

# Victorian Newborn Screening Review Committee

## Final report for the Minister for Health

August 2006

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## Executive summary

Following much discussion in the media concerning the issue of newborn screening for genetic conditions a key stakeholder meeting convened by the Health Services Review Council was held in November 2003 to discuss all the relevant issues.

Following this meeting a Review Committee comprising representatives of the Department of Human Services (DHS), Office of the Victorian Privacy Commissioner (OVPC), Office of the Health Services Commissioner (HSC), Genetic Health Services Victoria (GHSV) and the Public Records Office (PRO) was established to undertake further discussion on the issues and provide a paper for the Minister for Health with the recommendations of the Review Committee.

The Review Committee has had extensive discussions on issues concerning consent to testing of newborn babies; issues relating to retention and storage of the screening cards; access to the cards for quality assurance purposes as well as for research purposes; access to the cards by the parents or the individual whose blood is on the card; access by law enforcement agencies; and issues relating to ownership of the cards and the blood sample on the cards. The Review Committee has also taken advice from academics, researchers, health practitioners, and legal counsel.

This is the final report of the deliberations of the Review Committee. It should be noted that whilst the Victorian Privacy Commissioner supports many of the Review Committee's recommendations as interim measures, he has some additional concerns and recommendations that are outlined in his Supplementary Report (Appendix 3).

### The Review Committee makes the following recommendations:-

- 1.1 That the consent for the program and the consent for access for secondary uses be separated into two processes.
- 1.2 That informed written consent for the newborn screening tests be obtained prior to the blood sample being collected.

- 1.3 That parents be provided with the following options when exercising informed written consent prior to testing:
  - Consent for testing and retention for 2 years in the testing laboratory for quality assurance purposes
  - Consent for their child's card to be retained under long term storage after the 2 year quality assurance period\*
  - Consent for their child's card to be accessed for any research purposes\*\*

Note:

\* Parents can request that their child's card be transferred to them after 2 years (see recommendation 2.1)

\*\* Any access for *identified* research will still require informed written consent at a later date (see recommendation 3.6)

- 1.4 That refusal for testing should be noted in the hospital record and signed by a parent. Parents who refuse testing of their newborn babies should be referred to GHSV for advice and discussion.
- 1.5 That DHS continues its discussions with hospitals in relation to implementation of the above recommendations relating to informed written consent prior to testing.
 

Note: It will be important to monitor the effects on uptake of newborn screening i.e. rates of parental consent, following any proposed changes to current practice.
- 1.6 That DHS funds an education program targeting general practitioners, obstetricians, midwifery nurses and the general public in order to raise awareness of the newborn screening program and of the importance of discussing it during the antenatal period.
  - 2.1 That parents should be informed that:
    - The newborn screening cards will be retained indefinitely under specific safeguards including high level of physical security;
    - Parents or the child (upon reaching 18 years of age) can request that their card be transferred to them after the minimum quality assurance period of two years (see also recommendation 3.13).
  - 2.2 That Victoria should re-assess its policies on retention and storage of newborn screening cards in response to any recommendation on this issue that may be made at a national level.

- 2.3 Following the two-year quality assurance period during which the cards are stored at the screening laboratory, that the newborn screening cards continue to be stored under the current secure storage arrangements that have been appointed under s.12 of the Public Records Act.
- 2.4 That the custodianship of the cards stored at the Approved Public Record Office Storage Suppliers (APROSS) be the subject of contractual arrangements between DHS and GHSV.
- 3.1 That all access to the cards including punched out blood spots should comply with current updated protocols as in Appendix 2. Such access protocols should continue to be further reviewed by the DHS Newborn Screening Program Advisory Committee.
- 3.2 That documentation provided to parents about the newborn screening program should include information that access to the newborn screening card for secondary purposes may occur in specified circumstances.
- 3.3 That parents should continue to be given the opportunity to opt out of having any research conducted on their child's newborn screening card and that fact ie if they choose to opt out, should be clearly identified on the card at the time the blood is collected.
- 3.4 That GHSV continue current procedures to have cards permanently marked where the parent has decided to opt out of having any research conducted on their child's card.
- 3.5 That applications for access to de-identified blood spots for research purposes be allowed provided the research has been approved by an institutional Human Research Ethics Committee, and the DHS Newborn Screening Program Advisory Committee be kept informed of such applications.
- 3.6 That any application for research on identified cards be allowed only if:
  - Informed consent is obtained from the parents of the child;
  - The research has been approved by an institutional Human Research Ethics Committee; and
  - The DHS Newborn Screening Program Advisory Committee approves the project.
- 3.7 That access to all blood spots, (even de-identified blood spots), for research purposes not be allowed where the parent has previously indicated that they did not wish to have research conducted on their child's card including the blood spot.
- 3.8 That any access to the cards by law enforcement agencies should only be permitted by court order.
- 3.9 That the Minister for Health refers to the Attorney General the issue of authority for law enforcement agencies to collect genetic samples in line with the recommendation of the ALRC/AHEC report entitled "*Essentially Yours: The Protection of Human Genetic Information in Australia*".
- 3.10 That GHSV ensure that cards released for forensic identification purposes are returned according to current procedures.
- 3.11 That on the written request of both biological parents the card should be transferred to the parents provided the identity of the parents and child can be verified. If the biological parents are separated and one biological parent has requested transfer of a card and the other biological parent either cannot be found or has refused consent for transfer, the principles of the Family Law Act should apply.
- 3.12 That decisions regarding transfer of cards to blood relatives other than biological parents should be reviewed by the DHS Newborn Screening Program Advisory Committee on a case by case basis and in accordance with current legislation.
- 3.13 That the Parent Information Brochure be revised to advise parents that after the two-year minimum storage period for quality assurance purposes, they can apply to have the card transferred to them. The same principles apply to the individual himself or herself once they reach the age of 18 years.
- 4.1 That the Minister considers all three options provided in relation to clarification of outstanding legal issues ie referral to the Law Reform Commission, new specific legislation for the program, and the option of changes to existing legislation.

## Introduction

In March 2003, the Australian Law Reform Commission published its report “Essentially Yours” on the protection of human genetic information. In addition, since then, there has been media exposure, meetings, and discussions between representatives of the Department of Human Services (DHS), Offices of the Privacy and Health Services Commissioners (OVPC) (HSC), Genetic Health Services Victoria (GHSV), the Public Records Office (PRO), and other interested parties, regarding issues relating to the Newborn Screening Program and the newborn screening cards (also known as Guthrie cards).

On 26 November 2003, a key stakeholder meeting was convened by Mr Michael Gorton, President of the Health Services Review Council, to look at ways of progressing issues concerning informed consent for newborn screening, and ownership, retention, storage, authorised uses, and legal status of the cards.

A recommendation from this meeting was that a small Review Committee comprising representatives from the DHS, OVPC, HSC, GHSV, and the PRO be established to take forward the issues and provide the Minister for Health with an options paper.

Privacy laws have changed the environment in which the Newborn Screening Program operates. It is necessary to decide how the Program is to comply with these laws, or whether the Program is so unusual in that it needs a purpose-built framework.

The information and health privacy laws broadly create new standards for handling people’s personal and health information including:

- Collection, with proper notice;
- Use and disclosure;
- Access for the individual; and
- Storage and retention.

Three new laws (*Health Records Act 2001 (Vic)*, *Information Privacy Act 2000 (Vic)*, *Privacy Act 1988 (Cth)*) and two old ones (*Public Records Act 1973 (Vic)* and the *Human Tissue Act 1982 (Vic)*) apply.

In various ways, these laws apply to the Newborn Screening Program and to the blood samples and data derived from them. So it is necessary to determine:

- Whether currently the Newborn Screening Program in Victoria complies with these laws;
- If yes, are the standards (taken together) sufficient in the unusual circumstances of the Newborn Screening Program, to maintain public confidence, obtain benefits and manage risks;
- If no, what can Victoria do to:
  - change practices to become compliant;
  - regularise past conduct that may not have been compliant and may create ongoing liability;
  - create a legal framework commensurate with the risks, the benefits and the need to maintain public confidence in the Newborn Screening Program.

Developments at the national level are relevant and may affect Victoria’s decisions and timing. Alongside this process, the Australian Health Ministers’ Advisory Council established the AHMAC Advisory Group on Human Gene Patents and Genetic Testing to provide a national source of advice on issues relating to the human genetics program.

The Newborn Screening Review Committee has taken some interim steps, and has prepared this final advice for consideration by the Minister for Health.

## Terms of reference

The Victorian Newborn Screening Review Committee met for the first time on 12 February 2004 and agreed to the following terms of reference:

- To develop an options paper for the Minister for Health that examines issues and makes recommendations in relation to policies and procedures relative to the Newborn Screening Program. In particular the following issues will be addressed;
  1. Collection of blood specimen
    - (i) informed consent to testing
    - (ii) informed consent to the retention of the card
    - (iii) informed consent to use of the card by third parties
  2. Storage
    - (i) retention period
    - (ii) storage requirements
    - (iii) security
    - (iv) impact of public records on above
  3. Access to newborn screening cards
    - (i) by parent
    - (ii) by third parties
  4. Legal status of newborn screening card
    - (i) ownership
    - (ii) public record status
    - (iii) characterisation of card vs. blood

## Background

The goal of newborn screening is early identification of children affected by congenital and metabolic disorders for which medical treatment can be promptly initiated to avert metabolic crises and prevent irreversible neurological and developmental sequelae. Early identification of these conditions is crucial, as timely intervention can lead to a significant reduction of morbidity, mortality, and associated disabilities in affected infants.

Newborn screening is the first and conceivably the most successful example of population-wide screening. Performed within the first few days of life, drops of blood are collected from a newborn's heel and are analysed, providing information that can alter the course of the baby's life. Newborn screening is one of Australia's most impressive public health achievements and one of the most reliable components of child health services.

The classic example is newborn screening for phenylketonuria or PKU. PKU is an autosomal recessively inherited condition resulting in the absence or inactivity of the enzyme phenylalanine hydroxylase.

In the 1930s George Jervis at Letchworth Village State School in Thiells, New York, identified 50 clients whose mental retardation was attributed to PKU. He pursued the study in four state institutions to identify a total of 185 PKU cases among 15,000 clients. Whilst little could be done for these adults, work of others suggested that early diet therapy could prevent development of the mental retardation usually seen in PKU. Early therapy depended on early detection of the affected child—before appearance of symptoms. Robert Guthrie, a microbiologist and paediatrician at State University of New York, Buffalo, devised a simple, inexpensive test that allowed screening for PKU to be done shortly after birth. Hence the term “Guthrie Card”.

Newborn screening is a public health program that involves a network of medical practitioners, midwives, laboratory personnel, administration, speciality care centres, and family members. It is not simply a test. The flow of the program should ensure that all babies' parents are given the information and opportunity to consent to the collection of the sample, the sample is collected and sent to the newborn screening laboratory, the results are generated, and any abnormal results followed up, including any need for repeat samples. Affected children and their families are referred into the clinical care system for ongoing management.

In Australia, screening programs for PKU began in the 1960's and were soon expanded in the 1970's and 1980's to include screening for congenital hypothyroidism and cystic fibrosis. In Victoria, newborn screening was initially conducted through Kew Mental Hospital in 1965 before moving to Mont Park Hospital in 1967 and finally to Victorian Clinical Genetics Service (VCGS) now known as Genetic Health Services Victoria (GHSV) in 1991, when the Mont Park laboratory closed down. Genetic Health Services Victoria was established in 1988 and funded by the DHS to provide specified genetic counselling and diagnostic services to the people of Victoria. DHS provides the funding to GHSV under a standard DHS Service Agreement. A search of DHS files does not provide any further information about this transfer of responsibility, including the custodianship of the newborn screening cards. Victoria is unique in that the newborn screening service is contracted to a private sector (not for profit) agency.

In 2001, Victoria expanded its newborn screening program to include the detection of a number of metabolic conditions according to their characteristic pattern of metabolites in the blood using technology called tandem mass spectrometry (TMS). Over 20 conditions including PKU can be detected by TMS and treated before the babies get sick. This brought the program into line with newborn screening programs conducted in New South Wales and South Australia. Currently, protocols for newborn screening are recommended by the Newborn Screening Committee of the Human Genetics Society of Australasia. However, newborn screening is administered at a State/Territory jurisdictional level and practice is not uniform in all jurisdictions.

In Victoria, all newborn screening cards, since the inception of the program, have been retained. For two years the cards are stored on site at the GHSV newborn screening laboratory, then archived in a secure off site facility. The current collection of cards contains the dried blood spots of approximately 2 million newborns. This figure increases each year with the birth of about 65,000 newborns.

In order to assure quality of the newborn screening testing, it is necessary to keep the cards for at least this 2-year period. It should be acknowledged that GHSV has been proactive in setting up secure storage facilities for all newborn screening cards and in developing protocols for the program that have stood up well to scrutiny.

The Australian Law Reform Commission (ALRC) and Australian Health Ethics Committee's report entitled *"Essentially Yours: The Protection of Human Genetic Information in Australia"* concluded that it is desirable to have national standards for the development and implementation of population genetic screening programs and newborn screening programs. Accordingly, the Australian Health Ministers' Advisory Council's Advisory Group on Human Gene Patents and Genetic Testing is collaborating with the Human Genetics Society of Australasia in developing nationally consistent standards on newborn screening programs. The draft national policy document includes issues of consent, storage, retention period, access, conditions included in the program, data collection and reporting, and the process for approval of new tests/conditions in the program. The AHMAC Advisory Group has circulated a draft document and expects to finalise this in the next 12 months. The recommendations contained in this Report will need to be reviewed in the light of the final report from the AHMAC Advisory Group.

In summary, Victoria is reviewing the newborn screening program for the following reasons:

- Although there is support for national guidelines, there will be an inevitable delay in their production.
- Victoria is unique in that the collection of the cards is held by a private sector (not for profit) agency.
- Research and anecdotal evidence suggests that parents may not know their baby is being tested, and that the blood may also be used for other purposes.
- There is a need to promote the program and reassure parents that appropriate safeguards are in place.
- Greater clarity is required about what protections currently apply, including to DNA samples, and whether they are adequate.

## Issues

### 1. Consent for testing and quality assurance

Informed consent is the process by which an individual chooses to participate in a medical procedure or healthcare activity. Crucial elements to this process include knowledge of the purpose and nature of the intervention, potential risks and benefits, and reasonable alternatives to participation. The level of information detail necessary for “informed” consent is different for different individuals, depending on their desire to know.

As part of the expanded newborn screening program, DHS developed “Guidelines for Newborn Screening: November 2001” which were distributed to all maternity hospitals in Victoria. These guidelines specify that informed verbal consent from parents or guardians is required to be obtained by the hospital staff prior to the baby being tested. There should be documentation in the mother’s/baby’s hospital record stating that there has been discussion about the newborn screening test. The hospital record should also show a record of completion of testing. If parents wish to refuse testing on behalf of their baby, they should be referred to a newborn screening counsellor at GHSV for discussion. Any parents refusing testing are requested to sign a written statement saying that they understand the potential risks to the healthy development of their baby. The newborn screening pamphlet, which provides information to parents to enable the process, is recommended to be given to parents prior to delivery, and should be available for review after the baby’s birth.

Representatives from newborn services have brought to attention a significant gap between the guidelines and current practice in seeking consent from the parent(s) for newborn screening. Blood sample collection for testing is often performed in the nursery in order “not to upset” the mother. A research study performed at the Royal Women’s Hospital documented that only 26.5% of mothers knew their baby had undergone the newborn screening test. There was also the view among hospital staff that there is no need for consent to testing as this is regarded as part of expected standard of care. Most parents were not aware that blood samples are retained and may be used for secondary purposes under some circumstances e.g. ethics approved anonymised research. Some of the barriers to obtaining true informed consent include staff workload and turnover, and language issues.

The Parent Information brochure, which had been in use for several years, was revised in 2001. From the number of pamphlets requested by the maternity hospitals, it is believed that the brochure is provided to the parents but there is little or no evidence on whether the brochure is read and understood. The Parent Information brochure has recently been revised again to include information on the retention of the cards and the possible access to the card for quality assurance or approved research purposes (see Section 3). The brochure is currently available in 10 community languages.

In addition to the Guidelines, GHSV undertook an extensive education program for midwives.

The current DHS guidelines for the process of obtaining consent are described above. In practice, the major maternity hospitals have advised that they operate on a practice of implied consent, in that the information is provided to the parents in an “antenatal showbag” and consent is assumed unless there is objection. The rationale for this approach is that newborn screening is part of standard care that parents would expect hospitals to undertake. This is contrary to the increasing recognition of the need for informed consent prior to the undertaking of public health programs as well as other procedures, particularly those performed on healthy children/adults. The responsibility for gaining consent rests with the practitioner at the hospital who collects the sample on behalf of the program.

It is regarded as reasonable to also include the concept of retention for quality assurance purposes only, for a minimum period of two years, in the initial consent for testing.

Access to the blood spot is essential in case of a false negative result. If an infant whose newborn screening test was negative is later diagnosed with one of the conditions that were screened for, it would be necessary to go back to the newborn screening cards of all babies tested on that day (or perhaps a longer period) to ensure that there were no other undiagnosed/misdiagnosed children. Access to anonymised newborn screening cards may also be necessary when the service establishes new or improved tests such as those using tandem mass spectrometry (approximately 10 cards accessed).

Options for implementing informed consent procedures include:

- Obtaining informed verbal consent and then proceeding with testing;
- Obtaining informed verbal consent and then proceeding with testing but have the fact of obtaining verbal consent noted in writing.
- Obtaining informed written consent to testing either at the time of pre-admission administrative details being completed or at the time of carrying out testing.

In 2005, DHS commissioned the Health Issues Centre (HIC) to investigate the most effective and acceptable method of obtaining and recording informed consent for testing. The HIC submitted their final report to DHS in December 2005. Consultations identified significant support for both written and verbal consent models and while consensus could not be reached by the Project Advisory Group, it was clear that the “consultations identified a large majority of support from both health professionals and consumers for a written consent model”. The report also recommended that the consent for the program and the consent for storage and access be separated into two processes.

The aim of newborn screening must be to maximise the uptake of this vital public health program. A more structured consent process with detailed retention options could alleviate many of the concerns associated with long-term storage of the newborn screening cards.

## Recommendations

- 1.1 That the consent for the program and the consent for access for secondary uses be separated into two processes.
- 1.2 That informed written consent for the newborn screening tests be obtained prior to the blood sample being collected.
- 1.3 That parents be provided with the following options when exercising informed written consent prior to testing:
  - Consent for testing and retention for 2 years in the testing laboratory for quality assurance purposes
  - Consent for their child’s card to be retained under long term storage after the 2 year quality assurance period\*
  - Consent for their child’s card to be accessed for any research purposes\*\*

Note:

\* Parents can request that their child’s card be transferred to them after 2 years (see recommendation 2.1)

\*\* Any access for *identified* research will still require informed written consent at a later date (see recommendation 3.6)

- 1.4 That refusal for testing should be noted in the hospital record and signed by a parent. Parents who refuse testing of their newborn babies should be referred to GHSV for advice and discussion.
- 1.5 That DHS continues its discussions with hospitals in relation to implementation of the above recommendations relating to informed written consent prior to testing.
 

Note: It will be important to monitor the effect on uptake of newborn screening i.e. rates of parental consent, following any proposed changes to current practice.
- 1.6 That DHS funds an education program targeting general practitioners, obstetricians, midwifery nurses and the general public in order to raise awareness of the newborn screening program and of the importance of discussing it during the antenatal period.

## 2. Retention and storage of the cards

At present the cards collected in hospitals are sent to GHSV for testing and are retained in the newborn screening laboratory for a quality assurance period of two years. Following this period the cards are transferred to an offsite secure storage facility and retained indefinitely.

### (a) Retention

Health privacy principle 4.2 provides that a health service provider must not delete a child's health information unless the deletion is permitted or authorised under the regulations or any other law, or the deletion is not contrary to law and occurs after the child attains the age of 25 years. That is, the default minimum period for which a newborn screening card should be kept is 25 years. This implies that consent is not needed for retention of the cards for a minimum of 25 years but it would be prudent to inform parents that the cards are to be retained. Informing parents of retention is also consistent with HPP1.4, which requires notice to be given about why the health information is being collected and to whom it is usually disclosed.

It should be noted that separate retention and disposal requirements apply to those cards that are public records. The current Disposal Authority under the Public Records Act requires the cards to be retained for 25 years and authorises their transfer to a parent/guardian or child (aged 18 or over) after the quality assurance period of two years. As noted earlier HPP4.2 allows for information to be disposed of before the child turns 25 if this is authorised under another law. The Review Committee recommends that the newborn screening cards be retained in accordance with the National Pathology Accreditation Advisory Council guidelines, currently specified as a minimum of 25 years.

The law states no maximum period for retention where health information is held by a health service provider. If the cards are transferred to an organisation that is not a health service provider (such as the Department of Human Services), HPP4.5 requires destruction of the cards if they are no longer needed for newborn screening or for any other purpose that is authorised under the Health Records Act or another law. It is noted however that the current information pamphlet provided to mothers states that the cards would be stored indefinitely.

### (b) Long-term storage

For two years of the quality assurance period, the cards are stored in locked filing cabinets in the screening laboratory.

Currently long term storage of the cards is in sealed boxes by a sequential laboratory ID number. Storage is in a metropolitan secure off-site facility: in a locked concrete vault in a locked storage facility. Access is possible only when a senior designated person from the storage facility accompanies a designated person from the laboratory.

The cards record the mother's name, the child's date of birth, the child's gender, and the name of the hospital of birth. The control record that identifies which one of the hundreds of boxes contains a particular card is on a computer in the newborn screening laboratory. Three identifiers are needed: the name of the mother, hospital of delivery and date of delivery.

The control record also includes the result of the newborn screening test and access history details. There is no other information on the database. The card can neither be accessed nor identified on computer by just the name of the baby. The computer database is secured by password and results of all tests and access details are encoded.

DHS and PROV have inspected the security of the long-term storage facility and are satisfied that the current storage meets the requirements for storage of public records. DHS and PROV oversee the transfer of newborn screening cards from GHSV to the Approved Public Record Office Storage Supplier (APROSS) facility as approved under s.12 of the PRA, and Standard PROS 99/04.

Once transferred, the cards will be in the custody of DHS, and not the Keeper of Public Records.

## Recommendations

- 2.1 That parents should be informed that:
  - The newborn screening cards will be retained indefinitely under specific safeguards including high level of physical security;
  - Parents or the child (upon reaching 18 years of age) can request that their card be transferred to them after the minimum quality assurance period of two years (see also recommendation 3.13).
- 2.2 That Victoria should re-assess its policies on retention and storage of newborn screening cards in response to any recommendation on this issue that may be made at a national level.
- 2.3 Following the two year quality assurance period during which the cards are stored at the screening laboratory, that the newborn screening cards continue to be stored under the current secure storage arrangements that have been appointed under s.12 of the Public Records Act.
- 2.4 That the custodianship of the cards stored at the APROSS be the subject of contractual arrangements between DHS and GHSV.

### 3. Access to and secondary uses of the cards

Currently there are no plans to destroy the collection of newborn screening cards. Having such a collection means that access needs to be strictly controlled and only under specific circumstances including for diagnosis and research. These are now considered in detail below.

#### (a) Diagnosis of other conditions in individual infants

- (i) A child may present with a condition that is possibly due to infection during the pregnancy or at the time of labour. The same infection may not cause any symptoms in an infant or young child. If the child's blood shows evidence of previous infection (via antibody testing), the neonatal specimen can be tested for evidence of the same infection. Comparison of the two results gives an indication of when the child was infected. An example is a child who presents in the second year of life with deafness and who has antibodies for cytomegalovirus (CMV). If the newborn screening specimen is negative for CMV, then it is very unlikely that the deafness is related to the CMV infection. However, if the newborn screening sample contains CMV antibodies, then this is evidence that a prenatal CMV infection may have caused the deafness. This testing would occur with the consent of the parent/s.
- (ii) The newborn screening specimen of a child who has died from a genetic disease, such as muscular dystrophy can be used to determine the actual genetic mutation that resulted in the muscular dystrophy. This will allow close blood relatives of the child (eg siblings) to be tested to see if they are a genetic carrier of the mutation. It may also allow pre-natal testing of future pregnancies of the parents. Use of the newborn screening card for this purpose would only be with parental consent.

#### (b) Research

- (i) The use of newborn screening cards is a convenient and inexpensive method of undertaking population based epidemiological research. An example is for the determination of the prevalence of a particular disease-causing mutation (the mutation might not have 100% penetrance; that is, it may not always cause the disease and knowing the mutation prevalence compared to the disease prevalence helps to sort out what other risk factors contribute to causing the disease). For this sort of research, anonymised samples are appropriate, such as using punched out blood spots from 1000 consecutive cards from a randomly chosen month. There is no possible way of linking the result of the testing for the gene mutation with the card that it came from. Currently this is only permitted where there is an approval from an appropriate Human Research Ethics Committee (see Appendix 2).
- (ii) A group of children with a particular disease may have been identified. Cards of these particular individuals could be used to determine what proportion of people with the disease has a specific mutation that is known to be associated with the disease. In this situation, the individuals are identified by the researcher, the individual cards are accessed and then the blood spots given to the researcher in a de-identified fashion so that it is not possible for anyone to determine which individual has the mutation that is being tested for. Currently this is only permitted where there is an approval from an appropriate Human Research Ethics Committee (Appendix 2).

At the time the blood spots are collected, the Review Committee recommends (see also recommendation 1.3) that parents be given the opportunity to opt out of any research, identified or de-identified, being conducted on their child's blood spot. This fact ie consent or refusal of consent for access for research purposes should continue to be clearly identified on the card itself.

## (c) Access by parents or individuals over the age of 18

After the initial quality assurance period of 2 years, parents can apply to have their child's newborn screening card transferred to them. The same principles apply to the individual himself or herself once they reach the age of 18 years.

The current parent information brochure needs to be revised to include these details concerning possible transfer.

Protocols in relation to access by parents (or individuals over the age of 18) are covered in the DHS Guidelines for Access to Newborn Screening Cards (see Appendix 2) and the current Disposal Authority issued under the Public Records Act. It should be noted that the DHS Guidelines require written applications from both biological parents and it is recommended that this practice continue. In the event of parents being separated, the principles of the Family Law Act should apply.

An application for transfer of a card from blood relatives other than biological parents should be reviewed by the DHS Newborn Screening Program Advisory Committee on a case by case basis and in accordance with current legislation.

## (d) Access by law enforcement agencies

Under the *Health Records Act 2001*, the health information on the cards can be used or disclosed (without consent or a court order) for the purposes of identification of bodies, or for the identification of a person known or suspected to be dead or missing (HPP 2.5). Health information can be disclosed for secondary purposes with consent (HPP2.2 (b)), if the use is required or authorised under law pursuant to HPP 2.2(c), or for health research in the public interest where information is de-identified or if identified has been approved by an ethics committee (HPP 2.2 (g)).

In January 2003, GHSV and Victoria Police entered into a Memorandum of Understanding (MOU) to allow police access to newborn screening cards by court order. The MOU was intended to ensure that the cards are not handed over simply upon police request, but only where police had court authority.

Newborn screening cards can be used for identification of a body or body parts. Currently this is only done on court order or at the request of the Coroner. Prior to 2004 there was no formal procedure to ensure that cards released for forensic identification were returned to GHSV.

Since 1989, the Victorian Crimes Act has provided a legislative framework for police to obtain DNA samples from volunteers, suspects and convicted offenders for the purpose of investigating crime or identifying unknown missing or deceased persons. That Act contains a number of safeguards relating to collection, use, disclosure, retention and destruction of DNA profiles, genetic samples and related information. For example, police are generally required to get either consent or court authority before obtaining genetic information. Volunteers can limit how their genetic information is to be used, for instance, restricting its use to the identification of missing or deceased relatives rather than for the investigation of current or past crimes. Police are obliged to destroy DNA profiles and genetic samples, such as those obtained from juvenile offenders who do not re-offend after a set time. Police must also destroy DNA samples and genetic information obtained from consenting volunteers who revoke their consent, unless police obtain a court order authorising retention.

The Australian Law Reform Commission (ALRC)/ Australian Health Ethics Committee (AHEC), in its report on the protection of human genetic information, examined the issue of access by police to stored genetic samples outside of the federal forensic procedures law, which is similar to the Victorian legislation. The ALRC/AHEC considered that there is a public interest in ensuring that the safeguards set out in this legislative framework are not undermined by informal collection of genetic samples by police and recommended (Recommendation 41-13) that the Commonwealth forensic procedures law be amended to provide that law enforcement agencies only collect genetic samples (including stored samples) by consent or pursuant to a court order. The Review Committee takes the same view and considers that the Victorian forensic procedures provisions (contained in Part 3 of the Crimes Act 1958 (Vic)) should also reflect

recommendation 41-13 of the ALRC/AHEC report. While this is currently the case for obtaining samples from suspects (see s464R of the Crimes Act 1958), it does not apply to stored samples of genetic material.

As the Victorian Crimes Act is currently under review, it is an opportune time to make a submission that consideration be given to amending the Crimes Act in accordance with the ALRC/AHEC recommendation in relation to stored samples. Alternatively, relevant amendments can be introduced earlier, together with other legislative changes that are recommended in this Report.

The secondary use of punched blood spots from the newborn screening cards should always be accompanied with a commitment to destroy the sample as soon as the tests for which the bloodspot was punched out have been completed. This is provided for by privacy principle 4.5, which states that an organisation that is not a health service provider (eg a research body) must take reasonable steps to destroy health information if it is no longer needed for the purpose for which it was collected or any other purpose authorised by the *Health Records Act* or any other.

In September 2004, GHSV conducted an internal audit of the extent and nature of access granted to the newborn screening cards since 1991. In December 2004, the Health Services Commissioner advised GHSV that she was satisfied that this audit was properly conducted, that an access protocol is in place, and that the protocol was currently being considered by the Review Committee. The audit report is at Appendix 1. For current practice/protocols for authorisation of access please see Appendix 2.

In 2005, DHS established a Newborn Screening Program Advisory Committee to oversee the development and implementation of protocols and procedures relating to the newborn screening program. This includes advice to GHSV on individual applications for transfer of and access to newborn screening cards for secondary purposes, eg for research, from parents, the Coroner etc.

## Recommendations

- 3.1 That all access to the cards including punched out blood spots should comply with current updated protocols as in Appendix 2. Such access protocols should continue to be further reviewed by the DHS Newborn Screening Program Advisory Committee.
- 3.2 That documentation provided to parents about the newborn screening program should include information that access to the newborn screening card for secondary purposes may occur in specified circumstances.
- 3.3 That parents should continue to be given the opportunity to opt out of having any research conducted on their child's newborn screening card and that fact ie if they choose to opt out, should be clearly identified on the card at the time the blood is collected.
- 3.4 That GHSV continue current procedures to have cards permanently marked where the parent has decided to opt out of having any research conducted on their child's card.
- 3.5 That applications for access to de-identified blood spots for research purposes be allowed provided the research has been approved by an institutional Human Research Ethics Committee, and the DHS Newborn Screening Program Advisory Committee be kept informed of such applications.
- 3.6 That any application for research on identified cards be allowed only if:-
  - informed consent is obtained from the parents of the child;
  - the research has been approved by an institutional Human Research Ethics Committee; and
  - the DHS Newborn Screening Program Advisory Committee approves the project.
- 3.7 That access to all blood spots, (even de-identified blood spots), for research purposes not be allowed where the parent has previously indicated that they did not wish to have research conducted on their child's card including the blood spot.

- 3.8 That any access to the cards by law enforcement agencies should only be permitted by court order.
- 3.9 That the Minister for Health refers to the Attorney General the issue of authority for law enforcement agencies to collect genetic samples in line with the recommendation of the ALRC/AHEC report entitled *“Essentially Yours: The Protection of Human Genetic Information in Australia”*.
- 3.10 That GHSV ensure that cards released for forensic identification purposes are returned according to current procedures.
- 3.11 That on the written request of both biological parents the card should be transferred to the parents provided the identity of the parents and child can be verified. If the biological parents are separated and one biological parent has requested transfer of a card and the other biological parent either cannot be found or has refused consent for transfer, the principles of the Family Law Act should apply.
- 3.12 That decisions regarding transfer of cards to blood relatives other than biological parents should be reviewed by the DHS Newborn Screening Program Advisory Committee on a case by case basis and in accordance with current legislation.
- 3.13 That the Parent Information Brochure be revised to advise parents that after the two-year minimum storage period for quality assurance purposes, they can apply to have the card transferred to them. The same principles apply to the individual himself or herself once they reach the age of 18 years.

## 4. Legal Issues

The Review Committee had initially identified a number of unresolved legal questions in relation to the program.

DHS has proceeded to obtain legal advice from a QC as well as the Victorian Solicitor General on these issues and the summary that is provided below incorporates this advice.

We can now consider these issues under the relevant legislation:

### (a) PUBLIC RECORDS ACT (PRA)

Questions that arise are:

- Are newborn screening cards collected in hospitals ‘public records’ for the purposes of the PRA? Consequently, is the Disposal Schedule valid and is the GHSV validly authorised to deal with access?
- If the answer is no, would a declaration by the relevant Minister in relation to newborn screening cards under section 16(1) of the PRA be valid?

Legal advice from the Solicitor General states that only those cards collected in public hospitals and public health services are public records. It is likely that cards collected in denominational and private hospitals are not public records. However the Solicitor General has advised that under s 2(2) of the PRA the Governor in Council may determine that any office or body is or is not a public office and that any record is or is not a public record within the meaning of the PRA. Therefore it would be possible for a determination by Governor in Council that newborn screening cards created in the private sector are public records.

The Solicitor General also advises that such a determination would clearly apply to existing cards held by GHSV and could also be expressed to apply to cards created in the future.

After being kept in the newborn screening laboratory for two years, all newborn screening cards are transferred to approved storage under 2.12 of the PRA in accordance with Disposal Authority PROS 99/04. Once transferred the cards are deemed to be in the custody of DHS and not in the custody of the Keeper of Public Records.

It should be noted that the Solicitor General also advised that the Disposal Schedule was considered to be consistent with the provisions and within the scheme of the PRA.

### (b) HEALTH RECORDS ACT (HRA)

- Are newborn screening cards ‘health information’ for the purposes of the HRA and to what extent do the Health Privacy Principles apply to their collection, use, disclosure and retention?
- If the PRA is considered to apply to the newborn screening cards, to what extent would the HRA possibly be read down due to inconsistency with the PRA?

The Solicitor General has advised that newborn screening cards are “health information” for the purposes of the HRA. The Health Privacy Principles apply to the collection, use, disclosure and retention of the Guthrie cards except to the extent that (i) there is an inconsistency between the HR Act and another Act; (ii) where compliance with the HRA would contravene another Act, regulations or an order of a tribunal or a court; or (iii) where an act that would constitute a breach of certain Health Privacy Principles is necessary for the performance of a contract entered into before 23 November 2000. The application of the HRA to newborn screening cards is not limited by the PRA.

However, health privacy principle 1, which dictates the conditions by which health information can be collected, does not apply to cards collected before the commencement of the Act on 1 July 2002. This means an individual is unable to make a complaint to the Health Services Commissioner concerning the way health information was collected where the collection occurred before 1 July 2002.

The Service Agreement with DHS and the requirements of the law binds GHSV. The Solicitor General has confirmed that GHSV is a health service provider to which the HRA applies.

## (c) HUMAN TISSUE ACT (HTA)

- Do either sections 42 or 44 of the HTA cover the collection of newborn screening cards in Victoria
- If section 42(1)(a) is considered to apply to newborn screening, is the current procedure under the DHS Guidelines for Newborn Screening for obtaining consent sufficient for the purpose of complying with the consent requirement?
- If consent is not being sought in accordance with the Guidelines but instead relying on the argument that implied consent is already present as the newborn screening program is part of the standard care that parents would expect hospitals to undertake, is there a breach of the HTA?
- Does the current procedure whereby a nurse or a midwife carries out the test comply with the terms of section 42(1)(a)?
- If no statute law is found to apply, what requirements for consent would exist under the common law for removal of blood?

The advice received from the Solicitor General confirmed that the current practice of nurses extracting the blood sample probably contravenes the HTA. If the removal of blood from newborn babies is to avoid the prohibition under s 44 of the Act, then it is necessary for the procedure to be carried out by a registered medical practitioner. This must require that at least a registered medical practitioner supervise the screening procedure. While it may be acceptable for a nurse to extract the blood the level of involvement of the medical practitioner must be sufficient to say that the medical practitioner “carried out” the procedure—it would not be sufficient for a nurse to extract the blood and the blood be tested by a laboratory technician without direct supervision by a registered medical practitioner.

DHS is taking steps to propose suitable amendments in order to rectify this unintended consequence of the HTA.

It is also necessary that the informed consent of the parents be obtained. The consent may be either express or implied. It would not be sufficient to infer that parents would have consented had they been made aware that the procedure would occur. The Solicitor General has advised the Newborn Screening Guidelines are adequate for the purpose of satisfying the requirement under the HTA that consent be obtained but this requires that the Guidelines are provided to prospective parents.

## (d) PRIVACY ACT (PA)

- Is GHSV subject to the PA?
- Is there an inconsistency between the application (as determined in the above questions) of Victorian laws and the PA?

The Solicitor General has advised that GHSV is not subject to the PA. The advice from the Solicitor General states that she sees no inconsistency between the *Privacy Act* and the HR Act. However, inconsistency should be assessed on a case-by-case basis.

## (e) Application of Victorian laws to the blood in isolation—that is when removed from the card

- Is the blood when removed from the card (ie. punched out of the card) ‘health information’ under the HRA and/or a ‘public record’ under the PRA?

The Solicitor General advises that blood when removed from newborn screening card is not health information for the purposes of the HRA if the identity of the person from whom the blood was taken cannot be established. She also advises that blood removed from the newborn screening card is not a public record under the PRA.

## (f) “Ownership” of blood samples

The Review Committee notes that the legal status of the blood sample is not clear in current legislation. The card itself is a health record, and as such is the property of the institution that has collected it. At common law, courts have traditionally held that there is no property in human tissue. Therefore if the blood sample is removed from the card, its legal status is unclear.

The fact that there is no ownership in human tissue was discussed at length in the Australian Law Reform Commission (ALRC) and Australian Health Ethics Committee’s report entitled *“Essentially Yours: The Protection of Human Genetic Information in Australia”*, which concluded that it did not support the adoption of a legislated property right to human tissue.

It should be noted that there are many other collections of both blood and other specimens (Pap smears, tissue blocks etc.) that are human tissue and therefore not “owned”.

As indicated above, it is evident that there are still some issues that remain unresolved—for example the legal status of blood samples.

The Review Committee has discussed many options in trying to resolve some of these complex and intricate issues but wishes to stress that attempts to resolve these questions should not in any way jeopardise the continuation and strong support for the newborn screening program. This program is and should continue to be a vital public health program that prevents severe morbidity in some Victorian babies every year.

However the Review Committee would like to put forward the following options for consideration by the Minister for Health:

**Option 1**

The legal issues surrounding the newborn screening program be referred to the Victorian Law Reform Commission for a complete examination. This would facilitate community consultation around issues such as custodianship of the blood samples, retention and access.

**Option 2**

The preparation of specific new legislation covering all aspects of the newborn screening program. This would enable clarification of all the issues that may currently be unclear in legal terms.

**Option 3**

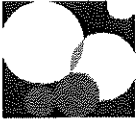
The option of amending the Human Tissue Act only, in accordance with the advice provided by the Solicitor General, in order to address the unintended consequences of that legislation. This would apply to the issue of who could collect blood samples in hospitals. This option would also require clarification of the issue of custodianship of the newborn screening cards after they are transferred to the APROSS using current legislation and the service agreement between DHS and GHSV.

**Recommendation**

- 4.1 That the Minister considers all three options provided ie referral to the Law Reform Commission, new specific legislation for the program, and the option of changes to existing legislation.

## Appendix 1

### Audit on Access to Newborn Screening Cards



Genetic  
Health

Promoting choice through  
diagnosis, counselling, support,  
education and research

2 September 2004

## AUDIT ON ACCESS TO NEWBORN SCREENING CARDS

### Introductory note:

Newborn screening is universally offered in western countries. It is population-wide screening aimed at early identification of children affected by congenital and metabolic disorders for which medical treatment can be promptly initiated to avert metabolic crises and prevent irreversible neurological damage or death. Performed free of charge within the first few days of life, drops of blood are collected from a newborn's heel and are analysed, providing information that can alter the course of the baby's life. The samples are collected in 100 maternity hospitals in Victoria with informed verbal consent from parents or guardians. Newborn screening is one of the most reliable components of child health services.

In Australia, screening programs for PKU began in the 1960's and were soon expanded in the 1970's and 1980's to include screening for congenital hypothyroidism and cystic fibrosis. In 2001, Victoria expanded its newborn screening program to include the detection of a number of metabolic conditions using technology called tandem mass spectrometry (TMS). In Victoria, newborn screening was initially conducted through Kew Mental Hospital in 1965 before moving to Mont Park Hospital in 1967 and finally to GHSV in 1991. DHS provides the funding to GHSV under a standard DHS Service Agreement.

All newborn screening cards, since the inception of the program, have been retained in accordance with NPAAC, Public Records and HGSA guidelines although in recent times NPAAC Guidelines have been revised and we have not altered our practices of retaining the cards in perpetuity. The cards are stored on site at GHSV newborn screening laboratory for two years, then archived in a DHS-approved secure off site facility. A 25 year retention period is now recommended by both NPAAC and Public Records.

In the 1990s the advent of DNA technology and the TMS made it possible to do tests on small stored samples for other purposes. By 2000 we were aware that the cards needed greater protection with regard to both storage and access protocols. Tighter identifying

procedures were introduced after a set of cards had not been identified accurately when the family requested that they be “returned” to them. The current protocols were introduced after that event to provide greater scrutiny and security.

Since 2001 Genetic Health Services has voluntarily initiated discussions about retention, storage and access issues with the DHS and the Health Services and Privacy Commissioners. Following some media interest, a key stakeholder meeting, auspiced by the Health Services Review Council, was held, on 26 November 2003, to look at ways of progressing issues concerning informed consent for newborn screening, and ownership, retention, storage, authorized uses, and legal status of the cards. A recommendation from this meeting was that a small working group comprising representatives from the DHS, OPV, HSC, GHSV, and the PRO, be established to take forward the issues and provide the Minister for Health with an options paper. The paper is close to completion.

### **Impact of newborn screening**

With an average birth rate of 60,000 pa some 2 million babies have been screened since the program began. In just the past 15 years this has meant that we prevented potential intellectual disability in 112 children born with PKU (phenylketonuria) and 260 babies with congenital hypothyroidism. Since the introduction of TMS we have diagnosed 22 babies with rare metabolic conditions. It is of note that these include 10 babies diagnosed with MCAD deficiency. Prior to the expanded program we diagnosed three of these babies after death through the Coroner. We have not had a coroner’s case diagnosed of babies born since TMS began!

**It is critical that concerns about potential future misuse of the newborn screening cards should not get in the way of the newborn screening program.** Having essentially eliminated intellectual disability resulting from conditions diagnosable through the program, it would be truly sad to have a single child not diagnosed and treated as a result of the recent confusion of facts in the media.

### **Audit on Access.**

The following audit is based on a variety of measures and involved all newborn screening staff, some of whom had been with the program before it came under GHSV. Our previous estimate on number of cards accessed was around 1000, as documented in our database. The additional cards identified by the audit were of anonymous samples. It is because they are anonymous these were paper records and were not part of the identified database. All occasions of access since the cards came under the care of GHSV are included in the accompanying table.

## **Explanatory notes to the occasions of access to the Newborn Screening Cards.**

1. **QA:** these are studies performed to standardize tests as a quality assurance measure
2. **Diagnosis** with parental consent includes retrospective diagnosis in a deceased individual at the request of their blood relatives, who wish to establish whether or not they have inherited the gene for the condition and could be at risk of passing it to their child and tests on a living child for convenience with parental consent.
3. **Coroner:** for forensic identification
4. **Police:** GHSV has a Memorandum of Understanding with the Victoria Police to ensure that cards can only be obtained by court Order. Three of the cards requested were for identification of deceased persons. Such requests are now directed through the coroner. There was one request (prior to my time) by court order for a criminal investigation
5. **Research** access requires Hospital Ethics Committee approval.
  - **Identified samples** only with consent
  - **Anonymous** samples without specific consent. There is no identifying or health information available about anonymous samples. These are obtained by “punch” sample from a newborn screening card blood spot transferred to an unlabeled tube and the original card is filed. It is then impossible to trace which one of a thousand possible samples originated from which card.
  - **De-identified**, without consent – these may be selected on the basis of health information eg baby who died of SIDS or on the basis of being the next card in storage eg of a baby who is born full term. Once the sample is obtained however the tube is unlabeled and thus de-identified. To the researcher the sample is of unknown identity but theoretically the newborn screening laboratory could trace the identity in some cases. Our preference is to avoid this option.

**Associate Professor Agnes Bankier**  
**Director**  
*Genetic Health Services Victoria*

## Access Report

| Indication                                      | Number             | Date               | ID  | Ref   | Person                 |
|---|--------------------|--------------------|---|-------|------------------------|
| <b>QA</b>                                       | <b>Total 106</b>   |                    |   |       |                        |
| Organic acid study (anonymous)                  | <b>106</b>         | 26/11/92 - 5/8/98  | Establishing TMS standards                    |       | David Mellington, Duke |
| <b>DIAGNOSIS WITH CONSENT</b>                   | <b>Total 102</b>   |                    |   |       |                        |
| MCAD DNA analysis                               | <b>30</b>          | 12/11/90 - 8/6/01  |   |       |                        |
| DNA group for mutation testing                  | <b>10</b>          | 29/4/94 - 4/4/03   |   |       |                        |
| DHPR testing                                    | <b>7</b>           | 24/9/96 - 26/6/97  |   |       |                        |
| Mzs mutation                                    | <b>1</b>           | 25/11/98           |   |       |                        |
| NSW Metabolic lab                               | <b>5</b>           | 5/8/99 - 29/8/00   |   |       |                        |
| Biotinidase testing                             | <b>3</b>           | 10/5/00 - 21/11/03 |   |       |                        |
| GHSV Metabolic lab                              | <b>9</b>           | 20/11/00 - 22/1/02 |   |       |                        |
| CMV testing                                     | <b>14</b>          | 11/2/02 - 17/8/04  |   |       |                        |
| Galactosemia tests                              | <b>8</b>           | 13/5/92 - 4/8/04   |   |       |                        |
| Reye syndrome/MCAD                              | <b>15</b>          | 19/03/93           |   |       |                        |
| <b>IDENTIFICATION</b>                           | <b>Total 33</b>    |                    |   |       |                        |
| Coroner's Court                                 | <b>29</b>          | 26/10/91 - 20/7/04 |   |       |                        |
| Victorian Police                                | <b>3</b>           | 16/4/99 - 3/1/03   | Identification of deceased                    |       |                        |
|   | <b>1</b>           | January 2000       | Investigation by Court Order                  |       |                        |
| <b>RESEARCH</b>                                 |                    |                    |   |       |                        |
| <b><i>With consent</i></b>                      | <b>Total 299</b>   |                    |   |       |                        |
| Cerebral palsy study (ongoing)                  | <b>247</b>         | 10/06/93 - 23/2/04 | HEC 99095C                                    | 6     | Dinah Reddihough       |
| Eczema study                                    | <b>2</b>           | 14/9 - 16/9/97     | HEC approved – part of a large clinical study |       |                        |
| MRI twin brain development study (ongoing)      | <b>38</b>          | 15/12/03 - 4/2/04  | HEC 050/ST RWH                                |       | Terrie Inder           |
| Gestational influences on twins study (ongoing) | <b>12</b>          | 16/4 - 4/2/04      | HEC 99/08                                     |       | Morley                 |
| <b><i>Anonymous/De-identified</i></b>           | <b>Total 2518</b>  |                    |   |       |                        |
| Deafness study 1                                | <b>1086</b>        | 1984               | EHRC 22061: Carrier rates in Victoria         | 4 & 5 | Henrik Dahl            |
| MCAD study                                      | <b>419</b>         | 18/10/90 – 19/1/95 | UK  | 3     | Peter Campbell         |
| Deafness study 2                                | <b>500</b>         | 2002               | HEC 97083E: Frequency of Cx26 mutations       |       | Henrik Dahl            |
| Intussusception study                           | <b>160</b>         | 1/02/01            | HEC 20079                                     | 2     | Graeme Barnes          |
| Danks MCAD study (de-identified)                | <b>353</b>         | 1989 – 1991        | UK  | 1     | David Danks            |
| <b>TOTAL OCCASIONS OF ACCESS</b>                | <b>3058</b>        |                    |   |       |                        |
| <b>TRANSFERRED TO PARENTS</b>                   | <b>Requested</b>   | <b>68</b>          | April 02 – August 04                          |       |                        |
|   | <b>Transferred</b> | <b>54</b>          | April 02 – August 04                          |       |                        |

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## Appendix 2

Guidelines for Access to Newborn Screening Cards January 2005

## NEWBORN SCREENING CARD ACCESS

### PURPOSE

The purpose of this document is to provide guidelines to Genetic Health Services Victoria staff for the handling of requests for access to Newborn Screening cards.

### SCOPE

This procedure applies to any request for access to Newborn Screening cards.

### RESPONSIBILITY

- Access to Newborn Screening cards is restricted according to this procedure.
- The Head of the Newborn Screening/Metabolic Laboratories ensures that all Newborn Screening laboratory staff comply with this procedure.
- The person in the position (ie Level of Delegated Authority) responsible for the various stages of fulfilling the request for access (as detailed in the "General Comments" section of this procedure) ensures appropriate access to the Newborn Screening cards.

### ABBREVIATIONS

|          |   |
|----------|---|
| DHS      | Department of Health Services   |
| GHSV     | Genetic Health Services Victoria  |
| HGSA     | Human Genetics Society of Australasia   |
| NBS      | Newborn Screening   |
| NBSAC    | Newborn Screening Advisory Committee  |
| NBS card | Newborn Screening card (previously known as Guthrie card)   |
| NPAAC    | National Pathology Accreditation Advisory Council   |
| PRA      | Victorian Public Records Act (Act No 8418/1973<br><a href="http://www.austlii.edu.au/au/legis/vic/consol_act/pr1973153/">http://www.austlii.edu.au/au/legis/vic/consol_act/pr1973153/</a> ) |
| QA       | Quality assurance/assessment  |

|   |                                  |                       |
|---|----------------------------------|-----------------------|
| VCGS Laboratories                                   | BG-P-202                         | Version: 5            |
| Biochemical Genetics - Newborn Screening Laboratory | Prepared by: J Pitt/ A Robertson | Date issued: 06.01.05 |
|   | Authorised by: A Bankier         | Page 1 of 8           |

## NBS Program

Newborn Screening enables every child born in Victoria to be tested in the newborn period for a number of serious diseases, the treatment of which may potentially prevent the complications of intellectual or motor disability or death.

Blood spots are taken on or about the third day of life by heel prick and placed on a specifically designed card. The card also contains identifying information such as name, date of birth, hospital of birth, parent(s) name(s). For most cards, the given name of the child is not recorded on the card.

The card is considered a Health Record and a Public Record. There is no consensus on the ownership of the blood spot.

The card is under the guardianship of Genetic Health Services Victoria (GHSV) and can only be accessed according to specific and approved guidelines.

The card is retained by GHSV according to the Human Genetics Society of Australasia (HGSA) Policy Statement on Retention, Storage and Use of sample cards from Newborn Screening Programs, the National Pathology Accreditation Advisory Council (NPAAC) Guidelines for Retention of Laboratory Records and Diagnostic Material (2002) and the Public Records Act (PRA) (1973).

The secure off-site storage facility has been approved by both the DHS and the Public Records Office Victoria.

## NBS Card Collection

***The collection and consent procedure is the responsibility of the maternity hospital / midwife under the direction of the DHS.***

|   |                                  |                       |
|---|----------------------------------|-----------------------|
| VCGS Laboratories                                   | BG-P-202                         | Version: 5            |
| Biochemical Genetics - Newborn Screening Laboratory | Prepared by: J Pitt/ A Robertson | Date issued: 06.01.05 |
|   | Authorised by: A Bankier         | Page 2 of 8           |

## GENERAL COMMENTS

1. Access to NBS cards for confirmation or repeating of tests recently performed by the NBS laboratory, for QA or for auditing techniques does not require written request. Internal approval of the Head, NBS/Metabolic Laboratories or the Senior Scientist, NBS Laboratory is required.
2. For all other purposes, before a NBS card is accessed:
  - a written request is required,
  - guidelines must be followed and fulfilled,
  - the Director of GHSV must know about the request.
3. Approval for requests for access (including out of state requests) to NBS cards requires compliance with the following:

### Coroner

- Access for forensic identification of deceased by the Coroner must be requested in writing.
- The procedure for the return of NBS cards is described in steps 7-10 of this document.

### Police

- As outlined in the current Memorandum of Understanding with Victoria Police, a court order is required for police to access NBS cards.
- Living individual: Requests for access to NBS cards of a living individual must be directed by a court order and can only be approved by the GHSV Director.
- Deceased individual: Requests for access to NBS cards of a deceased individual should come through the coroner.

### Research Studies

- Hospital or DHS Ethics Committee approval is required.
- Identified samples:
  - GHSV requires consent for all identified research.
- Anonymous samples:
  - Consultation with the Director of GHSV is required.
  - The cards of children whose parents who have opted out of anonymised research are not to be used.

### Physician (usually metabolic) requesting diagnostic testing

- A request form must be completed.
- Written parental consent must be provided.

|   |                                  |                       |
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## Private individual (Parent or Individual whose blood it is)

- NBS cards are kept for two years for QA purposes.
    - Cards will not generally be transferred in this period.
    - The PRA Disposal Schedule allows for transfer of the NBS card under special circumstances. ([http://www.austlii.edu.au/au/legis/vic/consol\\_act/prs1973153/s17.html](http://www.austlii.edu.au/au/legis/vic/consol_act/prs1973153/s17.html))
    - Any such request may be referred to the NBSAC for decision.
  - Individuals may request access to their NBS card from the age of 18 years.
  - A signed statutory declaration regarding identity as biological parents / individual must be submitted.
  - Parents / individuals are to sign a disclaimer for the transfer of the card.
  - The NBS card will be sent by registered mail. GHSV takes no responsibility for NBS cards lost in transit.
  - Parents / individuals may collect NBS cards personally.
  - Separated parents:
    - This follows the principle of the Family Law Act regarding the custodial parent. ([http://www.austlii.edu.au/au/legis/cth/consol\\_act/fla1975114/](http://www.austlii.edu.au/au/legis/cth/consol_act/fla1975114/))
    - If a request for transfer is received from the parent with whom the child permanently resides, that parent (who is usually the mother) is asked to provide a Statutory Declaration from the separated parent consenting to the transfer.
    - If this is not provided, transfer of the card to the residential parent can be made in exceptional circumstances.
    - In case of dispute, the request may be referred to NBSAC for a decision.
4. Parents / individuals can nominate that there be no use of the NBS card other than for Newborn Screening and QA purposes unless explicit parental / individual consent has been obtained. Cards will be visibly identified as such with a label. A notation will be made in the database.
  5. The NBS laboratory computer database is only accessed by NBS laboratory staff who have signed a Privacy Agreement. The database has password protection.
  6. All access is recorded in a database and subject to a quarterly audit.

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## Level of Delegated Authority for the Approval of Access to and the Handling of NBS Cards

| LEVEL OF DELEGATED AUTHORITY   | TASK   |
|--|--|
| <b>Assessment of the request</b>   |  |
| Head, NBS/Metabolic Laboratories or Senior Scientist, NBS Laboratory<br><br>Clinical Quality Assurance Manager   | QA purposes<br>Repeating tests recently performed.<br>Diagnostic testing requested by a physician.<br><br>All other requests as per GHSV Guidelines including requests from: <ul style="list-style-type: none"> <li>• the coroner</li> <li>• non-NBS laboratories</li> <li>• researchers</li> <li>• public (including the individual &amp; parents)</li> </ul> |
| <b>Approval of the request</b>   |  |
| Senior Scientist, NBS Laboratory<br><br>Head, NBS/Metabolic Laboratories or Senior Scientist, NBS Laboratory<br><br>Assessed by Clinical Quality Assurance Officer<br>Approved by Director, GHSV<br><br>Clinical Quality Assurance Manager<br><br>Director, GHSV | Requested access for: <ul style="list-style-type: none"> <li>• QA purposes</li> <li>• repeating tests recently performed</li> <li>• diagnosis</li> <li>• “no access” requests</li> <li>• research (either with consent or anonymous)</li> <li>• transfer of card to biological parent or individual</li> <li>• court/police.</li> </ul>                        |
| <b>Database search</b>   |  |
| NBS laboratory staff   | Database search for NBS card number.   |
| <b>Documentation</b>   |  |
| NBS laboratory staff   | Documentation (password protected & logged) of: <ul style="list-style-type: none"> <li>• sending / receipt of cards</li> <li>• pertinent information.</li> </ul>   |
| <b>Retrieval of NBS card</b>   |  |
| NBS laboratory staff   | Retrieval from storage boxes.  |
| <b>Transfer of NBS card</b>  |  |
| Head, NBS/Metabolic Laboratories or Senior Scientist, NBS Laboratory   | Sending / delivering the NBS card.   |
| <b>On return of NBS Card</b>   |  |
| Head, NBS/Metabolic Laboratories or Senior Scientist, NBS Laboratory   | Receiving & refiling returned NBS cards.   |

## PROCEDURE

### 1. Receiving the written request.

If received by the laboratory, note the date/time received on the request.

Make a photocopy of the request for the NBS laboratory.

Forward the original request to the appropriate GHSV staff member(s) for assessment and approval.

### 2. Assessing & approving the request.

Assess the request against the guidelines outlined in “General Comments”. If guidelines have not been fulfilled, inform the person making the request, giving the reasons for this. If insufficient information has been provided, ask the person making the request to submit the further information.

Ensure that the request has sufficient identifiers (eg DOB, hospital of birth, mother’s name at time of birth, baby’s name, address at time of birth).

Return the written request and completed forms to the Newborn Screening Laboratory.

### 3. Searching the database.

Search the database using the supplied identifiers.

Confirm by matching the date of birth with gender, hospital of birth and the surname (mother’s or baby’s).

A minimum of 3 matching identifiers (not including gender) is necessary before concluding that the correct card has been selected.

If surname and DOB are the only identifiers recognised from the database, examine all possible matching NBS cards for further identifiers which had not been entered into the database (eg address).

If there is insufficient information to make a match with at least 3 identifiers, contact the person making the request who must be able to verify other identifiers used to make a match.

When the correct NBS card is found, write the unique laboratory identifier number on the request.

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#### 4. Accessing the card.

Only approved staff may retrieve cards.

Cards may be retrieved:

- only after guidelines have been fulfilled or
- as required for retesting by the NBS laboratory.

#### 5. Confirmation that the correct card has been selected.

Double-checking is done by a second scientist to confirm that the correct card has been selected according to the criteria listed in step 3.

This is documented on the request, signed and dated.

Enter into the computer record:

- the date of retrieval
- further demographics eg address, parents' names...
- where the NBS card has been sent
- why the NBS card was requested
- the date the NBS card was sent from the laboratory
- the date of expected return

#### 6. Confirmation that all has been done.

Before the NBS card is dispatched, a NBS laboratory scientist confirms that the:

- request has been approved
- NBS card is the one requested
- information has been entered into the computer
- cards accessed for anonymous research are recorded in the database according to the project title, ethics approval, number and date range. (Currently these records are only in hard copy.)

This confirmation is recorded on the request with signature and date.

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## 7. Dispatching the card.

Only the Newborn Screening Laboratory Senior Scientist or the Head of NBS/Metabolic laboratories may dispatch NBS cards.

By hand:

- The person receiving the card must sign on the request for the NBS card and print their name, department and contact number.
- If a GHSV staff member signs any document, GHSV retains a copy of that document.

By mail:

- on receipt of a statutory declaration.

A record is kept of:

- the address
- date of sending
- date of expected return
- contact name.

## 8. Monitoring cards that have been removed from the file.

The NBS laboratory will request an expected date for the return on any NBS cards accessed. A quarterly audit is made of NBS cards that have been accessed and not returned. A list is generated for any outstanding cards including those transferred to the coroner. The list is reviewed and the relevant person(s) (including the coroner) contacted to prompt the return of the card.

## 9. On receiving cards that had been removed.

Enter into the computer record:

- the date the card was returned
- results if they are relevant to NBS testing

## 10. Refiling.

NBS card: refiled (in-house or off-site) as soon as is practicable by NBS staff

Requests: kept with the Clinical Quality Assurance Manager

Approval forms: NBS laboratory

## 11. Recording access.

Records are kept of all access to NBS cards at each stage of the procedure.

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## Appendix 3

### Supplementary Report of the Privacy Commissioner

## Supplementary report of the Victorian Privacy Commissioner

I support Victoria's newborn screening program and have confidence in Genetic Health Services Victoria, which currently operates the program under contract to the Department of Human Services. I urge parents to continue to have their babies tested in the newborn screening program for the rare conditions which, if detected in the early stages of life, can be treated.

I support the Review Committee's recommendations as far as they go, but I regard the measures proposed as temporary.

This is a supplementary report to the Review Committee's final report (draft dated 19 May 2006), prepared because I believe the Review Committee's work, although valuable, does not go far enough in alerting the Minister and, through her, the Victorian Government, Parliament and the community, to the scope of the challenges inherent in the ongoing newborn screening program and in the archive of more than two million cards that the program has so far produced.

The public interest in maintaining confidence in newborn screening will not be served by artificially insulating the newborn screening program from the large public policy issues that arise from humankind's rapidly growing knowledge of genetics. We will serve the public interest best if we acknowledge – and make clear to the public – that the newborn screening program is unavoidably connected to advances in genetics, and that the implications of this can be managed properly under law by confident use of the familiar techniques of a democratic society.

Genetic knowledge has accelerated since 2000 when the sequencing of the human genome was announced. Applications of that knowledge, inside and outside the health sector, in government and commerce, are proceeding. The relevant market is global. It will not tarry for Victoria, or any other jurisdiction.

Obtaining and analysing a person's genetic data, and using that data for a range of private and public purposes, brings fundamental values into play. Can and should a part of a person's body – and the genetic data latent in it – be capable of being owned? If so, is property law adequate to govern the issues arising from the mining of genetic data in a market for human tissue samples? To what extent is an individual to be able to control what is to be done with his or her genetic data, particularly as more and more can be known or inferred from that data? Since a person's DNA can be revelatory about him or her *and* his or her blood relatives, it is necessary to consider what in Europe is known as the 'privacy of the biological group'. This means the privacy interest shared by a group of people, related by blood, when genetic data is extracted from the body of any individual from that group.

Genetic knowledge offers great benefits and threatens serious harms. Both need attention. What we know, what we infer, and what we do and do not do as a result of the knowledge and the inferences, will have wide effects. Humility is essential. Much remains to be learned. Those who are not literate in the science must nevertheless work at understanding enough of it to assist in the process of absorbing into law and policy the consequences of the science. We cannot outsource that process to the specialists. They do not want us to do so. Some of the finest scientists in this field have called for greater attention by policymakers and the public generally to the implications of the knowledge geneticists are developing.

As with past technological breakthroughs, the community and its representatives should adapt confidently using techniques that have served us well in the past. Well-tested democratic processes - which compel transparency, dispersed power, balancing mechanisms, review, and opportunities for adjustments - should be scrupulously followed. Governments in Australia generally have been comparatively slow off the mark, in contrast to the nation's distinguished scientific community and some in commerce.

The basic issues before the Review Committee since its inception in November 2003 have been known for some years. The Department of Human Services has or ought to have been aware of

issues related to the custody and control of newborn screening cards since at least 1998.<sup>1</sup> The Australian Law Reform Commission pointed to the issues in the process leading to its report on *The Protection of Human Genetic Information in Australia* in March 2003. Overseas references abound.<sup>2</sup>

It is essential that Victoria act without further delay to build a legal framework designed specifically for the unique and complex balancing of rights and obligations inherent in applications of genetic knowledge. The newborn screening program is the place to start.

In practice, the sources of much potentially valuable genetic knowledge are the collections of human tissue samples which over the years accumulate in public and private hands for specific purposes. (Examples include blood banks, pap smear tests, biopsy material.) Newborn screening programs have created in the past, and continue daily to build, one such a collection. Collections of newborn screening cards contain certain basic information about a person on the card and in the associated database, together with a sample of the person's blood soaked into each card. (The cards and the database are kept separately.) DNA is stable in dried blood. Guthrie Card collections are therefore potential troves of genetic information about known persons. Although collected for the specific purpose of screening a newborn baby for certain health conditions, the cards represent rich potential for research, law enforcement, identity management and other purposes. That potential cannot and ought not be dealt with in anything but a temporary way by uncoordinated adaptation of generic laws, procedural guidelines, Ministerial Councils' statements, memoranda of understanding and outsourcing contracts.

Newborn screening programs offer a unique opportunity for a statutory response that is tailored to the programs. They offer a chance to legislate in relation to genetics issues within workable bounds. The screening of a newborn is by definition a specific once-only interaction between an individual and the state. (It will typically be the first such interaction, preceding even the registration of the baby's birth at the Registry of Births, Deaths and Marriages.)

It is practicable to establish in one statute the necessary framework to govern –

- authority to add new tests to the screen as tests become available;
- processes for obtaining and recording parents' consent;
- standardised testing procedures in the public and private sector;
- quality assurance;
- secure storage of the cards (both the large archive and all future cards);
- access to the cards by the parents and, on reaching maturity, the persons tested;
- access to the card by others, such as researchers, for authorised purposes;
- ownership of the cards themselves, the intellectual property derived from the blood in the cards and (if human tissue can be owned in law) the blood and the DNA in it;
- return/authorised disposal of the cards;
- oversight, accountability and reporting to Parliament.

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<sup>1</sup> Charles Lawson and Rebecca Smith, "Protecting Genetic Materials and Genetic Information: A Case Study of Guthrie Cards in Victoria" (November 2001) 9 *Journal of Law and Medicine* 215.

<sup>2</sup> Privacy Commissioner (B.H. Slane), *Guthrie Tests: A Report by the Privacy Commissioner Following his Inquiry into the Collection, Retention, Use and Release of Newborn Screening Test Samples, Pursuant to section 13(1)(m) of the Privacy Act*, September 2003, <http://www.privacy.org.nz/filestore/docfiles/70989185.pdf>.

In my view, the work of the Review Committee, together with other information to which this supplementary report refers, demonstrate that existing elements of Victorian law and administrative practice applying to the collection are not adequate to meet the current and foreseeable challenges of managing the archive and the ongoing program.

I recommend that the Minister and her colleagues in Government view the Review Committee's work as a preparatory step to an inquiry with sufficient powers, expertise and resources to examine and report on:

- first, purpose-built newborn screening program legislation; and,
- second, the desirability of establishing a statutory Human Genetics Commission for Victoria along the lines of similar entities already operating or recommended in other jurisdictions.

The Review Committee's groundwork should make the next process quicker.

Acting in this way now will assist Victoria to respond adequately in the public interest to the issues that will continue to emerge from growing genetic knowledge.

## **I. Consent for Testing and Quality Assurance**

### ***Consent for testing***

The report suggests that there are three options for implementing informed consent procedures, two relying on verbal consent obtained prior to testing, and one relating to obtaining informed written consent at the time of pre-admission or testing.

The report does not adequately consider the possibility of seeking and obtaining consent at a much earlier period, during the course of pregnancy and prior to admission. Early attention to consent would avoid many of the issues that arise in the context of trying to gain consent when parents are in the midst of delivery and the aftereffects of birth. Fathers are relevant; their DNA as well as the DNA of mother and baby, is implicated.

Early information and consent procedures provide parents with the time and opportunity to obtain sufficient information on which to base their decision. It allows such decisions to be made at a time that is not filled with the joy, exhaustion and other circumstances that attend childbirth. These circumstances are likely to affect the quality of consent, which ought always be informed and voluntary.

While consent prior to admission for delivery is the ideal, this may not always be an option, or parents may choose to delay their decision about testing until after their child is born. As there is at least a 3-day window in which the tests can be performed, consent to testing could be sought at a time in that post-delivery period when parents are able to give their informed consent without the obvious distractions associated with the immediate aftermath of childbirth.

**Recommendation 1.** *Parents should be provided with information about newborn screening tests, the implications (beneficial and otherwise) of the tests, available treatments and their rights of refusal. This information should be conveyed in a manner that allows time for reflection and consideration of the implications. Information should be provided early during prenatal care and/or during the third trimester.*

**Recommendation 2.** *Parents should have the option of consenting to testing prior to admission for delivery, and given the option of declining or agreeing to tests that may either not meet the criteria (in Recommendation 8 below) or that are being piloted.*

**Recommendation 3.** *Consent to testing, and consent to uses and disposal, can be sought separately. The hospital should have primary responsibility for seeking consent only to testing. An independent statutory entity should be responsible for seeking consent from new parents about use and disposal of the cards, for*

*responding to requests by parents or newborns (who have reached maturity) about uses and disposal of their archived card, for securing cards and for ensuring that the uses of the cards comply with law and the terms of any consent given.*

### **Consent to retention for later uses**

Where parents can exercise choice about how the card is to be later used or disposed of, that consent could be obtained prior to admission or deferred at their election or where prior consent is not practicable. Newborns, upon reaching the age of maturity, should have the right to control the use and disposal of their card. The report makes recommendations that will allow parents to exercise some control over subsequent use and disposal of the card. However, the focus is on future cards. The report does not adequately address how people can exercise similar control over the use and disposal of an archived card.

**Recommendation 4.** *Consistent with notice obligations under privacy laws, parents should also be informed about the usual uses and any rights of access they may have to the card, along with any options they may have relating to later use or disposal.*

**Recommendation 5.** *While the information about testing, use and disposal should be made available to parents at an early stage (during pregnancy and prior to delivery), the obtaining of consent could be deferred to a later time, or occur in two stages. Deferred consent to testing, for instance, could occur at the parents' option or in circumstances where it is not reasonably practicable to obtain consent prior to admission.*

**Recommendation 6.** *Where lawful and practicable, parents should have the option of consenting (or withdrawing their consent) to other uses of the newborn screening card and disposal at any stage, including during pregnancy and at any time after testing. Newborns (upon reaching maturity) should also have the option of consenting to uses and disposal of their card, or to withdraw any such consent given by their parents on their behalf.*

**Recommendation 7.** *Parents should have the option of consenting to:*

- *Option 1: testing under the newborn screening program, with a mandatory two-year period of retention for quality assurance purposes, during which no other use is made of the card (including de-identified research) except where required by law, and after which the test results are retained for the requisite 25-year period but the card is disposed of (eg, by returning it to the parent or destroyed at the parents' election);*
- *Option 2: the same as in Option 1, except that the cards may be used for de-identified research or otherwise by parental consent or where required by law;*
- *Option 3: the same as Option 2, except that the cards may be retained indefinitely or until disposal is requested by the parent or the newborn when she or he reaches maturity, during which the card may be used by consent, where required by law, or for any other purpose that is clearly set out in purpose-built legislation.*
- *Any use that is required or authorised by law should be accompanied by safeguards that address potential privacy risks arising in relation to the health-related and non-health genetic information about the individual or any blood relative.*

### **Authorising which tests newborns will be screened for**

The report does not address the issue of how, or who, authorises the tests that are conducted under the newborn screening program, and whether parents have any option to decline certain tests. Accelerating genetic knowledge is producing more tests that may – with varying degrees of reliability – detect or predict certain conditions in the individual being tested. It is necessary without delay to bring into focus the power and accountability under law of those who approve the tests in the newborn screening program.

With the introduction of new technology, such as tandem mass spectrometry ("TMS"), it will be possible to detect conditions for which there is not yet any effective treatment. The Human Genetics Society of Australasia ("HGSA") suggests that, while a number of conditions can be detected on a single TMS run, laboratories may wish to electronically suppress the detection of some of these conditions. The HGSA recommend that conditions included in the newborn screening program comply with these criteria:

- there is a benefit for the individual from early diagnosis;
- the benefit is reasonably balanced against financial and other costs;
- there is a reliable test suitable for newborn screening; and
- there is a satisfactory system in operation to deal with diagnostic testing, counselling, treatment and follow-up of patients identified by the test.<sup>3</sup>

In the USA, the Task Force on Newborn Screening recommended these criteria for including screening tests:

- a. the condition being tested is an important health problem that occurs frequently enough to justify screening an entire population;
- b. the treatment for the condition is effective when initiated early, accepted among health care professionals, and available to all screened newborns; and
- c. the test is simple, safe, precise, validated, and acceptable.<sup>4</sup>

**Recommendation 8.** *Newborn screening should be restricted for the time being to conditions for which there is a demonstrated benefit to the infant from early diagnosis, including the availability of treatment, pending the establishment of a statutory scheme to regulate the process through which new tests are to be added to the screen, or removed from it.*

**Recommendation 9.** *New tests should be authorised only by an independent statutory body, comprised of representatives from the health sector, community and other areas of expertise relevant to the consideration of medical, legal, social and ethical issues arising in the context of genetic testing.*

## II. Retention and Storage of the Cards

### *Do current laws require cards to be kept for 25 years?*

As noted elsewhere in the report, legal advice indicates that the protections and retention obligations under the Public Records Act and the Health Records Act may not apply to the blood when removed from the card. As recognised by the ALRC and AHEC in their joint report, it is unclear whether current privacy laws protect tissue samples (the blood) as distinct from health and other personal information (the data recorded on the newborn screening card, and the test results derived from analysing the blood).

<sup>3</sup> Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australasian College of Physicians, *Newborn Screening*, February 1999, para 2, <http://www.hgsa.com.au/policy/ns.html>. These criteria were incorporated into the HGSA's revised policy, but with a significant alteration that extends the benefit of early diagnosis to include benefit to the family: *Newborn Blood-Spot Screening*, HGSA Policy Statement, 2004, HGSA-RACP Newborn Screening Joint Subcommittee, <http://www.hgsa.com.au/Word/HGSApolicyStatementNewbornScreening0204-18.03.04.doc>.

<sup>4</sup> American Academy of Pediatrics, National Task Force on Newborn Screening, "Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future – A Call for a National Agenda on State Newborn Screening Programs" (August 2000) 106(2) *Pediatrics* 389-422 at 394, available at <http://pediatrics.aapublications.org/cgi/content/extract/106/2/S1/389>, visited 8 December 2003.

As a matter of public policy, it is not clear why blood contained on a card should be treated differently from blood contained in a test tube. The report suggests the latter must be retained under privacy and public records laws for a period of 25 years and therefore parental consent for retention for this period of time is not required. This aspect of the report appears to contradict the apparent choice that is to be given to parents to consent to the retention of cards for two years only for quality assurance purposes. If there is a legal obligation to retain and not destroy or otherwise dispose of the cards before the child turns 25, then any parental choice at the time of testing is illusory.

Given the legal advice obtained by the Review Committee, it is not clear that the retention obligations necessarily apply to the blood contained on newborn screening cards. It may be that the retention and handling obligations apply only to the test results and recorded health information, and not to newborn blood soaked into cards.

The ALRC/AHEC report considered a number of options for ensuring tissue samples receive equivalent protection to health and other personal information. Two of these options were to amend privacy laws to ensure they apply both to genetic information and to genetic tissue samples; or to amend Human Tissue Acts to address the collection and handling of tissue samples. The ALRC/AHEC preferred the first option and the Commonwealth Government has begun to implement some of the ALRC/AHEC recommendations by recently introducing a Bill to amend the federal privacy law so that it expressly covers health-related and non-health genetic information collected and handled by private sector organisations (the *Privacy Legislation Amendment Bill 2006 (Cth)*). The Commonwealth Government has declined, however, to amend the federal privacy legislation so that it expressly applies to genetic tissue samples, saying (in its response to the ALRC/AHEC report) that the Human Tissue Act is the more appropriate vehicle to regulate the use and handling of genetic samples.

Given the power of genetic data and the lack of certainty around what, if any, obligations apply to tissue samples (as compared with health information and other records), it is preferable that there be legislative clarity. It is no surprise that laws devised in other eras (eg *Public Records Act*) for other settings (eg *Health Records Act*, dealing with information not tissue) and before the sequencing of the human genome should be, alone or in combination, inadequate to the issues that the newborn screening program now poses. As will be apparent throughout this supplementary report, the number and significance of the issues beg for the introduction of a purpose-built law to provide clear and comprehensive guidance about the collection and handling of newborn screening cards and to protect the genetic privacy of newborns and their blood relatives.

**Recommendation 10.** *Legislation should be introduced to clarify the retention and disposal obligations that apply to newborn screening cards, as distinct from the health-related and non-health information contained on the cards and derived from analysing the blood.*

**Recommendation 11.** *As suggested by the ALRC/AHEC, privacy laws should be amended to provide clear protection for not only genetic information, but also genetic samples. Amending privacy laws provides additional clarification that genetic information that is latent in, or derived from, blood receives additional privacy protection.*

### ***Long-term retention of the “biobank” for uses other than newborn screening***

In recent years, some countries have participated in the creation of biobanks containing population DNA samples for use by researchers. These biobanks were established through various combinations of consent, legislation and commercial contracts or licences. Examples include the United Kingdom Biobank<sup>5</sup> and the Icelandic *Act on a Health Sector Database*,<sup>6</sup> which

<sup>5</sup> See the official website for the UK Biobank is <http://www.ukbiobank.ac.uk/>.

<sup>6</sup> Iceland's biobank is described by Tómas Zoëga MD and Bogi Andersen MD, in *The Icelandic Health Sector Database: deCODE and the “new” ethics for genetic research*, 18 September 2000, [http://www.mannvernd.is/english/articles/tz\\_database.html](http://www.mannvernd.is/english/articles/tz_database.html).

established a biobank under law and authorised the grant of a monopoly licence to a biopharmaceutical company, deCode genetics.<sup>7</sup>

In Victoria, the practice of retaining indefinitely newborn screening cards collected over the past 30-40 years has effectively resulted in the creation of a potential population biobank containing the genetic data of more than two million Victorians. Victoria's potential biobank, unlike those established in overseas jurisdictions, was created by default rather than design. It was developed from the specific act of testing newborns for a limited set of treatable conditions. Consent to participate in a biobank was not sought. Legislative safeguards were not crafted. It is perhaps not surprising that some parents express some concern when they discover for the first time that their newborn's blood has been retained and may be used for research and other purposes without their knowledge or consent.<sup>8</sup> Victoria ought not close its mind to the potential benefits of a biobank. Nor ought it shut its eyes to the fact that its collection of newborn screening cards may form the basis of such a biobank.

As noted in the report, many of the newborn screening cards contained in the archive have been collected and retained without parental knowledge or consent and in breach of the Human Tissue Act. If this archive is to be retained into the future, then its status must be regularised – whether by consent of the individuals whose blood is involved (or their parents, in the case of children), and/or by legislation.

It is my strong view that Victoria's accumulated collection of newborn screening cards (the archive) should not be destroyed – certainly not without first consulting the community. There are clear public benefits for retaining the archive, supplemented by new cards collected over time. These public interests include public health research and victim identification. However, it must be recognised that, if the newborn screening cards are to be retained beyond the two-year quality assurance period, then the nature of the collection essentially changes. The cards effectively become part of a potential biobank, accessible for research and other uses unconnected to the newborn screening program. If Victoria is to maintain the current and ongoing collection of newborn screening cards for public interest uses unrelated to newborn screening, then the resulting biobank should be expressly regulated by law with clear protections about permissible uses and enforceable rights for parents and newborns (upon reaching maturity) to consent or opt-out of such uses, and to seek the return or disposal of the card. The legislation should also set out an express period of retention of the cards.

Retention periods applying to newborn screening cards collected in the future could be variable, depending on the scope of parental consent. For instance, legislation could require newborn screening cards to be retained for two years only, for quality assurance purposes, where parental consent has not been obtained for a longer retention for other unrelated uses. Where parents do consent to unrelated uses, such as research or other permissible uses (prescribed under law), a longer period of retention can be set. For instance, parents may agree for the cards to be retained for a period of 10-15 years for research use, or for a longer period in case of the need for victim identification. Indefinite retention raises other issues requiring thorough enquiry and debate. The individual will not benefit after his or her death. The genetic privacy of their blood relatives is important. New uses are likely to be made of samples with the advancement of genetic knowledge. New applications in commercial and other contexts are likely.

Community consultation, parental consent (and the ability of the newborn, upon reaching maturity, to revoke that consent), and legislation are all essential ingredients in determining and enforcing appropriate uses and retention periods for the cards and the blood/DNA in them.

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<sup>7</sup> These and other biobanks, and the authorities that underpin them, are also discussed in Annex 2 in France's National Consultative Bioethics Committee for Health and Life Sciences, *Ethical issues raised by collections of biological material and associated information data : "biobanks", "biolibraries"*, Opinion no. 77, 20 March 2003, [http://www.ccne-ethique.fr/english/avis/a\\_077.htm](http://www.ccne-ethique.fr/english/avis/a_077.htm).

<sup>8</sup> Such anxiety may persist despite a donor consenting to participate in a biobank: Klaus Hoeyer, "Ambiguous gifts: Public anxiety, informed consent and biobanks", Chapter 6 in Richard Tutton and Oonagh Corrigan (eds), *Genetic Databases: Socio-ethical issues in the collection and use of DNA*, 2004, Routledge: London.

**Recommendation 12.** *Consistent with other laws and practices governing the donation of blood and other human tissue, parents and newborns (upon reaching maturity) should be given the option to consent to the retention of blood for purposes other than newborn screening. Any other use of retained cards should be clearly set out in purpose-built legislation applying clearly to newborn screening cards.*

**Recommendation 13.** *A minimum retention period should be clearly established in law, accompanied by protections against unauthorised use, and allowing parents at any time, and newborns upon reaching maturity, to seek the return or disposal of their card. Retention periods could be variable, depending on the purpose for retention and any consents obtained. Community consultation should be engaged in to determine the appropriate retention period(s) for the cards.*

**Recommendation 14.** *The archived newborn screening cards should not, as a collection, be destroyed until and unless the community indicates support for such a proposal and an appropriate entity expressly authorizes, and afterwards verifies, destruction.*

### **III. Access to and Secondary Uses of the Cards**

The report proposes a number of secondary uses that should occur, including: diagnosis of health conditions in infants; epidemiological research and assessment of the prevalence of a condition within the community; access by parents or newborn at maturity; use by the Coroner; and use by law enforcement agencies with court order.

#### ***Diagnosis of conditions in individuals***

Use of newborn screening cards to diagnose the health condition or cause of death of a newborn or blood relative, with parental consent, is endorsed and regarded as consistent with privacy laws in that consent is a clear basis for use and disclosure of health and other personal information. Consideration should of course be given to any contrary views a mature person might have about whether their genetic information should be disclosed to other relatives. An appropriate framework to give that consideration and make enforceable decisions needs to be created.

**Recommendation 15.** *Use and disclosure of newborn screening cards should occur with appropriate consent. Where the card of a mature person is concerned, whether alive or deceased, their known views about disclosure or non-disclosure should be taken into account. The legislative framework recommended elsewhere in this supplementary report should make specific provision for these matters.*

#### ***Epidemiological research and public health surveillance***

The report's discussion of research use does not adequately reflect the inherent ethical and legal complexities. Parental choice, identification of genetic conditions without being able to inform the individual concerned, paternity and ethnicity testing, and commercial use of genetic knowledge are all areas that require greater consideration in this context of a new born screening program and its archive.

The report refers to population-based research and surveillance of the prevalence of health conditions, using de-identified cards, without parental consent but with ethics approval by a Human Research Ethics Committee. The report notes that, in some cases, a gene mutation may be discovered but there may be no possible way to identify the individual from whose card it was derived.

In principle, consent should be the primary mechanism for undertaking research. Where it is not practicable to obtain consent, privacy laws permit such research to proceed if it is in the public interest and complies with other safeguards. Health research generally requires ethics approval. However, the ALRC/AHEC report found that the ethics approval system was not ideal and could be significantly improved. The ALRC/AHEC found that many ethics committees lack resources and the relevant expertise, and that the operation of these committees could be improved to be more transparent and accountable when reviewing proposals to undertake human genetic

research. In my view, Victoria ought to act on these findings. The newborn screening program is the current issue requiring an improved approach, but there are bound to be others.

The report also refers to the use of cards to identify the proportion of people who carry a particular genetic mutation known to be associated with a disease. On the one hand, this type of prevalence testing can potentially benefit identifiable individuals by allowing them to have available treatments or make necessary lifestyle changes. On the other hand, such surveillance may adversely impact on individuals who do not wish to know of the condition (for instance, because there is no effective treatment available, or because of the effect such a condition might have in obtaining insurance or employment). This is the issue sometimes summarized as the right *not* to know. It cannot be wished away. Genetic advances are forcing it on communities everywhere. It is necessary that testing now be directly regulated under legislation by an appropriately independent, expert and supported statutory entity, working with a framework created by processes superior to those with which the Review Committee was equipped.

Consideration should also be given to the implications of the commercial potential to commercially exploit genetic samples without the knowledge of, or any benefit to, the individual whose tissue/DNA is used. Commercial uses ought not be precluded precipitately, but neither ought they evolve by default, by uncoordinated consequences of various outsourcing or other contracts, or by neglect by Executive and Legislative of their proper roles in animating public interests that commerce cannot be expected to animate, nor condemned for failing to consider.

**Recommendation 16.** *Where practicable, parents (or newborns upon reaching maturity) should be given the option of consenting (out of revoking their earlier consent) to the use of their card for research, whether identified or de-identified research.*

**Recommendation 17.** *De-identified public interest research without consent should only occur after consideration by a health ethics review committee where their decisions are made by members with the relevant expertise, in an accountable way (such as with oversight by an independent statutory entity) and made transparent (such as through publication). De-identified research should not use any cards where consent was expressly withheld for such use.*

**Recommendation 18.** *Given the potential for discrimination and other harms arising from detection of genetic and other health conditions, any de-identified testing of newborn screening cards to detect the prevalence of health conditions or genetic mutations in the community should occur only with clear legislative authority.*

**Recommendation 19.** *Where de-identified public interest research or public health surveillance is proposed and it is likely that the individuals whose blood is used may benefit from knowledge of any detected conditions, consideration should be given to either obtaining prior consent or establishing a mechanism where the card can be re-identified (by, for instance, procedure under law to be followed by the custodian of the cards).*

**Recommendation 20.** *Parental and individual choice to participate in research should be informed by whether the research is likely to result in any commercial applications. Non-consensual use of newborn screening cards for research with commercial arrangements should only occur where authorised by law.*

### ***Access by parents or individuals over the age of 18***

The report suggests that parents can request that newborn screening cards be transferred to them after the two-year quality assurance period has ended and, similarly, the individual whose blood is on the card can seek a transfer of the card when they turn 18 years of age.

If the newborn screening cards (including the blood/DNA embedded in the cards) are subject to the Health Records Act, then it may not be lawful to transfer the card to the parent or child before the child turns 25 unless specific legislative authority applies. Legal advice suggests that any such authority under the Public Records Act is limited to cards collected by public hospitals only. Private hospitals may, in addition to not being covered by the Public Records Act, be subject to different disposal obligations under the federal Privacy Act (eg, the cards may have been required to be destroyed or de-identified when no longer needed).

Neither the Health Records Act nor the Public Records Act provides a universal entitlement for parents to seek a transfer of their newborn's card. Access rights under the Health Records Act (or any privacy law) will not assist in the transfer of the card back to the parent or individual since those access rights are limited to a right to inspect and copy of the card, not to obtain custody of the card (including the blood) itself. The current Disposal Authority issued under the Public Records Act may assist parents in obtaining their newborn's card where it was created in a public hospital. However, this Disposal Authority may be regarded as deficient in that, as currently drafted:

- it permits transfer of cards at any time after they are created, irrespective of the recommendation in the report that newborn screening cards should be retained for at least two years for quality assurance purposes;
- it does not adequately take into account the rights of the child to be involved in decisions affecting their interests. For instance, the Disposal Authority:
  - may allow the child's card to be transferred to one or both of his/her parents despite the child's objection; and
  - does not permit transfer of the card to children or young people prior to their turning 18, despite their having sufficient understanding and intelligence to give valid consent (Gillick test<sup>9</sup>);
- it does not adequately address the risk of non-consensual paternity testing or some other use that may not be in the newborn's best interests;
- where transfer of the card is refused, it is unclear whether individuals have any right to seek a review of that decision.

The report goes further than the Disposal Authority in requiring both biological parents to submit written applications requesting a transfer, and suggests that other blood relatives can request a transfer. The current Disposal Authority (as at 19 May 2006) does not require a written application, and permits a transfer to one or more parents or guardians. There is no requirement for both parents to request the card, and there is no obligation for the requesting parent to be the biological mother or father of the child. There will be situations where one parent (or guardian) only seeks a transfer of the card. There could be legitimate reasons for this, including the other parent not being alive or having given up (formally or informally) any role in the care and custody of the child.

The Review Committee wrestled with these complications of various existing laws for too long. In my view, the complications simply demonstrate that a purpose-built statute is required to deal with the issues that the newborn screening program and its archive pose.

**Recommendation 21.** *There should be clear and comprehensive legislative authority for parents/guardians or the newborn (upon reaching maturity) to seek the transfer or disposal of their card. This is best achieved through purpose-built legislation, rather than through the Public Records Act, as newborn blood/DNA should not in principle be deemed to be a record of the State. The legislation should specify whether transfer can be sought at any time, or whether cards must be retained for a minimum of two years for quality assurance purposes.*

**Recommendation 22.** *The legislation should address the manner in which applications for transfer are made, including whether the consent of both parents (whether biological or adoptive) are required and whether there*

<sup>9</sup> The Gillick test comes from the English House of Lords case of *Gillick v West Norfolk AHA* (1986) AC 112, which has been applied in Australia for many years in relation to determining when minors are capable of giving informed consent to a particular action or arrangement. In *Gillick*, their Honours said: "A minor is, according to this principle, capable of giving informed consent when he or she 'achieves a sufficient understanding or intelligence to enable him or her to understand fully what is proposed'".

*are circumstances where consent from one parent or guardian is sufficient. The legislation should also require any requests by parents or guardians for transfer to be made in the best interests of the child.*

**Recommendation 23.** *To minimise the risk of non-consensual testing and other uses of the card that may not be in the child's best interests, Victoria should without further delay adopt the ALRC/AHEC recommendation to introduce a criminal offence for non-consensual genetic testing.*

### ***Access by blood relatives and other third parties***

The report also suggests that newborn screening cards can be transferred to blood relatives of the child. The report recommends that such requests be referred to a newborn screening advisory committee. That committee has no tailored legal basis, nor public accountability commensurate with its responsibilities. Although the report gives the example of transfer requests being made by grandparents where the parents are deceased, the recommendation (as drafted) allows transfer despite the parents being alive and irrespective of whether the newborn is an adult at the time of the request.

Transfer of newborn screening cards to third parties should only occur by consent of the individual concerned, or with express authority under law. If, for instance, the card is needed to determine paternity for family law proceedings,<sup>10</sup> or in order to ascertain a child's eligibility under a will or an insurance policy, a court order or other legislative authority should be a requirement.

As noted earlier, the federal Privacy Act is currently being amended to allow for genetic information to permit disclosure to lessen or prevent a serious threat to an individual's life, health or safety.<sup>11</sup> This amendment is intended to allow disclosure (in accordance with NHMRC guidelines to be approved by the federal Privacy Commissioner) of an individual's genetic information where there is a serious (but not necessarily imminent) risk to the health of a genetic relative. If passed, this amendment will provide GHSV with authority under law to disclose the cards or the results of genetic testing to an individuals' blood relatives without seeking consent from the parent or the individual (whether a child or an adult) and despite any known objections.

Better legislative safeguards (in the federal privacy legislation and in any purpose-built Victorian law) are likely to be required to protect the individual's genetic privacy and to maintain public confidence in the newborn screening program.

**Recommendation 24.** *Transfer of newborn screening cards to blood relatives or other third parties should only occur by consent of the individual concerned, or with express authority under law. Legislative safeguards are required to ensure that the individual whose blood is on the card is notified of any request for their card and given the opportunity to object to the proposed use.*

**Recommendation 25.** *The Minister for Health and the Attorney-General should consult with their federal counterparts to ensure that the Privacy Legislation Amendment Bill does not allow disclosures that could compromise public confidence in the newborn screening program.*

<sup>10</sup> In the New Zealand case of *H v G*, a court order was obtained under the Status of Children Act requiring the health provider to release a deceased baby's newborn screening card to H to allow him to establish whether he (rather than G's husband, O) was the baby's biological father: High Court (Auckland), 10 May 1999, M1868/98, Salmon J. Also see *H v G* (1999) 18 FRNZ 572, where the Morris J later accepted the admissibility of the DNA evidence obtained under earlier court order, despite G's claim it was obtained in breach of the Health Information Privacy Code. And see G's subsequent complaint to the Health and Disability Commissioner that the newborn screening card was collected and retained without consent, and a right of return ought to have been provided: Auckland Healthcare Services Limited, New Zealand Health and Disability Commissioner, Report on Opinion - Case 99HDC09011, 4 August 2000, <http://www.hdc.org.nz/files/pageopinions/99hdc09011.pdf>.

<sup>11</sup> Item 5 of Schedule 2, *Privacy Legislation Amendment Bill 2006 (Cth)*.

### ***Use for victim identification***

The report notes that newborn screening cards are obtained by the Coroner to identify a body or body parts, and this is done under court order or at the request of the Coroner. The report recommends a formal procedure be established to ensure the return of the cards.

I endorse this recommendation, which accords with my recommendations last year to the Victorian Parliament's Law Reform Committee during its inquiry into the review of the Coroners Act. In my submission, I suggested that the Coroner's authority to obtain newborn screening cards should be clarified and be accompanied by safeguards to limit other uses of cards and to ensure their return:

A coroner's powers of access to stored tissue samples (eg newborn screening cards) should be expressly authorised. Where a coroner considers it appropriate to obtain a sample (for example, for identification purposes in connection with an inquest), a formal order under law should be made, with specificity as to purpose, and clear requirements about persons responsible for providing the card and for its security and return.

Authorised use of newborn screening cards for disaster victim identification should not be limited to the Coroner. Police play a role in identifying victims (and potential perpetrators) in the aftermath of an accident, bombing or natural disaster. Identifying victims of the Bali bombing and World Trade Center attack are examples of the value of genetic matching.

Although police already have some authority under the Crimes Act to collect genetic samples from volunteers for the purpose of identifying missing or deceased persons, this authority does not extend to obtaining access (without consent) to newborn screening cards. The current Memorandum of Understanding between the Chief Commissioner and GHSV, while a welcome temporary measure, is inadequate. MOUs are unenforceable. A legislative framework is required. Direct access to these cards should be authorised only under specific law and with similar safeguards such as would apply to the Coroner. Additional safeguards or authorities are likely to be necessary, however, where the genetic sample is used to identify a suspect in a criminal investigation.

Although newborn screening cards may be obtained by consent, there may be circumstances where it is neither possible nor desirable to seek consent. For example, delaying the identification of an accident victim in order to secure consent could increase the grief that the family and community may already be experiencing. The ALRC/AHEC noted that, following the Bali bombing, it was necessary to identify victims' remains as quickly as possible in order to release them to the family for burial. Newborn screening cards are regarded in the United States as a preferred sample for identifying human remains.<sup>12</sup>

The report refers to the Health Records Act and notes that health information may be disclosed for the purpose of identifying a missing or deceased person (HPP 2.5). This authority may be inadequate, given the legal advice that the blood (especially when removed from the card) may not be "health information". Victim identification requires the removal of the blood from the card so that it can be matched with the victims' remains. There should be clear legislative authority for the Coroner and police to obtain a card, and to extract and analyse the blood embedded in the card, for the purpose of victim identification. Protection under law should not fall away when newborn blood is removed from a newborn screening card.

**Recommendation 26.** *Legislative authority should clearly permit the use of newborn screening cards for victim identification by the Coroner or police. The authority should specify the conditions under which the cards may be directly accessed without having to seek consent from the victim's relatives or next of kin. Safeguards should prohibit any other uses of the cards or the data extracted from the blood/DNA and ensure the cards (and*

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<sup>12</sup> US Department of Justice, Technical Working Group for Mass Fatality Forensic Identification, *Mass Fatality Incidents: A Guide for Human Forensic Identification*, National Institute of Justice special report, page 29, June 2005, <http://www.ncjrs.gov/pdffiles1/nij/199758.pdf>.

any samples extracted from the cards) are returned or destroyed. Other authority should be relied upon where genetic samples and data are sought for the purpose of the investigation of crime (see below).

### ***Use by police for the investigation of crimes***

Newborn screening cards have been sought by police for the purpose of investigating a crime. In New Zealand, for instance, the newborn screening cards of two murder victims were used to identify spots of blood found at an alleged crime scene and used in evidence at the trial.<sup>13</sup>

In Australia, newborn screening cards were obtained by West Australian police in May 1997 during an investigation into what was regarded as one of the State's worst cases of incest. Police believed a man was the father of at least 5 of his daughter's 8 children. Both the mother and her father were charged. Police were unable to get blood samples directly from the children, as the mother refused to let her children undergo blood tests. A search warrant was then obtained allowing police to seize the children's newborn screening cards, which were held by the Princess Margaret Hospital. The blood on the cards was tested so the result could be used as evidence against the woman and her father in the incest case.<sup>14</sup>

The incident led to public concern about the continued willingness of parents to consent to newborn screening if police could later access the cards without their consent in the context of a criminal investigation.<sup>15</sup> The WA Health department – together with the Princess Margaret Hospital, King Edward Memorial Hospital, and Genetic Services of WA – subsequently introduced a policy of requiring the cards to be destroyed after two years.<sup>16</sup>

It is essential that public confidence in the newborn screening program not be undermined by any concern that the cards could be routinely accessed by police, under an ordinary search warrant and without notice, for the purpose of investigating crime.

In Victoria, as noted in the report, police access to newborn screening cards is governed by a Memorandum of Understanding between the pathology lab (Genetic Health Services Victoria) and Victoria Police. The MOU is intended to ensure the cards are not handed over simply on request, but only where there is specific court authority.

The report also notes that the Health Records Act allows disclosure of health information where authorised or required by law (HPP 2.2(c)).

Neither the MOU nor the Health Records Act provide adequate protection because:

- both the Health Records Act and the MOU would effectively allow what happened in WA to happen in Victoria. The cards were sought under authority of law (HPP 2.2(c)); the WA police had obtained a search warrant (court authority, under the MOU);
- neither the MOU nor HPP 2.2(c) require other (preferred) alternatives to be utilised, such as police seeking a fresh sample from the individual concerned, or police obtaining consent from the parent or newborn (if mature) for release of the newborn screening card;
- neither the MOU nor the Health Records Act require prior notice to be given to parents or newborns (if mature) when faced with a specific demand by police (under warrant) for a newborn screening card, thereby depriving them of any opportunity to challenge the warrant;

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<sup>13</sup> Katie Elkin and Prof. D. Gareth Jones, "Guthrie cards: Legal and ethical issues" (October 2000) 1(2) *New Zealand Bioethics Journal* 22. Also discussed by Katie Elkin in the Health Research Council of New Zealand's *Ethics Notes*, Issue no. 3, September 2000, <http://www.hrc.govt.nz/assets/pdfs/publications/en-sept00.pdf>.

<sup>14</sup> Steve Pennells, "Baby test cards seized", *The West Australian*, 24 May 1997.

<sup>15</sup> Steve Pennells, "Police test worry: AMA", *The West Australian*, 2 August 1997.

<sup>16</sup> Western Australia, *Parliamentary Debates*, Legislative Council, 14 March 2000, pages 4645-4646 (Questions without Notice from the Hon. Norm Kelly to the Hon. Peter Foss, Attorney-General representing the Minister for Health).

- the application is likely to be made *ex parte*, depriving the court of a public interest advocate to put, in each case, the countervailing arguments and to test the police arguments; and
- the existence of the established legislative scheme for obtaining forensic genetic samples (the Crimes Act) is ignored.

Victoria has in the *Crimes Act* authorised police to obtain genetic samples from volunteers, suspects and offenders for the purpose of investigating crimes (including past “cold” cases). The Crimes Act generally requires samples to be obtained by consent or pursuant to a forensics sampling order issued by the court. Various safeguards apply to restrict collection and use of samples, and to require destruction. These protections would not apply if police were to obtain newborn screening cards under an ordinary search warrant.

The report notes the ALRC/AHEC’s findings that police access to newborn screening cards for the purpose of investigating crime may result in the circumvention of existing safeguards that apply to forensic DNA sampling under criminal procedures laws. I endorse the Review Committee’s recommendations that legislation be introduced to ensure that the Crimes Act is the principal mechanism for accessing genetic samples for the investigation of crime, in line with the recommendations of the ALRC/AHEC. The forensic sampling provisions under the Crimes Act should expressly allow samples to be obtained from newborn screening cards, which is a less intrusive option than some of the other types of collection authorised under that Act (such as extraction of blood or levering out hair from a person’s scalp).

In my submission to the Victorian Parliament’s Law Reform Committee’s inquiry into forensic sampling and DNA databases, I suggested a number of safeguards that should accompany any legislative authority given to police to access newborn screening cards. Any use should:

- be subject to clear purpose limitations;
- be a technique of last resort in only the most serious cases;
- not result in the addition of the DNA or derived data to any other database;
- require informed consent in all but the most unusual cases; and
- in all cases require a court order made after public proceedings about which reasonable notice should be given to relevant parties to put appropriate submissions to the court.

Newborn screening cards of persons who are alive and not missing should not be released for forensic purposes otherwise than with consent or under the forensic procedures provisions of the Crimes Act. These statutory provisions may need to be amended to ensure that genetic samples can be obtained from child volunteers. Where children do not have the capacity to consent, consent can be sought from their parent or guardian. Consistent with international obligations to respect the rights of the child, any parental or court decision to allow a child’s genetic sample to be used for forensic purposes should involve consultation with the child or young person, in so far as appropriate for their age and maturity.<sup>17</sup>

**Recommendation 27.** *Legislation should be introduced to prohibit newborn screening cards from being released for the purpose of criminal investigations unless done with consent or under the forensic procedures provisions of the Crimes Act. The Crimes Act should be amended to permit newborn screening cards to be obtained by consent of the individual whose blood is concerned, or by consent of a parent or guardian where the child does not otherwise object, or by a court order under that Act.*

<sup>17</sup> See my July 2002 submission to the Victorian Parliamentary inquiry into forensic sampling referred to in this supplementary report, especially paras 114-118.

**Recommendation 28.** *The child or young person whose blood is implicated should participate, to the extent appropriate for their age and maturity, in any parental or court decision granting access to their newborn screening card for forensic purposes.*

**Recommendation 29.** *Any authority to use newborn screening cards for criminal investigations should be accompanied by legislative safeguards to limit collection, use and retention of the cards and data derived from the blood/DNA.*

### ***Commercial sale or licensing***

As discussed earlier in this Supplementary Report (under the heading of Retention), there is increasing interest in using population genetic sample (biobanks) for pure and applied research in commercial settings. An important trend in pharmaceutical research for instance, is towards personalising treatments on the basis of genetic knowledge. It is essential to reassure parents and the community that newborn blood/DNA is not sold or licensed to commercial organisations without their knowledge and consent.

**Recommendation 30.** *Legislation should expressly prohibit the sale or licensing of newborn blood/DNA for commercial purposes without the knowledge and consent of those persons affected.*

### ***Any other uses***

Any other uses, such as in the context of employment or insurance, should be prohibited where that is likely to compromise the continuing willingness of parents to participate in the newborn screening program.

**Recommendation 31.** *Any secondary uses of newborn screening cards should be compatible with the primary purpose for collecting the cards – ie, secondary uses should not compromise the newborn screening program, and should be clearly authorised under law or in accordance with the subject (or subject's parent/guardian's) consent.*

### ***Who determines the circumstances when newborn blood/DNA can be released?***

The report recommends that decisions to grant access to newborn screening cards be made by a Department of Human Services Newborn Screening Program Advisory Committee.

In my view, it would not be appropriate for decisions of this sensitivity to be left to the discretion of a departmental committee whose perspective may be inherently focussed on health issues without due regard to the wider implications raised by genetic data. Given the lack of clarity about what, if any, laws apply to authorise, restrict or prohibit access to and secondary uses of the cards, it is desirable that such decision-making be put on an appropriate statutory footing. Administrative arrangements lack the necessary transparency, enforceability and rights of redress that should properly be set out in purpose-built legislation.

**Recommendation 32.** *Legislation should prescribe the circumstances in which newborn screening cards or the blood/DNA in them may be released. Such decisions ought not be a matter of administrative discretion. Parliament is the appropriate decision maker for policy decisions of this scale and sensitivity and the proper architect of a framework for decisions in particular cases. In my view, a Victorian Human Genetics Commission should be considered.*

## **IV. Legal Issues**

As stated in the report, during the Review Committee's work, legal advice was obtained on a number of issues affecting the collection, handling and status of newborn screening cards.

Contractual arrangements (service agreements) have not addressed the handling of the archive or the management of access to the cards as they are collected by GHSV. (A new contract was under negotiation between GHSV and DHS as the Review Committee's work came to its end.)

Statutory protections under privacy and public records laws do not address the issues in a clear or comprehensive manner.

In my view, it has become clear that the current legal protections are inadequate for the reasons outlined below. Purpose-built safeguards should now be legislated.

***It is necessary to regularise past & ongoing collections of newborn blood***

As the report notes, the Solicitor General has advised that the current practice of newborn screening is likely to breach the Human Tissue Act 1982 (Vic) where:

- parental consent is not obtained, despite medical staff believing consent was not required or could be implied as part of the standard care received from hospitals; or
- blood being taken by nurse or midwife, rather than registered medical practitioner, as required by that Act.

Collecting tissue without the necessary authority is a criminal offence under the Human Tissue Act, despite any good faith belief by health practitioners that they were acting in accordance with the standard of care parents might expect of them.

Moreover, although legal advice was not sought on this issue, collection without consent may result in civil liability (such as for assault and battery) – particularly where newborn screening cards were collected before the Human Tissue Act came into force (in April 1983).

**Recommendation 33.** *The Human Tissue Act should be amended to reflect the accepted practice of midwives and nurses taking blood for newborn screening.*

**Recommendation 34.** *Consideration should be given to amending the Human Tissue Act to address potential civil and criminal exposure arising from administration of the newborn screening program, noting that:*

- *any amendment should maintain a commitment to obtaining adequate parental consent in future; and*
- *any retrospective amendment to the Human Tissue Act should be accompanied by guaranteed rights and safeguards for the newborn screening cards collected in the past.*

The Review Committee avoids the issue of ownership, but I believe it must be resolved. First, it is important to distinguish between ownership of the cards and ownership of the blood/DNA soaked into each card. Second, it is useful to distinguish between ownership of real property, ie the cards themselves, from intellectual property derived from research using cards.

The blood/DNA is at the heart of the ownership question, from both principle and practical perspectives. Can bits of people be "owned"? It remains open in law whether there is or ought be property in human tissue and, if so, the details of that proposition. The debate is at least as old as slavery.

While the newborn screening laboratory, Genetic Health Services Victoria ("GHSV"), has been careful not to assert ownership over the newborn screening cards,<sup>18</sup> there is some authority<sup>19</sup> for pathology laboratories being regarded as owners of tissue they have analysed. If ownership is

<sup>18</sup> Genetic Health Services Victoria, "Guthrie cards: Legal status", last updated 18 September 2003, <http://genetichealthvic.net.au/pages/diagnosis/guthriecards.html#p3>. Genetic Health Services Victoria, "Retention of Guthrie cards: Reassuring parents" (February 2004) Vol 5(2) *Medicine Today* 68 at 70 <http://www.genetichealthvic.net.au/pages/diagnosis/guthriecards.pdf>.

<sup>19</sup> See Chapter 20, ALRC/AHEC *Essentially Yours* report, esp paras 20.11 ff.

asserted by the laboratory, difficulties may arise in securing the collection and limiting its use. In my view, legal concepts of ownership and property are not as useful in this context as concepts such as trusteeship and fiduciary duty. Be that as it may, the legal terrain is complex and to some extent unexplored. Legislative clarification is desirable to reassure the community that pathology laboratories do not have legally enforceable property rights in newborn screening cards and to clarify whether it is possible in law for any entity, including the State of Victoria, to “own” the blood/DNA in the cards.

**Recommendation 35.** *Legislation should clarify that no entity (whether in the public or private sector) can assert ownership over newborn bloodspots, and should clarify the ownership of the cards (separate from the blood/DNA) and the intellectual property that may be derived from them.*

### ***Government custodianship is limited and uncertain***

Retention and disposal of newborn screening cards is currently dealt with under the Public Records Act and the Disposal Authority issued under that Act. These statutory obligations (as currently drafted) require the cards to be held for at least 25 years and allow GHSV to transfer custody to parent/s or guardian/s or the newborn (upon reaching the age of 18 years).

However, as the report notes and the Solicitor General advises, the operation of the Public Records Act is limited. The Public Records Act does not provide comprehensive and adequate protection for the archive of newborn screening cards because:

- the Public Records Act does not apply to newborn screening cards created in private hospitals. Newborn screening cards collected by public hospitals are “public records”, but those collected by private hospitals are not. Accordingly, any authority or obligation to ensure secure storage, mandate retention, and allow for transfer to parents under the Public Records Act simply does not apply to any newborn screening cards created in private hospitals; and
- the Public Records Act does not regulate newborn blood, if it is removed from the cards, as it is not a “public record”. Use of newborn screening cards for research and forensic purposes, which necessarily requires analysis of the blood after it is punched out of the newborn screening card, may therefore not be subject to any safeguards offered by the Public Records Act.

So, application of the Public Records Act (and any Disposal Authority issued under it) to births in *public* hospitals is limited. A person’s entitlement to the possession of their own (or their child’s) newborn screening card is, at best, uncertain where the baby was delivered and the test undertaken in a private hospital.

### ***Newborn bloodspots ought not be regarded as a “public record”***

Although there is an ability under the Public Records Act to deem newborn screening cards (wherever created) to be public records, in my view this is not the preferable option. Applicable law should be tailored to address the core issue which is the growing significance of the knowledge that can be derived from blood/DNA. The Public Records Act applies to some extent, because of the chance event that blood/DNA is soaked into cards.

The Public Records Act is not the appropriate mechanism for ensuring the security, retention, destruction or transfer of the cards. As a matter of public policy, newborn blood ought not be regarded as a “public record”. It is questionable to act as if parents who consent to have their newborn tested for preventable diseases thereby hand over ownership or control over their baby’s blood/DNA to the State (or a hospital or a private sector non-profit laboratory conducting the testing under contract for the State). Victoria should do better than to manage the program with a legal framework designed principally to deal with paper documents and other media that contain information, but not designed to deal with human tissue or the genetic data it contains.

Deeming the State (or another party) to be the owner of newborn screening cards may be contrary to community expectations and the public interest for these reasons:

- anecdotal and focus research<sup>20</sup> suggest that parents who agree to have their newborns tested assume that the blood is destroyed after the analysis is complete, and are surprised to find out that it has been retained indefinitely and held in the custody of a private sector laboratory. The ALRC/AHEC report makes a similar finding;<sup>21</sup>
- parents may not consider that their agreeing to test their baby constitutes a transfer of ownership or custodianship over their baby's blood, or results in their baby's blood becoming a record of the state;
- the general aim of public records or archival laws is to enable the State to see to the safe-keeping of records worthy of preservation for evidential, administrative or research purposes. It is questionable whether these aims are universally relevant to newborn screening cards;
- the assumption of custody or control by the State (or any other party) may limit or remove any control parents or individuals may have over the retention period and the availability of their cards to others, including researchers and police; and
- if such a transfer of ownership/custodianship (to the State or otherwise) is a consequence of parents agreeing to have their baby tested, parents may become reluctant to participate in the newborn screening program. This would clearly be contrary to the public interest underpinning this public health program.

Newborn screening cards should not be deemed or regarded as "public records", as the consequence of doing so may require the preservation of newborn blood for archival and other purposes, potentially make it accessible to the public after a period of time (unless a decision is made to the contrary under the Public Records Act), and may not accord with the public interest in favour of individuals retaining sovereignty over their tissue.

**Recommendation 36.** *Newborn screening cards should not be deemed or regarded as "public records". The Public Records Act should not apply to newborn screening cards, which should instead be protected by purpose built legislation that regulates the preservation and disposal of the cards (wherever collected), including the blood on the cards, in accordance with community expectations and parental and individual consent.*

**Recommendation 37.** *Custodianship over human tissue (rather than ownership), including blood embedded in newborn screening cards, should be addressed. A trusteeship or fiduciary obligation model seems preferable, with the State of Victoria as initial trustee or fiduciary for all cards pending the exercise by the parent/subject of their rights.*

**Recommendation 38.** *In principle, the person whose blood is collected should be considered the primary controller of their genetic tissue and any health or non-health information derived from analysing the blood. Individuals should remain sovereign over their own tissue unless a purpose-built law expressly states otherwise.*

**Recommendation 39.** *Where tissue is collected with the necessary consent or authority, the collector should be regarded as the custodian and be obliged under law to the trustee/fiduciary and/or the person whose tissue is involved, to take appropriate steps to protect the tissue sample and any data derived, its storage, use, transfer and return/destruction.*

<sup>20</sup> See unpublished report commissioned by the Victorian Department of Human Services in 2005 relating to Informed Parental Consent for Newborn Screening in Victoria.

<sup>21</sup> See para 19.60-19.62 of the ALRC/AHEC *Essentially Yours* report.

### ***Privacy laws do not provide clear or comprehensive protection***

The report notes, and the Solicitor General advises, that the protection under the Health Records Act is limited in that the Health Records Act may not apply to blood when it is removed from the card. As the value of using the card (for diagnostic, forensic or research purposes) requires the blood to be separated from the card, it would be a matter of serious concern if privacy protections no longer applied.

The Health Records Act, like most privacy laws, is also limited in that:

- The Collection Principle (HPP 1) does not apply to cards collected before 1 July 2002 (when the Health Records Act came into force).<sup>22</sup> Accordingly, there is no right of complaint or redress under the Health Records Act where a parent or individual wishes to complain that their newborn screening card was collected unfairly, unlawfully or without notice of future uses.<sup>23</sup>
- The Access Principle (HPP 6, complemented by the Freedom of Information Act) does not provide parents or newborns (upon reaching maturity) with an entitlement to seek custody of their newborn screening card. The access provisions allow for the card to be inspected and copied only. Inspecting and photocopying the card is of little use to parents and individuals when what they are seeking is a transfer of the card to their custody.
- The Use and Disclosure Principle (HPP 2) may not be adequately tailored to protect newborn screening cards from uses that might be contrary to the wishes of the parents and individuals concerned. For example, as noted earlier, police may obtain access to a newborn screening card for the purpose of investigating a crime without having to seek the consent, or give notice to, the individual involved. Also, researchers may be able to use newborn screening cards with ethics committee approval but without notice or consent.
- The Destruction Principle (HPP 4.2) prohibits newborn screening cards from being destroyed before a child turns 25 years, unless that destruction is authorised by separate legislative authority – despite any parental objection to the ongoing retention of newborn bloodspots beyond the 2 years needed for testing and quality assurance.

Advice from the Solicitor General was also sought about the application of the federal Privacy Act to GHSV and the general interaction of the federal privacy law with the Health Records Act. However, the request for advice from the Solicitor General was limited in that she was not asked about whether the federal Act applied to newborn screening cards collected prior to the introduction of the Health Records Act or outside of the contract with the State of Victoria (through DHS). Nor was legal advice sought about the effect of specific areas of potential inconsistency between state and federal privacy laws.

The Solicitor General advised that, prima facie, GHSV is a private sector organisation that is regulated by the federal Privacy Act. Where newborn cards are collected and handled under State contract, then these acts and practices are exempt from the federal Privacy Act. The federal scheme is designed to allow the states to handle privacy matters arising under state contracts. But the breadth of the exemption depends on each particular contract.

In the past, the State contract between DHS and GHSV has concentrated on the delivery of newborn screening services and does not address the custody or handling of newborn screening cards, despite the archive being handed over to GHSV to manage in the late 1980s/early 1990s,

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<sup>22</sup> Section 20(1), Health Records Act 2001 (Vic).

<sup>23</sup> Cf the findings of the Health and Disability Commissioner in New Zealand, where the health provider to obtain informed consent from the mother to the collection and retention of her newborn's bloodspot card was in breach of the Code of Health and Disability Services Consumers' Rights: *Auckland Healthcare Services Limited*, New Zealand Health and Disability Commissioner, Report on Opinion - Case 99HDC09011, 4 August 2000, <http://www.hdc.org.nz/files/pageopinions/99hdc09011.pdf>.

together with the ongoing collection of cards as they are tested. The handling of the archive (amassed since the 1960s) and ongoing collection of newborn screening cards may therefore continue to be covered by the federal Privacy Act. The Health Records Act may apply as well, as it applies to GHSV both in its capacity as a contracted service provider and as a health service provider operating in Victoria.

Consequently, the existing laws may produce inconsistencies in the following contexts:

- where the newborn screening card relates to a deceased child or adult, it is unclear whether privacy obligations will apply. Although the Health Records Act protects the health privacy of individuals for 30 years after death, the federal Privacy Act does not;<sup>24</sup>
- there may be no restriction on how the newborn screening cards are used or disclosed where they were collected before the federal Privacy Act private sector privacy amendments came into force (21 December 2001), as that principle under the federal Privacy Act expressly does not apply to archived information;<sup>25</sup>
- if the current *Privacy Legislation Amendment Bill 2006* is passed, newborn screening cards may be disclosed to blood relatives without the consent of the parent or individual whose blood is contained in the card if this would lessen or prevent a serious threat to the individual's life, health or safety and the disclosure is in accordance with guidelines issued by the federal Privacy Commissioner. This authority is more permissive than under the Health Records Act, which prohibits such disclosure unless:
  - the threat is not only serious, but imminent under HPP 2.2(h), and the disclosure is in accordance with guidelines issued by the Health Services Commissioner; or
  - the disclosure is to a family member and this is necessary to provide appropriate health services to or care of the individual, but only to the extent reasonable and necessary and where the disclosure is not contrary to any known objections by the individual (HPP 2.4).

It is not my intention to query this particular policy decision here. The point is to show that the operation of Commonwealth legislation can affect in practical ways the administration of the newborn screening program and archive, without Victoria having necessarily considered that effect and made its views known. And without, perhaps, the Commonwealth having considered the effect on newborn screening programs, which are the responsibility of the states.

**Recommendation 40.** *If the purpose-built statute that I recommend is not the preferred option, and the Victorian Government chooses to continue to manage the newborn screening program within the framework of current laws, the problems with privacy laws (state and federal) should be systematically addressed, in consultation with the Commonwealth, specifically with newborn screening in mind.*

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<sup>24</sup> The federal Government has recently noted (in its response to the ALRC/AHEC report) that this issue is being considered in the context of the National Health Code (<http://www7.health.gov.au/pubs/nhpcode.htm>), which proposes to extend privacy protection to deceased persons for 30 years after their death.

<sup>25</sup> Section 16C, *Privacy Act 1988 (Cth)*. Cf section 20, Health Records, which does apply the Use/Disclosure principle to information that is already held or archived. Note, at the time the private sector privacy law was introduced, the federal government justified s. 16C on the basis that imposing such obligations would result in unjustifiably high compliance costs: See para 8.6, House of Representatives, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000*, <http://www.aph.gov.au/house/committee/laca/Privacybill/chap8.pdf>). The Victorian government argued against s. 16C, flagging that it would create disparities between existing and new collections, and create practical problems for organisations administering the same types of personal information, collected over time: See paras 8.10-8.11 (footnotes omitted), House of Representatives, *Advisory Report on the Privacy Amendment (Private Sector) Bill 2000*, <http://www.aph.gov.au/house/committee/laca/Privacybill/chap8.pdf>.

## **V. Conclusion**

Although the Review Committee's report has indicated some of the problems and complexities of trying to apply existing laws to the newborn screening program, it has not done enough. Nor has it taken the next obvious step, which is to conclude that the existing laws cannot be applied like ill-fitting patches to the newborn screening program with any reasonable expectation that they will deal adequately with the issues it presents for decision now and in the near future.

This Supplementary Report explains that I have reached that conclusion and why I recommend augmentation of the Review Committee's proposed measures pending purpose-built legislation for the newborn screening program and the establishment of a statutory Human Genetics Commission for Victoria.

Paul Chadwick  
Victorian Privacy Commissioner

10 July 2006

The Privacy Commissioner acknowledges the work of Michelle Fisher, Manager, Policy, in the preparation of this Supplementary Report and as an OVPC representative on the Newborn Screening Review Committee 2003-06.

