

Joint response from the Faculty of Public Health and the Public Health Genetics Unit to the Social Science Research Unit's consultation on *The storage and use of newborn babies' blood spot cards: a public consultation*

Q1a. Please consider the following statement and tick one of the 5 options below:
It is appropriate that blood spot cards can be used by laboratories as described above to monitor and improve the screening programme.

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

The screening programme is an important public health activity. The quality of the programme must be maintained through monitoring of the current process and developing new methods for testing and new tests for future screening in order to best serve the public.

Q1b. Do you have other comments about the use of blood spot cards to monitor and improve the screening programme?

No.

Q2a: Please consider the following statement and tick one of the 5 options below:
It is appropriate that stored blood spot cards be used for the benefit of individuals and their families.

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We agree that individual families should be able to derive some direct benefit from participating in the programme. If a diagnosis can be made from a blood spot that will provide information to an individual regarding a death, and some comfort can be gained from that knowledge, we see this as a beneficial use of the cards.

Q2b: Please consider the following statement and tick one of the 5 options below:
Blood spot cards should be stored for more than 5 years for uses that directly benefit families.

1. Strongly agree **X**
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We support storing blood spot cards for a longer period than 5 years, in order to benefit families and for research purposes.

Q2c. Do you have other comments about the use of blood spot cards for individuals and their families?

No.

Q3a. Please consider the following statement and tick one of the 5 options below:
It is appropriate that blood spot cards can be used to monitor health in the general population.

1. Strongly agree **X**
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We strongly agree that blood spot cards should be used to monitor the public's health. It is a logical way to gather population data in order to pinpoint trends and inform future decisions on health services, expansion of the screening programme, etc. We agree with your current procedure, that data from the cards are anonymised for this use.

Q3b. Do you have comments about the storage of blood spot cards, beyond the 5 years required by the screening programme, for monitoring health in the general population?

We support the storage of the cards beyond 5 years in order to add to the public health monitoring data available.

Q4a. Please consider the following statement and tick one of the 5 options below:
It is appropriate that blood spot cards can be used to answer questions about health problems.

1. Strongly agree **X**
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We strongly support the use of blood spot cards in research into specific health questions. Of course, any proposed use of the card information would need to be approved by a local or multi-centre research ethics committee and the data from the card anonymised, except in the case of a court order or if its use is in the public interest.

Q4b: Do you have other comments about the storage of blood spot cards, beyond the 5 years required by the screening programme, for research to answer questions about health problems?

The use of genetic information in medical research will only increase in the future and more researchers may wish to use the anonymised data from the blood spot cards in their work. It would be unethical to destroy this valuable resource. Of course, adequate safeguards must be put into place to protect an individual's genetic information, as well as any other identifiable data, available from the blood spot card. In most cases, only anonymised data from the cards should be used in research.

Q5a. Please consider the following statement and tick one of the 5 options below:
It is appropriate that blood spot cards are stored, beyond the 5 years required by the screening programme, to develop equipment and tests.

1. Strongly agree
2. Agree **X**
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We support the use of blood spot cards to develop new equipment and tests.

Q5b. Do you have any comments about commercial companies using blood spot cards to develop equipment or tests?

The involvement of commercial companies in the development of equipment and tests should be subject to appropriate safeguards and to making available to parents information about possible commercial use. For example, participants would need to know that their samples could be used by commercial companies, but only if appropriately anonymised. They would need to understand that their donation was a gift and that they would not themselves benefit from any discoveries or products that came from using their data. They should be informed that commercial investment is necessary to create, test and market new equipment and that this investment could in future ultimately benefit them. It would also be important for individual parents to be able to opt out of such use if they so desired.

A profit-sharing scheme should be considered for companies using the blood spot cards to develop equipment or tests. Companies could be required to return a small amount of any profits made to the UK Newborn Screening Programme Centre in return for access to the resource. In this way, the public would benefit in some way from the use of their data.

Commercial companies should receive only anonymised data for use in their work. If for some reason identifiable data is needed for their research, it must be shown to be in the public interest and have received appropriate research governance and ethics approvals.

Q6a. Please consider the following statement and tick one of the 5 options below:
It is appropriate that blood spots can be linked to additional information for research or public health monitoring

1. Strongly agree
2. Agree
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

We agree that it is appropriate to link blood spot cards to other databases in order to conduct research or public health monitoring. Taken alone, some data might not appear important. But when data is linked to other data, it can become very useful. It would be against the public interest to not allow public data to be linked if it can aid research into health. If possible, the data from the cards should be anonymised. If identifiable data is needed and the research is deemed to be in the public interest, care must be taken to protect the confidentiality of the data. Researchers must abide by all applicable law and follow research governance and ethical review procedures.

Q6b. Do you have any other comments about the linking of additional information to the blood spots? If yes, please specify exactly what you are concerned about and why.

No.

Q7a. Please consider the following statement and tick one of the 5 options below:
It is appropriate for stored blood spot cards to be used to help with forensic police work with a court order.

1. Strongly agree
2. Agree **X**
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Q7b: Do you have other comments about the storage of blood spot cards beyond the initial 5 years required by the screening programme, to help with forensic police work?

It is appropriate for the police to be able to access an individual's blood spot card with a court order. The courts must continue to prohibit the police from testing a large number of cards in an attempt to identify a criminal.

Q8a: Please consider the following statement and tick one of the 5 options below:
If blood spots are requested for research or public health monitoring, the request should be refused if it would use up all the remaining blood (ie leave insufficient blood for tests which may directly benefit the individual or their family in the future.)

1. Strongly agree
2. Agree **X**
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Some blood should always be left for the family if there is potential benefit. If blood spot cards are retained for more than 5 years and if using up the blood becomes a potential problem, then new technologies should be investigated to determine if the amount of blood donated can be stretched. However, the needs of the individual or their family should take precedence over any future research projects.

Q8b. Do you have other comments about keeping some blood especially for uses that directly benefit the family?

No.

Q9a: Do you agree that there is a need for ongoing public involvement in the management of the UK newborn blood spot bank?

1. Strongly agree
2. Agree **X**
3. Neither agree nor disagree
4. Disagree
5. Strongly disagree

Please give your reasons for your answer:

Public involvement in activities such as this is the norm in our society and should continue. They provide a much needed lay perspective to the decision making process.

Q9b: Which of the proposed models do you think should be used?

1. Neither the public panel nor the 5 yearly public consultations
2. The public panel only
3. The 5 yearly consultations only **X**
4. Both the public panel and the 5 yearly consultations

Please give your reasons for your answer:

It is unclear in the consultation for what purpose the public panel would need to be formed. The UK Newborn Screening Programme Reference Group and Expert Groups currently have parent/lay representatives. How would the job of the public panel differ from that of these groups? We do see the benefit of the 5-yearly public consultation exercise and would advocate its creation.

Q9c: Do you have any other suggestions or comments about ongoing public involvement in the management of the stored blood spot cards?

No.

Q10: The questions above ask for your views on:

- the benefits and challenges of research using stored newborn blood spot cards, and
- the management of the UK newborn blood spot bank

Are there any other questions that you feel are important for us to consider?

If you have any other views about the storage, use or management of newborn blood spot cards please add them below.

We wish to confirm that access to data from card spots in identifiable form should only be allowed for tests where there are direct benefits to the patient/family, where there is a court order, or where there is a clear public interest, for example in the case of research that requires some degree of identification to link to other

data. In this latter case, strict data protection measures must be place and research governance and ethics approval obtained for any research conducted.