issued a report following his inquiry into the collection, retention, use and release of newborn metabolic

screening test samples. The report identified areas of concern and recommendations for the programme that can be viewed online at: www.privacy.org.nz/filestore/docfiles/70989185.pdf

Quality assurance for the Newborn Metabolic Screening Programme

An integral part of any screening programme is ensuring that all aspects of the programme are of high quality – it is therefore necessary to use some blood left after testing to check the testing procedures.

The Code of Health and Disability Services Consumers' Rights 1996 specifically permits the use of leftover blood without further consent for professionally recognised quality assurance programmes, an external audit of services or an external evaluation of services.

The laboratory that runs the testing for the NMSP must also be accredited with the International Accreditation New Zealand (IANZ). IANZ check through all the procedures associated with the programme to ensure the programme is safe and running to a high standard.

Research for the Newborn Metabolic Screening Programme

The Code of Health and Disability Consumers' Rights 1996 allows for blood remaining on the blood spot card after screening is complete to be used without seeking consent again for research that is approved by an ethics committee. To date, no research has occurred on any New Zealand stored blood spot material.

The balance between safeguarding the NMSP and supporting health research (by providing blood spot cards for research) is one that has been debated at length by the NMSP Advisory Group.

Current practice allows for parents/caregivers who do not want blood spot cards to be available for such residual use, to have the samples returned (through right 7(9) of the Code of Health and Disability Services Consumer Rights 1996 – see pages 6 and 7).

Access by New Zealand Police

Very occasionally, the New Zealand Police, on behalf of a family, request access to a specific blood spot card to help identify a deceased or missing person. The NMSP has a Memorandum of Understanding with the Police regarding this access, and over the last 10 years approximately 15 blood spot cards have been used for such purposes. More details concerning possible circumstances in which the New Zealand Police may wish to access a specific blood spot card are given in section 4.1 below.

The Memorandum of Understanding can be viewed on the Ministry of Health website at: www.moh.govt.nz/newbornscreening.

3 Consent for Newborn Metabolic Screening

In this section, we seek your views on what is important for parents/caregivers to know about newborn metabolic screening. We present a brief summary of the current situation and then offer some suggested guidelines for you to consider.

3.1 Current situation

Newborn metabolic screening has been an accepted part of neonatal care in New Zealand for nearly 40 years. Screening newborns for metabolic disorders should only occur with parental/caregiver consent (New Zealand currently has very high consent rates). There are public health benefits to screening newborns for metabolic diseases.

An unpublished survey of Lead Maternity Carers conducted in 2002, regarding information provided to parents/caregivers on the NMSP, presented a number of key findings, including the following points.

1. Parents/families cared for by Lead Maternity Carers receive information on newborn metabolic screening in a number of ways (often more than one), including the parent/caregiver information brochure (80 percent), in antenatal class (70 percent) and by talking with the Lead Maternity Carers (86 percent).
2. Information about the programme is given at different times and often more than once – in the third trimester (60 percent), after delivery but before the test (73 percent) and at the time of the test (52 percent).
3. A proportion of Lead Maternity Carers felt more information was required than is included in the parent/caregiver information brochure – particularly relating to storage and future use of blood spot cards.
4. Over 75 percent of Lead Maternity Carers considered that parents/caregivers find the current process for informed consent for newborn metabolic screening successful.

The survey also revealed that not all parents/caregivers receive the parent/caregiver information brochure.

In the New Zealand NMSP, approximately 70 blood samples per month (out of approximately 4600 samples) are unsuitable for testing. Generally, this is due to insufficient blood being collected. In such instances, the Lead Maternity Carer is then contacted to collect a second sample. A second sample may also be requested when the initial sample is tested and there is an abnormal result.

3.2 Guidelines and questions regarding information and consent

The NMSB would like to improve the guidelines in regard to:

- when parents/caregivers should be informed of the Newborn Metabolic Screening Programme
- obtaining the parents'/caregivers' informed consent to proceed with newborn metabolic screening
- obtaining the parents'/caregivers' informed consent for storage and future uses of newborns' blood spot cards
- how consent/refusal should be recorded for newborn metabolic screening and storage
- the procedure followed for requesting second samples.

Proposed content and availability of the parent/caregiver information brochure

The parent/caregiver information brochure for newborn metabolic screening should include details about:

- the conditions screened for, their cause, symptoms, treatment and incidence
- the process/procedure of collection of blood and who does the test
- the benefits and risks of screening
- the risks of not screening
- the possibility of needing a second sample if the first one is not adequate for testing purposes
- the consent and refusal process for screening
- the accuracy, risks and incidental findings associated with the screening process
- how parents/caregivers will be informed of screening results
- the importance of responding to a positive or inconclusive result
- the screening programme's policy for blood spot card storage, the reasons for storing blood spot cards, potential uses of stored blood spot cards (including the testing of new technologies) and options for retrieving cards from storage for return to parents/ caregivers
- how to obtain further information on newborn metabolic screening.

Information for parents/caregivers on the Newborn Metabolic Screening Programme should be available in a variety of forms (for example, as a hard copy provided by the Lead Maternity Carer and electronically from a website) and should be translated into several languages.

Question 1

Do you agree with the proposed content and availability of the parent/caregiver information brochure?

Yes, I agree with the proposed content and availability of the brochure.

Comments

The brochure must clearly state how long the card will be stored for and where, and highlight the fact that parents can ask for the card to be returned. This information must appear near the beginning of the brochure and not be tucked away at the end!

The process for requesting the return of blood spot cards must be simplified and consumer friendly. Parents Centres would recommend that a tick-box is included on the card itself requesting the return of cards to the parents or caregivers.

The possibility that the left over blood can be used for research and the card can be accessed by the NZ Police must also be stated very clearly in the brochure.

Proposed guidelines for obtaining consent to participate in newborn metabolic screening

At a suitable time during pregnancy, parents are to be told about newborn metabolic screening by the Lead Maternity Carer and are to be provided with the parent/caregiver information brochure on newborn screening.

After birth and before the blood sample is collected, the Lead Maternity Carer is to check that parents/caregivers have previously received a copy of the parent/caregiver information brochure, that they understand the purpose of newborn metabolic screening and that they consent to the blood sample being taken.

The Lead Maternity Carer's discussions with parents/caregivers about newborn metabolic screening should cover:

- the disorders screened for
- how screening can help newborns who suffer from such disorders
- if screening reveals a risk for a disorder, more testing and examination by a specialist is then required to confirm or rule out a diagnosis
- the parents'/caregivers' right to refuse the test on the baby's behalf
- the rare but possible risk to the baby of delayed diagnosis of a screened metabolic disorder
- how the blood sample is taken and the fact that sometimes a repeat sample is needed
- Lead Maternity Carers are sent monthly reports on their babies screened for the previous month
- parents/caregivers will only be contacted if a problem is detected, that is, if the result is abnormal or if another sample is required for technical reasons
- how long the blood spot cards are stored and what stored blood spot cards may be used for
- the security and access of stored blood spot cards
- the right of the parent/caregiver to request the return of the blood sample.

The discussion should provide the parents/caregivers with the opportunity to ask questions.

A record of the parents'/caregivers' consent (or refusal) is to be written in the newborn's notes and Tamariki Ora/Well Child health book.

Question 2

Do you agree with the proposed guidelines for obtaining consent from parents/caregivers to participate in newborn metabolic screening?

Yes, I agree with the proposed guidelines but suggest some changes.

Comments

The proposed guidelines above state:

The discussion should provide the parents/caregivers with the opportunity to ask questions

Parents Centres suggest that the following wording is added to the above statement:

and to spend further time discussing and considering their consent or refusal with each other without the LMC or person undertaking the test being present.

3.3 Guidelines and questions regarding refusals

Very rarely, parents/caregivers refuse to have their baby screened. The NMSP does not always know about these refusals and therefore is unable to say why parents/caregivers refuse. They are also unable to provide further information or assistance in accessing further information if parents/caregivers require it.

The NMSP would like Lead Maternity Carers to record all refusals to have newborns screened and the reason(s) for refusal. This will allow the NMSP to tailor educational material and features of the consent process to ensure that all practitioners and parents/caregivers are informed and able to access screening at any stage. It will also allow for closer scrutiny to confirm nothing is missed when a card is received late because the parents/caregivers originally refused screening and then changed their mind.

Proposed guidelines for recording screening refusals

If parents/caregivers refuse screening, the reason for their decision should be assessed and further information offered.

The refusal by parents/caregivers and the reason(s) for refusal are to be:

- recorded in the baby's notes by Lead Maternity Carer
- recorded in the Tamariki Ora/Well Child referral by Lead Maternity Carer.

With parent/caregiver approval, the newborn blood spot card should be filled in to include the demographic information completed for the baby, and write 'refusal' and the reason for refusal on the card. The Lead Maternity Carer should then send the 'refused' card to the laboratory.

Question 3

Do you agree with the proposed guidelines for recording newborn metabolic screening refusals?

No, I disagree with the proposed guidelines for the reason(s) supplied below.

Comments

Consenting or refusing should be recorded appropriately in the medical record.

An informed refusal of screening does not have to contain reasons or justifications, however these may be included in the medical records **if** provided, but must not be made a requirement of the parents/caregivers.

As refusal for the procedure has been given there is no clear reasoning as to why the card needs to be sent other than for data gathering. This is both unnecessary and would in fact require the consent of the parents/caregivers.

In some countries, parents/caregivers who refuse screening for their baby are asked to sign a form confirming their decision. This form states that the parents/caregivers are aware of the consequences or risks of not having their baby screened – most importantly that the conditions screened are serious and can cause death if not identified and treated. To date, in New Zealand, parents/caregivers have not been asked to sign such a form.

Question 4

Should parents/caregivers be asked to sign a form to confirm their refusal of newborn metabolic screening?

No

Comments

This may be seen by some as an attempt to gain informed compliance as the signing of a form may be viewed as intimidating behaviour by the parents/caregivers to the extent that they end up giving their consent.

On those occasions all that is needed is further time to consider the information provided and to perhaps ask more questions or receive interpreter services. Parents/caregivers should be given both the time and space they need to make their decision and their right to refuse must be respected.

It is the responsibility of the person undertaking the procedure to gain consent and document accordingly and not up to the person receiving the procedure to document their refusal!

3.4 Guidelines and questions regarding repeat samples

Sometimes the laboratory will request a repeat blood sample. This may be because the first sample was inadequate (not enough blood was supplied) or because the test shows an abnormal result. The NMSP currently either phones or writes to the Lead Maternity Carer and requests a repeat sample. However, sometimes the laboratory does not receive the repeat sample.

Proposed guidelines for requests of repeat samples

The laboratory contacts the Lead Maternity Carer to inform them of the unsuitable/ abnormal nature of the initial test result.

The laboratory:

- requests a repeat sample be sent as soon as possible
- explains the reason(s) for needing a repeat test.

The Lead Maternity Carer:

- informs the parents/caregivers as soon as possible of the initial test result and the importance of having a second sample taken from the baby
- explains why the repeat sample is necessary and that it will be used for the same purposes as the original sample
- records consent for the repeat sample in the baby's notes.

The Lead Maternity Carer is responsible for collecting and transporting the blood spot card to the laboratory or notifying the laboratory of a refusal to provide a repeat sample.

Question 5

Do you agree with the above proposed guidelines for requests of newborn metabolic screening repeat testing?

Yes, I agree with the proposed guidelines.

Comments

4 Storage and Use of Residual Newborn Blood Spots

Here we seek your views about what blood spot cards should be used for after the initial screening has been completed and how the cards should be stored. We present a brief summary of the current situation and then offer some suggested guidelines for your consideration.

4.1 Current storage and uses in New Zealand for residual blood spot cards

In New Zealand, blood spot cards are stored indefinitely after screening is completed. Storage is secure and physical access to these cards is limited to specific screening programme personnel with appropriate permission.

Currently, parents/caregivers or guardians, and ultimately the individuals themselves, have the right to have their newborn's blood spot card returned to them at any time. Each year, approximately 700 of the 60,000 cards are requested back by parents/caregivers.

After screening, blood spot cards are currently used in the following circumstances:

4.1.1 Direct benefit for the family/whānau

If a baby has died but the cause is unclear, at a doctor's request and with parental/caregiver consent, the baby's blood spot card can be tested to try to identify the cause of death. Also, further research involving a dead baby's blood spot card may provide valuable information for families about the risks of that condition recurring in future offspring.

4.1.2 Programme audit and quality control

Residual blood from the cards is used to monitor the screening programme. This is integral to ensuring that the programme is functioning properly, for instance, to double check the accuracy of the screening tests or to confirm a result. Stored blood spots are also used for professionally recognised quality assurance programmes. The Code of Health and Disability Consumers' Rights 1996, right 7(10) (see pages 6 and 7), allows residual blood spot material to be used without consent for professionally recognised quality assurance programmes, an external audit of services or an external evaluation of service. Quality assurance practices use stored blood spots for up to 10 years.

4.1.3 Setting up additional tests for the New Zealand NMSP

Anonymised blood that is left over after screening tests have been completed may be used to set up new screening tests for existing disorders or for different disorders.

4.1.4 Forensic use

Very occasionally, the New Zealand Police will request access to a specific blood spot card. Such requests will be made to:

- identify a deceased or missing person
- help with other coronial inquiries.

For instance, Police may request, on behalf of the family, a blood spot card to identify a body burnt in a house fire or to identify victims of a natural disaster. Blood spot cards have also been used in criminal cases to match biological material from victims found at a crime scene.

Note: These tests have only ever been used to identify a victim, not a suspect.

The NMSP has a Memorandum of Understanding with the New Zealand Police regarding their access to blood spot cards. The overriding principle for this Memorandum is that the blood spot card and information associated with it should be collected for health purposes only, and the New Zealand Police should have recourse to the blood spot cards and associated information only rarely and as a last resort.

Over the last 10 years, approximately 15 blood spot cards have been accessed by the New Zealand Police for such approved purposes,

The Memorandum of Understanding between the New Zealand Police and the NMSP can be viewed at: www.moh.govt.nz/newbornscreening.

Question 6

Please consider the following statement and tick the most applicable of the options below.

The current New Zealand Police access to blood spot cards is appropriate.

No, I disagree with current New Zealand Police access for the reason(s) supplied below.

Comments

The collection and use of blood spot cards is part of a screening test designed to screen newborns for a range of rare disorders. The blood spot cards must not, by default, become a national DNA database – access to the cards by the New Zealand Police indicates that in fact that is what the NMSP has become.

This is unacceptable, especially as consent for this has not been obtained by either the parents/caregivers of our current newborns and children or the children – who are now consenting adults – whose DNA information is currently stored and therefore accessible.

4.1.5 Court orders

Courts have separate rights, which override any other legislation or policies. Blood spot cards held by the NMSP are no different to hospital records or medical files held by doctors in relation to the powers of the Courts to order access or use the sample or information.

Under current law, a court can provide a written court order to the NMSP requiring the release of a blood spot card. There have been three instances of such requests being made in the last seven years, all regarding paternity cases.

4.2 Future storage of residual blood spot cards

In New Zealand, blood spot cards are currently held indefinitely by the laboratory. They are held in secure storage with restricted access.

The NMSP and its advisory group have reviewed length of storage many times in the last 15 years and the decision has always been to continue to retain the cards indefinitely. There is no international standard or benchmark for storage time – it varies internationally between three months (for instance in France) and indefinite storage (for instance some Australian states, California and New Zealand).

The overriding principles for any decision regarding length of storage are to protect the rights of newborns taking part in the programme and to ensure the blood spots are accessible for legitimate purposes only.

Currently, in New Zealand, the blood spot cards with the written information about the newborns are legally required to be kept for a minimum of 10 years. However, the blood spots themselves do not fall under any minimum legal requirements for duration of storage.

Question 7

How long do you consider blood spot cards should be stored for?

Another time period

Comments

Parents Centres believes that there is no reason to store the blood spot cards indefinitely or in fact for any prolonged period of time. If in fact the cards are to be used for the quality assurance activities then this should be a sufficient timeframe to undertake those activities.

No other test in New Zealand subjects the consumer to becoming part of a national DNA database that can be accessed by the NZ Police and Courts. Consent for this has not been gained for those blood spot cards currently in storage and informed consent for this

is unlikely to be gained – assuming it is made clear - by consumers (in this case parents/caregivers) in the future.

At the end of the specified time period the cards should then be destroyed or returned to the parents/caregivers.

3 Potential future uses of residual blood spot cards

New Zealand blood spot cards are not currently used for any purposes other than those discussed in section 4.1, but in other countries they have other approved uses. For instance, the United Kingdom and the United States use blood spot cards for research purposes. Examples of research that has been undertaken in other countries using blood spots include:

- developing new tests for conditions that are new to the screening programmes
- assessing how often infectious diseases such as Cytomegalovirus (CMV) occur during pregnancy
- testing for environmental or chemical exposure
- investigating possible links between Sudden Infant Death Syndrome (SIDS or cot death) and specific genetic variants.

The New Zealand collection of blood spot cards has not been used for research to date.

The New Zealand Code of Health and Disability Consumers' Rights 1996 allows for blood remaining on blood spot cards after screening has been completed to be used without seeking consent again for research that is approved by an ethics committee. Generally research uses many hundreds of blood spots. Any researcher can submit a request to an ethics committee for the use of residual blood spots. If approval is granted by the Ethics Committee, the researcher still has to approach the programme for release of the samples.

The New Zealand Health and Disability Ethics Committees provide independent ethical review of health research and innovative practice to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those people with diminished autonomy.

Further information on the New Zealand Health and Disability Ethics Committees can be found at: www.newhealth.govt.nz/ethicscommittees/

In many cases, but not always, the New Zealand Health and Disability Ethics Committees seek guidance from other sources. The NMSP requests your views on the acceptability of requiring the New Zealand Health and Disability Ethics Committees to always ensure notification and approval is sought from the National Screening Unit in regard to requests for the use of stored blood spot cards for research.

Such a requirement would ensure that the National Screening Unit is aware of each request, and ensure the integrity and safety of the NMSP and the rights of the newborns

taking part in the screening programme. Therefore, approval must be given from both the National Screening Unit and Ethics Committee before access to samples is granted.

Question 8

Do you consider that this process of formal notification and approval from the NSU in addition to Ethics Committee approval regarding research requests for residual blood spots is an adequate safeguard for the programme?

No

Comments

Given that blood spot cards have not previously been used for research, the issue of research in the future is obviously not likely to arise. However, if the cards are destroyed in the timeframe Parents Centres recommends then this makes it even more unlikely that there will be the possibility to undertake research.

Question 9

Do you have any other comments?

At no time has any parent or caregiver ever consented to their baby's blood spot cards being accessed by the NZ Police or Courts. To use the NMSP is not a national DNA database and any future use of the cards must be clearly consented to by the parents/caregivers at the time of the procedure. Therefore adequate and consumer focus tested literature must be provided, preferably in several languages.

5 Details of Respondents

We would like to know more about you, to allow us to take into account the range of people responding to this consultation. All personal information will be stored securely and will only be accessed by the research team. We will only report your responses if you give us your permission to do so, and if you prefer us to do this anonymously, we will adhere to your wishes. We will only use these details as specified and will not provide them to third parties.

Please complete and return with your response.

Name: Viv Gurrey

Organisation: Parents Centres New Zealand Incorporate

Address: PO Box 54 128, Mana

Telephone: 04 2332022 x800

Email: v.gurrey@parentscentre.org.nz

1 Are you responding as an individual or on behalf of an organisation?

Organisation

Are you or the organisation based in New Zealand?

Yes, based in New Zealand

2 Please tick which description(s) below best describes you.

Please note that we do not consider this to be appropriate or relevant – especially when the feedback is being submitted on behalf of an organisation.

a) Demographics

Sex Female

Age 30–50

Which ethnic group(s) do you belong to?

New Zealand European

b) I am:

c) I am:

d) I am:

e) I am:
A member of an organisation protecting consumer rights

f) I am:

3 Please tick the appropriate box to indicate your preference.

My response may be quoted in the report

Yes

If you have answered 'yes' to the above question, please indicate your name and/or the title of your organisation, as it should appear in print:

Name Viv Gurrey

Organisation Parents Centres New Zealand

Thank you for participating in this important consultation. The NMSP appreciates the time and effort you have given. A report of the findings from this consultation will be available on our website.