



Newborn Blood Spot Cards: Consent, Storage and Use – A Public Consultation
Focus Groups

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Focus Groups

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Contents

1.0	Executive Summary	4
2.0	Introduction	9
2.1	Background	9
2.2	Objectives	10
2.3	Approach	11
2.4	Sample	11
3.0	Knowledge of storage and uses	16
4.0	Screening and testing	19
4.1	The screening aspect of the current programme	19
4.2	Identifying cause of death	23
4.3	Testing for additional metabolic disorders and other conditions	25
5.0	Programme audit and quality control	30
5.1	Overall response	30
5.2	Benefits	30
5.3	Downsides and concerns	31
6.0	Research	32
6.1	Overall response	32
6.2	Factors underlying agreement or disagreement with research use	34
6.3	Parameters around research use	36
6.4	Benefits	38
6.5	Downsides and concerns	39
7.0	Police and Court access	40
7.1	Police access	40
7.2	Court access	42
8.0	Storage, information sharing, legislation and other safeguards	43
8.1	Storage	43
8.2	Information sharing	47
8.3	Legislation and other safeguards	47
9.0	Cultural considerations	55
9.1	Māori cultural considerations	55
9.2	Pacific peoples' cultural considerations	57

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1.0 Executive summary

Research New Zealand was commissioned by the National Screening Unit (NSU) to conduct focus group discussions in order to provide an understanding of people's perceptions and expectations about the future storage and use of newborn blood spot cards.

Introduction

Public opinion on the consent, storage and future use of Newborn blood spot cards was sought through a web based questionnaire¹ and focus group discussions (the subject of this report).

Seven focus group discussions were conducted between September 3rd and 19th, 2007, with a carefully selected sample of n=37 participants. Each focus group lasted between 2 to 2 ½ hours in duration.

Group participants were primarily selected on the basis of ethnicity (i.e. Māori, Pacific Peoples, Asian Peoples and New Zealand Europeans) and included new parents and adults (18-37 years) with no children. The overriding objective of the focus group discussions was to understand people's perceptions and expectations about the future storage and uses of blood spot cards.

Headed by Corrine de Bonnaire (Director, Qualitative Research – Research New Zealand), the research team responsible for the facilitation, analysis and reporting of the focus groups included the Māori and Pacific research specialists.

The overriding objective of the focus group discussions is to understand peoples' perceptions and expectations relating to the **future storage and uses** of residual blood spot cards. More specifically, this included understanding peoples':

- ◆ Responses to the use of blood spots for additional **screening/testing** purposes, including:
 - ◆ Treatable vs. non-treatable metabolic disorders.
 - ◆ Metabolic disorders vs. other conditions (e.g. Hepatitis).
 - ◆ Early onset vs. later onset (e.g. Diabetes).
 - ◆ Identifying cause of death.
- ◆ Responses to the use of blood spots for **programme audit and quality control**.
- ◆ Responses to the use of blood spot samples for **research**.

¹ Please refer to *Newborn Blood Spot Cards: Consent, Storage and Use – A public Consultation. Responses to the Public Consultation document, Research New Zealand, October 2007.*



- ◆ Responses to the use of blood spots by the **Police and Courts**.
- ◆ Expectations in relation to safeguarding **access, storage and uses**, including:
 - ◆ Legislation.
 - ◆ The Memorandum of Understanding with Police.
 - ◆ Ethics Committee and the National Screening Unit.
 - ◆ Physical storage of blood spots and information about newborns.
 - ◆ Information sharing.

When considering the key findings of this qualitative study, it is important to remember that these findings are based on a relatively small sample, selected to reflect the **diversity** of likely responses to the future uses and storage of blood spot cards. Furthermore, while the sample was specifically selected on the basis of ethnicity (i.e. Māori, Pacific people, Asian people and NZ European), it is important to acknowledge that the final sample was not able to reflect the diversity within each ethnic grouping (e.g. the Pacific participants only included those of Samoan descent and the Asian participants only included those of Indian and Chinese descent).

Finally, as a qualitative research study, the objective of the focus group discussions was to provide an **understanding** of the findings, rather than to quantify these. Therefore, while it is possible to identify variations in responses, it is not possible to extrapolate these findings in quantitative terms (i.e. in terms of prevalence) to the general public, or to specific (e.g. ethnic) groups.



Key findings

Consent

First and foremost, it should be noted that participants were **supportive** of screening, however, for related matters (i.e. consent, storage and use) sat on a continuum depending on their attitudes and beliefs.

Against this background, none of the participants (including the parents) **could recall** being fully informed about the storage of, and all the potential uses of their (child's) blood spots. Knowledge as such, was limited to the screening aspect of the programme and some parents thought participation was mandatory.

Considerable discussion was generated about the need to ensure that all parents in the future were fully informed about, and had consented to, the storage of their newborn's blood spot cards, as well as **all** possible uses of the blood spots.

In this regard, some participants felt that consent should be asked for, **each and every time** that their (child's) blood spots were used for **any** purpose.

Other participants were happy to provide their final consent when the heel is pricked, albeit, they expected to be invited to specifically consent for storage and each of the possible uses of the blood spots (e.g. tick boxes for screening, quality control, and research).

Some thought that consent should be sought again at 18 years of age. Others suggested the following, to ensure consent is fully informed in the future:

- ◆ Providing Lead Maternity Carer's (LMC's) with support materials (e.g. brochures, FAQ's) and training.
- ◆ Providing parents with written and verbal information about the programme well before the birth.
- ◆ Providing parents with enough time to make a considered decision (appreciating that some will want to consult with family and friends).
- ◆ Recording consent and refusals in writing.
- ◆ Ensuring written and verbal information is easy to understand (e.g. brief, translated).



- ◆ Ensuring that the following information is highlighted (in written materials and verbally):
 - ◆ The reasons for/benefits of testing.
 - ◆ Right of refusal.
 - ◆ Requests for repeat samples.
 - ◆ Storage.
 - ◆ Retrieval.
 - ◆ All current and potential uses of the blood spots.

Storage

Focus group participants were surprised to learn that blood spots were stored and while they were spread in terms of their response, some reacted emotionally to this news.

Only some participants were comfortable with the concept of indefinite storage.

Some wanted their (child's) blood spot cards returned after screening, or within a time frame that they regarded as adequate for quality control and audit purposes (e.g. within a year).

Other participants wanted their (child's) blood spot cards returned on, or before, their death. The rationale for this varied, and included:

- ◆ Not being able to see any personal benefits for storing their blood spots after this point in time.
- ◆ Being concerned that their blood spots might be used in ways in which they were uncomfortable with (and they would no longer be able to monitor this).
- ◆ Wanting their blood spots to be buried with them (e.g. this is a cultural consideration for some Māori and Pacific peoples).



Uses

Participants were universally supportive of the **screening** aspect of the programme; and of extending the programme to include additional metabolic disorders and conditions, so long as they first present in infancy or early childhood, and can be treated by diet and/or medication (as is the case with the metabolic disorders currently screened for).

Responses to the use of blood spots for **research** varied:

- ◆ Some welcomed the use of their blood spots in research, and were happy to leave research decisions to the Ethics Committee and the NSU.
- ◆ Some do not want their (child's) blood spot used in any research (because they have not explicitly consented to this use).
- ◆ Some were ambivalent about this use and so wanted to consent, **each and every time** that their blood spot might be used for research purposes.

Participants were generally comfortable with the following uses of their (child's) blood spots:

- ◆ Quality control and audit purposes.
- ◆ To identify cause of death.
- ◆ Court and Police access, with the safeguard of the Memorandum of Understanding between the Ministry of Health and the NZ Police (as is currently in place).

Cultural considerations

This focus group research revealed cultural considerations relevant to Māori and Pacific peoples.

Some Māori and Pacific peoples believe that: blood is sacred; blood spots continue to remain a part of the person they were taken from; and bodies should be buried whole (with all organs and blood).

These beliefs have ramifications for the development of: verbal and written communications; and the guidelines related to future uses (including research), storage, and retrieval of blood spot cards.

Some NZ Europeans also have strong emotional relationships with their blood spots, with similar ramifications for the development of the programme.

No specific cultural considerations were identified for the Asian peoples included in this research.



2.0 Introduction

The subject of this report is to present the results of focus group discussions conducted as part of the consultation seeking public opinion on the consent, storage, and use of newborn blood spot cards.

2.1 Background

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 Newborn Metabolic Screening Programme (NMSP), the Ministry of Health seeks public views through public consultation on these issues. The National Screening Unit (NSU), the Ministry of Health unit that governs the NMSP, and the NMSP Advisory Group regard the integrity of the NSMP as critical, and therefore, wish to ensure that participation in the programme is not compromised. This consultation is being conducted by the NSU with public opinion being sought through the following channels:

- ◆ A web-based questionnaire (with printed copies also available)².
- ◆ Focus group discussions. (This is the subject of this report).

Research New Zealand was commissioned by the NSU to conduct, and report on, focus group discussions about the future storage and use of blood spot cards. The results of these discussions, in conjunction with the results of the web-based questionnaire, will be used by the NSU and the NMSP Advisory Group to make recommendations about improvements to the NMSP.

² The findings of this stage of the consultation are reported in *Newborn Blood Spot Cards: Consent, Storage and Use – A public Consultation. Responses to the Public Consultation document*, Research New Zealand, October 2007.



2.2 Objectives

The overriding objective of the focus group discussions is to understand peoples' perceptions and expectations relating to the **future storage and uses** of residual blood spot cards.

More specifically, this includes understanding peoples':

- ◆ Responses to the use of blood spots for additional **screening/testing** purposes, including:
 - ◆ Treatable vs. non-treatable metabolic disorders.
 - ◆ Metabolic disorders vs. other conditions (e.g. Hepatitis).
 - ◆ Early onset vs. later onset (e.g. Diabetes).
 - ◆ Identifying cause of death.
- ◆ Responses to the use of blood spots for **programme audit and quality control**.
- ◆ Responses to the use of blood spot samples for **research**, including:
 - ◆ Developing new screening tests.
 - ◆ Research into early vs. late onset conditions.
 - ◆ Identified vs. anonymised research.
 - ◆ Commercial (e.g. insurers, pharmaceutical) vs. university research.
- ◆ Responses to the use of blood spots by the **Police and Courts**, including:
 - ◆ Identifying deceased or missing persons vs. criminal suspects.
 - ◆ Paternity testing.
- ◆ Expectations in relation to safeguarding **access, storage and uses**, including:
 - ◆ Legislation.
 - ◆ The Memorandum of Understanding with Police.
 - ◆ Ethics Committee and the National Screening Unit.
 - ◆ Physical storage of blood spots and information about newborns.
 - ◆ Information sharing.



2.3 Approach

This research involved seven focus groups conducted between September 3rd and 19th, 2007. Each focus group included between four to six participants, and lasted between 2 to 2 ½ hours in duration.

At the completion of each focus group, participants received an incentive or koha to the value of \$60. This was offered as a sign of goodwill and to cover any other costs participants may have incurred (e.g. transportation and childcare).

2.4 Sample

As is the case with all qualitative research, the focus group sample comprised a relatively small sample (i.e. n = 37). Given the need to **understand**, rather than measure responses, the sample was carefully selected to reflect the ethnic diversity of New Zealand's population.

Participants were recruited on the basis of the following selection criteria:

- ◆ **Parents** of children whose youngest child is less than 5 years of age and born in New Zealand.

Parent participants were identified as the person, *mostly responsible for the health decisions made with regard to children within their household*. As anticipated, in most cases, this was the mother. A total of n=4 fathers participated in the parents' focus groups.

- ◆ Adults **aged 18-37 years of age**, who are **not** parents.

The inclusion of this particular cohort represents the full age range of consenting adults who potentially have blood spot cards in storage (given that the national screening programme for PKU (Phenylketonuria) was introduced in 1969).

- ◆ **Age and gender** (these criteria are relevant in the case of adults **aged 18-37**, who are **not** parents).
- ◆ **Ethnicity** (Māori, Pacific peoples, Asian peoples and New Zealand Europeans). The Pacific participants within the final sample were all of Samoan descent and the Asian participants were of Chinese and Indian descent.



- ◆ **Location.** Focus group participants were recruited from the geographic locations within which the researchers had the strongest community networks.
 - ◆ The Māori sample was recruited from Hamilton and the greater Wellington area (including Porirua, Hutt City and the Kapiti Coast).
 - ◆ The Pacific sample was recruited from both South Auckland and the greater Wellington area.
 - ◆ The NZ European and Asian sample were recruited from the greater Wellington area.

Participants were recruited using both a network approach and by a fieldwork recruitment company (Reid Research Services).

A total of seven focus groups were conducted, as summarised in Table 1.

Table 1: Summary of focus group structure

	Total	Māori	Pacific peoples (Samoan)	Asian peoples (Chinese & Indian)	NZ European
Parents of children aged up to 5 yrs, born in NZ	4	1	1	1	1
Adults aged 18-37 yrs, who do not have children	3	1	1		1
Total	7	2	2	1	2

A total of two focus groups (one with parents and one with adults with no children) were conducted each with Māori and Pacific participants (as these populations are regarded as priority groups by Government) and with NZ European participants (given the significant size of this population group). One group was conducted with Asian parents.

Each focus group included between four and six participants. Based on our experience, this number is considered to be optimal in terms of involving all participants and generating rich and productive discussion.

Participants excluded from this research included:

- ◆ Health sector workers.
- ◆ Those who had participated in qualitative research in the last six months.



2.4.1 Group facilitation

Headed by Corrine de Bonnaire (Director, Qualitative Research – Research New Zealand), the research team responsible for the facilitation, analysis and reporting of the focus groups included the following qualitative researchers, and Māori and Pacific research specialists:

- ◆ **Michelle Simpson-Edwards** and **Camilla Sutton** - Senior Qualitative Researchers (Research New Zealand).
- ◆ **Teresa Taylor**, Ngāti Kahungunu (ki Wairarapa), Ngāti Raukawa (ki te Tonga) – Māori Researcher (T & T Consulting Ltd.).
- ◆ **Mary Autagavaia** - Pacific (Samoan) Researcher. (Pacific Quest).

Māori and Pacific focus groups were co-facilitated by research specialists from the participants' ethnicity and experienced qualitative researchers. The Māori and Pacific researchers ensured that cultural protocols were followed and that participants were comfortable. They were also involved in the development of the focus group discussion guide and the analysis stage of the project. This ensured that issues of cultural significance were identified and addressed both within the group setting, and throughout the analysis process.

To aid the facilitation of the focus groups, a discussion guide, based on the focus group research objectives, was developed in close consultation with key personnel from the NSU. The guide was used as an aide memoir by the researchers, rather than as a questionnaire. See appendix A for a copy of the discussion guide.

In order to ensure that participants were well enough informed about the programme to be able to comment on its various elements, information about storage, and each of the current and potential uses of blood spots, was summarised, and then presented to participants in a building blocks approach. Each aspect of the programme was presented in writing (on stimulus cards), read out (or paraphrased) by the group facilitator and then discussed within the group. See Appendix B for a copy of the stimulus cards.

In order to help track changes in participants' attitudes over the course of the session, participants were asked to rate their support for the various uses of bloodspots (using self-completion rating scales), at the beginning and the completion of the focus groups. See Appendix C for a copy of the self-completion rating scales.

In general, as a result of participants' knowledge improving during the course of the focus groups, they became more generally predisposed to screening and related matters, although there were some noticeable exceptions. This was evident in terms of the way participants responded to questions using the rating scales.



At the end of each focus group session, participants were provided with a sheet (developed by key staff from the NSU), documenting the answers to some frequently asked questions (FAQs), and providing a contact point for further information. Attached to this information sheet was a paper copy of the form for requesting the return of blood spot samples. See Appendix D for a copy of the FAQs.

2.4.2 Analysis and reporting

To ensure its robustness, the analysis of the outputs from the focus groups, and the preparation of the report, was multi-staged and inclusive.

In addition to taking notes during the group, discussions were audio taped (after informed consent has been obtained) and subsequently transcribed. The main purpose of the transcripts and notes was to provide an information base for analysis, although a selection of anonymised verbatim have been used in this report to illustrate points made.

The same researchers, who completed the interviewing, also completed the analysis and reporting of the results. The members of the research team worked closely together, and continued to peer review one another during the analysis and reporting stage.

The analysis was completed on a thematic basis. To assist with the analysis, debriefing sessions were held following each focus group. This approach allowed for the identification of insights from the analysis on a progressive basis.

2.4.3 Limitations of this research

It is important to note that the findings in this report are based on a small sample (n=37), selected to reflect the **diversity** of likely responses to the future uses and storage of blood spot cards³.

Furthermore, while the sample was specifically selected on the basis of ethnicity (i.e. Māori, Pacific people, Asian people and NZ European), it is important to acknowledge that the final sample was not able to reflect the diversity within each ethnic grouping (e.g. the Pacific participants only included those of Samoan descent and the Asian participants only included those of Indian and Chinese descent).

Finally, as a qualitative research study, the objective of the focus group discussions was to provide an **understanding** of the findings, rather than to quantify these. Therefore, while it is possible to identify variations in responses, it is not possible to extrapolate these findings in quantitative terms (i.e. in terms of prevalence) to the general public, or to specific (e.g. ethnic) groups.

³ See section 2.4 for a detailed discussion of the sample selection criteria.



2.4.4 Confidentiality & ethical considerations

All Research New Zealand employees sign employment agreements containing confidentiality clauses and conform to the obligations and responsibilities contained within the Privacy Act 1993 and the Market Research Society of New Zealand's Code of Practice - including those that concern **the anonymity of clients and respondents**, and the confidentiality of information supplied by both. The following principles are always observed:

- ◆ **Participation in any research process is purely voluntary and by invitation.** All participants were recruited on an informed consent basis (i.e. they were informed of the high level objectives of the research and who the research was for at the time of recruitment). The purpose of the research and reassurance of confidentiality of response was also explicitly reiterated at the beginning of the focus groups (as required by the Market Research Society of New Zealand Code of Practice). Respondents were informed of their right to withdraw their participation in the research process at any stage.
- ◆ **All respondent data is treated as confidential** and respondents are assured of this when they participate. In reporting, any identifiable information is removed to ensure anonymity of respondents.
- ◆ **Only staff assigned to specific project work have access** to the data files required. Interviewers see only the information needed to conduct and complete the interviews. They do not have access to any other information regarding respondents, or client data files.
- ◆ **Information collected as part of a research process is proprietary to the client** commissioning the research. Researchers do not have the right to release that information to a third party without the expressed permission from the client.



3.0 Knowledge of storage and uses

Discussion early on in the focus groups revealed that levels of knowledge about the storage and uses of newborn blood spots were very low (even amongst parents). Both knowledge and interest in the topic increased during the course of each discussion.

Knowledge about the storage and use of blood spots was scant, even amongst parents. In fact, some of the focus group participants with no children knew absolutely nothing at all about the screening programme or blood spots.

While all parents could remember their baby's heel being pricked (some vividly recalling the upset that went with this) their knowledge, was generally restricted to the screening aspect of the programme. Very few participants were aware that the blood spots were stored, or were aware that the blood spots could be used for anything else (e.g. Police access, quality control and research).

I didn't know it was being stored until you brought it up. (Pacific Parent)

It is quite a lengthy process for them though with the little card, they need to put the bloodspot on it. In fact it is horrible. (Asian Parent)

If participants knew the name of the programme, it was remembered as the “*Guthrie test*”, “*the PKU test*”, or simply, “*the heel test*”.

Participants (including parents) generally, either did not know, or were vague, about what, and how many, disorders were being screened for. More often than not, it was assumed that only one or two conditions were being tested for. Some suggested that it was a test for genetic disorders, or for abnormal thyroid function.

I know that there is something that they test for that if it is picked up in the first week of the babies life it can be corrected, but if they don't it can't, but I don't know what it is. (Māori Parent)

They are trying to catch them early so that they can be treated early. Does it have anything to do with some heredity conditions that can be carried on to other children? (European Parent)

I thought it was specifically to do with checking if there was an abnormal thyroid function, whether it was over active or under active. (Asian Parent)



None of the people we spoke with mentioned that the programme screened for metabolic disorders and very few had any ideas as to what a metabolic disorder is, or what a screening programme is.

Smears. Breast screening. Measuring against a normal pattern of what blood does and then check to see what differences or deviations there are from that pattern. (European Parent)

Other details recalled about the heel prick included that the blood spots were collected a few days after birth, and that the baby may have been pricked more than once.

My second daughter, they pricked her heel three times, but I didn't mind that, but they said they needed to make sure that she is all right before we left the hospital. (Pacific Parent)

If participants had any idea of who was responsible for the programme, they assumed it was a Government department, such as the Ministry of Health. None had heard of the National Screening Unit.

Someone in Auckland. (European Parent)

The fact that it is the Ministry of Health and it is a Government organisation, it makes it more comfortable. (Asian Parent)

Some participants were aware of controversy surrounding consent and the ownership of the cards.

I have also seen a year or so ago in the paper about it, and it must be why they are having these meetings now; about the controversy and what was happening to them and some parents didn't know. (European Non-Parent)

In the absence of specific knowledge about the uses and storage of blood spot cards, some participants made assumptions about the blood spot cards and their uses, on the basis of their learnings from popular forensic TV shows, like CSI.

Of course everyone has watched CSI, even the most stupidest people have got some knowledge of scientific explanations of what blood does and how it works, we have all got really educated from it. (European Non-Parent)

I did once hear a rumour that the last spot on the card they keep for the baby's DNA, so that if the child ever goes missing, or in later life commits a crime. (Māori Parent)

Discussion early on in the focus groups revealed that not all parents believed they had been well informed about the programme, prior to screening. Experiences in this regard varied considerably. Those who felt they were best informed (albeit, not necessarily well informed), recalled being given the *Your Newborn Baby's Blood Test* brochure, and learning about the screening programme in



ante-natal classes. At the other end of the spectrum, were those who could not recall being told anything⁴.

I don't ever remember talking about the Guthrie test, I vividly remember talking about the Vitamin K and it really being a debate for us, and I don't believe we were ever given an option. (European Parent)

In the last four years I have had three children and I have never seen that (i.e. the brochure). (European Parent)

⁴ See chapter 8 for a full discussion about informed consent.



4.0 Screening and testing

Without exception, participants ranked the screening of metabolic disorders as the most important use of blood spots. The key benefit and motivation to participate in the screening programme is the belief that this is in the best interests of the newborn. Participants were all comfortable with the use of blood spots to identify cause of death.

Some participants want to see the programme extended to include as many metabolic disorders and other conditions as possible. Others only want the programme to be extended to include other disorders and other conditions which can be 'treated', and which present in infancy, or childhood.

4.1 The screening aspect of the current programme

In order to ensure focus group participants were able to make informed comments about the (current and potential) storage and uses of blood spots, information about each different use and storage was presented to participants in writing (on stimulus cards), was presented orally by the group facilitator, and was then discussed within the group.

The screening aspect of the current NMSP was presented to participants as such:

The Newborn Metabolic Screening Programme (i.e. Guthrie test)

Metabolic disorders are rare, inherited disorders that can cause ill health, learning disabilities and death.

Currently, the programme tests newborns for 28 disorders (e.g. Cystic Fibrosis, PKU), which can all be treated by diet and or medication, provided the disorder is identified early.

Testing takes place before the baby shows signs of any of these disorders. Blood is collected through a heel prick and placed on a blood spot card that is sent to the National Testing Centre for testing and storage.

4.1.1 Overall response

All focus group participants were *supportive*, or *very supportive*, of the use of bloodspots for the screening of metabolic disorders and regarded this as the most important use of the blood spots.

As already discussed, prior to being presented with more detailed information (i.e. as presented in the stimulus card), parents had significant gaps in their knowledge about the programme:

- ◆ None of the parents we spoke to had appreciated that the programme specifically screened for *metabolic* disorders.



- ◆ None knew that it screened for so many disorders.
- ◆ Very few had any real appreciation of the seriousness of the disorders that were being screened for.
- ◆ Very few realised that the blood spot cards were stored after screening and that they had been collected since 1969.
- ◆ Very few realised the blood spots were used (or could be used) for other purposes.

4.1.2 Benefits

Parents participate in the screening programme for the simple reason that it is **in the best interest of the newborn and the family**.

We just consent because we want the best for our child. (Pacific Parent)

Until I had her I had all these highfaluting ideas - it was, "I don't know if I want this or that." But once she was born it was a given, whatever needs to be done lets just get it done. You just want the absolute best for them. (Asian Parent)

In the same vein, some parents talked about how guilty they would feel if their child developed a disorder, if they had not participated in the programme.

If you didn't do something like that and something did happen you would feel bad, because there are these things that they can pick up, you would want to know as soon as possible, you wouldn't want your child to suffer. (Asian Parent)

Asked about the benefits of participating, parents talked about the advantages that come with knowledge. That is, parents want to know if their newborn has a metabolic disorder, so they can **plan and prepare**, and, as such, take the best possible care of their child. Similarly, they talk about the "*peace of mind*" associated with learning that, "*they probably haven't got these things.*"

Then it would be quite useful to know that later on in life, if I had access to my card and it showed that I was a carrier for something, then it would affect whether I decided to have children or not, because at this stage I don't know. (Māori Non-Parent)

If your child has some kind of disability or disorder you are going to want to know as early as possible so you can treat it, so you know how to best care for your child. If you are a first time parent and you have a child that has this disorder you would want to know when they are young, rather than making a sibling for them and before you know you have got two with the same thing. (European Non-Parent)

In addition to the benefits to their own child and family, some people were mindful of, and valued, the **benefits to the wider community** (i.e. benefits to other children, reductions in health costs).

If it saves money for the taxpayer, if you pick it up early. (European Parent)



If it is useful for the whole population, I agree. (Pacific Parent)

If it is picked up early it potentially has less of a cost to the health service, and for the parents too. (Asian Parent)

Some commented that having access to the programme is “a *privilege*,” that “*most kids in the world don’t get*.”

I wouldn’t have it any other way, that is what you do for your kids, anyone’s kids; not just your own. You want to make sure that we are healthy, and we are in a country that is in a position to be able to do all this sort of stuff, so, let’s do it! (Asian Parent)

4.1.3 Downsides and concerns

Participants identified the following downsides and concerns with the screening aspect of the current NSMP programme. Importantly, these concerns were regarded as relatively unimportant, compared with the benefits:

- ◆ Concern that ‘no news’ could give parents a false sense of security (i.e. “*that nothing was going to go wrong*”).
- ◆ The short-term distress for baby and parents when the heel is pricked.

Only a very short-term upset, for a long-term gain. (European Non-Parent)

- ◆ The shock of finding out that their newborn is sick, especially if they hadn’t understood what their baby was being screened for.

It concerns me that mothers may not know [what it is about]. They are not fully informed about what it is and what it is for. It could just be a doctor, or the midwife coming back and saying, “Your child has got this disease,” and it is like, “What? How do you know?” which is quite frightening. (Māori Non-Parent)

- ◆ Concern that parents should have access to counselling, if it is discovered that their newborn has a disorder.

There should be a counselling procedure involved if you were to tell the parent of a newborn child that their child’s blood indicates that they have got Cystic Fibrosis. (European Non-Parent)

- ◆ Concerns about the potential for mix-ups between cards (and getting the wrong results).

I think the concerns for me are that this appears to be quite manual, so human error, handwriting could be an issue. So, the results may come back from an incorrect form. (Māori Non-Parent)



The news that blood spots are stored following screening led some participants to start to think about, and express concerns about, the storage and other uses of the blood spots. These concerns are discussed in greater detail in the following sections of this report.

We don't know how long the bloodspots are kept for. We don't know what is done with them afterwards. We don't know what kind of research is done with them afterwards. (Asian Parent)

I don't understand about the rights that are given when you provide the sample, but I suppose someone that could benefit from it would be the Police, if they know there is a huge bank of DNA information. (Māori Non-Parent)

They might be using it for the wrong reasons, and it could be illegal. (Māori Parent)



4.2 Identifying cause of death

The use of blood spots for identifying cause of death was presented as follows:

Identifying cause of death

Using blood spots to identify cause of death, if this is unclear. The results of the testing may also identify the risks of a condition occurring in other family members.

4.2.1 Overall response

Focus group participants were unaware that blood spots have been used to identify cause of death. The use of blood spots for this purpose was generally supported, albeit that some participants made it clear that they expected to be asked permission to use their child's blood spots for this purpose.

4.2.2 Benefits

The benefit most often associated with this use of the blood spots, was that it would allow people to **plan** (e.g. if there were a genetic component that could affect other members of the family), and it would **assist them with their grieving** (e.g. providing a sense of closure).

If you had a child die you would want to know why. You would want to know what has happened, and whether it is genetic, and if any other children had it. (Asian Parent)

I reckon if the family aren't sure and wanted to know the cause of death, then it is a good way again. (Pacific Non-Parent)

The results of testing may also identify the risk of a condition occurring in other family members, so you know for future reference. (Māori Parent)

Some participants also imagined other benefits of using blood spots to identify cause of death, including, increasing the effectiveness of the current screening programme, and/or developing new tests, so that the programme can be extended.

I suppose the other advantage to this is testing above and beyond the 28. So, if they collect information on this, then they might be able to add another five; so I would say that is another big advantage if they do that, because they can only pick up more [disorders]. (European Parent)

If it helps somebody clarify another disorder that can save any other children's lives, then I would want to do it, to save anyone else from the same sort of pain. (European Parent)



4.2.3 Downsides and concerns

Participants expressed the following concerns in relation to using blood spots for this purpose:

- ◆ Concern that blood spots should only be used in this way with the consent of the family.

I think it should be consulted with the family first. It depends if the family has a say on it. (Pacific Non-Parent)

I think, as family members, it is our right to be informed of what is happening. It is just a bit of blood, but that blood still belongs to our children, and if they are asking permission, yes, sweet as. But to go ahead and do it without our knowledge would be really rude. (Māori Parent)

- ◆ Concern about the effectiveness of the screening programme, if babies are dying.

It rings alarm bells for me, because there are obviously still children slipping through the cracks, as in, some of the disorders are not being caught by the original screening test. As a parent it is almost that you are lulled into a false sense of security. If nothing showed up, there can't be anything wrong. (European Parent)

- ◆ Concern about how bad news would be communicated to parents who had lost a child, and the need to respect the wishes of those parents who do not want to know the results.

If they found out that there was an inherited genetic disorder; if you are either having more children, or already pregnant, then you realise that you could potentially have been responsible for the death of your own child. It would be incredibly disheartening. I suppose it comes down to saying, "Do you want to know the results or not?" (European Parent)

It is a question of how it is done. You wouldn't want to open the post one day and find out. I have had friends in exactly the same situation, and they actually chose not to find out. They categorically did not want their daughter put in a box. (European Parent)

- ◆ Concern that information about genetic predispositions could be used to the disadvantage of future generations (e.g. being penalised by insurance companies).

This goes into the conspiracy theory. Something I read recently is that potentially in the future, insurance companies will refuse to insure you if you have got a genetic disposition. That is a bit worrying if you have got breast cancer, or whatever, then the chances are that you may not be able to get life insurance. Whilst this is not applicable now, in five years I think it will be and that is scary - scary for our children. (Asian Parent)



4.3 Testing for additional metabolic disorders and other conditions

Participants were presented with the following statements to promote discussion about how, if at all, they would like to see the screening aspect of the programme extended in the future; and what, if any, parameters/boundaries they want around extensions to this aspect of the programme.

Testing for additional metabolic disorders

Extending the current screening programme to include the early detection of other metabolic disorders (e.g. Duchenne Muscular Dystrophy).

Testing for other conditions (i.e. not metabolic conditions)

Extending the current screening programme to include the early detection of other conditions (e.g. hepatitis).

4.3.1 Overall response

Participants varied, in terms of how they wanted to see the screening aspect of the programme extended.

Some participants wanted to see the screening aspect of the programme extended to include as many serious and/or life threatening conditions as possible. These participants generally reflected the view that, *if it is possible to find out they want to know, and the earlier the better.*

If there is a potential, I want to know earlier. I want to know before the baby is foetus size if it can be done. (Asian Parent)

I would like them to test for whatever they possibly could, and I would like to know the result. (European Parent)

Also, who cares if it is not treatable? I would want to know that my child has got that, and if you are only using the same prick you can you just test that same blood, then why not? (Māori Non-Parent)

Other participants were more circumspect. They were comfortable with some extensions to the current screening programme, but were unsure about, or clearly did not want others.

I think it depends on who you are, because it would kind of feel like you have got a death sentence hanging over you - everything would be bittersweet. But for me, I think it would depend on whether you could make changes, or do anything to prevent it, because I would want to know if I had the possibility of contracting something in the next ten years. I would want to know now, so I can make changes to prevent it. Whereas, if it is something



that happens, regardless of how you live your life, then I don't know. (European Non-Parent)

I don't know what would be best for me, or the child, or anything really. (Asian Parent)

4.3.2 Acceptable extensions to the screening aspect of the programme

All focus group participants were comfortable with extending the programme to include additional metabolic disorders and other conditions, so long as they:

- ◆ Have a serious effect on quality of life, or are life-threatening (i.e. not baldness).
- ◆ Can be 'treated' (i.e. that the outcomes for the child can be significantly changed through diet and/or medication, as is the case for the metabolic disorders that are currently screened for).

Test for the things that we can change and make a difference. Like in that first card it said, "Change by diet and medication", great, fantastic! Don't tell me stuff that is wrong with my kid that I can't do anything about. How much would you want to wrap your kid in cotton wool? (European Parent)

If there is something I can fix I would like to know about it. (European Parent)

- ◆ Present during infancy or early childhood.

4.3.3 Benefits

The key benefit of extending the programme to include 'serious' additional metabolic disorders and conditions that can be treated and present in infancy or early childhood, are the same as for the current screening aspect of the programme. That is, it is **in the best interest of the newborn and the family**.

Yes, for your own wellbeing, for the person, or the child, it would be better to know. (Asian Parent)

Other benefits associated with extending the programme are:

- ◆ It allows people to **plan and prepare** (i.e. with greater knowledge they feel more empowered).

I would want to know so you can prepare yourself mentally. Rather than all of a sudden, it happens, and you think, "Oh Christ, how am I going to get through this?" (European Parent)

If I knew deep down that my child has got this incurable disease, I might do things a little bit differently. It would help the child too, if the disease was fatal, but it didn't turn up until the 30's. It gives them the opportunity right now to have kids. (Māori Parent)



Being armed with that knowledge would be quite powerful, because you can make decisions that will affect your mental and physical health. I have had friends who have had Muscular Dystrophy, and I have sat all the way through secondary school and watched them rot away. If a parent can tell a child what's going on, you can then maximise their life for them, or they can maximise their own life. If I found out that I had Muscular Dystrophy, and I was likely to die in ten years time, I would go crazy, do all those things I want to do, I would go and travel. (European Non-Parent)

- ◆ It would mean avoiding the drawn out (expensive and emotionally draining) process of finding out what is wrong with their child later.

It would also be quite stressful going through the process of finding out what is exactly wrong with the child. (Asian Parent)

4.3.4 Downsides and concerns

Some participants definitely **did not** want, or were unsure about, extending the screening aspect of the programme to include disorders and conditions that:

- ◆ Are **not** regarded as serious (i.e. do not, “*effect lives drastically*”, or are not life threatening).
- ◆ Might never eventuate (i.e. predispositions).

I was just thinking, maybe not necessarily these particular diseases, or disorders, which are clear-cut, but things like depression... If a baby gets tested and their brain hormones sway to depression, but they may not, they may live their life without needing medication, and they lead a good life and they can do things, they can operate, is it really necessary to be tested for, do you really need to know? (European Non-Parent)

- ◆ Cannot be ‘treated’.

If you can't do anything about it, what's the purpose? (European Parent)

- ◆ Present in later childhood or adult years.

The downsides and concerns associated with extending the programme to include these types of disorders and conditions are largely associated with the negative impacts on the quality of life for the child and family while waiting for the disorder or condition to present. More specifically these include:

- ◆ The emotional distress associated with knowing.

It is like finding out when somebody has got cancer. You didn't know it was going to happen but you deal with it right there and then, which is really hard. I think I would really hurt if I knew something was going to happen to my child in the future, I don't think I would be able to handle it. (Asian Parent)



Wouldn't you just end up in a waiting game? Waiting for it to happen. You are constantly on the edge of your seat. (European Parent)

- ◆ Changing the way they would live their lives; and the ways in which they, and others, would treat their child (e.g. wrap them up in cotton wool, others might shun them).

I don't know. If you know that around 20 they might get something, it is like this time bomb in the background. It could potentially change your whole life, potentially change the way you treat that child. It would then have a psychological affect on the child. You have set the clock ticking and you might change your whole behaviour change the child's life; whereas, if you didn't know or knew later... But, then again, you want to plan. (Asian Parent)

Other parents knowing they might have a condition like hepatitis. They might be like, "I don't want you near my child". (European Parent)

I am a firm believer that we should be living each day not knowing what tomorrow holds, like maximising what you have got today. I enjoy every day that I have with my children. If I suddenly found out... we would just run with the punches, because there are obviously going to be thousands of things that they can't test for. I think we get to that point too where we just start playing God. (European Parent)

- ◆ The disorder or condition might never eventuate, or there might be a 'cure' by the time the child grows up.

I have got two minds about that, because you could spend your life worrying when it is going to develop, and it might not develop, or it could be really late and you have spent the last five years worrying, and your kid could end up in cotton wool. (Māori Non-Parent)

Our mothers and grandmothers had children without any of this and some of us will develop certain illnesses that can, or can't, be treated. I wonder if too much knowledge might actually cause us to make bad decisions, or limit what we can, and can't do. Just go with the ride and whatever will be, will be. You want to protect your children, but something like that which is going to develop in their forties. Where are we going to be in forty years time? We have made such advances in the last forty years. (Asian Parent)

I wouldn't want to know, because it is just like someone saying, "In five years you are going to be hit by a bus and die," and I wouldn't want to know that. Sometimes, it is hard to know that some of those things are actually going to happen when they say they might happen, because I know of people that have been told that, "By the way you have got cancer," and they always ask, "How long have I got?" and they are told, and sometimes they are told and they outlast it. My grandmother was told she had breast cancer, and she was told that would be it. Well, she out lived the breast cancer and died of old age. (European Parent)



Some of the parents, who were unsure if they wanted to know if their child might develop a disorder or condition in the future, suggested that providing their GP (rather than them) with the results might be a solution. This would mean that **if** their child did develop problems, their GP would be in the know, and could help them to manage it.

It would be helpful, when someone has got something wrong, as it seems to take six months for the doctors to figure out. If you imagine the GP had a file that could help for a quick diagnosis. (European Parent)



5.0 Programme audit and quality control

Once the benefits of the programme audit and quality control were explained, participants were generally comfortable with the use of blood spots for this purpose.

5.1 Overall response

This aspect of the current NMSP was presented to participants as such:

Programme audit and quality control

If a baby has one of the disorders tested for, but does not have a positive test result, some of the blood can be tested to try and ensure the same mistake does not happen again.

Stored blood spot cards are used to improve current tests and methods of testing (e.g. calibrating new testing equipment).

Participants were not aware that blood spots were used for the purposes of programme audit and quality control. While most were happy for the blood spots to be used for this purpose, some had to first come to terms with the **shock** of learning that their (child's) card had been kept, and was (or could be) used for purposes other than screening.

Compared with storage and other uses of blood spots, this use of the blood spots generated relatively little discussion.

5.2 Benefits

The benefit associated with using blood spots for this purpose is greater trust and confidence in the programme.

It is accurate information. It is a huge benefit. It puts trust into the whole scheme. We may not have much trust if you are not testing, and making sure what you are saying is actually genuine. (Asian Parent)

Before, I was wondering, what is the point in keeping these cards? But, I guess that shows that even maybe later in my life I might develop a disorder, and why wasn't it picked up then, so going back and double-checking. (Māori Non-Parent)



5.3 Downsides and concerns

Some participants expressed the concern that care should be taken not to use too much blood for audit and quality control purposes, because it may be needed for other purposes.

It is not a lot of blood on a card. Let's say that they were doing these kinds of tests, but then I needed the blood for something medically, and they go, "Sorry, we have been calibrating off your blood, so we have got no more." Where is the line drawn? (European Parent)

Some were uncomfortable with the concept of their (child's) blood spots being used to test new equipment.



6.0 Research

Responses to the use of the blood spots for research purposes varied. Some participants welcomed the use of their blood spots in any research that is “*for the common good*”. In contrast, are those who believe that blood spots should **not** be used in any research (because they have not specifically consented to this use). Others were ambivalent about this use, and wanted to be asked to consent for each research project that their (child’s) blood spot might be used in.

6.1 Overall response

Participants were presented with the following statement as a start point to stimulate discussion about their thoughts and feelings about the use of blood spots for research purposes and what, if any, parameters/boundaries they want around this use.

Research

Blood spots could be used for research purposes. For example:

- *to identify reasons for cot death.*
- *to develop tests for metabolic disorders that currently cannot be screened for.*
- *to develop tests to identify other conditions that might develop later in life (e.g. diabetes).*

This research would need to be approved by an Ethics Committee.

Very few focus group participants were aware that their (child’s) blood spots were being stored, and could potentially be used in research.

Discussion about this use of blood spots elicited a relatively strong response from some focus group participants, and consequently debate was lively within some groups, as different views were shared.



Responses to using blood spots in research varied, and can be considered as sitting along a continuum, anchored at one end by those who are 'advocates' for this use, to those who are 'opponents':

- ◆ **Advocates** are very comfortable, even excited, by the prospect that their (child's) blood spots could be used in research that will benefit the community.

I just think, potentially, it is an excellent data source, and it could be used for so many good things. Maybe that is the key, good things and bad things. (European Non-Parents)

Once we get to identifying the reasons for cot death, we can then get to identify the true risks, and get to preventing cot death, which is something I think for mothers with young children is a huge thing. Also, anything along those kinds of lines, once we get to identifying why these things have happened, we can get to the preventing stage. Everything has to have steps, and that is kind of like the first step. So, I think that is a real positive thing. (Māori Parent)

Yes, I say, "Research away," and I don't have a problem with in the future, if things change, if the ideals of society change, they use it for something that I would be opposed to now. That is the way of progress. (European Non-Parents)

- ◆ **Ambivalents** see both the pros and cons of blood spots being used in research (i.e. they are in the middle of the continuum). These participants want to be asked for consent, each and every time their (child's) blood spot is used in research (regardless as to whether the research is anonymous, or identifiable).

I would prefer they ask to get consent. (Pacific Parent)

I think anything that concerns your child's health and wellbeing has to be a good thing. The only thing I am aware of is misconceived information being given. It would be nasty to be told that this is going to happen, and then it didn't happen. That has a sort of a con to it as well. If I was told that at ten years old something weird was going to happen with your child and I just sit there waiting. Whereas, if I didn't know we would carry on like normal. There are two sides to that coin. Do I want to know, or do I not want to know? Sometimes, it is better not knowing. (Māori Parent)

If my blood spot was there and they did a research on it I would feel like, "You didn't have my permission so..." but I still see the benefit for other future disorders. I reckon they should get permission from the individual. (Pacific Non-Parent)

- ◆ **Opponents** do not want their (child's) blood spots to be used for any research because consent has not historically been specifically sought for this purpose.

The stuff that is there now shouldn't be used. (Māori Non-Parent)



I guess you have got problems there in the fact that no one consented, no one from 1967 has consented for them being used for research. Whereas, maybe on that form you could tick, "Yes, I am happy for it to be used for research in the future." But, I don't know how I would feel if somebody rang me up and said, "We are actually using yours for research, and we have found out that you have got this disease." (Māori Non-Parent)

6.2 Factors underlying agreement or disagreement with research use

The key factors differentiating responses towards the use of blood spots for research purposes are peoples:

- ◆ Relationships with their blood spots (i.e. whether, or not, they regard them as a part of themselves, or not).
- ◆ Trust and confidence in the bodies involved in the research (e.g. the researchers, the Ministry of Health and the Ethics Committee).

Advocates

Those comfortable with the use of blood spots in research were generally trusting of the various bodies involved (i.e. the researchers, the Ministry of Health and the Ethics Committee).

It is the name, "Ethics Committee". It is a word people trust. (European Non-Parent)

This says, "Approved by the Ethics Committee." You just have to trust that they are not going to do anything. I am a very trusting person. (European Parent)

I am quite trusting in them, even though I don't know who they are or anything; they are ethical so they can't make stupid decisions. (European Parent)

I don't really worry about that too much, because I don't think I have heard anything like that happening with a Government department, so much that it does cause me to worry about what they are going to do with our things. If it is for the greater good, then you are going to go with it. (Asian Parent)

They were also generally much more rational and pragmatic (rather than emotional) in the way that they talked about blood spots and how they could be used. That is, they did not regard the blood spots as a part of them any longer.

You seem to have quite an issue with the fact that it is yours so you own it, but I don't really see it that way, it is just blood. (European Non-Parent)

I don't see it as being part of me once it is taken out of my body; it is not mine kind of thing. (European Non-Parent)



Those comfortable with the use of blood spots for research were also generally positive about the indefinite storage of their blood spots. In this regard, some see the stored cards as assets that increase in value over time (i.e. with each generation).

I think the longer it sits there the more interest it will gain, because at the moment there is not as much of a range of people's blood, but in ten, twenty, thirty years, there is going to be quite a bank. That it is going to be a range from people that are grandmothers right down to newborns. (European Non-Parent)

Ambivalents and Opponents

Some of the participants, who were uncomfortable or ambivalent about the use of blood spots for research, expressed an emotional and or spiritual connection to their (child's) blood spots. Such participants talked about "their" blood spots, as though they were still a part of them.

These same participants were also more likely to express anxieties about the storage of their (child's) blood spots⁵, and in relation to uses of their blood spots, other than for screening purposes.

It really is the knowledge factor. It doesn't feel right. It is the fact that they are there and we don't know and I think that is the thing that makes your stomach churn. (European Non-Parent)

People who expressed this type of relationship with their blood spots included participants of various ethnicities (i.e. some Maori, Pacific and European).

Some of the participants who feel uncomfortable with the use of blood spots in research also expressed concerns related to the trustworthiness of the bodies associated with the research process (i.e. their ethics and objectives), including the involvement of the Ethics Committee.

Trust no one. That is my rule. Just trust yourself, and trust God. (Pacific Parent)

I trust them to a point but I don't know whether I would trust them in five years. I don't know what they would be like in the future, they have been good until now but they might not always be so. That is why I think they should be destroyed when people die. (European Non-Parent)

⁵ See chapter 8 for a discussion of the storage of blood spots.



6.3 Parameters around research use

Those who were the most comfortable with the concept of their blood spots being used for research were also the most open to the type of research their blood spots might be used in.

In contrast, those who were uncomfortable, or ambivalent, about the use of their (child's) blood spots in research were the most sensitive to potential misuse in this regard.

All participants agree that research needs to be for the "common good", and must not disadvantage any individuals, or groups.

Some participants expressed the following concerns about the use of their blood spot cards in certain sorts of research:

- ◆ Concerns expressed in relation to blood spots being used in **identified research** are similar to those expressed in relation to extending the screening programme (i.e. the emotional hurt, the negative impact on their quality of life while waiting for a disorder/condition to eventuate). It is important to note that the concepts of anonymous, versus identified research, were not well understood by some participants, and were regarded as largely irrelevant by others.

Everyone would need to go through the anxiety of wanting to know something. It might drive you nuts. Just imagine if you knew your baby was going to have Downs Syndrome. (Māori Non-Parent)

- ◆ Concerns that blood spots should not be used for frivolous/unimportant research (e.g. development of lifestyle drugs).

Yes, I think it is a definite no, for lifestyle drug companies and cosmetic companies to have access to the blood spot. (European Non-Parent)

They should only be using it for things that benefit the wider community like researching into metabolic disorders and things like that, rather than wasting our blood in our Government's database for the latest super drug which next year is going to be off the market and they will bring in something new. (European Non-Parent)

- ◆ Some participants were definitely uncomfortable with the concept of research being undertaken by a **commercial enterprise** and the concept of researchers making some **financial gain** out of research involving their blood spots.

That is where I have a problem. If somebody is creating a disease from this research, and then goes off to create a drug that will cure that to make huge amounts of money. We have to be mindful. (Asian Parent)

Commercial is for their own commercial purpose, at the end of the day. For example, a pharmaceutical company is doing the research to sell their drug. Whereas, the



Ministry, they're doing the research for the better of the people. Also, pharmaceutical companies have heaps of money. (Māori Parent)

I wouldn't consent at all if it were commercial, only if it was health studies. (Pacific Parent)

Something that is developed by the Government to screen newborn babies in NZ should not be used for commercial purposes at all. (European Non-Parent)

In contrast to this view, other participants were comfortable with the concept of researchers benefiting financially from blood spot research, so long as the outcomes of the research were of benefit to the community (e.g. the development of a drug to combat cot death).

With pharmaceuticals somebody has got to make the drugs secure so there is no real issue. (Asian Parent)

- ◆ Anxiety was expressed about the use of blood spots in genetic engineering (i.e. cloning), or in research that involved mixing animal and human DNA. It is important to note, that even those who were generally supportive of the use of blood spots in research expressed concerns about their use in this type of research. While participants were unlikely to believe an Ethics Committee would approve such research in today's environment (i.e. because of the potential public backlash), some participants were concerned that this type of research might become acceptable (and as such might be approved) in the future. The belief that their (child's) blood spots might be used in ways that they are uncomfortable with in the future impacted on decisions about the length of storage and retrieval of cards⁶.

I don't have a problem with it. It is just a prick, and they get over it, unless they use the blood to clone my daughter. (Asian Parent)

I am comfortable to do research on most of these things, but where it is mixing my daughter's, or my son's blood with an animal's blood. That is what scares me. (Asian Parent)

I don't like the idea of genetic mutations and changes because it is not natural, so that is where I draw the line there. But I do trust the Ethics Committee to represent me. (European Non-Parent)

⁶ Refer to chapter 8 for further discussion on storage and retrieval.



6.4 Benefits

Participants identified the benefits of using blood spots in research, as some, or all, of the following:

- ◆ Benefits directly relevant to **them and their children and future generations of their family**. Importantly, some participants were clear that they were uninterested in their blood spot cards being used in research, unless they could see obvious benefits to themselves, or their children

If the research was relevant to me personally, I would probably say yes to it. I would go ahead and give them permission to use the blood. (Pacific Parent)

- ◆ Benefits related to **the wider community and future generations**.

If it is for the greater good, then that is fine. (Asian Parent)

Yes, and I think that is a good way too, because if we know our children are at risk for diabetes, we would know right from day-one not to do those naughty things that we all do, because it works. (Māori Parent)

I don't mind if it helps the world, or the future. (Māori Non-Parent)

I am quite happy for mine to be used after I have passed away, because I would hope that my life somehow benefits somebody, whether it is now or in the future. (Māori Non-Parent)

- ◆ Assisting with **medical advancements**. Some participants saw allowing their (child's) blood spot to be used in research as their way of giving something back. Their rationale was that they were more than happy to benefit from such developments (e.g. new drugs and treatments), so saw no reason why they shouldn't also contribute.

I think it boils down to how there is going to be potential cures in the future for things that aren't necessarily around at the moment. I think this is probably one of those steps in that direction, and you can't have that and not have this. (Asian Parent)

The only way to progress is to do the research. You can't get away from it. There are diseases around that we don't know enough about. (Asian Parent)



6.5 Downsides and concerns

Participants identified the concerns of using blood spots in research as some or all of the following:

- ◆ Concerns that **blood spots might be used up in research**, and, as such, won't be available when the individual, or the family, needs them.

I would hope that they would only use one more spot for research and the same one for lots of research, so there is no more spots, because you don't know what could happen in the future, and you may need those two spots for more information that benefits you and your family. (Māori Non-Parent)

- ◆ Concerns about the **logistics** surrounding research, in particular, if the cards are handled with care and respect, and whether they are returned to the NSU.
- ◆ Concerns about **where and how blood spots are stored**.⁷
- ◆ Concerns about the **Ethics Committee** (e.g. who is on the Ethics Committee, whether their views are being represented, and how decisions are made)⁸.

That was all I wanted to know. Are our cultural views being represented when this research is being considered? Whether, or not, it coincides with our cultural beliefs. Is there someone on that committee that knows? (Māori Parent)

Reflecting their discomfort, even anxiety, about the use of blood spots for research led some participants to ask about the ownership and retrieval of bloodspots.

⁷ See chapter 8 for a more detailed discussion on storage.

⁸ See chapter 8 for a more detailed discussion about Ethics Committee involvement.



7.0 Police and Court access

Participants were generally accepting of Court and Police access to the blood spot cards, with the safeguard of the Memorandum of Understanding in place.

7.1 Police access

This aspect of the current NMSP was presented to participants as such:

Police access - Identifying deceased or missing persons

Police access to blood spots is restricted to identifying deceased or missing persons. Blood spot cards are only used for this purpose as a last resort and usually with explicit parental consent. The agreement between the Police and the Ministry of Health is a Memorandum of Understanding.

Prior to attending the focus groups, no participants were aware that blood spots could be, and have been, used for by the Police to identify deceased, or missing persons.

Participants' trust and confidence in the Police varied considerably - from very trusting to, not trusting at all.

Personally, I don't have any issues with the Police. I think hopefully there is enough governing bodies within the Police force to make sure it is not abused. There are easier ways of abusing their power than going through and getting blood spot stuff. (Asian Parent)

I lost my trust with the Police since the Nicholas case. It is not all the Police; there are people that are really good and honest. (Pacific Non-Parent)

I don't really trust them. I grew up in a bad place, and just didn't like cops. It might be different for other people. When I go to the movies in town, you see the cops hassling Polynesians and Māoris. (Māori Non-Parent)

The level of trust participants' expressed in relation to the Police, generally determined the amount of access they wanted the Police to have to the blood spots and for what purposes.

All participants were comfortable with the Police having access to blood spots, as a last resort, to identify deceased, or missing persons. In fact, some participants applauded this particular use.

In this situation, where remains of a body are found, I don't have a problem with it. If that was my child I would want to know. (Māori Parent)

I wouldn't need a box for this. That's okay with me, because I think it is phenomenal! That to me is a reason to store the blood. If my child was missing and they had something that



could prove that, that was my child. I think that is a really positive way to use the blood. (European Parent)

I can't see a disadvantage. They already have to go through the court. They can't just rock up into the thing. It is hard for them to get into it, which is a good thing, I agree with the use of it, if they are trying to find out stuff like that. I can't think of any disadvantages. (Pacific Non-Parent)

Personally, if someone I knew went missing, and then they found a body that was unidentifiable, but they thought it was them; if it was the only way to get closure on it, then, yes, I would want to know if it was my friend. (European Non-Parent)

The Memorandum of Understanding between the Ministry of Health and the Police generally reassured those with any hesitations about current Police access⁹.

Some participants want to see the Police use the blood spots to identify those involved in criminal activity, as well as using them to identify deceased and missing persons.

Other participants were adamant that they do not want Police to have any greater access than they already have to the cards, as dictated by the current Memorandum of Understanding.

I wouldn't want the Police to have more Power. (European Parent)

Some Māori and Pacific participants wanted reassurance that the Police were treating the blood spots with the appropriate respect.

So long as it is treated with respect. Do they take it with them, or is it all done for testing or the matching at that place? (Pacific Parent)

⁹ See chapter 8 for further discussion of the Memorandum of Understanding.



7.2 Court access

This use of blood spot cards was presented to participants as such:

Court access - Paternity testing

Courts have separate rights, which override any other legislation or policies allowing them to access all hospital and medical records. As such, they can access blood spot cards (e.g. for paternity testing).

Most participants were comfortable with court access to the cards for paternity testing.

If they have gone through that court system to get that, I don't have a problem. (Pacific Parent)

Some participants wondered for what other reasons the court might access the cards (outside of paternity cases). In this regard, some thought blood spot cards should be used to identify the perpetrators of crime.

A number of participants also wondered whether those who had been adopted could use their blood spot cards to identify their mothers.

So adopted children could potentially go in and get a court order to find out who their mother is, if the mother's name is on the card? (Asian Parent)

What happens to children who are adopted? The only reason I ask, is there will be children out there who want to know who their birth parents are. Maybe, they could go back to their blood spot card? (European Parent)

What if you are giving up a child for adoption, and this child is looking for its long lost mother, and they just come and they find that blood, and it somehow matches yours? (Pacific Parent)



8.0 Storage, information sharing, legislation and other safeguards

While some participants are comfortable with the indefinite storage of their blood spots others want them back immediately after screening, or at death.

Participants were generally happy with the information sharing, legislative safeguards associated with the programme. Participants want to be fully informed and to be asked to consent for storage and **all** current, and potential, uses.

8.1 Storage

This aspect of the current NMSP was presented to participants as such:

Physical storage of blood spots and information about newborns

Blood spot cards are stored indefinitely after screening is complete. Storage is secure and access to the cards is limited. Blood spot cards include the following information:

-The baby's name, sex, place, date and time of birth, National Health Index (NHI) number, birth weight and gestational age, date and time of sampling.

-The mother's name

- Lead Maternity Carer (LMC) contact details.

8.1.1 Overall response

Focus group participants (including parents) were surprised, even upset to learn that their (child's) blood spots were being kept indefinitely (as even parents had no recollection of being informed of this). Participants that reacted with the greatest distress to this learning were those with a spiritual, and/or emotional relationship with their blood spots.

As for storage, I just think, what can they do with just a little bit of blood on cardboard? But, to me, that is playing with my son's blood. You are playing with my family, and I don't like that, unless they ask permission first, that is fine, but just to go ahead and play with blood that came out of my kids, that is something I don't like. So, consent is a big issue. It is a very big issue, because you might as well just come and take my son and keep pumping blood out of him, but the mothers are just walking around not knowing that they are doing this. (Pacific Parent)



I give blood at the blood bank, and I don't have a problem with that, because it is used to save lives. But this storing a little card with my blood on it, what's it doing there? There is just something that freaks me out about that. (European Non-Parent)

I feel completely gob-smacked. I thought it was this compulsory test that tests for four things and then they biff it. (European Parent)

As well as reacting emotionally (at least initially), participants typically responded to learning that blood spots were stored with many questions about where and how they were stored. For some, the fact that they had not been informed about what they regard as such an important matter, raised concerns and suspicions about how their blood spots were being used.

I didn't know that they kept it and stored it. I thought they just did the tests and discarded it. What do they keep it for? (Māori Parent)

At the back of your mind, you think, what potentially could happen with some ruthless organisation that gets hold of it? (Asian Parent)

8.1.2 Optimal storage time

Participants varied in relation to how long they thought that the blood spots should be kept for, and also their rationale for this.

At the two extremes of the spectrum of views are those who think that the blood spots should:

- ◆ Be kept indefinitely.

If it helps our children, then I would change my mind, and say, "Just keep it forever". (Pacific Parent)

It is a bit like when people hoard things, then if they need it one day, then it's there. (Asian Parent)

- ◆ Not be kept at all (i.e. should be returned immediately after screening).

I like the idea of testing for certain metabolic diseases, but I don't know, there is something that rubs me the wrong way about the fact that they keep them. Once it is tested, destroy it. It is not yours. (European Non-Parent)

A number of participants indicated that they thought that blood spots should be returned to the next of kin at death, or only kept for a time period that approximated the average lifespan (e.g. 80 or 100 years).

I would say, leave mine until I die. (Pacific Parent)

The reasons behind this preference varied, and included the following:



- ◆ Some wanted the blood spots returned on death, so that the person could be buried whole.

They need to make allowance for the oldest child to be able to ask for the card back after you have passed away. Then the blood spot card can still be with you. You are buried, but part of you is still floating around. (Pacific Parent)

- ◆ Some could see no further need to keep the blood spots, as the individual could no longer personally benefit from it.

I think that once the person has passed away, it is no good to anybody. (Pacific Parent)

- ◆ Some were concerned that they would no longer be able to monitor the way that their blood spots were being used.

Once I am dead. I want it back, because, then I don't have the right to say yes, or no. (European Non-Parent)

- ◆ Some were concerned that ethical standards would change over time and that their blood spots might be used for research that they are uncomfortable with.

So, I think it is great that we have a right to request the return of them, but I will keep it in the blood bank, because I like that idea of ongoing research for good reasons. But, then, once I die, it goes with me, or to my family, because it is still my property. If my children in sixty years time, when I have kicked the bucket say, "No, put it back," they are informed enough to make that decision. Then that's cool. (European Non-Parent)

8.1.3 How blood spots are stored

In the absence of any information to the contrary, some participants assumed that the blood spots were stored as part of a high-tech DNA database.

It is like another set of fingerprints, isn't it? I would imagine everything is on a database. (Asian Parent)

Participants who appreciated the value of their blood spots were worried that if it was not stored and transported with care, that their (child's) blood spot could no longer be used. For some Māori and Pacific participants, these concerns were a reflection of the sacred nature of their (child's) blood. European participants with a more spiritual/emotional relationship with their blood spots expressed similar concerns.

Specific concerns, in relation to the handling and storage of blood spots, included:

- ◆ Concerns about the blood spots rubbing together, and, as such, blood intermingling and becoming contaminated.



Is there anything that separates every card? Is there any chance that blood on one card can get onto the card of another? (Māori Non-parent)

They should use something like gladwrap, something that will cover it, so that it is not contaminating other people's blood. They might get it mixed up with someone else's. Then there could there be a risk that it is used for something else that you are not aware of. (Pacific Parent)

- ◆ Concerns about blood spots getting lost, or destroyed.

It is bit too prehistoric to me. It sounds like the old library. I have got visions of boxes with rows and rows of cards. Is it fire proof? Is there a chance of it being accidentally destroyed? Is it duplicated somewhere else? (Asian Parent)

If it got lost, that would bother me, because it is something precious. (Pacific Parent)

- ◆ Concerns about blood spots (and therefore results) getting mixed up.

My concern with this is mistakes, using the wrong card for the wrong person, and then they will treat the wrong person. It has happened with prescriptions, because this happened with my baby. I looked at the prescription, and it wasn't for my baby. (Pacific Parent)

- ◆ Concerns about who had access to the blood spots while they are in storage. Importantly, most participants seemed to be reassured in this regard, once they learnt that only a few people within the NSU have access to the blood spots.

- ◆ Concerns about the way in which blood spots are handled (i.e. with care and respect). Such concerns were of particular concern to some Māori and Pacific participants.

They must treat the blood with respect. People may not realise that the blood belongs to the person. (Pacific Parent)

Reflecting the perceived importance of their blood spots, some participants expressed an interest in visiting the storage facility.

Is there a certain place for families to go in to see if it is stored properly, just in case it gets mixed up with another baby's blood, and then they go to do tests on that baby, and it is the wrong baby, and they might detect that something is wrong? (Pacific Parent)



8.2 Information sharing

Compared with access to the blood spots themselves, participants were generally unconcerned about the access to information related to their blood spot cards.

Participants make the assumption that they are able to freely access information associated with their own, and their child's, blood spots (including the results of their tests). As discussed in the section on Court access, some participants expressed concern that adoptive children may be able to find out the identity of their natural mother from their blood spot card.

Some suggested that the information related to blood spots should be held on a central database that could be accessed by health providers, including their GP.

If I am travelling to the top of the North Island, and get sick at Cape Reinga, I would see more benefit if my GP could access a central database. So, not just necessarily showing your bloodspots, but the bloodspot being part of a database of information that is accessible by medical people. (Māori Non-Parent)

8.3 Legislation and other safeguards

This aspect of the current NMSP was presented to participants as such:

Legislation

Consumer rights and provider obligations in relation to obtaining, storage and use of blood spot cards are covered by legislation:

- Consumers (or their parents/guardians) must give their informed consent before blood is collected.*
- Consumers have the right to request the return or disposal of the blood spots at any time.*
- Blood spots can be used for research approved by the Ethics Committee (i.e. without seeking consent from the consumer).*
- Blood spots can be used for programme audit and quality control purposes (i.e. without seeking consent from the consumer).*



8.3.1 Informed consent

Learning for what was perceived to be the first time (during the focus groups) about the storage and the different possible uses of blood spots generated considerable discussion about both, the fact that they could not remember being asked for their consent, and the importance of ensuring that consent is fully informed in the future.

The past and present

None of the participants in the focus groups **believed** that they had been fully informed about all the current, and potential, uses of their blood spots, and the fact that they are stored indefinitely.

I didn't get anything like this (i.e. the brochure). I think I got told something very briefly and then they did it. When you have a baby, you just do everything you need to do, so you just do all these things. (Asian Parent).

In fact, some parents were surprised to learn that they actually had a choice to participate, or not. These parents simply recalled the screening as just one of a number of things they were expected to do when their baby was born.

So, people can turn it down? I don't recall being given an option, and I gave birth within the last year. (European Parent)

I think the thing is, when they ask you about whether you are happy for these tests to be done, you have just come out of labour, and in my case dosed up anyway. I have read about it beforehand, but even though I had read about it, I was not really in any position to argue the case, or not. It was a case of, "Fine, have it done," but, there is not that much information, and even if there is, you are not in any real state to take it in and make a decision, because it is so soon after the birth, which it has to be. (Asian Parent)

For some, in particular, those with strong spiritual and/or emotional connections with their (child's) blood spots, learning for the first time that their card was being stored indefinitely, and could be used for a range of purposes, resulted in considerable upset.

I feel very out of control all of a sudden. The blood on the card is not your's anymore. (European Parent)

Now, knowing what I do about storing the cards for people who are dead, because my parents have passed away, now knowing that information, I am emotional knowing that part of them is still there. (Pacific Parent)

To be honest, I have got quite angry knowing that. It has disturbed things for me. (Pacific Parent)

Do they have to ask me to use it now? No. That, in my opinion, sucks. (European Non-Parent)



The future

Looking to the future, all participants concurred that it was important that parents are given every opportunity to make **fully informed** decisions about their newborn's blood spots.

It is fine to do the tests that need to be done at the beginning, but probably at that time people/parents should be made aware of what happens with this blood, given a choice of whether they would like them to store it, or not. (Pacific Parent)

To this end, participants talked about:

- ◆ The importance of giving parents the time they needed to make an informed decision.
- ◆ Making sure that the information is shared well before the birth.
- ◆ Making sure the information is understood (e.g. that the language used is well understood, including providing translations/translators, if required).

I don't even know the meaning of the word 'paternity'. (Pacific Parent)

Sometimes too, it is not understanding, because, talking about our own community, sometimes people just say, yes and no, and not know what the reality of what the discussion is about. So, I think that is the other way of misunderstanding. (Pacific Parent)

- ◆ Educating midwives, so that they can more effectively pass the information on to parents.

The majority of heel pricks are done by midwives. So, why don't they educate the midwife to pass on this information, when they are doing the tests? Part of the midwives' contracts they should have to pass on that information. (Māori Parent)

- ◆ Making written consent a requirement (e.g. a signature at the bottom of the blood spot card).

By giving a written consent, it is informing. They are getting the information out there, like the information we have had today. Because, currently, that information is not getting out there, so it is just another way of spreading the word. (Māori Parent)

I think there definitely needs to be a signature on that card from a parent, and if possible the name of the dad. (European Parent)

In relation to the provision of consent, participants felt strongly that they should be specifically asked to consent to storage, and each and every current, and potential, use of their (child's) blood spots (including research and quality control). In fact, some participants indicated that they wanted to be asked for their consent on every single occasion that their blood spot is used.

I just don't think there is enough informed consent. To me, I feel like you are making one decision, but you are actually involving several other decisions, without being able to say, "Yes, I want this done, but not this and this." That has to come from the informed consent,



which doesn't happen. But, what I am saying is, as soon as you agree to even having the blood done, you agree to the whole package, and I don't think that is necessarily how I would want it done. (European Parent)

A tick box style consent form that provided parents with the options of having their card returned immediately after screening, or for their card to be kept to be used for additional purposes (e.g. research), was suggested as one way of ensuring parents were clear about what they were consenting too, and of giving them the choice to opt in, or out, of particular uses.

Yes, and that literally will be a box, "Do you want this returned after we have done our tests? Or, do you want it destroyed?" Because, what is the point in returning it? At least that way you actually destroy it, and you know it is destroyed. (European Parent)

Blood spots can be used for programme audit and quality control purposes, without seeking consent from the consumer. I don't agree with that. If it is being used outside of what we have given our consent for, then we haven't consented for it. They could do these tests, and we wouldn't even know, but who does that blood belong to? To us, or the Ethics Committee? I know I have had a blood spot taken, I don't know if I want my blood being used for different purposes, or my child's. If you are going to have a signature on here, then that needs to be on there too, that it can be used for research. It wouldn't be hard to have a tick box, "I give consent for the generic test; I give consent for my blood to be used in the future for research". (Māori Parent)

Some participants thought that blood owners should be asked to re-consent to the storage and use of their cards once they reached the age of 18 years.

Then make you aware that if you don't want it to be used for research purposes from the age of 18, you may ask for your card back, then you have made that consent. Otherwise, if you are happy for it to be used for research, then it stays there, and it has been consented for. I guess that way you get around the fact that your parents have consented. (Māori Non-Parent)

I think that from the age of 18, the actual person needs to consent. (Maori Non-Parent)

8.3.2 Return of blood spot cards

Very few of the focus group participants were aware that they could ask for their blood spot back at any time.

Does the bloodspot belong to us, or to the National Screening Unit? Who does it actually belong too? Can I get it back and destroy if I wanted to? Do they tell us this, because I don't remember being told? (Asian Parent)

Following learning about the various current, and potential, uses of their (child's) blood spot cards and their indefinite storage, the revelation that they could retrieve their (child's) blood spots, immediately if they wanted to, or at any time in the future, left some participants feeling reassured and much more in control.



*For me, with this whole issue, it is a knowledge thing. It is like, do parents know they can say no? Do parents know they can take it back? And the thing is, until this became an issue last year, a lot didn't know that they could. And, a lot of people still don't know that they can get it back. Until I was in this room I had no idea that I could say, "I want it back."
(European Non-Parent)*

This knowledge was particularly important for those participants who were ambivalent, or uncomfortable, with some of the current and potential uses of blood spots.

It was also really important for those participants who believe that bodies should be buried intact. This included some Māori, Pacific and European participants.

*You might say spiritual, because it is part of you, and it is like that whole thing of organ donation, and giving organs when you die. I would want my body back to me intact.
(European Non-Parent)*

I feel quite emotional now. I have learned a lot today. My parents have passed away. I feel upset if they still have their blood spots and they are not with my parents. (Pacific Parent)

Importantly, very few participants indicated that they would be requesting the return of their blood spots in the near future. Some, however, indicated that they would ask for them back, so that they could be buried with their blood spot cards. Some even went so far as to talk about taking measures to ensure that their blood spot cards would be returned on their death (e.g. attaching the request for return of the blood spots form with their Will).

Because, I would seriously consider having mine returned. Though, I probably wouldn't. But, I wouldn't feel happy myself dying, that my blood was still there. (Māori Parent)



8.3.3 Memorandum of Understanding between the Ministry of Health and the Police

Most participants (including those with little trust and confidence in the Police) were comfortable with the current Memorandum of Understanding between the Police and the Ministry of Health. That is, participants were reassured by the knowledge that blood spots could only be accessed by Police as a last resort (i.e. when there were no other sources of identification); that the Police needed to request specific cards (i.e. they could not go on a “*fishing expedition*”); and, with the exception that they were a suspect in a murder enquiry, that the next of kin would be asked for their consent.

One parent expressed an interest in seeing the document, because they felt that the term ‘*Memorandum of Understanding*’ conjured up the image of a very informal agreement that might be open to abuse.

The wording ‘Memorandum of Understanding’ is like it is a very unofficial agreement. I am quite happy with the whole thing. I just think, ‘Memorandum of Understanding’ is a very informal term. It is just the wording that makes it sounds very informal. (European Parent)

None of the focus group participants wanted to see legislation developed to dictate Police access to the blood spots.

I would rather this ‘Memorandum of Understanding’ than legislation, because the way things go through parliament, they can be bastardised in umpteen different ways, by umpteen different people, with different agendas. This should be an agreement between the Ministry of Health and the Police, not political parties, who say, “This is how it is going to work.” (European Parent)

8.3.4 Role of the Ethics Committee and NSU in approving research

Ethics Committee involvement

Learning that there is an Ethics Committee, that must approve any research involving blood spots, is reassurance enough for some participants. This says to them that their (child’s) bloodspots will not be used for anything other than research that is ethically sound, and will benefit the community.

Their decisions are based for the people, and around the people. (Asian Parent)

I am comforted by the fact that a higher Ethics Committee, or power, will watch out for the things I care about, like cloning, and will stop that from happening. (European Parent)

Some participants acknowledged that they do not have the knowledge and expertise to make informed decisions about research, and, as such, welcomed the expertise of the Ethics Committee to do this on their behalf.



Whichever committee is the body to look after this, and make sure it is done properly, is doing it for the good of the community; be that the country, or the world. We can't make that decision. We don't know enough to make that decision. We don't know enough to make any informed decision. (Asian Parent)

They know more than we do. (Māori Non-Parent)

As discussed in the chapter on research (chapter 6), those participants who were ambivalent, or uncomfortable with the use of their (child's) blood spots in research, were less likely to be comfortable with handing over control for decision-making, in relation to their (child's) blood spots to anybody. That is, regardless of the Ethics Committee involvement, they still want to be asked for consent for each, and every, use of the blood spots.

Even if the Ethics Committee give an okay, I would still like to know. I would still like to have the right to give my consent. They probably don't use every single blood spot card that is in there; they are probably randomly picked, but, those that are random, should still have the right to say, "No, use somebody else's". (Māori Parent)

Approval by the Ethics Committee only, or the Ethics Committee and NSU

Participants varied in their response to the question as to whether decisions related to the use of blood spots for research purposes should be the responsibility of the Ethics Committee alone, or both the Ethics Committee and the NSU.

Those who thought that decisions regarding the use of blood spots should be made by the **Ethics Committee alone**, gave the following reasons:

- ◆ Having both parties is an unnecessary duplication of resources, which won't lead to better decisions (necessarily), and will make the process more cumbersome, and expensive.

I think the more people you put in committees, the harder everything gets. Ethics Committee can ask the NSU for advice, or clarification. (European Parent)

It seems a bit of duplication, two separate bodies making decisions. (European Parent)

- ◆ Concerns that NSU are "too close" to the programme, which may result in a conflict of interest.

They (NSU) have a biased vote though. That would be my concern. (European Parent)

I just go with the Ethics Committee, because, I think they come from an unbiased thing, and I think they, within themselves, could also have a differing opinion anyway. You have got six people in this room, and we have all got different opinions. Therefore, you don't need, necessarily, the other party. It would be surplus to



requirements, in my view, because their [the NSU's] reasoning behind it is always going to be more research. So that would be an instant vote. (European Parent)

But then, won't they [the NSU] have more reason to approve it, because, they are more likely to be the ones wanting to do it? (Māori Non-Parent)

Going down that inside knowledge thing, potentially, that could be disadvantageous, because it could cloud judgements, and stuff. (European Non-Parent)

Those who thought that decisions regarding the use of blood spots should be made **jointly by the Ethics Committee and NSU**, gave the following reasons:

- ◆ Two bodies are better than one, because both parties will bring different perspectives and considerations.

I think we need to know what the realm of the Ethics Committee is. Not necessarily who they are, that too, but what they are actually agreeing too; whether there are other elements that they are not potentially taking into consideration. So, maybe, the screening people should actually be involved in, and they will be looking at things from one point of view. They can look at the whole package, and go, these are the issues that are going to arise out of this, let's have a look at the whole situation. Ethically, this is all fine, as opposed to other things, other reasons. I just think you want to cover all your options, and not potentially have anything come out of it that could have been picked up. Just covering all your bases. (Asian Parent)

It is quite good to have two bodies, so that if they both agree, then you can be clear that everybody agrees. That this is a good idea. But, if they are divided, there has to be a good reason for it. (European Parent)

I think that it is important that both of them have a say, because, it is just part of checks and balances. How can you trust just one person, one party? It just seems safer if there are two, and they both agree. (European Non-Parent)

- ◆ NSU should be involved in the decisions, because they are the “guardians” of the blood spots, and will ensure that only research of benefit to the programme, and the wider community happens.

NSU will make sure that we don't do research that is not going to be of benefit to people. (European Parent)

I think they should be involved, because they are the one who cares. (Pacific Non-Parent)

I think the people in the lab should be involved in the Ethics Committee. (Pacific Non-Parent)



9.0 Cultural considerations

This focus group research revealed cultural considerations relevant to Māori and Pacific Peoples, that have ramifications for the development of the guidelines related to the future uses and storage of blood spots.

Importantly, some European participants reflected strong emotional relationships with their (child's) blood spots, with similar ramifications for the development of the guidelines related to the future uses and storage of blood spots.

The Asian participants in this research did not identify any specific cultural considerations relevant to this topic. It should however be noted, that this focus group research did not reflect the diversity of the Asian population in New Zealand.

9.1 Māori cultural considerations

Some Māori research participants exhibited a strong spiritual and emotional relationship with their blood spots. This is underpinned by the following beliefs:

- ◆ Blood is sacred, or tapu.

Yes, because, blood is tapu, and while it is for health and purposes, it is okay, but to hold someone's blood, you can do lots of nasty things with it, and lots of nasty repercussions can come back to you. In days of old, they would kill the chief of the tribe, and the enemies would smear themselves in their blood, because that blood was said to have been of that chief's status, and once they had that blood on them, his people couldn't kill them, because they had the tapu blood on them. That is how much mana blood holds! It is what flows through our bodies. It is what makes us what we are. In saying that, I wouldn't say, "No," because, if it is something that can help my baby, and while she is still alive, then there is nothing that can come of it. But it is definitely tapu, no matter what. I think if people knew they were keeping the blood they might change their minds about whether, or not, to do it. (Māori Parent)

- ◆ Blood spots continue to be a part of the person from whom they came from.
- ◆ Bodies should be buried "whole" (i.e. with all organs and blood).

We were talking about the blood, if it is going to be disposed of in Māori terms it should come back to the person. It should come back to us to bury it with our placenta, once those tests are done. (Māori Parent)

Everything goes back to the ground. (Māori Parent)



These cultural considerations have ramifications for the development of the guidelines for the future storage and uses of blood spots, including communications about the NSMP.

Some of these ramifications are as follows:

- ◆ **Communications** – Communications need to acknowledge the cultural significance of the blood spots, and provide legitimate reassurances that the blood will be treated with appropriate care and respect.

It is just about informing. Just making it clear that these things are kept. At the end of the day, I still would do it. Even a pamphlet. I think it is also about the Ministry being culturally aware: that this is our protocol, and they know. I think it is them going out of their way, and saying, "You are Māori, we are going to keep these blood spots, is that going to affect your decision in having this test?" I think nine people out of ten are going to say, "No, do it," but, the odd one may say, "Oh, what, you keep it, hang on, hey do they need to hold it?" (Māori Parent)

- ◆ **Storage and retrieval.**

- ◆ On the basis of their beliefs, Māori may want their blood spots returned at their death, or sooner (for their own safekeeping).
- ◆ Blood spots must be stored and handled with care and respect. Concerns about the possibility of blood spots touching/rubbing together, and, as such, the possibility of blood intermingling needs to be dispelled.

- ◆ **Current and future uses** – Guidelines need to take into consideration any likely, or potential, apprehension about current and future uses of the blood spot cards over an above screening. For example this could include:

- ◆ Provision to opt in, or out, of different uses at time of initial consent.
- ◆ Communicate appropriate reassurances (e.g. the role of the Ethics Committee, and ensuring appropriate Māori representation on the Committee, with reassurances about the limitations of Police access).

Someone that knows, with Kaumatua status. But then, also, the other thing that I am aware of that each area has different beliefs. So, cultural representation. I would also hope that my own area was represented, because what we do at home may not necessarily be what these guys do at home. Especially, when we are talking about blood and stuff like that. I see it as no different to my child going in for an operation, and no one just takes my child in for an operation, because we do things first, processes that we do as a family first. (Māori Parent)



9.2 Pacific peoples' cultural considerations

Some of the Pacific research participants also exhibited strong spiritual and emotional relationship with their blood spots.

Because I see blood as quite an important thing, in a spiritual way, and in a personal way. So, I am interested to know what they do with children's blood. It is not something to tamper with in a way that you are not aware that it is happening. (Pacific Parent)

The beliefs underpinning this relationship included the following:

- ◆ Blood is regarded as sacred, because it is necessary for life itself, and because of its strong links to Christian religious beliefs (i.e. the blood of Jesus Christ marking the cleansing of sin).

To me, even to my family as well, it signifies just life and that is very important to me. Not just spiritually, but personally, as well. There are a lot of things that I can explain about what blood means to me, but that is all that is coming to mind right now. Life is precious and blood represents life. In my faith, the blood Jesus is significant, as well, and it is Holy. (Pacific Parent)

- ◆ A person should be buried “whole” (i.e. with all body parts intact), otherwise the deceased will not cross over peacefully into the next life, and will roam this life until they do so.

These cultural considerations, along with a focus on the potential benefits of the uses of blood spot cards for the community (in particular, the Pacific community) and future generations, have ramifications for the development of the guidelines for the future storage and uses of blood spots, including communications about the screening programme. The ramifications are similar to those discussed in relation to Māori.

Because it is someone's life on a card, people might know about how people feel about that, but all the professionals who need to access that just to treat it with respect. The card belongs to a person whether they are alive, or dead. (Pacific Parent)



Appendix A: Discussion Guide

NEWBORN BLOODSPOT CARDS (#3639)

A. Objectives

The overriding research objective of the focus group discussions is to understand health consumers' perceptions and expectations relating to the potential **future storage and uses** of residual blood spot cards.

More specifically, this will include understanding health consumers':

- ◆ Responses to the use of blood spots for additional **screening/testing** purposes, including:
 - ◆ treatable vs. non-treatable metabolic disorders
 - ◆ metabolic disorders vs. other conditions (e.g. Hepatitis)
 - ◆ early onset vs. later onset (e.g. Diabetes)
 - ◆ to identify cause of death.
- ◆ Responses to the use of blood spots for increasing the **effectiveness** of the screening programme, i.e. programme audit and quality control.
- ◆ Responses to the use of blood spot samples for **research**, including:
 - ◆ developing new screening tests
 - ◆ research into early vs. late onset conditions
 - ◆ identified vs. anonymised research
 - ◆ commercial (e.g. insurers, Pharmaceutical) vs. University research.
- ◆ Responses to the use of blood spots by the **Police and Courts**, including:
 - ◆ identifying deceased or missing persons vs. criminal suspects
 - ◆ paternity testing.
- ◆ Expectations in relation to **safeguarding** access, storage and uses, including:
 - ◆ legislation
 - ◆ Memorandum of Understanding with Police
 - ◆ ethics committee and the National Screening Unit

- ◆ physical storage of blood spots and information about newborns
- ◆ information sharing.

B. Introduction (20 min)

Objectives: To ensure informed consent to participation in the focus groups and comfort with the process. To gauge initial thoughts and feelings in relation to the topic.

Research New Zealand

- ◆ Researchers to introduce themselves and explain Research New Zealand's role in the research (i.e. conducting research on behalf of MoH).
- ◆ Explain how participants were selected to participate.
- ◆ Explain the purpose of the research:
 - ◆ To understand views about how the blood spots taken from newborn babies (i.e. from the heel prick) should be stored and used in the future.
 - ◆ Focus groups are part of a public consultation process. The results will be used to inform the development of policies and guidelines in relation to the Newborn Metabolic Screening Programme.
- ◆ Reassure confidentiality (i.e. the MRS Code of Ethics), and explain that responses will be reported collectively and will only be used by the purposes of the research (individual responses will not be identifiable).
- ◆ Explain how the group discussion will be run:
 - ◆ The length of the discussion approx. 2.5 hours.
 - ◆ Our interest in exploring and understanding their thoughts and feelings. There are no right or wrong answers. It is important that the group respects different views.
- ◆ Re-confirm consent to audiotape and transcribe groups.
- ◆ Ask participants to turn off their mobile phones.

Group participants

- ◆ Invite Rs to introduce themselves (first name and other relevant information (e.g. number of children and ages) and relationship to anyone else they have come to the groups with)
- ◆ *Using the whiteboard record responses* - Explore **knowledge** of the Newborn Metabolic Screening programme (a.k.a. the Guthrie test, heel prick, PKU test), including:
 - ◆ Rs understanding of what a screening programme is (including examples of other programmes they may know of).
 - ◆ Who they believe runs/is responsible for the NMSP programme (e.g. NSU, MoH, DHB) and how they feel about this.
 - ◆ If knowledge is low - use prompt card (with a brief description of the programme) to assist with the discussion
- ◆ *Individual exercise using pen and paper* – Ask R's to **rate** their interest in the topic; how informed they believe they are; as well as their support for screening, indefinite storage and for future uses of blood spots.

C. Response to future uses of blood spots - screening/testing (30 min)

Objective: To understand responses to uses of blood spots for screening/testing.

Present Stimulus card 1. -The current NMSP

- ◆ Discussion to understand: whether screening is supported, or not, the **benefits**, and any **concerns/issues** (including cultural) for **themselves, or others**.
- ◆ If concerns/issues - What would make them comfortable with screening (e.g. what is their understanding of population screening, what information/safeguards/other need to be in place).

Present Stimulus cards 2 -Testing for additional metabolic disorders, testing for other conditions (not metabolic), identifying cause of death.

- ◆ Discussion to explore and understand whether each of these uses is acceptable, or not, benefits, and any concerns/issues (including cultural) for them or others, in relation to the use of blood spots for screening/testing:
 - ◆ additional metabolic disorders
 - ◆ other (not metabolic) conditions

- ◆ cause of death
- ◆ early vs. later onset conditions (i.e. problems which become evident at the baby stage vs. later (e.g. teens, adult years))
- ◆ treatable vs. non-treatable conditions
- ◆ benefits for other family members vs. newborn.
- ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other, need to be in place).

D. Response to future uses of blood spots – increasing the effectiveness of the programme (20 min)

*Objective: To **understand** responses to the future use of blood spots for increasing the effectiveness of the programme.*

Present Stimulus card 3 - Programme audit and quality control

- ◆ Discussion to understand: whether there is awareness of this use, or not; the **benefits** and any **concerns/issues** (including cultural) for **themselves, or others**, in relation to current programme audit and quality control uses.
 - ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other need to be in place).

E. Response to future uses of blood spots – Research (30 min)

*Objective: To **understand** responses to the use of blood spots for research purposes.*

Present Stimulus card 4 - Research

- ◆ Discussion to explore and understand if this use is acceptable, or not; the **benefits**, and any **concerns/issues** (including cultural) for **themselves or others** in relation to the use of blood spots for:
 - ◆ developing new screening tests (i.e. for disorders which can not currently be identified through screening)
 - ◆ research into early vs. late onset conditions (i.e. problems which become evident at the baby stage vs. later (e.g. teens, adult years))
 - ◆ identified vs. anonymised research (i.e. results can be linked back to the newborn vs. not)
 - ◆ commercial (e.g. insurers, Pharmaceutical) vs. university research

- ◆ other research uses
- ◆ research that benefits other family members not the newborn (e.g. for disorders such as ? which the parents may have but not realise as yet).
- ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other need to be in place).
- ◆ Specifically, probe in relation to:
 - ◆ Ethics Committee's role (i.e. benefits/concerns)
 - ◆ (Current) role of ethics committee and (potential) role of the National Screening Unit (NSU) in approving research (i.e. is approval from Ethics Committee alone adequate, or should approval be required by both Ethics Committee and The National Screening Unit (the unit within the MoH responsible for the NMSP?).

F. Response to future uses of blood spots – Police and Courts (30 min)

*Objective: To **understand** responses to the use of blood spots by the Police and the Courts.*

Present stimulus cards 5 - Identifying deceased or missing persons, paternity testing

- ◆ Discussion to understand if the use of newborn blood spots by the Police and the Courts is known of, or not; the **benefits**, and any **concerns/issues** (including cultural) for **them or others**, in relation to:
 - ◆ identifying deceased or missing persons
 - ◆ paternity testing
 - ◆ other potential uses by the police or courts, e.g. identifying crime suspects.
- ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other need to be in place).
- ◆ Specifically, probe in relation to:
 - ◆ The Memorandum of Understanding (i.e. benefits/concerns)
 - ◆ Issues of trust with the Police

G. Response to future uses of blood spots – Storage, Information sharing and Safeguards (30 min)

*Objective: To **understand** views about the future storage, information sharing and safeguards in relation to access, storage and uses.*

Present stimulus card 6- Physical storage of blood spots and information

- ◆ Discussion to understand acceptance, or not; the **benefits**, and any **concerns/issues** (including cultural) for **them or others** in relation to:
 - ◆ The storage of blood spots and information sharing
 - ◆ Indefinite storage vs. other (preferred) storage times
 - How long do Rs consider Blood Spot Cards should be stored for? How come?
 - ◆ Who should have access to information, for what purposes?
 - ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other need to be in place).
 - ◆ Specifically, probe in relation to:
 - ◆ Issues of trust of health authorities/providers.

Present stimulus card 7 – Legislation

- ◆ Discussion to understand awareness, or not; **benefits**, and any **concerns/issues** (including cultural) for **them or others** in relation to the current **safeguards**/controls around access, storage and use of blood spots:
 - ◆ the legislation
 - ◆ other safeguards (recap as necessary re: the Memorandum of Understanding with the Police and Ethics committee/NSU approval for research).
- ◆ If concerns/issues - What would make them comfortable with this use (e.g. what information/safeguards/other need to be in place).

H. Sum up and conclusion (20 min)

Objective: To ascertain changes in views in response to participation in the session

- ◆ *Individual exercise using pen and paper*
 - ◆ **Repeat** exercise asking Rs to **rate** their interest in the topic; how informed they believe they are; their support for screening, indefinite storage and for future uses of blood spots.
 - ◆ Ask Rs to **prioritise** the use of blood spots (i.e. for screening vs. research vs. quality control vs. police and courts uses).
- ◆ Thank Rs for their participation and ask for any further comments or questions.
- ◆ Provide FAQ sheet and close session.



Appendix B: Stimulus Cards

The Newborn Metabolic Screening Programme (i.e. Guthrie Test)

Metabolic disorders are rare, inherited disorders that can cause ill health, learning disabilities and death.

Currently, the programme tests newborns for 28 disorders (e.g. Cystic Fibrosis, PKU), which can all be treated by diet and or medication provided the disorder is identified early.

Testing takes place before the baby shows signs of any of these disorders. Blood is collected through a heel prick and placed on a blood spot card that is sent to the National Testing Centre for testing and storage.

Testing for additional metabolic disorders

Extending the current screening programme to include the early detection of other metabolic disorders (e.g. Duchenne Muscular Dystrophy).

Testing for other conditions (i.e. not metabolic conditions)

Extending the current screening programme to include the early detection of other conditions (e.g. hepatitis).

Identifying cause of death

Using blood spots to identify cause of death, if this unclear.

The results of the testing may also identify the risks of a condition occurring in other family members.

Programme audit and quality control

If a baby has one of the disorders tested for, but does not have a positive test result, some of the blood can be tested to try and ensure the same mistake does not happen again.

Stored blood spot cards are used to improve current tests and methods of testing (e.g. calibrating new testing equipment).

Research

Blood spots could be used for research purposes. For example:

- ◆ to identify reasons for Cot death
- ◆ to develop tests for metabolic disorders that currently cannot be screened for.
- ◆ to develop tests to identify other conditions that might develop later in life (e.g. diabetes).

This research would need to be approved by an Ethics Committee.

Police access- Identifying deceased or missing persons

Police access to blood spots is restricted to identifying deceased or missing persons.

Blood spot cards are only used for this purpose as a last resort and usually with explicit parental consent.

The agreement between the Police and the Ministry of Health is a Memorandum of Understanding.

Court access - Paternity testing

Courts have separate rights, which override any other legislation or policies allowing them to access all hospital and medical records. As such, they can access blood spot cards (e.g. for paternity testing).

Legislation

Consumer rights and provider obligations in relation to obtaining, storage and use of blood spot cards are covered by legislation:

- ◆ **Consumers (or their parents/guardians) must give their informed consent before blood is collected.**
- ◆ **Consumers have the right to request the return or disposal of the blood spots at any time.**
- ◆ **Blood spots can be used for research approved by the Ethics Committee (i.e. without seeking consent from the consumer).**
- ◆ **Blood spots can be used for programme audit and quality control purposes (i.e. without seeking consent from the consumer).**

Physical storage of blood spots and information about newborns

Blood spot cards are stored indefinitely after screening is complete. Storage is secure and access to the cards is limited.

Blood spot cards include the following information:

- ◆ **The baby's name, sex, place, date and time of birth, National Health Index (NHI) number, birthweight and gestational age, date and time of sampling.**
- ◆ **The mother's name**
- ◆ **Lead Maternity Carer contact details.**

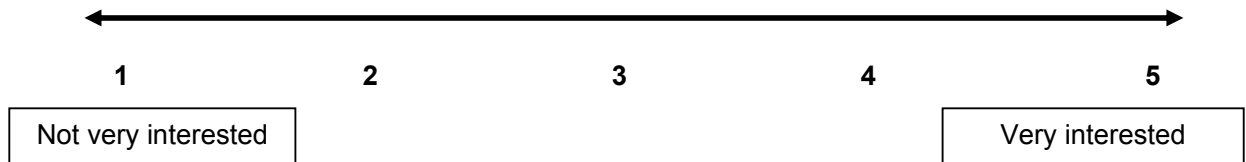


Appendix C: Self-Completion Rating Scales

Please write your first name here _____

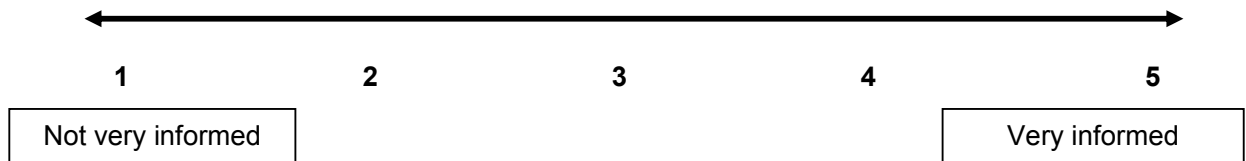
Rating scale two

1. Rate your interest in the **future uses and storage of newborn blood spots**, by circling one of the numbers on the rating scale below.

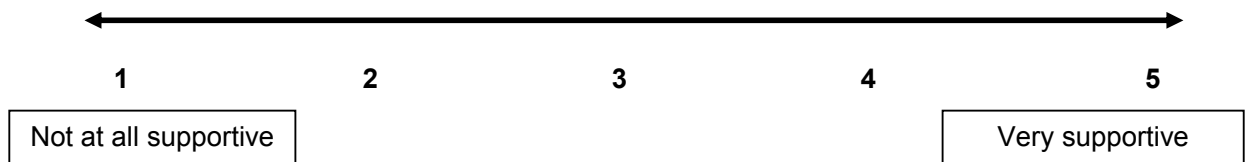


2. Rate how **informed** you believe you are about this topic.

Circle one of the numbers



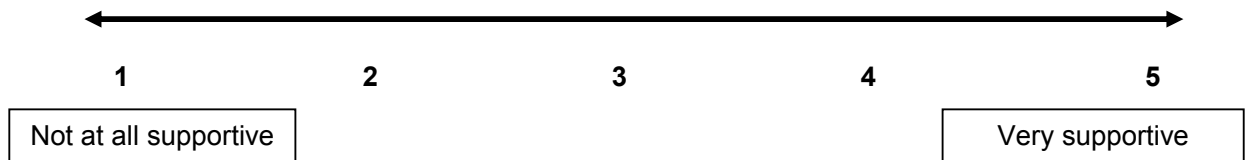
3. Rate your support for the use of newborn blood spots for **the screening of metabolic disorders**.



If you don't know, or are unsure tick here

4. Rate your support for the use of newborn blood spots for **research purposes**.

Circle one of the numbers



If you don't know, or are unsure tick here



Appendix D: Frequently Asked Questions

Thank you for taking part in the group discussions regarding newborn metabolic screening. Here is further information on the programme plus contact details if you have further queries regarding newborn metabolic screening or health services.

Information on the Newborn Metabolic Screening Programme (NMSP)

Why should my child have newborn metabolic screening?

Newborn screening is important because a baby with one of these illnesses will appear perfectly healthy. By the time symptoms are visible, irreparable damage may have occurred including mental retardation or sometimes, death.

Newborn metabolic screening enables rare, serious problems (disorders) that can be helped with a special diet or other treatment to be picked up early and treated. An example of a disorder screened is congenital hypothyroidism. This disorder affects infants from birth and results from a partial or complete loss of thyroid function. The thyroid makes iodine-containing hormones that play an important role in regulating growth and brain development. About 1 in 4,500 babies are born with congenital hypothyroidism. The New Zealand programme tests for over 20 metabolic disorders similar to congenital hypothyroidism.

My baby seems very healthy. Is screening still necessary?

Yes. Most infants with birth defects screened by this programme show no obvious signs of disease immediately after birth. In each of these disorders there is an "invisible" problem in one of the many chemicals which are produced naturally in the baby's body. Without a blood test these problems are difficult to find.

Who should have a newborn metabolic screening test?

Health Practitioners strongly recommend screening. It is not possible to tell if your baby has one of these disorders just by looking at or examining your baby. These

disorders can cause brain damage or death if not found and treated soon after birth. Babies who have these disorders will seem normal, but may get very sick if not found and treated.

When, where and how should the test be done?

The newborn metabolic screening test ('heel prick test') should be performed at 48 hours of age or as soon as possible thereafter. The Lead Maternity Carer (LMC) may do the test either in hospital or at home. Blood is collected from the newborn's heel and placed onto a blood spot card. The card is then sent to the laboratory (National Testing Centre) at Auckland City Hospital. The LMC will be contacted by the laboratory if there is a problem with the sample or if any follow-up is required.

What will the test cost?

The programme is free to babies born in New Zealand*.

*There are eligibility criteria relating to publicly funded services – please see the Ministry of Health website for further information.

Can I say no to the test?

Yes. New Zealand law says that parents may refuse the test. However, it is strongly recommended that your baby is screened – more than 99 percent of newborns in NZ are screened. Most developed countries screen for metabolic disorders.

What happens to the blood spot card after testing?

After testing is complete, the blood spot card is stored in secure storage with very limited access. Currently, access to the cards includes:

Direct benefit of the family/whanau. For instance, 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.

Programme audit and quality control. For instance to check screening results and to monitor the programme to ensure it is working to a high quality.

Setting up additional equipment for existing disorders. For instance to set up new equipment for the screening programme.

Forensic testing. For instance, to identify a deceased or missing person.

Court orders. Courts have separate rights and there have been a small number of instances in the past where blood spot cards have been requested through a court order for paternity purposes.

Can I get the blood spot card back?

Yes. You can request your baby's card back after screening is complete. If you would like to request your baby's card, please complete the form attached and send it to the National Testing Centre (address details are on the form).

What can I do if I have further questions?

The National Screening Unit website www.nsu.govt.nz has further information on newborn metabolic screening. Alternatively, you can contact Kathy Bendikson, Programme Manager, Newborn Metabolic Screening Programme (NMSP), National Screening Unit. Phone 09 580 9180.

email: kathy_bendikson@moh.govt.nz.

If you have further queries regarding health and disability services please contact the Health and Disability Services Advocacy Service on 0800 555 050.