Auckland Healthcare Services Limited

Report on Opinion - Case 99HDC09011

Complaint

The consumer complained about Auckland Healthcare's practices in relation to informed consent for neonatal blood tests. In particular her complaint was that:

- *The consumer's son was born at National Women's Hospital in early September 1997. While at National Women's Hospital the baby had a specimen of blood taken for Guthrie Testing.*
- *The consumer did not give consent for blood to be withdrawn from her baby for Guthrie Testing.*
- *The blood collection card was forwarded by National Women's Hospital to the National Testing Centre for indefinite storage.*
- *The consumer did not give permission for her baby's blood collection card to be stored indefinitely.*
- *The consumer did not give permission for the blood sample on the blood collection card to be used for any other purpose.*

Investigation Process

The complaint was received on 18 August 1999 and an investigation commenced on that date. Information was obtained from:

The consumer
Risk Manager, National Women's Hospital, Auckland Healthcare Services Limited
Director, National Testing Centre
Consumer's general practitioner

During the investigation, the National Testing Centre at National Women's Hospital was visited.

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Information Gathered During Investigation

The consumer's baby was born at National Women's Hospital in early September 1997. The consumer's general practitioner (GP) at the time, who was the consumer's Lead Maternity Carer, supervised the consumer during her pregnancy and delivered her baby. This was the consumer's third child.

The term Lead Maternity Carer (LMC) refers to the general practitioner, midwife or obstetric specialist who has been selected by the woman to provide her comprehensive maternity care including the management of her labour and birth.

Pregnant women must choose an LMC who will be responsible for their care throughout the antenatal, delivery and postnatal phases. An LMC may be a midwife, general practitioner or specialist obstetrician or a hospital providing maternity services.

Midwives, general practitioners or specialist obstetricians who are not employed by a hospital providing maternity services are known as independent LMCs. The consumer's GP was an independent LMC.

The consumer's baby was 10lbs 8oz when he was born. The consumer stated that there was concern that he may have had low blood sugar. The baby was referred to paediatric services and while he was in the post natal ward his blood sugars were closely monitored by a series of blood tests taken by heel prick sampling.

While the baby was in hospital a sample of his blood was taken by a member of Auckland Healthcare's staff for Phenylketonuria (PKU) and Guthrie Test analysis. This sample was obtained by a heel prick.

The consumer advised that she did not know that a blood sample for Phenylketonuria (PKU) and Guthrie Test analysis had been taken and that she did not give her consent for this sample to be obtained. The consumer stated that she likewise did not give her consent for this blood sample to be stored indefinitely by the National Testing Centre. The consumer further advised that she did not receive any literature informing her about PKU testing.

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Information Gathered During Investigation *continued*

The PKU or Guthrie Test screens the blood of new born babies for cystic fibrosis and congenital metabolic defects. If these defects are not detected at an early stage the child may be intellectually impaired, developmentally delayed or die. Early identification of cystic fibrosis is also advantageous to the future management of the child's health. The blood test records are retained after the original testing so that if there are any errors in the screening process and the child develops one of these deficiencies, the samples are available for re-testing so that future threshold screening levels can be adjusted. Guthrie Tests became a standard procedure in perinatal care in New Zealand in the 1970s.

Guthrie Testing is currently undertaken at the National Testing Centre (NTC). The director at NTC advised that there is a funding agreement for further tests between the Health Funding Authority and the National Testing Centre. There is now a 'bank' of Guthrie Test samples at the NTC from the majority of babies born in New Zealand in the last 28 years.

Auckland Healthcare contracts with the Health Funding Authority to provide the Guthrie Testing service. The National Testing Centre is part of Auckland Healthcare.

The baby died in late January 1999. In May 1999 the man who claimed to be the baby's father sought the assistance of the High Court to have the baby's blood sample released for DNA analysis, to prove paternity. The consumer opposed this application claiming that this was using the blood sample for a purpose other than the original intent.

In May 1999, in *H v G* (High Court, Auckland, M1868/98), Salmon J ordered that:

> *(i) Auckland Healthcare Services Limited shall produce to the Court the new born screening dried blood spot sample card, referred to in the affidavit of* [the director of NTC] *sworn* 29 *April 1999, for inspection by the court and/or for the purposes of making any experiment thereon.*
>
> *(ii) DNA sampling of that blood sample to be undertaken by DNA Diagnostics Limited at the expense of the plaintiff.*

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Information Gathered During Investigation *continued*

(iii) One half of the remaining samples on the new born screening dried blood spot sample card referred to above are to be used so that the remaining one half are available for separate analysis on behalf of the defendant should she wish to do so.

The PKU blood sample was released by the NTC in accordance with this Court order and tested for DNA identification by DNA Diagnostics Limited. The consumer appealed to the High Court against the results of the DNA identification being produced as evidence.

In August 1999 Morris J held that the analysis of the blood sample had been undertaken pursuant to an order of the Court and that the results of the DNA identification were admissible as evidence (*H v G* (2000) 18 FRNZ 572).

The director of the NTC stated that there are a number of occasions where PKU samples are released by the NTC. They are:

"*1) Where there is a mistake made in the testing of the sample and a case of one of the screened conditions is missed. In this situation the original sample would be sent to another new born screening laboratory for checking on different equipment. This is a crosscheck on the sample and also useful from quality assurance perspective. This release of the sample would be initiated by the Director of the NTC.*

2) The circumstances of family disease, for example cystic fibrosis. If there is to be a pre-natal diagnosis, then there may be a request for genetic testing from the previous child. In the case of cot death where there is a suspicion of some type of metabolic disease and it may not be possible to obtain another sample. These are almost always samples required where the child is dead and there is no other suitable sample, where they are looking for genes or molecules. The requests are made from the Specialist with specific or implied consent from the family.

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3) Requests from the Police, usually for dead people, and ID of human remains. This is usually with parental consent, take the example of the 'Sounds Murders'. There have been exceptions where the parents were implicated in the child's disappearance, and there was no consent, the Police obtained the sample by search warrant.

4) When parents request the return of the sample. The NTC publishes pamphlets to inform parents about Guthrie testing. The pamphlets which are distributed by the Lead Maternity Carer to parents has a paragraph on the back page notifying them that they can request the return of the sample. The paragraph informing parents that they may request the samples was added to the revised pamphlet June 1997. The NTC will return the blood samples to parents. The parents are given advice on how to keep the samples in a safe place as they may be required in future for screening purposes.

5) Court Order, which is a new situation for the NTC."

The director advised that there is a written protocol regarding the release of samples, however it is impossible to foresee every circumstance so generally the director deals with each request. The director stated that if she encounters any difficulties with the request, she takes advice from Auckland Healthcare's Risk Manager, the Advisory Committee or takes external legal advice. Almost all requests for the release of samples from NTC, except where parents are requesting return of specimens, are for samples where the person is dead. These samples are only required to be accessed if there is no other sampling available. The director considers that the possibility of the judgment in this matter opening the floodgates for other paternity issues is remote, given that it is rare for paternity issues to be raised on a dead person.

The director stated that she has tried to estimate how many of the PKU information pamphlets published for NTC, and distributed by them to Lead Maternity Carers (LMC), are actually given to the parents. She said that she distributes the pamphlets 'Your Newborn Baby's Blood Test' approximately in the same number as there are recorded births in New Zealand, but has no idea how many actually reach the parents.

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Information Gathered During Investigation *continued*

At the time of the baby's birth the responsibilities of LMCs to mothers and babies were detailed in the provisions of a "section 51 notice" issued by the Health Funding Authority Northern Office pursuant to s 51 of the Health and Disability Services Act 1993. Clause 3.4.5.1.4 of Part A of the notice specified that the LMC must ensure that the following services are provided following birth:

clause 3.4.5.1.4: SERVICES FOLLOWING BIRTH

> '*Newborn baby examinations, screening and follow up when required. This includes metabolic screening, hearing screening, and immunisation as appropriate (BCG, Hep B) (as outlined in National Well Child Schedule) and any other relevant screening programme purchased by the HFA*.'

The director of the NTC and the risk manager at Auckland Healthcare advised the Commissioner that it is the responsibility of the LMC to obtain consent from the mother for the Guthrie test. The director stated that she considered that it is the responsibility of the LMC to inform the parents of this test and ensure that the samples are collected.

The director advised that there are a raft of people who may take the PKU samples, including nursing staff, doctors and laboratory technicians. She said that the laboratory staff collecting the samples would answer any questions the parents may have, but they are not responsible for obtaining informed consent.

Auckland Healthcare advised the Commissioner that if parents do not consent to routine blood testing of their baby, this information is recorded on the baby's file by the LMC.

The risk manager at Auckland Healthcare stated to the Commissioner:

> "*It is not the responsibility of the Lab Technician to get consent, but the LMC, however the person taking the test always asks the mother's permission before going ahead, and at this time the mother has the opportunity to refuse.*"

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Information Gathered During Investigation *continued*

The risk manager explained the relationship between an independent LMC and Auckland Healthcare as follows:

"*The relationship between independent LMCs and Auckland Healthcare is regulated by an Access Agreement.*

The content of the access agreement is governed by clause 3.6 of the Notice under s 51 of the Health and Disability Services Act 1993.

Clause 3.6 specifies that Auckland Healthcare must offer an access agreement to all practitioners who have been issued notices under s 51.

Under the access agreement Auckland Healthcare has no right to dictate to the independent LMC his or her clinical management of patients including the completion of processes relating to information and consent. Responsibility for clinical management of patients rests entirely with the independent LMC. Clause 5.1 (i) provides that the independent LMC is

'... responsible for the proper and safe clinical conduct of labour, delivery and postnatal care for the women and their babies, as outlined in the North Health service specifications applicable to the Practitioner, until such time as a formal handover to secondary or tertiary care is competed in accordance with the referral criteria ...'

Auckland Healthcare's control over independent LMCs is limited."

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Information Gathered During Investigation *continued*

The risk manager also explained the process adopted at Auckland Healthcare to order neonatal blood screening when a woman has an independent LMC:

> "*The process by which an independent LMC orders a neonatal blood screening test is as follows:*
>
> - *When the baby is born the* [Auckland Healthcare] *midwife assisting the independent LMC completes a small label bearing the name of the baby, time and date of birth. In doing so the midwife is acting on the instructions of the independent LMC to initiate the neonatal blood screening process;*
> - *The label is sent to the clerk in the delivery suite who then sends it to the Admitting;*
> - *Admitting completes the handwritten details on the neonatal blood screening card with the baby's name, time and date of birth, and sends the card to the ward;*
> - *The clerk on the ward puts the neonatal blood screening card on a clip which is regularly checked by laboratory staff;*
> - *Once the baby is 48 hours old the laboratory staff uplift the card, and take the blood sample from the baby.*
>
> *The entire procedure is grounded on the independent LMC having discussed the neonatal screening test with the mother and obtained her consent. The reason for this is that only the independent LMC who is wholly responsible for the medical management of the mother and baby is in a position to obtain consent.*
>
> *Auckland Healthcare has no relationship with the mother and baby other than providing a delivery suite and accommodation on the ward and making laboratory services available. It is therefore unable to obtain consent or intervene in the care of the mother or baby in any way unless it is called upon to do so by the mother or the independent LMC or is acting in an emergency.*"

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Information Gathered During Investigation *continued*

The risk manager further stated:

> "*If Auckland Healthcare were to intervene in the care of women who choose an independent LMC, it would be doing so without the consent of the women and in a manner which conflicts with the philosophy of choice.*"

Auckland Healthcare provided a copy of its *Collection Services Manual* which it advised regulates the practice of laboratory technicians. This manual states in a number of places that it is the responsibility of the medical practitioner to ensure that the patient is informed about the reason for taking the blood sample and the treatment which may ensue, depending on the result of the laboratory test. "*The Manual states clearly that any questions which relate to the nature of the test and the reason for it rather than to the collection technique or procedure are to be referred to the medical practitioner or physician*."

The risk manager stated that:

> "*The reason for this policy is that laboratory technicians are not qualified to advise patients on anything other than the technique by which the sample or specimen is taken. They do not have medical knowledge or qualifications. It would therefore be inappropriate for laboratory technicians to attempt to answer patient questions about the nature of or reason for taking the sample.*"

The consumer's LMC stated that she probably would not have discussed PKU testing with the consumer during any of her antenatal visits. The LMC stated that as this test is not something that she is personally involved with (as it is undertaken by staff at National Women's Hospital), and as she does not initiate it, she does not think about getting consent.

The LMC said that she has not seen the information brochure 'Your Newborn Baby's Blood Test' distributed to all Lead Maternity Carers by the National Testing Centre.

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Information Gathered During Investigation *continued*

The LMC submitted the following response to the Commissioner:

> "*I was surprised by the response of Auckland Healthcare to this investigation. The neonatal metabolic screening test is a test that I had no physical or technical involvement in as* [the consumer's] *LMC. I did not make a formal request from hospital staff for the test to be done, nor was I present at the time the staff member performed the test. I did not personally have any knowledge of the competency level of the staff involved, and I think it would therefore be impossible for me to obtain fully informed consent, as I would be unable to give any assurance of the technical skills of the staff member.*
>
> *I would also refer you to the relevant clause of Section 51, as mentioned by Auckland Healthcare. Part A, clause 3.4.5.1.4 states that the LMC will ensure that the newborn metabolic screening service is provided. It does not state that the LMC is responsible for gaining consent for that service. Neither does my Access Agreement with National Women's Hospital make any mention of a requirement for the LMC to obtain that consent. I have discussed this issue with a number of my colleagues, and it is NOT the common practice for the LMC to do that, unless they are actually obtaining the sample from the baby.*"

In the course of this investigation, advice was also obtained from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the New Zealand College of Midwives, the Health Funding Authority and the Royal New Zealand College of General Practitioners. These organisations suggested that the issue of responsibility for obtaining informed consent for Guthrie testing has fallen between the cracks of contracting between LMCs and hospitals.

The general opinion was that the Guthrie Test is a routine medical procedure which usually occurs in hospital, but that the LMC is responsible for explaining the procedure and obtaining informed consent.

The advice was that the person taking the blood also has a responsibility to check that informed consent has been obtained and not to proceed if this is not the case.

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Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 7
Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

...

9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
10) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.

Clause 5 Other Enactments
Nothing in this Code requires a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

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Opinion: Breach

In my opinion Auckland Healthcare breached the Code of Health and Disability Services Consumers' Rights as follows:

Right 7(1)

No consent obtained for the collection of the Guthrie Test sample
The consumer stated that she had not given her consent for a blood sample to be taken from her baby for the purpose of a Guthrie Test.

The National Testing Centre publishes and distributes Guthrie Test information pamphlets to LMCs to assist them to inform their clients.

Auckland Healthcare states that it considers the primary responsibility to obtain informed consent is that of the patient's LMC, pursuant to the section 51 notice. I accept that under the terms of the Access Agreement with LMCs, Auckland Healthcare has limited control over LMCs. In Auckland Healthcare's view it was the responsibility of the consumer's LMC, to inform the consumer that there would be a request for this test on her newborn baby, to provide her with sufficient information for her to give informed consent and to obtain such consent.

Auckland Healthcare has advised that its policy is that laboratory technicians taking blood samples have a role in responding to parents' questions regarding the blood test sampling procedure but do not have responsibility to gain consent for the procedure.

The consumer's LMC has stated that she had no physical or technical involvement in the test and was not present when it was performed. Her view is that in these circumstances she could not obtain informed consent. She considered her obligation under Part A, clause 3.4.5.14 of the section 51 notice was to ensure that newborn screening was provided, not to obtain informed consent for the procedure.

In my opinion LMCs are responsible for informing women in their care about:

(1) the purpose of neonatal blood tests for PKU and Guthrie Test analysis;
(2) the right to give, or refuse, consent to such tests;

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Opinion: Breach ***continued***

(3) the purpose of storage of blood samples taken for PKU and Guthrie Test analysis;
(4) the right to give, or refuse, consent to such storage; and
(5) the right to have the blood sample returned or dispensed after testing.

The information brochure 'Your Newborn Baby's Blood Test' may need some revision to ensure that it spells out these elements of required information disclosure. Giving women a copy of the brochure, and any additional explanation needed, provides a simple and practical means for LMCs to comply with their duty to inform women about these issues.

In my opinion LMCs are also responsible for seeking consent from women (after such information has been disclosed) to:

(1) the taking of a blood sample from their newborn baby for PKU or Guthrie Test analysis;
(2) the storage of the blood sample.

LMCs should document the fact of disclosure of the information listed above and record whether consent was given or refused. If consent is given to the taking of the blood sample, but refused for storage of the sample, the LMC should record whether the woman wants the sample returned or dispensed of.

The LMC is responsible for ensuring that a copy of the documentary record of information disclosure and consent (or refusal) is provided to the hospital staff who initiates the neonatal blood screening process.

Hospital staff who collect specimens are health care providers undertaking a health care procedure and are bound by the Code of Rights. They should not undertake the Guthrie Testing procedure without ensuring that informed consent has been obtained. Auckland Healthcare has provided no evidence of a policy or procedure to demonstrate that staff check whether consent has been given. It is not sufficient to say that an assumption is made that informed consent has been given because Auckland Healthcare believed that the LMC has contractual responsibility to obtain this. The Health and Disability Commissioner Act does not allow contractual arrangements to supersede the law.

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Opinion: Breach *continued*

In summary, the collecting of the specimen is a health care procedure and cannot be undertaken without ensuring consent has been given. Auckland Healthcare's practices for the collection of specimens assume informed consent has already given and in my opinion this resulted in a breach of the Code with respect to the baby.

Right 7(9)

Retaining the baby's blood sample without his mother's consent
In my opinion Auckland Healthcare breached Right 7(9) for the same reasons stated in relation to Right 7(1). Auckland Healthcare Ltd assumed the LMC had obtained consent to the storage when in fact no consent had been obtained.

Opinion: No Breach

In my opinion Auckland Healthcare did not breach the Code of Health and Disability Services Consumers' Rights in regard to the following:

Right 7(10)

Releasing the blood sample without the consumer's consent
On 10 May 1999 Salmon J made an order which directed that "Auckland Healthcare Services Limited produce to the Court the new born screening dried blood spot sample card, referred to in the affidavit of the director of the NTC sworn 29 April 1999, for inspection by the court and/or for the purposes of making any experiment thereon". This order was sealed on 21 May 1999. The High Court order was made pursuant to section 16 of the Judicature Act 1908.

Accordingly, Auckland Healthcare was obliged to release the blood sample to the Court without the consumer's consent. In doing so it was not in breach of the Code of Rights, as clause 5 of the Code provides that "*[n]othing in this Code requires a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing any act authorised by any enactment*".

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Report on Opinion – Case 99HDC09011, continued

Actions

I recommend that Auckland Healthcare takes the following actions:

- Develops a policy to ensure that informed consent is obtained from parents or legal guardians for neonatal blood tests. The policy must ensure that, even where the consumer is a client of an independent LMC, consent has been obtained before blood is taken and stored.

Other Comments

National Testing Centre

Blood samples taken from newborn babies for Guthrie Testing have been stored at the National Testing Centre for 28 years. The samples are retained after the original testing so that if there are any errors in the screening process and the child develops one of these deficiencies, the samples are available for re-testing so that future threshold screening levels can be adjusted.

In June 1997 the National Testing Centre amended their pamphlet 'Your Newborn Baby's Blood Test'. A sentence at the end of the paragraph informing parents that the baby's blood sample card will be stored has been added and informs parents they may request the return of the sample.

A formal policy has yet to be developed for the National Testing Centre in regard to the storage of samples. The Advisory Committee has always recommended that samples should be stored indefinitely in line with general screening practice. I note that the Privacy Commissioner is currently undertaking an inquiry into the collection, retention, use and disclosure of Guthrie test blood samples.

Other Actions

A copy of this opinion with identifying features removed will be sent to the National Testing Centre, the consumer's GP/LMC, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the New Zealand College of Midwives, the Health Funding Authority, the Royal New Zealand College of General Practitioners and the Privacy Commissioner.