

STORAGE AND USE OF RESIDUAL DRIED BLOOD SPOTS

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Abstract. Newborn screening policy for Australia and New Zealand is developed by a committee of the Human Genetics Society of Australasia and the Royal Australasian College of Physicians Division of Pediatrics. Each program policy varies according to the local laws and customs. The residual dried blood spot policy recommends that each screening program develop its own policy taking into account the ownership of the material and the time of retention. Cards and associated records should be stored securely with regard to privacy issues. All uses of residual materials and access to stored material should be documented. Programs should state what permission and documentation is required for the use of samples in 1) investigation of cases missed by the screening program, 2) screening program development, method development and establishing normal ranges for new and existing tests, 3) requests from families for the return of samples, 4) requests from health professionals to use residual material for other health-related purposes, 5) research studies, and 6) coronial and forensic purposes. Storage of the samples must be appropriate to intended future uses and appropriate quality assurance material stored with the samples. Relevant privacy, legal and ethical issues should be considered when formulating storage and use policies. Use of dried blood spot samples for purposes other than newborn screening should also be covered.

INTRODUCTION

The newborn screening policy for Australia and New Zealand was developed by a committee of the Human Genetics Society of Australasia and the Royal Australasian College of Physicians Division of Pediatrics. Details of the committee are given elsewhere in this volume (Country Report – Australasia). Each program develops its own policy about the storage and use of residual dried blood spot samples. The policy varies according to the local laws and customs, but all are developed within the framework of the Australasian policy.

Policy development took into account previous national and international policies. Newborn screening cards are seldom mentioned in policies relating to retention of laboratory specimens. The National Pathology Accreditation Advisory Council (NPAAC) recommended that the sample cards be stored for 50 years although no justification or explanation was given for the recommendation (Human Genetics Society of Australia, 1999). The Royal College of Pathologists recommended storage for 20 years advising due care that no deterioration should occur and that records should be retained to prove the existence of a sample (Royal College of Pathologists, 1999). In Australia, various State Public Health Acts cover retention of laboratory samples and information, e.g. NSW legislation states records for minors should be

retained for a minimum of 15 years after the child reaches the age of 18 (New South Wales State Records Act, 1998).

Retention practices vary internationally. Some countries, for example Denmark, store cards indefinitely for screening program audits and for future research projects (Almind *et al*, 1996). Cards are destroyed soon after completion of testing in France (Association française pour le dépistage et la prévention des handicaps de l'enfant. Comité d'éthique, 1995) as in most programs in the United States. Recently, the Council of Regional Networks for Genetic Services (CORN) in the USA produced comprehensive guidelines for those laboratories developing policies to retain their sample cards (Therrell *et al*, 1996). Currently, the six screening programs in New Zealand and Australia store their sample cards for times varying from two years to indefinitely.

In Australia, it has been suggested that sample cards are owned by the hospital or laboratory that prepared them, like other hospital records (Skene, 1997). They may be owned by the laboratory which analyses and stores them. In New Zealand, in practice, samples belong to the person from whom they were collected but in the case of a deceased person, ownership is with the testing laboratory. In other jurisdictions, the state may own the sample. In both Australia and New Zealand, a principle of "informed refusal or dissent" has applied to sample

card collection rather than a requirement for informed consent (Skene, 1997). Testing for purposes outside those originally specified requires further informed consent, testing of unlinked (anonymous) samples (in some approved cases) or an intermediate course agreed by local ethical and regulatory bodies.

The possibility of misuse of the stored cards by insurers, employers and other third parties gives rise to issues which threaten privacy (Section 63. Health Services Act, 1991). The major public health value of the screening programs must not be jeopardised by concerns over misuse of the samples. Newborn screening programs should have a policy regarding the retention, storage and use of their sample cards. The policy should consider local laws and customs and be known to the public, and be regularly reviewed.

FRAMEWORK FOR POLICY DEVELOPMENT

The framework for the policy development is in five parts.

1. Ownership and retention issues

- Whoever owns the cards should be documented and further use should consider ownership.
- The time of, and purposes for, retention should be documented. Parents should know of the retention and possible uses.

2. Storage and release issues

- Storage should be in a manner appropriate to the intended use/s taking into account security, future access and possible deterioration of the samples.
- Appropriate quality control cards should be stored with the samples.
- Only newborn screening program staff should have access to the cards.
- Access to the cards should be documented.

The policy should state what permission and documentation are required for each type of use. Releases of residual samples should be documented including the purpose for release, what material was released, by whom it was used, and the authority for use. Possible uses include:

Investigation of cases missed by the screening program. This is the primary purpose of retaining screening samples. Confirmation of test results and any related testing may be done in the program laboratory, or sent to another laboratory with suitable methodology. This must be done on any reported missed case.

Other uses within the screening program including screening program development, method development and establishing normal ranges for new and existing tests. Approval may not be necessary if samples are not linked to identifying information.

Returns to the family should be dealt with in the same way as other requests for medical information from the institution.

Requests from Health Professionals. Use of the blood for family reasons should be accompanied by family permission.

Research Studies. Permissible with approval from a local ethics committee and the screening program advisory committee (where such exists).

Coronial and forensic. Parental or next-of-kin permission is necessary, or appropriate legal process should be followed. Ideally sample cards should not be released from a person who is neither dead nor missing as alternative systems exist or should exist for obtaining new samples.

3. Quality Assurance Issues

- Design should ensure that on retrieval, stored samples are suitable for intended use. The quality assurance system should cover collection, retention, storage, security and retrieval.
- Samples with known concentrations of the analytes tested should be stored with the sample cards.

4. Privacy, legal and ethical issues

- Storage should be secure so unauthorized access or use of the cards is prevented.
- The laws, customs and systems governing ethical and privacy principles will vary between jurisdictions and screening programs. The program should be cognizant of these and acknowledge them in policy development. In Australasia this includes the Privacy Acts (Australia 1988, New Zealand 1993) and other specific policies (NH&MRC National Statement on Ethical Conduct in Research Involving Humans, 1999; NH&MRC. Draft Guidance on Ethical Aspects of Human Genetic Testing, 1999; NH&MRC. Draft Guidelines for the protection of privacy in the conduct of medical research, 1999; Personal privacy protection in health care information systems, 1995).

5. Other uses of Dried Blood Spots

- Refers to the fact that dried blood on paper may be used for purposes other than newborn screening

Table 1. Releases of residual material in New Zealand 1995-2001.

Year	Forensic Use	Medical Use	Return to family
1995	1	0	0
1996	1	1	1
1997	1	3	6
1998	4	7	4
1999	3	10	96
2000	2	13	117
2001 (projected)	4	3	531

but the storage principles apply equally in other situations. Reference may also be made to the NH&MRC Guidelines for Genetic Registers and Associated Genetic Material (1999).

The full policy (HGSA, 1999) can be accessed at <http://www.hgsa.com.au>.

In New Zealand, it is considered that the residual dried blood spots belong to the person from whom they were collected. Table 1 shows the releases of residual newborn screening material made since 1995.

The dramatic rise in returns to family is due to significant publicity around two cases in which residual samples were used to establish identity of human material found at crime scenes. In both cases the material was thought to come from the victim of the crime, and in both cases the victim was missing thought deceased (as subsequently was proven to be the case).

The New Zealand Health and Disability Commissioner and Privacy Commissioner have conducted investigations into storage and use of residual samples from the newborn screening program. The Health and Disability Commissioner recommended that separate parental consent to storage of the sample be collected at the time consent to taking the sample is obtained.

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