

Summary Analysis: Submissions on *Draft Policy Options on the Secondary use and Retention of Newborn Metabolic Screening Programme Blood Spot Cards*, 15 September 2008.

The Ministry of Health held a workshop on 15 September to discuss the policy options and proposals for secondary use and retention of Newborn Metabolic Screening Programme blood spot cards. Workshop attendees were invited to make further written comment on the draft paper presented on the day. A brief summary of submissions received follows, which should be read in conjunction with the draft paper as presented (titled “draft policy options on the secondary use and retention of Newborn Metabolic Screening Programme blood spot cards” dated 15 September 2008). A total of seven written submissions were received.

Consent.

a). *Submissions on the consent process.* There was broad agreement that consent procedures can be enhanced. Submissions included: parents should be told of the test and retention of samples some time before birth so that they can consider their options; the consent process should address all secondary uses and the storage of the sample for clinical inquiry, and the benefits of secondary use. Time and capacity constraints on LMCs should be considered in improving the consent process.

b). *Written versus Verbal Consent.* *Written consent* was supported by some submissions. Reasons given included: the sensitivity concerning retention and potential secondary uses; written consent might assist LMCs to communicate with parents; and written consent might also assist informed consent for future unspecified research. *Verbal consent* was supported and considered appropriate by other submitters. Reasons given included concerns that signed consent may lead to a reduction in participation, and suggestions that requiring a signature would be a departure from common practice for other similar procedures.

c). *On the practicality of renewed consent:* Some considered the option of renewed consent at 16 was impractical, and it may be difficult to obtain clear responses from a sizeable proportion of the population, which would limit the research value of the collection.

Secondary Use of Blood Spot Cards.

There were divergent views over the appropriateness of secondary uses for blood spot cards. Secondary uses (such as use for clinical investigations) which involve specific renewed consent were generally supported. Opinion was divided on the use of blood spot cards for population research and on whether or not the medical benefits of population research outweigh privacy and third party access concerns, and whether or not those concerns are overstated. It was also noted that privacy concerns and the benefits of research use need not be opposed; means exist to reconcile these competing interests.

The following points were made in submissions:

a). *By those not in support of research use:*

- Arguments in favour of use of human tissue for unspecified population research may be valid, but rather than supporting the use of newborn blood spot cards for this purpose, they support the establishment of a properly defined, legislated and resourced biobank. Unspecified future research use of blood spot cards is considered inappropriate as it has the potential to undermine confidence in the Newborn Metabolic Screening Programme, and it is not considered the role of LMCs to obtain consent of parents for this future potential use.
- Use of samples for unspecified future uses could be seen as a contravention of consumer's rights. Unspecified future population research using the samples should not be allowed.
- The primary purposes for which the blood spot cards were collected should be taken to have expired sixteen years from the date of collection.

b). *By those in favour of research use:*

- Use of identified cards for ethically approved medical research, and use of de-identified cards for ethically approved medical research should be supported especially if the collection has the protection of an independent guardianship group.
- Priority should be for research that will add value to public health.
- Arguments against indefinite retention for research use are based on the principles of autonomy and consent. Yet arguments based on these two principles do not account for wider issues of justice, in particular the interests of those disadvantaged groups who bear the burden of genetic disease.

It was also considered that there is a strong framework (the Memorandum of Understanding) for the ancillary activity of police access, yet there is no such framework in place for research access.

Guardianship

Several views were offered on whether a guardianship group is needed for secondary uses, and on who might be appointed as members. Those in favour of establishing such a group felt that it would protect the public's trust in the collection. It was suggested that its role would be to consider ethical issues and make decisions on secondary uses of the cards both during and beyond the period they are required by the Programme. It was also suggested that this group could be either established as a new entity or as an expansion of an existing group.

Other submitters offered reasons as to why a guardianship group is not necessary. One submitter opposed to research use argued that, if no third party access is permitted, a guardianship group is not necessary. One party in favour of research argued that a guardianship or kaitiaki group is not needed, as it would only meet rarely and the current Advisory Group has the scientific expertise to undertake the role. It was further noted that cultural concerns are already addressed by the ethics committees.

Two submissions provided suggestions for membership of a guardianship group. One suggested membership should include medical researchers to ensure that research objectives (of community benefit) are fairly addressed. Secondly inclusion of broader consumer representation on the NMSP advisory group was also recommended.

Policy Process.

The following points were noted in submissions received:

- Policy discussion should clearly distinguish between (a) current and future practice and (b) policy relating to use and retention of the historical collection.
- It is inappropriate for non-NMSP considerations to influence policy decisions for the NMSP. If secondary uses are to be policy drivers, the debate should be expanded for wider public debate.
- Further discussion between the NSU, HDC, maternity care providers, Māori representatives and other consumers was suggested
- Decisions concerning the storage and use of cards should be made at the highest level, and should involve Cabinet consideration.

Disposal and Storage.

Both the risks of retaining blood spot cards indefinitely, and the risks of disposal, were covered in submissions received. Those in favour of indefinite retention argued against any decision that would prevent cards being available for the benefit they can bring to individual families and society. In their view, broad consent for future unspecified use should be obtained at time of collection.

Those opposed to indefinite retention argued on the basis such retention is unacceptable given the lack of informed consent for unspecified future use. Indefinite retention might be acceptable to some if a policy was put in place to prevent cards being made available for uses which do not involve renewed specific consent at the time of use.

It was argued that public confidence in the Newborn Metabolic Screening Programme may be undermined unless the stored cards are disposed of. Indefinite retention may also set a precedent for access to other collections. Given the frequency with which other samples are routinely destroyed the costs of disposing of the stored cards may have been overstated.

Several submissions were made on the disposal of stored samples. One suggested that destruction of cards should be planned with cultural concerns in mind, in particular those of Māori. A five year moratorium to inform people of their options in retrieving cards was also suggested. Another suggested that once cards are no longer required by the Programme they should either be destroyed (after an appropriate period to allow the individuals concerned to get them back) or transferred to the custody of a separate entity.

Other General Comments.

Further matters covered by submissions included the following:

- Legislation is needed to lock in any policy decisions made around the programme and ongoing custody of the collection.
- The considered lack of general knowledge amongst health consumers around the blood spot card collection is cause for concern.
- Further justification was required to support the Advisory Group recommendation that cards are required for a minimum of 16 years by the Newborn Metabolic Screening Programme.