

# Report on the Newborn Screening Card Archive Forum

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# Acknowledgements

We are grateful to all the people who attended this Forum and in particular:

**Participants in the Forum** (Appendix 1).

**Invited speaker:** Professor Martina Cornel (Professor of Community Genetics and Public Health Genomics, VU University Medical Center, Amsterdam and Chairperson, Neonatal Heelprick Screening Programme Committee, Netherlands).

**Invited speaker:** Professor Graeme Laurie (Chair of Medical Jurisprudence, University of Edinburgh, Founding Director of the JK Mason Institute for Medicine, Life Sciences and the Law and Wellcome Trust Senior Investigator).

**Invited speaker:** Dr Anne Cambon-Thomsen (Lead, European Common Service ELSI (Ethical, Legal and Social Implications) of BBMRI-ERIC<sup>(R)</sup> and Emeritus Director of Research at the CNRS (National Centre for Scientific Research, France) was invited to speak about issues relating to research biobanking and genetic testing. However, due to extenuating circumstances, she was unable to attend on the day.

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# Overview of the Forum

This section provides an overview of the Forum and sets out the background, current policy, purpose and the approach adopted.

## Introduction

The National Newborn Bloodspot Screening Programme (NNBSP) enables all newborn babies to be screened within the first few days of their life for six different conditions. A diagnosis at an early stage of life provides the opportunity to initiate treatment for any of the conditions, and thereby minimise the risk of permanent or severe physical and intellectual disability or even premature death.

From the inception of the NNBSP in 1966, all Newborn Screening Cards (NSCs) collected were retained indefinitely. Consent for screening was occasionally sought at the time of sampling and given verbally. Sometimes, it was simply implied. Information pertaining to the storage, retention and/or potential secondary uses of NSCs was not given.

In late 2009, a complaint was made by a member of the public to the Data Protection Commissioner (DPC) regarding the indefinite retention of NSCs without consent, which constituted a breach of the Data Protection Acts 1988 and 2003. The DPC upheld the complaint.

## Policy response

In response to the identified breach of the Data Protection Acts 1988 and 2003, a formal policy was agreed in 2010 requiring changes to the National Newborn Bloodspot Screening Programme; that NSCs be retained for 10 years and that those older than 10 years be destroyed. The current policy is set out in the *Review of Current Policy for the Retention of Newborn Screening Cards* (Department of Health 2012)<sup>1</sup> (Appendix 3). This policy was developed in 2010 with the Deputy DPC and representatives of the Health Service Executive (HSE), the Department of Health and Children (DoHC) and the Children's University Hospital, Temple Street (CUH T/S). Addressing both the legislative and ethical requirements of the NNBSP, it provides that:

1. The blood portion of the NSC be retained for 10 years and disposed of during the child's 11th year.
2. The parents/guardians receive specific information on how the NSCs are to be used and the duration for which they are to be retained.
3. Space be provided for a signature for written, explicit consent from the parents/guardians at the time the sample is taken.

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<sup>1</sup> [http://health.gov.ie/wp-content/uploads/2014/03/newborn\\_screening\\_cards.pdf](http://health.gov.ie/wp-content/uploads/2014/03/newborn_screening_cards.pdf)

4. A proposal be developed for the disposal of the archived NSCs within an agreed timeframe.

## **Background to the Forum**

In 2011, following representations regarding the proposed destruction of NSCs, the Minister for Health requested the HSE to review the policy. The Review of Current Policy for the Retention of Newborn Screening Cards group reaffirmed the original decision and the Minister for Health agreed to this recommendation in 2012.

In early 2013, the HSE ran a public information campaign informing the public of the existence of the Archive of NSCs, the requirement to dispose of the Archive, and the option to request having their NSC returned to them if they did not wish their NSC be disposed of.

On 25 March 2013, following representation by various interested parties, the Minister for Health directed that the destruction of NSCs should not proceed until legal advice had been obtained from the Attorney General and that the HSE was to proceed with fulfilling the requests already received. The HSE completed the fulfilment process in 2015. Details regarding this process and its completion are available on the HSE website<sup>2</sup>.

The State remains in breach of both European Union and national Data Protection legislation in relation to the retention of the Newborn Bloodspot Screening Card Archive without consent. The Data Protection Commissioner has ruled that the NSC Archive should be destroyed.

## **Purpose of the Forum**

The Department of Health hosted the Forum on Thursday, 27 October 2016. The aim of the Forum was to:

*provide key stakeholders with the opportunity to engage in deliberative dialogue with international experts in relation to the current and future position of the NSC Archive and within the broader context of biobanking and health research generally. This is to ensure that a diversity of views and perspectives inform the policy options and decision to seal this breach.*

Participants were asked to explore potential avenues for action, in order to seal the Data Protection breach, by taking account of the advantages and disadvantages of different approaches, including the costs and consequences. Specifically, it was noted that the Forum was not about having to necessarily agree the same position, but rather to ‘*think together*’ and to ‘*deepen understandings of the issues through collective insight*’.

It was also noted, however, that it was in the collective interest, regardless of one’s viewpoint, to reach a decision on the matter, as the breach in the Data Protection legislation

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<sup>2</sup> <http://www.hse.ie/eng/health/child/newbornscreening/newbornbloodspotscreening/disposal/>

*'is not going to go away'* and *'we cannot afford to hang around too long'*. It was also suggested, though, that *'with every challenge come opportunities for the future'*.

Some insight was provided into the policy-making process and the need to understand that policy is not a *'pure science'*, and that the role of the policy-makers is to listen to all the arguments and then reach a decision about how best to proceed.

### **Approach adopted by the Forum**

Stakeholders from a broad range of areas were invited to participate in the Forum. Prior to the event, each registered attendee was issued with the programme for the day (Appendix 2) as well as the document referenced above in respect of the current policy (*Review of Current Policy for the Retention of Newborn Screening Cards*), as background information. In total, 40 participants attended the Forum (Appendix 1).

The Forum commenced at 11.30 am and finished at 4.30 pm. The day was chaired by Ms Sylva Langford and, following a welcome by Dr Siobhán O'Sullivan, Department of Health, Mr Simon Harris, TD, Minister for Health, presented an overview of the key issues arising.

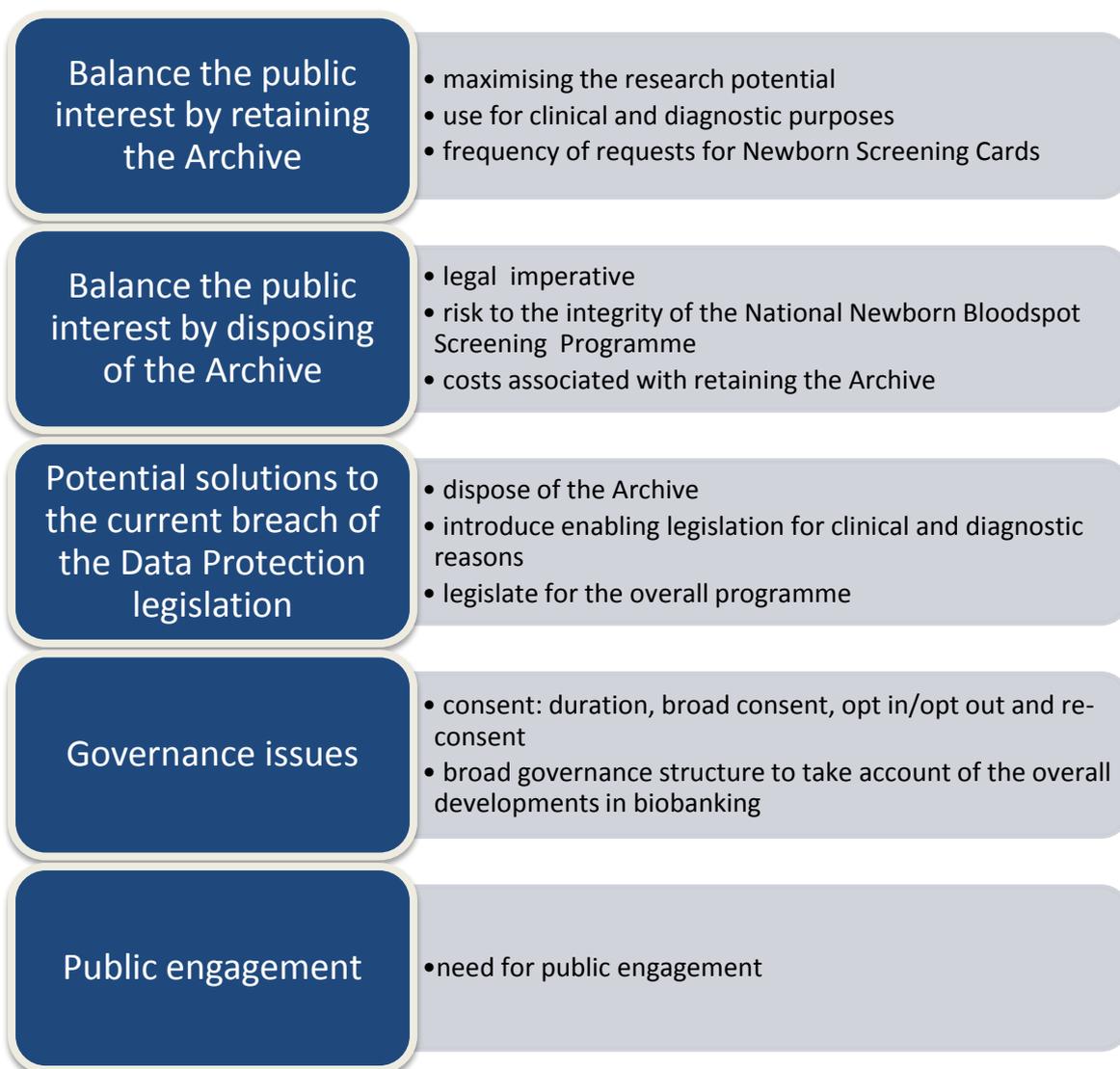
International speakers, Professor Martina Cornel (Professor of Community Genetics and Public Health Genomics, VU University Medical Center Amsterdam) and Professor Graeme Laurie (Chair of Medical Jurisprudence, University of Edinburgh), presented on their experiences in their respective jurisdictions. An overview of their presentations (copies of the Microsoft PowerPoint slides and summaries provided by the speakers) is given in Appendices 4 and 5.

A Question-and-Answer (Q&A) session with the two keynote speakers took place at the end of the two presentations. Following lunch, participants were allocated to one of five specific groups and were asked to focus on the key question area provided to the group for discussion. The key questions are provided in Appendix 6. A rapporteur from each group presented the feedback on responses to the key area for his or her group. Group feedback was followed by an open discussion between Forum participants. The session was closed by Ms Mary Godfrey, Department of Health.

Participants were advised at the start of the Forum that all sessions would be digitally recorded and transcribed for ease of analysis. Additional handwritten information collated during the course of discussions at each table was also analysed and used to supplement the feedback provided. These documents were used in a thematic analysis and form the basis of the following section of this report.

# Summary of key issues arising

This section provides an overview of the key issues arising at the Forum. It includes information presented by the national and international speakers, as well as participants in the Forum. A number of recurring themes emerged throughout the day and these are presented, in no particular order, in Figure 1.



**Figure 1: Overview of key themes emerging at the Forum**

# Balancing the public interest by retaining the Archive

Throughout the Forum, there were references to the need to balance the public interest in this Archive. This question also formed a key focus for one group discussion. It was noted, however, that this balance was *'not a mathematical process'*, but rather, *'a very complex fluid matrix'* with all the elements *'in a state of flux'*. Elements identified include:

- science, which is rapidly developing;
- public policy and social philosophy, which have undergone significant changes; and
- the definition of the 'public good', which has also shifted in recent years.

On the one hand, it was argued that it would be in the public interest for the Archive to be retained, as this would allow research to be carried out and the results could potentially contribute to the overall health and well-being of the population. It was also argued that the Archive had the potential to inform clinical and diagnostic decisions, and examples of this were highlighted and are presented later in this document.

On the other hand, there were concerns that the public interest could be compromised by the use of data from the Archive for secondary purposes, that is, for purposes other than neonatal screening. Specifically, there were concerns that: the Archive was in breach of the law; the integrity of the NNBS, which currently has an uptake of 99.9%, could be compromised; and there were costs associated with retention. Issues arising throughout the Forum in respect of these points are now considered.

Two main arguments were presented for retaining the Archive and these related to the research potential of the NSCs and their use in the diagnosis and potential clinical treatment of individuals. Within this, the uniqueness of the Archive and its potential in the area of Sudden Cardiac Death received considerable attention. These issues are considered below.

## Maximising the research potential

While it was noted that the research potential has not yet been quantified, it was suggested that as a unique archive, the research potential may be significant. Specifically, it was highlighted that this is the only biological archive which *'covers essentially 100% of the population'*. In contrast with other archives which are focused on people who have a *'reason to get into'* it, such as *'cancer or heart disease'*, the only qualification for having a blood sample in the NSC Archive *'is being born in Ireland'*. This makes it *'unique'* and *'different'* from every other archive. It was suggested that in terms of population studies, in particular epidemiological studies of genetics, *'there is nothing else to compare to it'*.

The Archive was referred to as '*a national cultural heritage*' and '*the idea of destroying it makes no sense*'. It was suggested that this was particularly the case at a time when genetic studies are becoming so commonplace and the gene pool of Ireland is shifting from a previously homogeneous population to one that is more heterogeneous, due to '*the new immigration*'.

An example of the benefits accruing from being able to access biological material was given in respect of cancer. In that case, research relating to epidemiology and biomarkers was undertaken on biological samples, and it was suggested that '*many of our advances in the genetic understanding of disease*' have been possible because we are able to access this material. An example given was rapid mutation and its significance in both breast and prostate cancer.

Some potential uses of research using the NSCs in the Irish context were also presented and these included: a) estimating genetic drift; b) estimating the prevalence of new conditions; c) estimating the prevalence of early onset conditions that present in early life; and d) the potential to link the data collected with health records later in life through biobanking. Examples were also provided, from the Netherlands, of research conducted on NSCs, as follows:

- The development of better tests to screen for potentially treatable conditions (e.g., a study was conducted on the NSCs to test sensitivity and specificity for Pompe disease)
- Prevalence studies (e.g., a comparison of the prevalence of HIV at different time points)

### **Broader research environment**

Some attention was drawn to the rapid changes in the research environment, with one participant noting that with improvements in technology, '*we may have better opportunities to do better research with these smaller amounts of samples*'. Attention was also drawn to the potential for improving the impact of Irish research in terms of its quality and reach, similar to the experience in Iceland, through the use of cardiovascular data.

It was noted that in the Netherlands, 10 questions per year are allowed using the group records and the majority of these are '*close to the context*', including, for example, ways to improve the sensitivity or specificity of diseases that are currently tested for using the NSCs. It was noted that a small number of questions (3–4) may be included from issues relating to newborn bloodspot screening. It was highlighted, however, that '*only a small number of academic papers come out of these requests*', which '*may not mean there are not more or that the findings are not being used in practice*'.

It was also suggested that there is a growing research demand and potential particularly around the use of the cards to conduct large-scale genomics and other studies.

One speaker raised a question about the need to quantify the use of NSCs in research, noting that it would be important to *'do a systematic review and find out whether there is value, and what were the claims of value, and how robust it is'* as a research source.

### **Use for clinical and diagnostic purposes**

Some discussion took place regarding the retention of the Archive for the purpose of clinical and diagnostic use, and much of this discussion focused on the area of sudden and unexpected cardiac death.

### **Sudden and unexpected cardiac death**

In the Irish context, the example of sudden cardiac death (SCD) was highlighted. It was reported that each year in Ireland that there are about 110 cases where a person under the age of 40 has died suddenly and unexpectedly of a genetic cause, and the only available tissue for genetic analysis relating to that person may be contained on his or her NSC. In these situations, it was suggested that identifying the gene mutation responsible for the death is *'critically important, not just to the first degree family members of the deceased, but to future generations in that family'*, since others in the family can then be identified and treated with *'medications or implanted cardiac defibrillators'*.

There was not agreement, however, that the NSCs were necessary for this and it was noted that there is an *'opportunity to save some tissue, some blood'* and *'DNA'* from people who have died unexpectedly. Clarification was provided on the current Irish situation, whereby in February 2015, a new code was agreed between the Irish Coroners Association and the Mater Hospital Biobank enabling a blood or tissue sample to be taken from every individual in Ireland whose sudden unexplained death is potentially due to a genetic condition.

It was also suggested, however, that this agreement (with the Irish Coroners Association) *'is not a perfect system'*, *'is not a mandatory system'* and *'is not carried out in the same way in every place'*, and that there are *'no protocols for it'*. It was also noted that while this agreement will resolve the issue in the future, there is a period of 31 years (from 1985–2015) in which 100 or more SCDs occurred in Ireland each year due to genetic reasons. It was suggested that in almost all of these cases, the only tissue remnants for DNA analysis are the NSCs.

Another issue was also raised in this regard. It was noted that, while the case of sudden and unexpected cardiac death was *'an excellent example of retention justified with care'* which can be legally justified *'on the basis of vital interest to the person'*, it did raise questions about the wider care and professional applications of generating that information. The following questions were raised:

- Does this approach mean you have a duty of care to family members, or where does that stop?

- Is there a consequent implication for professional responsibilities by using a resource to diagnose somebody who is dead?
- In whose interest is this being done, and what are the professional responsibilities that cascade from it?

In response to these questions, it was noted that these deaths run in families and consequently, it *'is for future generations'* and *'goes beyond the family's interest'* to the *'national interest'*.

### ***Examples of uses for clinical and diagnostic purposes***

The following are examples of cases from the Netherlands in which the use of NSCs was considered for the benefit of individuals:

- In the case of cytomegalovirus virus (CMV) infection, where it may be possible to identify whether this was congenital in nature and also, in respect of examining the DNA of the actual CMV virus.
- Where a child has died at a young age due to an unknown cause, and where later on (e.g., in the case of a subsequent pregnancy) consideration may be given to whether this resulted from genetic or metabolic causes.
- In the identification of victims using DNA, such as those who were burnt in the Enschede fireworks disaster in May 2000.

It was also highlighted that the research undertaken in Ireland using the NSCs on haemochromatosis demonstrated that the condition was very common in Ireland. It was suggested that this had been very helpful for many families.

### **Frequency of requests for Newborn Screening Cards in Ireland**

Some indication was given about the frequency of requests for the use of the NSCs for the benefit of patients. It was noted that, for minors, this is only done with the consent of the parents/guardians. It was also stated that each year, 60–65 requests from doctors to use NSCs for the benefit of their patients are received, about five of which relate to genetic tests on children under their care. It was also highlighted, however, that during the HSE fulfilment process a number of parents/guardians of children who had died from SCD had requested, and received, the NSCs for their deceased children. These are currently stored, on their behalf, by the Department of Clinical Genetics in Our Lady's Children's Hospital, Crumlin.

# Balancing the public interest by disposing of the Archive

As highlighted, it was also suggested that the retention of the Archive could be detrimental to the public interest and that the Archive should therefore be destroyed. The rationales for doing this were identified as: a) the legal imperative; b) the potential damage to the integrity of the NNBS; and c) the costs associated with retaining the Archive.

## Legal imperative

As noted earlier, the retention of the NSC Archive breaches the Data Protection legislation in both Ireland and Europe, and this was identified as '*a serious challenge*' that is '*not going to go away*'. It was also suggested that '*the first thing is to comply with the law*'. There are different legislative situations in respect of the NSCs, depending on the time of data collection, and these are:

- the historical Archive from 1984 to 30 June 2011, for which consent for retention and/or secondary use has been neither sought nor received;
- from 1 July 2011, in cases where consent has been obtained for screening and retention for 10 years, but *not* for any secondary uses, including, for example, research; and
- the situation in the future.

Two recent developments in Europe were identified as also being pertinent to the issue. First, the General Data Protection Regulation on the protection of individuals with regard to the processing of personal data was adopted by the European Parliament and the European Council on 24 May 2016. The provisions will be directly applicable in Ireland from 25 May 2018 and will replace the current Data Protection Directive of 1995 (95/46/EC). Elements relating to sensitive data, such as health and genetic data, have a particular relevance to the retention of the NSCs.

In addition, there is a new set of recommendations about research on biological materials of human origin, which was adopted by the Council of Europe Committee of Ministers on 11 May 2016. These recommendations are related to the removal, storage and use of biological materials for research purposes, taking into account new developments in biobanking. These recommendations are also relevant for this issue.

## Complexity of the legal context

It was noted that under current Data Protection legislation, consent is not always necessary as a legal basis. It was argued, however, that if consent was not required, a case would need

to be made for retention on the basis of public interest which, in turn, raises a set of questions such as:

- In what concrete ways is it in the public interest to do this?
- In what concrete ways is it necessary and proportionate to allow access to this collection for research?
- Could that research possibly be done elsewhere, with consent?

It was noted that if the research cannot be done elsewhere with consent, the argument for the public interest justification would be strengthened. However, the onus for this has to be on those who want to hold onto the information.

Further, it was suggested that even if this public interest can be justified, the requirements of fair and lawful processing, which include notifying citizens, are not removed. Even in situations where there is a research exemption, it is still imperative that people are notified, although it was noted there is a *'proportionality issue relating to that'*. It was further noted that it is not about finding people individually to obtain consent, but about ensuring that all has been done that is *'reasonable and proportionate in those circumstances'*.

A fundamental challenge being faced in Scotland (as there is currently a moratorium on the NSC collection) is the arbitrary holding of data with *'the hope for future value'*, which is deemed to be insufficient for its retention. The UK Information Commissioner has indicated that if data are being held for research purposes, research has to be conducted, or alternatively, there must be a very clear intention that specific research will be carried out.

While the issue of human rights was raised by one international speaker, in general, this issue was referred to only in the context of the need for consent within a legal framework for the retention and use of the NSCs. The retention of biological data (e.g., DNA from individuals who have been detained for crimes) has been considered in the UK under the UK Court of Human Rights, which found that this material is *'personal data within the data protection regime'*. One speaker concluded that, at a minimum, the NSC collection is personal data.

It was also suggested, however, that the data may be tissue and because the different ways in which research is regulated in Europe there is a need to have *'a joined-up government system that deals with all that, manages all that, but then still presents something that is responsible and lawful'*.

### **International experience**

It was pointed out that the situation in Ireland is not unique and that other countries have experienced this. The Dutch experience was outlined and it was noted that in the Netherlands, the NNBSB commenced in 1974 with a more coordinated and centralised approach to storing the cards adopted in 1993. Following a fireworks disaster, it was

suggested that the NSCs could be used to identify 23 children who had died in the incident. At this point, the issue of lack of consent was raised in the media.

The current policy in the Netherlands is that the cards are kept at five regional laboratories for one year for the purposes of quality control. Following this, there is an optional storage for four years to enable anonymous secondary use, particularly of research. The cards are then destroyed after a maximum of five years. Some consideration is now being given to retaining the cards for 16 to 18 years until the children become adults.

This was also the case in Scotland, where 2.5 million NSCs have been amassed since 1965, with consent only routinely being acquired from parents/guardians since 2003. In Scotland, the NSC is part of the medical record which provides a legal basis for the collection. However, it does not provide a legal basis for facilitating access to the data for other purposes, although it was suggested that anonymisation of the data may be helpful for these purposes.

### **Risk to the integrity of the National Newborn Bloodspot Screening Programme**

It was stated at the Forum that the NNBS is one of the most successful public health initiatives in the country, with a 99.9% uptake. Forum participants commented: *'we have a good system at the moment'* and *'nothing should be done to shake public confidence'*. They noted that the NNBS *'must not be compromised'* and that we need to keep the *'integrity of what is a very well-run programme'*. Further, it was stated that the use of NSCs for research purpose *'must always be secondary to the primary purpose of the cards'*, which is to screen infants for a range of conditions. Attention was drawn to the *'fragility'* of the system; and the vaccination programme was highlighted as one example in which public confidence was shaken, with the result that the uptake of this programme had fallen by 25%. Specifically, it was stated that:

*It is in all our interests in this country, from a policy point of view, from a clinician's point of view, from a parent's point of view that we ensure that the continued uptake of the National Newborn Bloodspot Screening Programme is maintained at the current level and also continues to hold public trust and public confidence.*

The importance of the public trust in the overall NNBS, and the primary intention of the NNBS to screen for specific diseases, was highlighted throughout the day.

### **Costs associated with retaining the Archive**

Some questions were raised about the investment required for the ongoing storage and governance of the Archive, and whether this would represent the best use of money in terms of health research. It was suggested that further information in terms of cost of storage, retention and examination all needed to be provided and considered. Specifically, it

was highlighted that *'we have areas within health where we can't even treat people who have diseases'* and *'we have no idea about what all this will cost'*. It was recommended that the opportunity costs of governing the existing Archive in terms of the overall health budget would need to be determined in greater detail.

A number of opportunity costs were also highlighted. One participant stated: *'We can far better use that money doing a huge Growing Up in Ireland study after which we [will] have an amazing amount of data'*. Another participant asked: *'How many 10-year-olds' life spans would you need to save with the programme in order to make it cost-effective and what kind of costs would be involved?'* It was also highlighted that *'there's great potential then for research, but that's not quantified, it's a potential'*.

It was reported that while some work has been undertaken to assess all the costs related to the Archive, it has been a difficult undertaking, largely because it is unclear how much of material currently in the Archive will be usefully retained. It was further reported that the financial estimates, based on personal contact with colleagues in other jurisdictions, were very high, and potentially in the region of millions. These costs would be associated with *'having to actually look at those cards, to sort them out, to store them correctly, to have the proper governance system around them'*.

One participant suggested that the cost of storing the NSCs currently, however, was *'not exorbitant'* being *'in the tens of thousands, not the hundreds of thousands'*. In relation to the current storage situation, it was noted that *'the early cards are not in good repair and there are some boxes in the very early days which we don't recommend should be used because they are contaminated'*. It was reported that the vast majority of the cards were sorted in 2014 to facilitate their return to parents/guardians, and that the cost of doing this was approximately €350,000. The HSE received 34,877 requests from members of the general public, of which approximately 73% were fulfilled. Reasons why the remaining 27% were not fulfilled related to:

- An inability to locate the cards
- Unsigned request forms
- Inadequate identification
- Uncertainty regarding guardianship of male requestors
- Requests from adopted persons
- Parents/guardians of children who turned 18 years during the time of processing the request
- An inability to match the name or the date of birth provided by the requestor.

Finally, it was strongly recommended that a cost-benefit analysis be undertaken on the NSC Archive.

## **Summary: Balancing the public interest**

In summary, extensive consideration was given, over the course of the day, to retaining and disposing of the Archive, both of which options, it was argued, could impact on the public interest. While a distinction was made between the various types of cards (those retained without consent from 1984 to 30 June 2011; those for which consent to retain but not conduct research had been obtained from 1 July 2011 to the present day; and future cards), in general, similar issues arose.

The rationales for retaining the Archive were twofold and related to the potential research uses, as well as the potential for diagnosis and treatment for individuals based on the genetic or other material available through the NSCs. The area of SCD was particularly highlighted. It was noted that, to date, only small numbers of requests had been received to do research on the NCSs.

Three key arguments were raised in identifying why the Archive should not be retained. These included: the legal imperative to seal the breach in the Data Protection legislation; the potential compromise to the current use and uptake of the NNBS; and the potential costs associated with preparing and maintaining the Archive for future use.

# Potential solutions to the current breach of the Data Protection legislation

Consideration was given to potential solutions to the current breach of the Data Protection legislation and this specific question was discussed by one group during the group discussions. Three potential options were presented and these were:

**1) Destroy all the samples.** This would have the benefit of ensuring compliance with the Data Protection legislation. It would respect the rights of individuals and their privacy. It was also suggested, however, that there would be some disadvantages for the individual, since this resource, which could potentially be used for medical diagnostics, would no longer be available. It was also noted that this would represent the loss of a potentially significant research resource for use in population genetics or other studies. This issue was stated to be the 'nuclear option'.

Later in discussions, it was suggested that only the blood spot specimen could be retained anonymously and this would contain no data except from the DNA. It was advised that this point had previously been raised by the Data Protection Commissioner as a possibility, and that while DNA might be useful for population-based research, it would be *'of absolutely no purpose at all in terms of clinical care'*.

**2) Introduction of legislation to deal with the issue.** This legislation would need to be retrospective as well as prospective, to take account of the changes in 2011. The legislation, which it was suggested should be *'enabling'*, would need to set out conditions about how the data should be handled, as follows:

- Retrospective data: it was suggested that this should have a very narrow remit. Specifically, these data would *only* be available for diagnostic and therapeutic use and the research component would be excluded because of the potential loss of *'public confidence'* and *'buy-in'*.
- Prospective data: it was suggested that *'renewed consent or modification of the current consent-based system to allow for research to be performed'*. While the consent would be a *'broad consent'*, it was suggested that it would nevertheless satisfy *'upcoming legislation'* on the need for it to be *'informed, specific and explicit'*.

It was also suggested that, taking account of the learning from the UK, there could be a research exemption so that there would be a facility to do research with the appropriate governance in place.

In respect of the *'thorny issue'* of consent, it was suggested that the current period of 10 years is *'somewhat arbitrary'* and that consent could be for 18 years, so that when the minor becomes a legally consenting adult, the sample can be destroyed.

It was argued that *'single issue'* legislation might have a better chance of *'getting passed rather than getting tied into a huge number of other legislative issues within the health area'*. It would have the benefit, therefore, of getting through the system quickly. This would preserve the Archive for use and would give certainty to the legal status of the cards.

It was suggested, however, that:

- There could be concerns arising from the legislation over the use of samples, particularly in how they might be handled for clinical and/or research use.
- It could be argued that the legislation should be focused on the bigger governance landscape relating to biobanking.
- A parallel public information campaign, which would be necessary, would nevertheless, give a different message from that of the 2013 campaign.
- It would clearly be putting the public interest before the right to individual privacy.

Some consideration was given to including an option to 'opt out' in the legislation, so that individuals could, if they wished, remove their data from the Archive. It was noted, however, that approximately 10% of cards were unable to be located in the previous process and this could potentially raise additional challenges.

**3) Putting a legislative framework in place for the whole National Newborn Bloodspot Screening Programme.** Attention was drawn to some states in the United States, where engagement with the NNBSPP is mandatory. It was suggested that the structuring of legislation to give clarity to the NNBSPP might be welcome, although as there is already a 99.9% uptake of the screening for six conditions under the current system, any changes to the *'legislative footing'* may create problems.

This approach was discussed in greater detail and a question was raised as to why it was necessary to *'legislate for this screening programme and not for all other screening programmes we have in the country.'* In response, it was noted that other programmes have introduced legislation, specifically the Cancer Programme, which, in the interests of the public, has waived consent for data to be used. Every individual's cancer diagnosis is recorded in the National Cancer Registry Ireland, regardless of whether consent is obtained. This sets a precedent for the NNBSPP.

Concerns were raised that not seeking consent would be akin to adopting a *'nanny state'* approach which, in turn, could result in a new set of problems in getting people to take part in the NNBSPP in practice. This could be particularly problematic for some groups, in terms of communication, particularly for those mothers whose first language is not English.

Another issue was raised about whether legislation of this type would require a constitutional amendment and it was suggested that Ireland has held referenda about issues that were potentially far less important. Information provided by one participant suggested that this would not be necessary. Furthermore, this participant indicated that the concept of '*a right to privacy*' was similar to other constitutional rights, in that it is subject to interpretation and is an 'implied right'. In addition, it was stated that '*information privacy*' has only come to the fore in the past 20 years and that the concept of privacy is something that is continuing to evolve in the context of '*changing societal views and other means*'. Supporting evidence for this contention was set out in the following three areas:

- The Oireachtas debate on the Data Protection Act in 1988, which was firstly to facilitate the development of the International Financial Services Centre and only secondly to protect privacy;
- Likewise, with the EU Data Protection Directive in 1995, where, again, privacy was the second reason, the primary reason being competition in the internal market; and
- EU General Data Protection Regulation 2016, which makes no reference to privacy.

It was suggested that privacy is a separate concept to Data Protection.

# Governance issues

Two main issues relating to governance were discussed and these emerged at all stages throughout the Forum. These were: consent and broader governance structure.

## Consent

Consent to retain and engage in secondary uses of the biological or other data collected as part of the NNBS is at the heart of the issues arising. Consequently, this formed a key part of the discussions throughout the Forum. As noted earlier, there are different situations pertaining. While there was no consent obtained for cards to be retained up until 2011, there was consent for cards to be retained from 2011 for 10 years, during which time they could only be used:

1. To check the baby's test results
2. To facilitate other tests recommended by the child's doctor, and for which parental/guardian consent has been sought
3. For quality assurance purposes to develop and improve the NNBS and, in turn, the health of babies and families in Ireland

Consent is not currently sought to use the card for any other secondary purpose, such as research. This is the existing policy and practice, which is compliant with Data Protection legislation.

It was noted that Irish culture has changed over time and that previously *'implied consent'* was often considered sufficient. It was suggested, however, that the retention of children's organs following post-mortem raised a number of important ethical and practical issues; and that stating *'we're doing this for your good and trust us'* is no longer acceptable.

## Non-consent-based justification

It was suggested that if the justification for retaining the pre-2011 cards was not a consent-based one, there were many questions to be considered. These included:

- What are the elements of the public interest case?
- Where is the evidence of use?
- Where is the evidence of benefit?
- What are the associated risks?
- What are the associated costs?
- Is this something that Ireland wants to invest in, to the exclusion of other things?

It was noted that while the *'public interest is always very appealing'*, a case has to be made and this has to be *'drilled down so that the detail is clear'*.

## Meaningfulness of ‘broad consent’

Broad consent which enables data to be used without specifying the exact purpose is in place in other jurisdictions, although some challenges arise in adopting this approach. The consent currently sought in respect of the UK Biobank, for example, is a ‘*broad consent*’, and it was noted that under this, individuals ‘surrender’ samples of blood and saliva, baseline data, and allow ongoing access to ‘*all sorts of health records related to themselves and to their families*’. It was suggested, however, that there is some ethical disquiet about this in the UK. Specifically, it was argued that broad consent is not sufficient unless there is a robust governance framework in place to support it. Questions about whether consent is ‘*meaningful*’ and ‘*whether it could be delivered in practice*’ were also raised. Two examples were presented of challenges in respect of the use of broad consent, as set out in the UK Biobank Ethics and Governance Framework,<sup>3</sup> which guarantees that:

a) ‘*Participants have an absolute right to withdraw at any time for any reason, and they don't have to explain themselves*’. This, it was noted, is ‘*fairly standard*’. If, however, no further use is to be made of the materials or the data, then they need to be removed from the IT database. This was identified as problematic, since ‘*a record of the fact that data had been destroyed had to be kept*’ by the IT system. This, in turn, meant that the UK Biobank could not actually hold to the guarantee that there would be no further use of their data. While some discussions took place about the need to re-consent almost 5.5 million people, it was ultimately decided that the Ethics and Governance Framework needed to be revised to state that the disposal of the data was guaranteed but would be retained for ‘*archival purposes*.’ The speaker highlighted that the main message here was that ‘*there are ways to respect people without necessarily going down the consent route*’. It was further noted that:

*‘Laws should not be a barrier if you think that policy is appropriate, justifiable and defensible’.*

b) ‘*No feedback*’ would be given, with the rationale being that ‘*this is a research endeavour*’. ‘*It is about developing a resource*’ and ‘*people are aware of that and are signing up to it*’. However, it was reported that this assertion was challenged very quickly in the context of trying to extend a protocol to include areas such as brain imaging, where radiologists identified problems on the images. Questions arose as to whether individuals needed to be informed about the findings. While this question was not resolved, it became clear, on reflection, that a ‘*hard “no feedback” policy*’ could not remain.

It was the view of the speaker that feedback may or may not take place, but that there must be a mechanism and overt policy in place to support it.

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<sup>3</sup> <https://egcukbiobank.org.uk/Ethics-and-governance-framework>

## **Opt in versus opt out**

The question of whether individuals should opt in or opt out was addressed in the Netherlands by the inclusion of a 'tick box' (*'The parent does not want the card to be kept for scientific research'*) which parents were asked to tick *'if [they] don't want research to be done'*. It was noted that according to the speaker, this system appears to be working well in the Netherlands and there has not been any public antipathy towards it since it has been introduced. However, it was also noted that there are an increasing number of parents/guardians who indicate they do not want their infant's card to be used for research (estimated to be about 2% currently).

## **Re-consent**

A question was raised about the need for re-consent by the child when he/she reaches 16 or 18 years (depending on the age requirement) since the original consent was provided by a parent/guardian. It was suggested that, in principle, when children reach adulthood they should have the option of re-consenting. One option presented was that everyone would be contacted at age 18 years for the purpose of determining whether they wished their blood sample to be retained or destroyed.

It was also noted, however, that some consideration would need to be given to the feasibility of this. If children's data are entered into large databases and there is no subsequent contact with the parents/guardians or children, this option could be very difficult to operate. It was stated that children should have the possibility of withdrawing their sample and this could potentially be addressed by placing the information on a website or in a journal.

It was suggested that it is not about *'ownership'* of the data but rather about control and respect, and the importance of being transparent about whatever is being done. It was noted that in the UK there is no express legal basis for the data, which are treated as part of the medical record. It was suggested that in this case, individuals can opt out, so long as enough information is available to remind individuals *'at the age of maturity that these data exist'*.

One speaker noted that a paper on re-consent has been accepted by a journal and will be published some in 2017.

## **Broader governance structure**

The second significant issue related to the need to take account of the broader governance environment, rather than simply focusing on one element such as the NNBSA alone. It was suggested that, in Ireland, *'we do not currently have systems in place to look at the context of the wider access to patient material in the first place'*. It was noted that there are a variety of different ethics committees around the country and these set out the procedures around samples for some research studies.

It was also stated that while the focus is on NSCs, the area of data sharing, broader data samples, biobanks and data banks is *'becoming massive'* and there is a need to have a system in place to provide strong governance which has the trust of the people. Examples of other biological sources included tumour tissue and blood samples. It was also suggested, however, that while the number of biobanks has increased rapidly over the past 10 years, these biobanks are very much at the stage of collecting samples rather than reporting on research that has used these samples.

The implementation of a broad governance approach was supported by a number of participants at the Forum. It was stated, for example, that we need to consider *'a top down'*, *'superstructure'* and *'helicopter'* approach that takes account of the larger context and puts systems in place for how material is handled. Within that, the NNBSPP cannot be *'handled in isolation'*; and strong caution was expressed about allowing this particular concern, which is *'time sensitive'*, to drive more important and broader considerations. Caution was also expressed about being *'over-reliant on the idea that we can get a nice quick fix on the law'*, which it was suggested moves too slowly relative to this rapidly changing environment.

There was a recognition that this broad governance structure is needed to build trust so that people can see that there are *'systems'* and *'people'* with the necessary expertise in place to know when it is appropriate to release and use personal information.

The governance structure, it was suggested, should be *'robust'*, *'adaptive'*, *'flexible'* and *'in place across the country'*.

### **Learning from other jurisdictions: UK**

Information was provided about the UK Biobank which had been set up in the context of an *'already complex and some would argue too burdensome'* regulated framework, but without the need for any specific legislation. There is, however, an Ethics and Governance Council which was necessary because of: a) the breadth of the project's purpose (broad consent); b) the long-term nature of the endeavour; and c) limitations in existing mechanisms, e.g., monitoring research was not a remit of a Research Ethics Committee. The overarching approach has a number of different components which are presented in Figure 2.

An Ethics and Governance Council (*independent critical friend*)

In-parallel development of protocol and governance (*adaptive*)

In-parallel engagement with the shifting landscapes (*reflexive*)

Engagement with participants and publics (*mutuality*)

**Figure 2: Components of UK Biobank Ethics and Governance Framework**

This approach provides:

*a transparent public account from UK Biobank about what it is doing, to whom [it owes] obligations, such as participants and broader publics, what [it] will and will ... not do, and lays out certain guarantees.*

The approach adopted was referred to as '*reflexive governance*' and benefits of adopting this type of approach were identified as:

- Being able to demonstrate its integrity of purpose, i.e., it makes it clear what it will and will not allow, and on what basis;
- The possibility of evolving over time, rather than being a structure, instrument or a document that is fixed at one point in time;
- Acting as 'the independent critical friend' which enables dialogues and teasing out the issues so that people can come to some sort of decision about what is going to happen, even if there is not complete consensus (which, it was noted, rarely took place in discussions at the UK Biobank);
- Demonstrating how there can be in-parallel development of protocols in government, and the need to recognise the importance of adaptiveness over time and an ability to engage with a shifting landscape and to learn; and
- Providing a mechanism which allows ongoing and meaningful engagement with participants and publics; while that role has now shifted to the UK Biobank itself, it was very useful for gaining feedback.

In addition to the issues previously highlighted around broad consent, the following example was given of where the reflexive approach that allowed for mutual learning, over time, by the UK Ethics in Government Council was helpful.

The following example was given:

A question was raised with members of the UK Biobank about whether the data included in the biobank could be used for cloning purposes. The strict answer was 'Yes', and this was

followed by an article in *The Lancet* highlighting this. The Ethics in Government Council responded to this and it was suggested that the response provided a measure of reassurance. Specifically, it was noted that saying ‘*Yes, it can happen*’ is not the same as ‘*Yes, it will be*’ happening.

### **Learning from other jurisdictions: Scotland**

An example was also provided in respect of the Scottish situation, where a broad governance approach has been taken to research governance and where the NSC collection is not seen as a specific instance that requires a dedicated governance structure, but rather, is part of an overall approach. Tissue acquisition and bio-repositories are seen as being linked to clinical research facilities and, while individual boards in Scotland are responsible for their own collections, there is an overarching uniform governance support and infrastructure that registers collections and a centralised approach for sharing policies and other practices. This approach through a bio-repository network provides:

- Access to annotated anonymised patient samples across all areas;
- Infrastructure that supports the researcher-led provision of material from within the NHS; and
- A streamlined process, complying with legal and ethical requirements.

In the context of approval, access to pathology as well as surplus diagnostic samples and associated clinical data are provided with consent, as long as the samples were originally collected primarily for diagnostic purposes and that such purposes have been fulfilled. This approach provides a single point of access to the entire NHS Research Scotland tissue resource.

With regard to the NSC collection in Scotland, however, there is currently a moratorium in place. It was stated that all four jurisdictions in the UK intend to conduct a public consultation on this matter. Issues arising from this approach include whether:

- There is adequate oversight of these collections.
- There has been adequate meaningful engagement.
- The governance is principles based, as articulated in Article 15 of the Council of Europe recommendation.
- There is an oversight mechanism that can be adopted to possible evolutions of the collection and of its management, as set out in Article 22 of the Council of Europe recommendation, 2006.

### ***Irish context***

As noted earlier, one option for sealing the Data Protection breach was that a similar governance structure be set up as part of a broader legislative approach. It was suggested that this structure would have a remit in determining whether there would be a ‘*research*

*exemption'* around the use of the data. An example of a research exemption given in another jurisdiction was identified as interviewing children and parents/guardians in cases of child abuse. It was suggested that this governance body would be required to engage with the public, demonstrate the public interest and convince the public about the trustworthiness of the process.

Some consideration was also given to the composition or characteristics of the people who might be involved and it was recommended that it include various representatives, including:

- Patients
- Legal experts
- Clinicians
- Researchers
- Ethical experts.

While there was no recommendation about the recruitment or appointment of the group, it was noted that it would be very important that it be independent.

In summary, it was noted a comprehensive approach to governance is required, not just for the NSCs but for the wider, and growing numbers of biobanks that are being developed.

# Public engagement

There was general agreement that there is a need for public engagement and information about all collections of data, including: a) who has access to them; b) who they are used by; and c) for what purposes. It was argued that there is a need to pay particular attention to the inclusion of all stakeholders, particularly families and children.

The experience of the Netherlands was also highlighted in this regard. In this context, a survey was conducted with relevant stakeholders by means of an online questionnaire, which was made available through a website ('9 Months Fair'), from which individuals purchase products related to *'getting pregnant, being pregnant, and having young children'*. Key findings highlighted that:

- A total of 90% of participants knew that heel prick tests are carried out on babies.
- A total of 26% of participants knew that all cards are destroyed after five years.
- Only 1.5% of the sample was aware that there was a discussion about prolonging the storage of the heel prick cards.
- More than 70% of participants indicated that they would agree to the use of the cards for aetiology and prevalence studies, as well for new test developments by universities.
- Less than half of the sample (47%) agreed that the cards should be used to identify crime suspects and the same number agreed to the use of the cards by a commercial company to develop new tests.
- More than half of (55%) participants indicated that they wanted the cards to be held indefinitely, with only 3% indicating they should be destroyed after one year. One in five (22%) participants agreed that the cards should be held for the current maximum of 18 years and just 13% of the sample felt they should be retained for 16 years.

While the option of engaging in an online forum where participants could ask questions was provided, it was reported that *'almost nobody wanted to talk about heel prick, just 100 in the whole country'*.

The question of how best to engage parents/guardians of healthy infants is under consideration in the Netherlands. No decision has yet been made. The following two options were presented.

### *A community values advisory board*

- Consideration would be given to issues relating to religion and ethnicity, among others, in the composition of the board, so that it represents '*not one but many different publics*'.

### *A participant association*

- This is where approximately 10 individuals would be selected to represent the voices of children and parents.

### **Figure 3: Options being considered in the Netherlands**

Other questions were also asked about what meaningful public engagement might involve, and about the importance of ensuring that '*the plurality of publics*' are engaged and heard by policy-makers. In the context of retaining the Archive, it was suggested that, in addition to making the case for the Archive, there are questions about how public interest and access are then actually arranged within the suggested solution. Two specific questions were raised in this regard:

- What are the requirements, in the case of those who are given access to the data for research purposes, to ensure that their publications are open access?
- What are the requirements, in the case of those who are given access, to ensure that their data are available for verification purposes, so that their findings can be confirmed?

It was suggested that public interest is not just about getting access and justifying retention and use; it is also about asking: '*What does meaningful access mean to advance the public interest?*'

In summary, there was some agreement that it was important to engage the public(s) in discussion about the issues arising, and a number of potential options were presented. These included suggestions about conducting a survey or developing a participation structure specific to the NNBSF.

# Summary

This report has presented the deliberations of the NSC Archive Forum held on 27 October 2016. The Forum was opened by Mr Simon Harris, TD, Minister for Health, chaired by Ms Sylva Langford and attended by 40 participants. The purpose of the Forum was to provide attendees with the opportunity to:

*engage in deliberative dialogue with international experts in relation to the current and future position of the NSC Archive and within the broader context of biobanking and health research generally. This is to ensure that a diversity of views and perspectives inform the policy options and decision to seal this breach.*

A number of issues emerged throughout the course of the Forum and these included: balancing the public interest by retaining the Archive and by disposing of the Archive; identifying potential solutions to seal the current breach in the Data Protection legislation; and issues related to governance and public information and engagement.

## **Balancing the public interest**

Balancing the public interest by retaining the Archive focused on two key issues. It was suggested that the public interest could best be served by retaining the Archive for the purposes of: a) clinical and diagnostic reasons; and b) research. In terms of research, it was argued that, in contrast with other archives, this one was the only biological archive that covers 100% of the population (individuals born in the Republic of Ireland from 1984). This, it was suggested, represents a unique resource and a cultural heritage. Some potential research uses that were identified included: estimating the prevalence of new or early onset conditions; estimating genetic drift within the population; the development of better screening tests; and the potential to link with data from other health records. The Archive as a resource to support a broader research agenda was also highlighted. It was noted that to date, however, these uses generally remained as an unrealised potential, since there had been very few actual requests for access to the Archive. It was recommended that a systematic review of the use of NSCs be conducted as a mechanism to identify the potential of this Archive.

A second way in which retention of the Archive was in the public interest related to its clinical and diagnostic use, and much of this discussion focused on sudden and unexpected cardiac death. It was stated that about 110 cases occur every year whereby a person has died under these circumstances and where the only available tissue relating to that person is the NSC. Attention was drawn to the new agreement between the Irish Coroners Association and the Mater Hospital Biobank, by which, in the future, a blood or tissue sample will be taken from every individual who has suffered from sudden and unexpected

cardiac death. It was noted that this system is not perfect and, while it will resolve issues arising in the future, it fails to resolve the difficulties arising in respect of people who died between 1985 and 2015. Other participants raised questions about the ethical issues arising in respect of care to members of the wider family and professional responsibilities arising.

Examples were also provided of clinical and diagnostic uses, such as CMV virus infection, diagnosis of genetic or metabolic problems for deceased children, and identification of victims.

It was also argued that it was in the best interest of the public for the Archive to be disposed of, and these arguments were mainly focused on: the illegal retention of the Archive; the potential damage to the integrity of the overall NNBS; and the costs associated with retaining the Archive. It was noted that the breach in the Data Protection legislation in Ireland and Europe relating to NSCs held from 1984–2011 was a '*serious challenge*' and that it was necessary to '*comply with the law*'. The legal situation was highlighted as being very complex, and it was noted that if the public interest was to be served, a number of questions would need to be addressed. These included: the need to make concrete the ways in which it supported the public interest; potential alternative sources of data for research purposes; the specific aim, objectives and rationale for the proposed research; and the need for lawful processing of the data. It was also pointed out that Ireland is not unique in this area, and that different solutions are in place in other jurisdictions.

Many concerns were raised about the potential damage to the integrity of the NNBS and it was stated that the current programme is one of the most successful initiatives in the country, with a 99.9% uptake. It was argued that it is in the interest of all stakeholders to maintain the current level of public trust and confidence, and that no actions should be undertaken that might put this at risk.

Finally, some issues were raised about the costs associated with retaining the Archive. It was noted that while these costs have not been clearly calculated, there are opportunity costs. It was recommended that these costs be calculated and balanced against the potential benefits of the NNBS.

### **Potential solutions to the current breach in Data Protection legislation**

Three potential options were presented in respect of sealing the current breach in Data Protection legislation.

First, it was suggested that the Archive be disposed of, although it was also recommended that the actual blood spot data could potentially be retained, provided they were anonymised.

Second, it was suggested that primary prospective and retrospective '*enabling*' legislation be introduced. In terms of the retrospective element, it was proposed that the Archive could be retained and this could be done in parallel with an information campaign to inform people about the change. This legislation would apply only to the use of the Archive for diagnostic or clinical reasons, and no research would be allowed. The benefits of this approach, it was recommended, would be that the legislation would have a very narrow focus and would therefore have a better chance of being passed.

Third, the option of placing the NNBS on a statutory footing was proposed. The National Cancer Registry Ireland was highlighted as setting a precedent in this area. Some concerns were raised about this approach, and it was suggested that, in practice, it would be difficult to implement, particularly with mothers whose first language is not English. Further it was suggested that the current uptake of 99.9% could be compromised by adopting a 'nanny state' approach.

## **Governance**

Two key issues arose in respect of governance. First, the absence of consent, which is at the heart of the issues arising and second, the need to situate the NNBS within a broader governance infrastructure.

In terms of consent, key issues arose related to the extent to which a '*non-consent*'-based approach could be justified. These issues included the meaningfulness of broad consent and whether it could be applied in practice; opportunities to opt in or opt out of scientific research; and the need to re-consent. It was noted that in the UK, the Newborn Screening Card is viewed as part of the medical record and consent is not sought for any secondary use. However, in the UK, there is an existing Ethics and Governance Framework which provides substantial guidance and a mechanism for reflexive governance, which helps to build and maintain public trust. Examples were provided of where this framework has been used to inform decisions about consent. These included: the '*absolute right*' to withdraw, which has subsequently proven to not to have been possible, and the '*no feedback*' rule, which again proved problematic in its implementation. Parents/guardians must opt out of scientific research on the NSCs in the Netherlands. While it was noted that this has not created any difficulties, it is becoming more common and now accounts for about 2% of the population. The child's right to re-consent to the use of his/her sample at age 16 or 18 was also raised, and it was suggested that some thought would need to be given to this issue.

Rather than dealing with the NNBS as a separate issue, it was suggested that there is a real need to develop a national infrastructure around biodata and biobanking. It was highlighted that this area is increasing and the need for strong governance is critical to build the trust of the people. This broader governance structure needs to be dynamic, so that it can adapt to the evolution in scientific methodologies. It also needs to be robust and nationally available. It was stated that the implementation of the Ethics and Governance Council in the UK is

guided by a framework that provides a transparent mechanism through which this can be done. A reflexive governance approach enables many different issues to be considered and a solution to be developed. It was suggested that a similar type of approach could be adopted in the Irish situation and that this structure could take account of the NSCs, but not be limited to these.

### **Public engagement**

The final area that emerged for discussion throughout the Forum related to the involvement of the public(s). There was a general consensus that providing information about all collections of data was necessary for the public(s). A number of different options were proposed, including, for example, a community values advisory board and a participant association, although no single approach was recommended.

### **Summary**

In conclusion, the discussions that took place throughout the course of the Forum were informed and considered, and presented a number of potential options for policy-makers to progress the issues concerning the current Archive of National Screening Cards within the context of the National Newborn Bloodspot Screening Programme.