

19 June 2007

Kathy Bendikson  
Ministry of Health  
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Dear Ms Bendikson

**Public consultation on consent, storage and use of blood spot cards**

Thank you for the letter dated 20 March 2007 from Karen Mitchell inviting comment on the consent, storage and use of blood spot cards (Guthrie cards).

*My comments*

As you have noted, Tina Mitchell was involved with the advisory group in the drafting of the consultation document and I provided my own feedback on what I considered were the key issues as part of that process. Overall, my view is that consumers want as much information as possible about blood spot cards. They want to know what they are used for, what happens to them after the tests have been completed, how long they are stored and how they get them back. I am concerned that, currently, this information is not routinely provided by LMCs when the heel prick test is offered to new parents. It may be that training in relation to explaining screening tests and consumers' rights needs to be introduced as a specific topic in midwifery and obstetric education.

I note that question 7 in the consultation document raises the issue of whether the blood spot cards should be destroyed after a certain period of time. In my view, New Zealand has a very valuable research resource in its blood spot card collection and it would be unfortunate if the cards were routinely destroyed. Provided consumers receive appropriate information about potential future uses for the cards and safeguards remain in relation to the approval of research applications, my preference would be for the cards to remain in indefinite storage.

*Consumer Advisory Group*

As you may be aware from discussions with Tina, an HDC Consumer Advisory Group was formed in June 2003 to provide advice and feedback to the Commissioner on strategic issues, including:

- the handling of consumer complaints about health and disability services;
- how to improve the quality of health and disability services;
- public interest issues where the Commissioner can take a lead;
- policy issues raised by the Commissioner; and

- promoting and educating the public on the Code of Health and Disability Services Consumers' Rights (the Code).

I have consulted with the Consumer Advisory Group in relation to your public consultation document and they have provided the following comments.

*Member A*

Member A is a solicitor and consultant on human rights and disability issues. Ms A noted that there are very strong cultural considerations that should be taken into account for Maori if the current system changes and blood spot cards are to be routinely destroyed. Maori consumers would need to be specifically informed that the cards will be destroyed and advised of their right to request that the cards be returned.

I agree that it is important to consider the cultural impact of destroying tissue and blood samples for Maori consumers. The process for storing, destroying and requesting blood spot cards should be carefully explained at the time when consent is obtained.

*Member B*

Ms B is an expert in women's health issues. Ms B responded to the questions in the consultation document as follows:

*Question 1*

Ms B noted the Privacy Commissioner's report on public concerns about access to blood spot cards in 1999 and suggested that the brochure for parents may be a good opportunity to address those concerns. For example, in addition to the listing the potential uses for the blood spot cards, the brochure could clarify what the cards won't be used for (eg, a national population DNA register).

Ms B agreed that it was very important for the brochure for parents to include information for parents on how to have the cards returned and how long the cards will be stored (once this has been decided).

Finally, Ms B noted that information about the right to refuse the test or to request the cards back must be presented in the brochure (and by LMCs) in a neutral way, with no judgement attached to such decisions. She noted that consumers can be very vulnerable to the way information is presented by the LMC and what other consumers "normally" do with their cards.

*Question 2*

Ms B re-iterated that the attitude and behaviour of the LMC can have a significant impact on the way a consumer interprets his or her rights under the Code. She suggested that until it becomes common for consumers to request their cards back, there is a risk that this will be seen as unusual. Ms B noted that ten years ago it was unusual for women to request their placenta after childbirth but that this is now routinely offered and accepted. In her view, the return of blood spot cards needs to be approached in the same way. As I noted above, this issue turns on LMC education.

Ms B said she has experienced first hand the difficulties that can arise when blood spot information is not communicated well. One of her family members was advised by an LMC via a telephone message that her baby had tested positive for a metabolic disorder and to call her for more information. The parents were left very distraught and anxious, and when they were advised that the condition was cystic fibrosis, the LMC was unable to provide them with any information about

the condition. It was apparent that the LMC had never had to deal with an adverse test result before.

Ms B said this have provided her with valuable first hand experience of the consequences of a positive result from a 'simple' heel prick. Her family member was left asking herself whether she should she have more children? Should she access genetic counselling before giving the matter further consideration? Should any future children to that relationship undergo preimplantation genetic diagnosis, given that that technology is now available? Should she request antenatal genetic testing and terminate any fetuses testing positive for the disease? Would she and her partner be considered irresponsible if they just went ahead and conceived more children regardless of the consequences? Could they expect any children with the condition to have the right to lung transplants to extend their lives later on?

While this level of information cannot be covered in pre-test information, Ms B noted that it is important for parents to be able to access this level of information very quickly after receiving a positive test result.

#### Questions 3 and 4

Ms B acknowledged the need to record the consumer's refusal of the test but queried whether the consumer would be told that the refusal form was being sent to the laboratory and what would happen if the consumer refused consent for that information to be disclosed?

Ms B also asked whether there was any potential for misuse of refusal forms. Is there potential for such information to be used against the parents later (eg, if a child develops a metabolic disorder and the parents are charged with neglect).

#### Question 5

Ms B agreed with the issues noted in the guidelines but noted that again, this comes down to whether the LMC has the appropriate communication skills to adequately explain this to the consumer. LMC education is required in this area.

#### Question 6

Ms B noted that there is a great deal of suspicion and mistrust about Police access to blood spot cards and that this concern is unwarranted as the situations when the Police might access them are so limited. She suggested that public reporting on this issue may allay public fears.

#### Question 7

Ms B suggested that the cards should be stored for 21 years but that, if the storage time is to be limited, it is very important for people to be told about this, and their right to request return of the cards, at the time when they consent to the test.

#### Question 8

Ms B suggested that, given the significance that the public attaches to researchers accessing blood spot cards (based primarily on concern about DNA studies) and the apparent lack of faith in the program's ability to withstand future demands from third parties, there should be an overarching independent stewardship group set up to guard against any unethical use of blood spot cards and related health information. Ethics Committees should be required to obtain approval from the stewardship group before blood spot cards can be used for any research and the group should be required to publish an annual report specifying the applications that had been received and whether

they had been refused or accepted. An established history of refusing research applications would be reassurance for the public that this valuable resource is being adequately protected.

In her view, such a group is necessary notwithstanding the roles played by the National Screening Unit and the Newborn Metabolic Screening Advisory Group, to guard against any undue influence from researchers. While Ms B accepts that some research is beneficial for the broader public interest, such interest must not override an individual's right to make decisions about how blood spot cards can be used.

#### Question 9

Ms B noted that while ethnicity and race are not recorded as part of the blood spot information, they are recorded as part of a baby's NHI information. She queried whether, once researchers had access, there was any potential for blood spot cards to be used inappropriately in race and ethnicity research.

Ms B makes a number of interesting points which I am sure will generate considerable discussion.

Thank you for the opportunity to provide further comments on the public consultation document. I look forward to receiving the results of the consultation in due course.

Yours sincerely



Ron Paterson  
**Health and Disability Commissioner**