STATENS SERUM INSTITUT

The Danish Neonatal Screening Biobank (DNSB)

In Denmark, all newborns are tested for a variety of serious congenital disorders by analysing a dried blood spot sample applied to a special filter paper (DBSS). The analysis is carried out by the Section for Neonatal Screening, Department of Clinical Biochemistry & Immunology, Statens Serum Institut, where surplus blood sample material has been stored in a locked freezer at -20°C since 1982.

Since the submitted sample only consists of a few drops of blood, the stored sample material is very sparse, which limits its applications. Personal data are kept separate from the blood sample, and only authorised personnel have access to these data.

The purpose of analysing and storing the samples in the Neonatal Screening Biobank is described briefly in a folder which is handed out to the parents in connection with the sampling.
The purpose of storing the samples in a biobank after completing the test for congenital disorders is described in more detail below.

The three main objectives of the biobank, in order of priority, are as follows:

1. Priority. The presence of the sample in the Neonatal Screening Biobank proves that Statens Serum Institut has received it and is responsible for analysing it according to the guidelines of the Danish National Board of Health. In case a child develops inexplicable symptoms or is underdeveloped later in life, the presence of the sample in the biobank may be of great importance, as the tests can be repeated. Furthermore, new analyses might have become available as a result of medical development since the child was born, and performing these could prove to be relevant. I many cases, being able to analyse stored biobank samples from inexplicably sick children has proved to be of inestimable importance in connection with diagnosis and treatment. In other cases, the samples may be used to perform special analyses in connection with certain disorders for which there are no routine examinations, for example infections which occur immediately after birth.

In connection with a deceased person, the sample in the biobank is often the only useable material for a number of important tests of great significance to the relatives. The biobank sample is only released for such tests with the consent of the closest relatives. The purpose of these tests can be to diagnose diseases which may be of significance when giving advice to parents who are planning a new pregnancy. Samples can also be used for genetic testing in connection with identification of victims of accidents, natural disasters or crime - in the same way as X-ray pictures from the dentist have been used for many years whenever possible. In these cases, the consent of the relatives or a court order will also be obtained when possible *.

*In this connection, it should be stressed that it is not possible to use the DNSB biobank as a criminal DNA register where individuals can be identified solely by means of a DNA profile found e.g. at a scene of crime. This is due to the fact that the DNA profiles in the blood samples in the biobank are unmapped and therefore not available for a search.

2. Priority. The Neonatal Screening Biobank plays a very important role in ensuring that Statens Serum Institut is able to perform the analyses of the newborns' blood samples as effectively as possible, as the borderline values of the individual markers of disorders are determined more accurately. Furthermore, it creates unique possibilities in connection with identification of new effective markers of serious congenital disorders which in future would form part of the newborn screening programme by routine.

3. Priority. In several cases, the Neonatal Screening Biobank has been used in different so-called "case control studies" where the levels of possible markers of disorders in children who later develop certain disorders (cases) are compared with the levels in healthy children (controls). These studies partly provide insight into the

mechanisms behind the origin of the diseases and may furthermore form the basis of the selection of new markers of disorders. As is the case with other tests based on blood samples from humans, such projects are only carried out after approval by the Scientific Ethical Committee System in Denmark. Projects using human biological material shall always be carried out according to The act on processing of personal data as specified by The Danish Data Protection Agency (www.datatilsynet.dk/english/). In order to ensure that there is always sufficient test material left for the purposes mentioned under point 1, an approval must furthermore be given by the "DNSB Steering Committee". Important diseases which are studied using these methods include diabetes, cerebral paralysis, autistic disorder and schizophrenia.

A person of age or the parents can inform the tissue use registry of the Danish National board of Health if they do not want the sample to be used in medical research: www.sundhedsstyrelsen.dk/vaev or tel.: 7222 7791.

In short, the Neonatal Screening Biobank is of great importance to the child, parents and future generations. It is important that Statens Serum Institut participates in an ongoing open dialogue about the biobank and its use. So far, there have not been any examples of abuse.

If a person does not wish the sample to be retained in the biobank, he or she can write to the Department of Congenital Disorders, Center for Neonatal Screening, Statens Serum Institut Artillerivej 5, 2300 Copenhagen S, and the sample will then be destroyed.

Comments, questions, etc. may also be addressed to Department of Congenital Disorders, Center for Neonatal Screening, Statens Serum Institut.

References

Norgaard-Pedersen B, Hougaard DM. Storage policies and use of the Danish Newborn Screening Biobank. J Inherit Metab Dis. 2007; 30: 530-6.