article

Guthrie Test Samples: Is the Problem Solved?

Cordelia Thomas LLB, LLM
Senior Lecturer in Law, Massey University, Wellington Campus

Abstract

Most babies born in New Zealand have a blood sample taken shortly after birth for the purposes of certain screening tests. The samples are retained indefinitely. This paper considers whether such samples are the property of the child and whether the present changes in the Health (National Cervical Screening Programme) Amendment Bill and the Code of Health and Disability Services Consumers' Rights 1996 are sufficient to resolve the issues. The paper expresses concern about the delegation of decision-making in this area to ethics committees.

Key Words
Guthrie test, property, anonymisation, research.

Introduction

For two centuries, body parts and tissues have enabled researchers to acquire information about illnesses and behaviours (Andrews and Nelkin, 2001). Sometimes the targets of such research are chosen because of their membership of groups, such as Ashkenazi Jews (*Greenberg and others v Miami Hospital Research Institute and others* 264 F. Supp. 2d 1064; 2003 U.S. Dist. LEXIS 8959; 16 Fla. L. Weekly Fed. D 417), serial killers[1] or homosexual men (LeVay, 1996). Some research, such as studies of the prevalence of a particular disease or the identification of a disease gene, requires tissue samples from a large number of individuals. In such research the researchers wish to gain access to tissue specimens that have been previously collected for other purposes and are thereafter retained. Such specimens may come from tissue that was removed in the course of screening, diagnostic or therapeutic procedures, autopsies, or the voluntary donation of materials such as blood or semen. Subsequently obtaining consent from such people may be time consuming and expensive and, in some cases, logistically impossible.

In New Zealand almost all babies undergo a screening test at around two days of age by means of a heel prick blood sample. The blood is used for a voluntary screening programme often called the 'Guthrie test' or 'heel prick test' to screen for genetic disorders such as cystic fibrosis. Seven different tests are applied to the sample. The test cards are analysed by the National Testing Centre, which is a division of Auckland Healthcare and then stored indefinitely, although the parents or the child may have them returned by request. Approximately 1.9 million samples are presently retained by the National Testing Centre. Concerns have been expressed about the status of this collection (Elkin and Jones, 2000; Privacy Commissioner, 2003).

There are changes to the law relating to National Screening Programmes in progress (Health (National Cervical Screening Programme) Amendment Act 2004) and the use of samples for research (Code of Health and Disability Services Consumers' Rights 1996 (Code of Rights)). This paper will consider the status of such sample collections and whether the changes are sufficient to solve the issues arising from any moves to use the sample collection for research purposes.

Status of the Samples

In Australia, it has been suggested that sample cards are owned by the hospital or laboratory that prepared them, like other hospital records and so they may be owned by the laboratory which analyses and stores them (Skene, 1997). In New Zealand, the ability of parents to obtain the cards suggests that they, in some sense, belong to the parents or the child.

The National Testing Centre adheres to an 'Administration Manual' of the Auckland District Health Board of 25 November 2002, which states: 'Samples retained by the screening program remain the property of the people from whom they were collected' (Privacy Commissioner, 2003, at p.5). The present common law position suggests that human tissue samples are property in limited circumstances.

The traditional position under the common law was that a human corpse could not be the subject of property rights. This rule gained support in a number of English cases and was generally accepted throughout the 19th century (*R v Sharpe* (1857) 169 All ER 959; *R v Price* (1884) 12 QB 247 and *Williams v Williams* (1881) 20 ChD 659).

Over the twentieth century, the common law moved towards recognising limited ownership interests in the area of preserved samples of tissue held, generally, in hospitals and clinical laboratories, and laboratory samples that have been commercially developed, such as cell lines. The shift away from the rule against property in corpses began when the High Court of Australia held that it was possible for human bodies and parts to become the subject of property rights, where work or skill have been exercised to preserve them (*Doodeward v Spence* (1908) 6 CLR 406).[2]

Reform of property law could provide individuals with the means to better protect the privacy of their genetic information. The exercise of information privacy rights and any property rights that may exist in human genetic samples need not conflict, in the same way that the right of access to medical records does not conflict with a medical practitioner's ownership of those records.The samples could be considered to be the property of the child with information being held about the mother who would consequently have privacy interests in the information. The child, once competent, would have the right to control the uses of the samples, but not necessarily the maternal information. Alternatively, as the parents have had the opportunity to uplift the cards (whether or not they were aware of this) and have not availed themselves of this opportunity, it could be argued that the samples have been abandoned. However it is difficult to apply this argument to the children, as at the time any information was provided they were infants and thus unable to be informed. Presumably the parents, as surrogate decision-makers, could abandon the samples on behalf of their children, but only if they were aware of the retention of the samples and the right to uplift them.

Cases to date have dealt with only very limited fact situations, as in *H v G* (unreported High Court, Auckland, Salmon J 14 May 1999 M.1868/98), where a putative father sought to disprove paternity of a deceased child by way of DNA testing of the sample acquired from the child shortly after birth. The putative father relied on Rule 322 of the High Court Rules which provides for the making of orders for the inspection of 'property'. The Rule provides:

> (3) In this rule 'property' includes any land and any document or other chattel, whether in the ownership, possession, custody, or power of a party or not.

Salmon J stated (unreported High Court, Auckland, Salmon J 14 May 1999 M.1868/98 at p.5): 'I have no doubt that the samples come within the very wide definition of property contained in the Rule and I find accordingly'. Whilst acknowledging the applicability of the Privacy Act and the Health Information Code to the situation, Salmon J held that although the samples were taken for a specific purpose, they would be permitted to be used for a purpose clearly not contemplated at the time they were taken. He held that the man had a legitimate interest in knowing whether he was the father of a living child and this could be extended to cover a deceased child, so that the man could have certainty on the issue and be able to grieve properly. Such interests were allowed to override the objections of the mother. The High Court upheld this decision on appeal (*H v G* (2000)18 FRNZ 572).

Another similar order has been made requiring the National Testing Centre to produce the sample card for a child who is still living and whose mother will not cooperate in a paternity testing procedure demanded by a man who claims to be the child's father (*S v T* [2003] NZFLR 223).A man applied for a child to be placed under the guardianship of the court in order that a buccal swab might be taken from the child for the purposes of determining whether the man was the father of a child. O'Regan J granted leave to apply for the order and indicated a willingness to make a formal order placing the child under the guardianship of the court if the mother did not facilitate the taking of the swab from the child. The decision was based on the ground that the child's welfare would be enhanced by having the issue of paternity resolved conclusively. The Guthrie card was unavailable for use in

paternity testing because the mother had uplifted the card from the National Testing Centre. O'Regan J accepted that as a parent she had the right to do so, without commenting on the legal status of the samples contained in the card.

Collection and Retention of Samples

The sample cards are special absorbent paper on which blood samples by way of a heel prick are collected from new born babies. In addition, information is collected about the baby, and often the mother, for identification, such as the name of the baby and the mother, the sex of the baby, the date of birth, sample details such as collection date and time, hospital at which birth took place and the referring heath care provider. There is also variable other information such as birth weight and mode of feeding specifically related to the interpretation of the test results (Privacy Commissioner, 2003 at p.3). A major area of concern is whether informed consent has been given by the mothers. In the 1980s at least, many parents were not advised that the test was voluntary, or that the samples and information about the mother were retained.[3] Although the National Testing Unit has produced a leaflet entitled 'Your Newborn Baby's Blood Test' and the obligation to provide the information rests with the mother's lead maternity carer (LMC), it is clear from the Privacy Commissioner's Report (2003) that often this does not happen. The Heath and Disability Commissioner decided that Auckland Healthcare had breached Rights 7(1) and 7(9) of the Code because of reliance on an assumption that the LMC had obtained consent for collection and storage of the blood sample (Health and Disability Commissioner, 2000).

In 1999, only seven of eleven maternity hospitals were distributing the pamphlet to mothers. Additionally, the leaflet does not present screening as a choice, but as something that will happen. It does not adequately explain that the sample and information will be retained, the reasons for the retention, or the uses to which both could be put. It mentions that the sample card can be returned after testing, the information implies that a letter should sent to the testing centre with the sample card rather than a statement that such a request may be made at any time after testing.[4]

Following completion of testing the screening programs retain the sample cards, primarily for screening program audit. When cases are missed by the screening programme, retention of sample cards enables a check for proof of the existence of a sample and reconfirmation of initial test results. Retention practices vary internationally. Some countries, such as Denmark, store cards indefinitely for screening programme audit and for future research projects. Cards are destroyed soon after completion of testing in France and by most programmes in the United States of America. Currently, the six screening programmes in New Zealand and Australia store their sample cards for times varying from two years to indefinitely (Human Genetics Society of Australasia).

Arguably in New Zealand the samples continue to be retained without consent. Even if the sample is released to the mother or the now competent child, information about the mother as well as the child continues to be retained (Privacy Commissioner, 2003 at p.8).

Concerns About Such Databases

A number of ethical and privacy concerns are raised by aspects of the handling of genetic samples and information held in human tissue collections. They have often been obtained for one purpose, such as newborn screening, and not explicitly for other, secondary purposes. Issues of consent and privacy arise when it is sought to use or disclose the samples or information for purposes for which consent may not have been obtained. Most stored tissue samples contain DNA, and some secondary uses may reveal information about an individual's genetic status, health, parentage or kinship. The familial nature of genetic information means that information may also be revealed about family members, such as the mother named on a newborn screening card (Lawson and Smith, 2001 at p.217).

One possible approach is to nationalise such collections. In Iceland, DeCode Genetics has gained the rights to investigate, store and commercialise the genes of the entire population of Iceland (Kunzig, 1998). In China, a project involving collection of blood samples from elderly persons to study the genetic basis of longevity, led to concerns about exploitation. The People's Republic of China established a regulation to protect the country as a whole, rather than individual contributors, against uncompensated removal by overseas interests of Chinese 'human genetic resources' (General Office of the State Council, 1998).

In a report released on 25 September 2003, the Privacy Commissioner stated that there was no adequate legal

protection for the samples against access by third parties or against future uses. The Privacy Commissioner recommended that:

- The Ministry of Health allocate clear responsibility and authority for the operation of the newborn metabolic screening programme;
- That the resultant body move urgently to develop clear rules for retention of the samples and any further use or third party access to those samples after consultation with stakeholders and the Privacy Commissioner; and
- Legislation be enacted to encompass these rules, and permission-granting structures. Such controls should be 'incorporated in legislation in such a way that they are clear, robust and enforceable'.

Screening Programmes and Access to Medical Records

The Privacy Act, Health Information Privacy Code and the Health Regulations do not apply to the holding and use of medical testing samples. The Government Health (National Cervical Screening Programme) Amendment Act will come into effect on 7 March 2005. Section 121A of the Health Act, which allows regulations to be made to govern the retention of health information, has been extended to cover specimens. The Amendment Act will initially apply only to the National Cervical Screening Programme (NCSP), but may be extended to any other screening programme by an Order in Council following consultation.[5] The relevance of this legislation is the potential to extend its opt-out process to other screening programmes, including the 'Guthrie tests'. Sample collections may be of greater research use when researchers are able to match the samples with the medical records of research subjects.

The amendment provides that all women will automatically be enrolled in the NCSP when they have a screening test, unless they advise the NCSP that they do not wish to be enrolled. Health professionals will be required to forward to the NCSP information about the screening test results, colposcopy results, and cervical biopsy results of all women. If a woman does not want her results to be retained by the NCSP she will be required to cancel her enrolment. NCSP evaluators will have access to information about women who are enrolled in the programme or who develop cervical cancer.

The amendment reverses the usual onus in that informed consent will be presumed unless the woman takes steps to action her lack of consent. The evaluation of the NCSP is essential, as was recognised in the report of the Ministerial Inquiry into the Under-Reporting of Cervical Cancer Smear Abnormalities in the Gisborne Region. However it is questionable whether the fact that this is a 'good cause' justifies the proposed procedure. It would be feasible to require that each woman complete a consent form at the time of her next screening test, in which she would be given sufficient information to make an informed choice whether she wishes to be enrolled in the programme and to enable her to choose the uses to which information relating to her could be put. The Parliamentary Health Committee chairperson noted:[6]

> We are aware that the idea of access to primary health care records concerns some women, however, we believe there are adequate safeguards in place to ensure screening programme evaluators are permitted access only to necessary health information. It is essential that evaluators have access to such records to carry out effective internal and external evaluations, and ensure the screening programme does its job of ensuring high quality cervical screening, assessment and treatment services, and continuous quality improvement.

The Green Party opposed removing the additional consent process, as it was concerned this undermines the privacy of personal health information and the confidentiality of the general practitioner-patient relationship, and could cause a backlash against the programme. Sue Kedgley unsuccessfully proposed an amendment[7] to ensure that the women concerned, or their personal representative if they have died, must give informed consent before health records held outside the National Cervical Screening programme, laboratories or hospitals could be accessed by an evaluator. It was suggested that this was essential so that women could have confidence that their private health information held by their doctor would remain private unless they chose to release it. Sandra Coney also opposed the amendment bill, pointing out that it is not possible to examine only the portion of the doctor's records relating to cervical screening as the health select committee appears to have envisaged.[8]

If this amendment were extended to the 'Guthrie test' samples, it might result in increased parental reluctance to consent to the tests through concerns that the child's (or the mother's) medical records might later be accessed, or that presumed consent might be applied to a variety of uses of the samples.

Amendment to the Code

Of even greater concern is the amendment to Right 7(10) of the Health and Disability Commissioner's Code, recently agreed to by Cabinet,[9] to allow use of bodily substances or body parts for the purposes of research that has received the approval of an ethics committee, or for the purposes of a professionally recognised quality assurance programme, or an external audit or evaluation of services that is undertaken to assure or improve the quality of services. In the discussion document, the Health and Disability Commissioner (Health and Disability Commissioner, 2004) refers to the use of the Guthrie samples stating:

> The requirement of informed consent has, in some cases, hindered valuable public health research. For example at a time of a rising rate of HIV infection in New Zealand, there is uncertainty about the prevalence of HIV infection among pregnant women. The best way to determine prevalence is to test, anonymously, blood from newborn babies collected on Guthrie cards. This type of unlinked anonymous monitoring is used in many countries because it provides scientifically unbiased information. However, in New Zealand, such research has not been possible because of the informed consent requirements in Right 7(10).Where research involves the use of specimens collected many years earlier, it may not be practicable to find the original donors and obtain consent to use the specimens.

The amendment is in accord with the recommendations in Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs developed by a joint subcommittee of the Human Genetics Society of Australasia and the Division of Paediatrics of the Royal Australian College of Physicians: [10]

> Requests to use the sample cards in research studies are permissible if the researcher has appropriate approval from a local ethics committee and the screening program advisory committee (where such exists). The research should be performed under conditions established by the screening program advisory committee and the ethics committee and conform to NH&MRC [National Health and Medical Research Council] guidelines.

This amendment places the maintenance of ethical standards firmly in the control of ethics committees rather than under the control of the person who is the source of the materials, although under Right 7(9) of the Code, the right to have the materials returned will remain.

The Review of the Regulation of Human Tissue and Tissue-based Therapies discussion document (Ministry of Health, 2004), states that there may be circumstances where important public health research would be prevented because it was not practical to obtain informed consent, such as where there would be problems of sample bias, or donors cannot be traced.

The document supports the approach taken in the amendment to Right 7(10) of the Code, in allowing such research to proceed on the basis that adequate protection for donors can be ensured by way of scrutiny by ethics committees which would consider on a case-by-case basis whether:

- The proposed outcome of the research justifies not seeking informed consent; or
- The type of research to be conducted means it is better not to seek informed consent.

The document implies (Ministry of Health, 2004 at p.27) that some types of research, such as cancer research might be upsetting and so the donors might be better not to know of their participation. This is a paternalistic assumption and involves ethics committees in a type of generalisation that is unjustifiable. It states that although the principle of informed consent should be foremost in the new legislative framework, the framework should allow the public good associated with the use of tissue to outweigh informed consent in such circumstances.

It may be problematic to achieve consensus about the nature of such circumstances. The National Advisory Committee on Health and Disability Support Services Ethics (NEAC), recently considered five options for policy on the secondary use of identifiable data, where the data is initially collected for a purpose such as health care and is then used for research (National Advisory Committee on Health and Disability Support Services Ethics, 2004).

The options were:

1. Statutory sanctioning of all research use of secondary data without explicit consent;
2. Regulatory endorsement of research use for the common good, without consent if necessary, plus the development of detailed guidance for ethics committees on when

identifiable data can be used without consent;
3. Consultation with the public about whether the presumption of implied consent for research use of data held by health care providers in New Zealand is justified;
4. Obtaining broad authorisation from all users of health services for the secondary use of data for research. This would require an opt-out option;
5. Requiring informed consent for all research uses of identifiable data.

NEAC sought comment from stakeholders on which of the options would best protect participants from harm, while enabling high quality research to benefit the community, but the responses were inconclusive.

In light of the amendment to Right 7(10), it is imperative that the consent procedures involved in the taking of the samples be explicit, informing parents of potential uses of the samples. As the uses may well increase over time, it is difficult to give specific uses, but the parents should be aware of the potential and be able to refuse or restrict uses other than the initial screening.

Uses of Samples

Guthrie test sample cards may be used for a variety of purposes apart from the initial screening tests (Policy Statement on the Retention, Storage and Use of Sample Cards from Newborn Screening Programs), some of which require identified samples and some involving anonymised samples. Some such uses are:

- confirmation of laboratory normal ranges (using anonymised samples);
- modification of existing screening tests (using either anonymised or identified samples);
- development of new screening tests (using either anonymised or identified samples);
- epidemiological or public health research (using anonymised samples);
- testing of deceased members of a family if a specific disorder is suspected or known (using identified samples);
- assisting in coronial and forensic investigations (using identified samples).

The samples are a valuable resource to assist in the resolution of certain crimes and police have accessed the samples of 15 people to identify bodies or body parts since 1995. Of these, parents gave approval in 14 cases and in one case a search warrant was needed because the parents were implicated in the murder of a child. The step father was later convicted of the murder in 1999.[11] The samples are held indefinitely unless the parents, or competent child, request that they be returned. The number of requests to have the samples returned has risen from none in 1995 to 775 in 2002 (Privacy Commissioner, 2003, p.6).

Such a large collection of blood samples is potentially a useful research resource. Newborn screening cards could be used, for example, in the detection of families carrying a hereditary heart disorder called Long-QT syndrome. It is thought that the disorder may be reponsible for up to a third of deaths attributed to Sudden Infant Death Syndrome (Lucey, 1999). If the mutation in the gene is able to be posthumously detected by use of the Guthrie cards of deceased babies, then living family members could be offered drug treatment to reduce their likelihood of sudden death(Chen, 2003). To seek the consent of the families whose child has died of Sudden Infant Death Syndrone may cause some distress to the bereaved parents, but the potential benefits are great.

Such targeted research would be impossible if the cards were not identified. Other uses, such as in epidemiological studies to determine the prevalence of a genetic mutation in the population, can be conducted on de-identified samples. Human tissue collections, particularly newborn screening cards, have significant potential value for population studies, including those that may help government and health system administrators to plan for the future health needs of the community. The collections can be used to study the interaction of genetic and environmental factors in disease over time, to examine the causes of genetic diseases, and to locate genetic mutations. Through such research, new diagnostic tools and treatments can be developed, which will have economic as well as medical value.

Anonymisation of Samples

There are two main forms of anonymity. Absolute anonymity arises if there are no means available to link the data to an identifiable individual. Proportional or reasonable anonymity exists when there are no reasonable means of identification of specific individuals (Laurie, 2002). This applies when anonymity is achieved by using linked or linkable coded information with access to the link appropriately controlled.

When anonymised samples are used, the sample identification does not contain the name of the baby or original sample

number. The samples may be tested without any identification, or new sample identification may be created and the code linking the new and old identifications destroyed. However, other information necessary for interpretation of test results may be retained and be linked to the new sample identity (Ellis and Mannion, 2001). Such processes are thought to comply with international standards of anonymisation (Council of Europe,1997), but anonymisation is only part of the processes necessary to ensure the respect for individuals.

Roche and others have argued that research would be permissible and no new consent required so long as the DNA is stripped of all identifiers (Roche, Glantz and Annas, 1996). A similar view was expressed by the English Court of Appeal (*R v Department of Health, ex parte Source Infomatics Ltd* [2000] 1 All ER 786), in holding that so long as the privacy interests of patients were protected by anonymity, no breach of confidence would occur if data were used for research purposes. Although this may reduce the risk of harm through misuse of information, it is not an absolute protection, particularly in light of increasingly sophisticated computers with the capacity to search multiple databases. In addition, it does not allow for any effective means to object to the uses to which the samples might be put.

The World Health Organisation Working Group on Genetic Databases has recommended (World Health Organisation and European Partnership on Patent's Rights and Citizen's Empowerment, 2001, para. 4.2):

> While the use of anonymisation can lead to a reassessment of the balance between the protection of individual interests on the one hand, and the legitimate pursuit of public interests on the other, it is recommended that any anonymisation process be overseen by an independent body that would have the following obligations:
>
> To scrutinise and ensure the legitimacy of requests to the database;
>
> To act, where possible, as an intermediary between the creators and the users of the database,
>
> In respect of decoding apparatus used to anonymise and/or link data held on the database, to maintain standards and keep anonymisation processes under review.

Although the Health and Disability Commissioner appears to accept the view that the key to solving the dilemma of using samples without consent is in unlinked anonymisation of the samples, this is not required by the amendment to Right 7(10). Ethics committees may impose such a requirement, but it is suggested that legislative control of the uses of such samples is necessary.

Anonymisation reduces the risk of harm through misuse of the samples and the quality of the relationship that the individual has with their sample is reduced, but the relationship does not cease. Issues of genetic privacy or cultural sensitivity may arise. Public policy may dictate that interests other than individual autonomy may weigh more heavily in the decision to allow the use of anonymised samples, but there remains the potential for the anonymity to be breached with potential harm to individuals.

Conclusions

Many of the babies from whom Guthrie test samples were taken are now adult. If consent were sought to continue to retain the samples and accompanying information, it would be required from the mothers and those children who are now competent to consent. Even destruction of the samples is presumably inappropriate without consent, and in any event this sample collection is a valuable resource able to be used for purposes such as the identification of dead persons in order to relieve the distress of families of missing persons.

In light of the wide and increasing variety of potential uses for such material and the potential commercial ramifications, it is inadequate to delegate the decision-making to unelected ethics committees on a case-by-case basis. Firm guidelines are required to ensure the absolute minimum intrusion into personal autonomy, by specifying that consent should be sought where it is practical to trace the sources of the material.

It is commonly argued that there is no need to seek consent because most people support medical research. In Maryland, when researchers requested parental consent to use Guthrie samples for subsequent genetic research, almost all of the parents agreed (Nelkin and Andrews 2001). However, the basic moral premise of research is that people are entitled to refuse to participate, even if the consequence is that researchers may not be able to recruit sufficient participants to achieve statistical significance for the research. With the increasing

sophistication of computer systems it should be possible to track the donors and seek consent in most cases involving samples obtained relatively recently.

In general, only samples collected a significant number of years ago, where there is no potential harm to donors, might justifiably be used without consent for public health research, and then only with anonymised samples and with ethics committee approval. It is accepted that it may be impractical to obtain consent from the children from whom the samples originated, as they may be difficult to trace, or may be dead. In such cases, ethics committees should be permitted to allow the use of the samples for research only if the samples are anonymised and if the committee is satisfied that the research is not of a sensitive nature and, in particular, is not culturally offensive.

With respect to future collection of Guthrie test samples, consent to research use should be sought from the mother at the time of collection. As the actual research purpose is probably as yet unknown, the consent could only be of a broad or generic nature. The mother should be able to restrict the types of research, put a time limit on use, and specify whether she would prefer re-contact if the research reveals medical information relevant to the ongoing health of the child or herself. This proposal does not amount to informed consent because the mother is not able to be informed of the specific nature of the research, but it is more ethically sound than the practice of collecting the samples for the purpose of screening and then allowing research use with ethics committee approval.

The present process of returning the sample card on request suggests a tacit acceptance that it belongs to the child. The concern that property rights in the self and thus in such samples will hinder research can be countered by the argument that a property construct would allow the recognition of the interests of contributors of samples who are vital to the success of research. A framework that provides that the donor has property in such samples could encourage the involvement of individuals in the research endeavour and increase trust.

It is more difficult, although not impossible, to fit information into the property paradigm and if property interests in information were accepted, collective claims to property information might arise, such as familial claims. However, genetic samples are the basis of genetic inventions which can be the subject of intellectual property rights. If legislation were to provide that the Privacy Act applied to the samples, this would allow protection of the information contained therein. The Health Information Privacy Code 1994 does apply to research, audit, or evaluation activities, in that any information obtained in carrying out these activities must not be published in a form that could reasonably be expected to identify an individual. However, the issues are greater than privacy alone and include resolution of parental conflicts, retention of the samples and future uses. If the samples were determined to be the property of the person from whom the sample was taken then remedies would be available for misuse, theft and unauthorised use.

Any legislation should include rules governing disclosure of newborn screening cards for law enforcement purposes. These rules should provide for disclosure only with the consent of the person sampled, or a person authorised to consent on that person's behalf, or pursuant to a court order, such as a search warrant.

Body tissue is useful to scientists who are seeking research information, to companies who need material for pharmaceutical products, to institutions such as insurance companies, and employers that seek predictive information and to those responsible for law enforcement. The issues are wide and public consultation is necessary to ensure there is sufficient trust. If collections of newborn screening cards are to be used in research, health authorities need to review the consent processes they use, and may need to engage with their communities in a discussion about the acceptable research uses of newborn screening cards.

This paper suggests that the amendment to Right 7(10) has not resolved the difficulties and signals a movement away from the current western emphasis on autonomy, as represented by informed consent. It raises general issues that extend beyond the scope of this paper. Those issues are: Who are the appropriate decision makers? Are these issues that should be determined by individual parents or children once competent, or should they be decided by researchers, overseen by ethics committees? Some researchers argue that studies on blood cell lines or genes should be exempt from the principles of consent, because of the use of replenishable tissue such as blood, and because requiring informed consent is burdensome and undermines biomedical research (Marshall, 1996). Alternatively, are these issues of such importance that they would be more appropriately determined by a democratically elected body?

Irrespective of the answers to these questions, this paper argues that the persons who are the source of such samples have ongoing interests in the uses to which they may be put. Even anonymous testing may raise objections, because the results may stigmatise the group of which the donor is a member or breach cultural values. The utilitarian perspective would permit certain societal interests in research to override individual interests. However, lack of clarity about retention periods and permissible secondary uses may reduce public trust in screening programmes. Participation in newborn screening is vitally important for the detection of certain treatable genetic conditions at an early stage and full participation in these programmes by parents should not be undermined by fears about the potential for subsequent use of the samples.

Notes

1 Convicted killer Ronnie Kray's brain was retained after his death, purportedly to facilitate a study of criminality. His family assumed they had buried his whole body but discovered months later that his brain had been removed and preserved for research purposes. Derek Brown, 'Head Case Rights and Wrongs', *Guardian*, June 7 1997, p.5.
2 The case concerned an action for the return of a two-headed foetus preserved in a jar of alcohol.
3 Author's personal experience following three births.
4 'Your Newborn Baby's Blood Test' at p6: 'If you would like your baby's card returned to you after testing write and ask for this and send the letter with the test card.'
5 Health (National Cervical Screening Programme) Amendment Act, s112ZF.
6 http://www.scoop.co.nz/mason/stories/PA0309/S00460.htm (last accessed 20 October 2003).
7 Supplementary Order Paper 2003 No 187.
8 Sandra Coney, 'Bill Compromises Women's Privacy', *The New Zealand Herald*, Tuesday, November 11 2003, A15.
9 CAB Min (03) 40/8, 8 December 2003.
10 http://www.hgsa.com.au/ (last accessed 15 March 2004).
11 Deidre Mussen, 'Controversial DNA from birth to be used in search for missing woman', *Sunday Star Times*, 5 October 2003, Edition B, p.11.

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