




Response to the Australian Health Ministers' Advisory Council (AHMAC) Advisory Group's Consultation Document

(Principles and Guidelines for Newborn Screening - a uniform approach to newborn screening based on bloodspots for Australia)

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BACKGROUND AND EXPERIENCE RELEVANT TO THE SUBJECT

Health Issues Centre is at the forefront of promoting consumer perspectives in the Australian health system. It is an independent not-for-profit organisation incorporated under the Associations Incorporation Act 1981. The Centre has operated since 1985 and has a strong reputation around Australia for its public interest research and analysis of the health system, particularly promoting awareness of consumer perspectives and needs.

Health Issues Centre works closely with consumers *and* health care providers and policy makers at all levels, and its membership reflects this variety of stakeholders.

Thus, Health Issues Centre's work is informed (and privileged by) consumer perspectives. However, it also seeks to understand providers' goals and contexts, and to work constructively to influence and assist them to take consumer perspectives more seriously and involve consumers more effectively. Health Issues Centre works to achieve this by undertaking research, policy analysis, information provision, and training and support for consumers and health care providers.

Health Issues Centre is currently completing a project for the Department of Human Services (Victoria) regarding informed parental consent and newborn screening. Health Issues Centre's responses to the AHMAC document are largely based on the findings from the consumer and health professional consultations undertaken as part of this project, and from the other projects the organisation has been involved in over the past few years. Other Health Issues Centre projects that have relevance to the issues being discussed in the AHMAC consultation document include:

- ***Exploring Patient-Centred Care in Maternity Care as a Vehicle for Safety and Quality*** in partnership with The Royal Women's Hospital, Melbourne, (current).
- ***Consumer Experiences of Complaints Processes in Victorian Health Practitioner Registration Boards*** with Resolution Resource Network (Department of Human Services, Victoria) 2004.
- ***Turning Wrongs into Rights: review of better practice complaints handling in health services with NSW Health Care Commissioner and College of Physicians*** (Australian Safety and Quality Council) 2004.
- ***Implementation of the New Patient Education Materials: An Evaluation Report*** (Austin Health) August 2003.
- ***Review of Confidentiality and Privacy in Public Health Legislation*** (National Public Health Partnership), 2002.
- ***Communicating with Consumers: Well written health information: A Guide*** with the Monash Centre for Clinical Effectiveness. (Department of Human Services - Acute Health), 2000.
- ***Communicating with Consumers: Good Practice Guide to Providing Information*** (Department of Human Services - Acute Health), 2000.

Health Issues Centre is appreciative of the opportunity to comment on the AHMAC discussion paper on the principles and guidelines for newborn screening across Australia. Although Health Issues Centre supports a uniform approach to the newborn screening program, we have very significant concerns regarding the proposed guidelines outlined in the AHMAC consultation document, and the assumptions underlying them.

Low consumer participation

Of greatest concern is the low level of consumer consultation that has gone into the development of the discussion paper and subsequent principles and guidelines. The presentation of the issues and the recommended guidelines appear to overly privilege health professionals' and researchers' viewpoints. Consideration for the consumer perspective appears to be highly diluted.

Guidelines not aligned with Principles

Several of the principles are not subsequently applied to the guidelines. The two most significant of these include:

- The guideline that "parents should be encouraged to discuss newborn screening with an appropriate health professional and to ask questions" makes a mockery of the principle that "parents are entitled to high quality information to inform their choice. This includes written information and discussion with an appropriate health professional". The guideline removes the responsibility from the health professional to adequately inform parents about newborn screening and puts it all onto parents. We believe it should read "Health professionals should ensure they have a detailed discussion with all parents about the newborn screening program, and give parents adequate opportunity to read the parent information pamphlet and ask questions prior to the collection of the blood sample".
- The guideline that "parents will only be contacted if there is a problem, that is, if a result is abnormal or if another sample is required for technical reasons" does not support the underlying principle that "parents have a right to information about their babies screening result". Health Issues Centre supports the implementation of a notification system for all newborn screening results, in line with virtually all other health screening programs.

Written Consent

Health Issues Centre supports the introduction of written consent for the newborn screening program. From our consultations both consumers and health professionals strongly supported written consent to ensure they are provided with all the necessary information to make an informed decision about the screening test. It is totally contradictory to advocate for written non-consent to ensure that parents are fully aware of the benefits and risks associated with their decision, and to not have the same standard applied for those who do consent.

Separation of Screening and Secondary Issues

To ensure issues surrounding the retention, storage, access and secondary uses of newborn screening cards do not jeopardise parents willingness to participate in the newborn screening program, Health Issues Centre strongly supports the clear separation of these issues from the actual screening test. Additionally, parents

should be well informed and allowed to make an informed decision regarding the storage, access and secondary use of their babies' newborn screening cards. Although the paper states only 65 newborn screening cards have been transferred back to Australian parents at their request, we think this does not give a full picture. Our research clearly identified that very few parents and indeed health professionals are even aware of this option.

Additional comments on other issues have been provided under each of the questions outlined in Appendix 2.

APPENDIX 2: (QUESTIONS FOR CONSULTATION)

Please answer the questions below and write your comments and suggestions in the spaces provided.

Agreement to Participate in Newborn Screening

- Q1** Parents should be able to choose whether or not they want their baby screened.

AGREE

The newborn screening program in Australia currently has voluntary participation which is the most appropriate and acceptable option. We would be concerned if mandatory screening was implemented such is the case in the USA. Parents should be strongly advised about the benefits of the screening program to their babies but they should ultimately have the right to choose if their baby is screened.

- Q2** The proposed agreement process will enable parents to make an informed choice based on reliable and evidence based information.

DISAGREE

The proposed consent process is not different to that specified in the current guidelines in Victoria. These are not working effectively. Recent consultations we have conducted with parents in Victoria has shown parents are not being given enough information about the newborn screening program to give their **informed** consent for the screening test. Further we do not see why they will work any better elsewhere. The guidelines proposed do not ensure that information is given to parents about storage, access and secondary use of the blood samples. Given that health professionals are not well aware of the storage and secondary uses (and hence cannot provide this information to parents), and updated parent information pamphlets are not being uniformly given to parents, stronger mechanisms need to be developed to ensure that information (both verbal and written) is provided to all parents and that a discussion with a health professional does take place prior to the sample being collected. The introduction of written consent and a checklist for health professionals will help improve upon current practices.

- Q3** The proposed approach for parents to refuse newborn screening and monitoring for this refusal is adequate.

DISAGREE

We support the proposed approach for parents to refuse the newborn screening test, only if the same standard applies for those consenting to the screening. Is written consent required merely to protect staff, or is it to ensure that parents have been fully informed and considered the issue seriously before refusing the test? If the latter, then why are such measures not sought or required for giving consent for the test. There is a flaw in the papers reasoning this matter. The United Kingdom (UK) model does not uphold written non-consent as it is seem as a coercive approach towards parents who choose not to have their baby's screened.

- Q4** The proposal to provide parents with information about reasons for a repeat blood sample is appropriate.

DISAGREE

Health professionals may not have the necessary knowledge base to inform parents about why the screening test needs to be repeated, nor to provide appropriate reassurance. We would be more in favour of this notification being undertaken by genetic counselors or specialists involved in the screening program.

- Q5** Newborn screening should be considered as an entire program. Parents should be able to opt out of the screening program but not out of selected tests.

(CONDITIONALLY) AGREE

It would be too complicated for most consumer to make decisions about individual tests. However, they do need to know that the tests are reasonable. Health Issues Centre agrees to this statement only if there is meaningful consumer input (via consumer peak bodies) in the inclusion of any new tests.

Provision of Information for Parents

- Q6** When should parents be told about newborn screening and provided with written Information about newborn screening?

BOTH PRENATALLY AND POSTNATALLY

Our research showed strong consumer support for information to be provided to them antenatally about the newborn screening program. Health professionals should therefore **ensure** that all parents are provided with written information antenatally (preferably early third trimester) and that they have a discussion antenatally with parents about the newborn screening program. The written information should also be available postnatally to act as a reminder to parents and for health professionals to discuss parental concerns or answer questions before the blood sample is collected.

- Q7** The parent information pamphlet should include information on:

- | | yes |
|--|------------|
| – Accuracy, risks and incidental findings of screening | ✓ |
| – Genes and DNA testing | ✓ |
| – The opportunity for discussion of information | ✓ |
| – Consent process and documentation | ✓ |
| – Options for refusal | ✓ |
| – Retention periods of newborn screening cards | ✓ |
| – Further uses of newborn screening cards | ✓ |

The parent information pamphlet should also include the contact details of the laboratory conducting the screening and information about parent / child access to the screening cards.

- Q8** It is proposed that newborn screening information for parents should cover ten aspects as listed on page 17. This would provide:

THE RIGHT AMOUNT OF DETAIL

The parent information pamphlet should also contain a website link to the laboratory conducting the screening and/or the relevant state health department where more detailed information about ALL the conditions screened for by the newborn screening program is made available.

- Q9** The proposed process for providing information about newborn screening will assist parents in making their decision.

DISAGREE

Our recent consultations showed a relatively poor level of knowledge by health professionals about the number of conditions screened for, storage, access and secondary use of newborn screening cards. Therefore all health professionals involved in providing maternity care should be provided with appropriate resources and up to date information about the newborn screening program, not just General Practitioners. These should include hospital, community and independently practicing midwives, maternal and child health nurses, GPs, obstetricians and paediatricians. All of these health professionals need to be incorporated into the processes proposed to provide parents (both public and privately insured) with adequate verbal and written information about the screening program in order to obtain their informed consent.

- Q10** The proposed guidelines for health professionals, recommending that parents should be encouraged to discuss newborn screening with an appropriate health professional are:

INSUFFICIENT

Health professionals have a responsibility to **ensure** that they make time to discuss the newborn screening program with parents. How can parents discuss newborn screening with health professionals if they are not informed appropriately about the screening program in the first place? Stronger, more prescriptive guidelines need to be developed for health professionals to ensure all parents are provided with adequate and consistent information about the newborn screening program. Multiple strategies also need to be put in place to assist in the implementation of changes in current practice, which is clearly required to improve upon the limited level of knowledge about the newborn screening program by both parents and health professionals. Use of a checklist for health professionals would facilitate this.

Retention, Storage, Access and Further Uses of Newborn Screening Cards

It is proposed that newborn screening cards be retained by laboratories for a period of time, and at the end of this time, be de-identified for longer term storage or destroyed.

Q11 How long should cards should be retained by laboratories in identified form?

(SCALE NOT APPLICABLE, SEE BELOW)

Parents should have the right to decide the length of time their child's screening card is further retained by the laboratories, and when it can be destroyed or transferred to them. They should also choose if they want identifiable information removed from their babies screening card.

Q12 Cards should be de-identified, by physically removing identifying information, for longer-term storage after how long?

(SCALE NOT APPLICABLE, SEE BELOW)

Parents should have the right to decide the length of time their child's screening card is further retained by the laboratories, and when it can be destroyed or transferred to them. They should also choose if they want identifiable information removed from their babies screening card.

Q13 Cards should be destroyed after how long?

(SCALE NOT APPLICABLE, SEE BELOW)

Health Issues Centre supports the screening cards being kept only for the minimum quality assurance period. As stated above, after this time parents should have the right to decide the length of time their child's screening card is further retained by the laboratories, and when it can be destroyed or transferred to them. They should also choose if they want identifiable information removed from their babies screening card.

Q14 The proposed guidelines are that all newborn screening cards be retained for a period of ten years as part of quality management and clinical investigations. As an alternative to an irreversible de-identification of the cards, the cards could be re-identified using a unique laboratory identifier by authorised individuals. Is this acceptable? What are your views on this?

This question relates to the management of a research database. As stated above Health Issues Centre believes this is totally separate from the newborn screening program and should be managed totally separately. As stated above, parents should be given the options for their baby's card to be identified or not.

Further, although written information can be removed from the screening card, DNA identification raises the question of whether or not the screening card can be truly de-identified. Re-identify cards using a laboratory identifier could become a pointless exercise leading to possible errors during the re-identifying process. We do not support this practice unless parents have given specific consent to their child's card being used in this way in a research database.

Q15 If re-identification of cards is acceptable as described in Q14 above, cards should be de-identified for research but linked via a laboratory number after how long?

NEVER

We do not believe this is a newborn screening program matter. As stated above, the practice of re-identification is not acceptable, unless parents have consented to having their babies' cards stored and accessed in the research database.

Q16 Identified residual newborn screening cards should be available for research purposes, given Human Research Ethics Committee approval.

DISAGREE

We do not believe this is a newborn screening program matter. As stated above, the use of the cards for research is not acceptable, unless parents have consented to having their babies' cards stored and accessed in the research database.

Q17 De-identified residual newborn screening cards should be available for research purposes, given Human Research Ethics Committee approval.

DISAGREE

We do not believe this is a newborn screening program matter. As stated above, the practice of de-identification or research use of the cards is not acceptable, unless parents have consented to having their babies' cards stored and accessed in the research database.

Q18 Residual newborn screening cards should be available for Human Research Ethics Committee approved research how long after collection?

(SCALE NOT APPLICABLE, SEE BELOW)

We do not believe this is a newborn screening program matter. As stated above, the use of screening cards for research is not supported, unless parents have consented to having their babies' cards stored and accessed in the research database.

Q19 Newborn screening cards should be considered as a population blood and DNA databank and be protected by nationally consistent regulations for clinical and research purposes.

DISAGREE

As stated previously, to ensure issues surrounding the retention, storage, access and secondary uses of newborn screening cards do not jeopardise parents willingness to participate in the newborn screening program, Health Issues Centre strongly supports the clear separation of these issues from the actual screening test. A separate arrangement to the newborn screening program should exist, where parents are asked for consent to having their babies' cards stored and accessed in a population databank. If the purpose and use of the databank is transparent and openly explained to parents, then nationally consistent regulations should apply to its access.

Q20 Newborn screening cards from individuals who are alive and not missing should not be released for forensic purposes if alternative samples are available.

AGREE

Given that forensic use can be confusing and linked with police use of the cards, this guideline recommendation would be strongly supported.

Q21 Parents or guardians may request to have their child's card transferred to them or destroyed after how long?

1 YEAR

Clearly parents need to be made aware that this is an option when they receive information about the newborn screening program and are requested to give their consent. Currently in Victoria very few parents and health professionals know that this can occur. The option of transfer should be available to parents at any time after the quality assurance period.

END OF QUESTIONS.