Public Health England

NHS

NHS Newborn Blood Spot Screening Programme

Code of practice for the retention and storage of residual newborn blood spots

1 January 2018

Public Health England leads the NHS Screening Programmes

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health, and a distinct delivery organisation with operational autonomy to advise and support government, local authorities and the NHS in a professionally independent manner.

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About PHE screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or better informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the four UK countries. The Screening Quality Assurance Service ensures programmes are safe and effective by checking that national standards are met. PHE leads the NHS Screening Programmes and hosts the UK NSC secretariat.

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This code of practice sets out guidance agreed from 1 January 2018 by the Blood Spot Advisory Group on behalf of the newborn blood spot screening programmes in England, Wales and Northern Ireland.

The programmes in Wales and Northern Ireland are seeking final approval of implementation dates and processes, and will communicate these with their respective Laboratory Directors.

Background to recommendations

Newborn blood spot screening programmes are highly effective public health programmes that have enabled earlier treatment and prevented life-long disability. Once screening tests have been completed, a small amount of each blood spot is left over (‘residual’ newborn blood spots) on the newborn blood spot card.

Testing of residual newborn blood spots is used to quality assure screening tests. For example, re-testing as part of a review of specimen quality led to a change in practice in 2015. It has also allowed genetic diagnosis, carrier testing and diagnosis for at-risk relatives of individuals who may have died of suspected genetic conditions and for whom the blood spot is the only remaining sample. Residual newborn blood spots have also been used to diagnose congenital infection in children who present with signs compatible with congenital infection at an age when it cannot be distinguished from acquired infection.

In addition, research and surveillance based on residual newborn blood spots has answered important public health questions and led to advances in antenatal and newborn screening which are to the benefit of children and their families. While this is not the primary use of residual newborn blood spots, it is important to enable this to continue in a properly regulated manner.

This code of practice updates that drawn up in 2005 and applies to all newborn blood spot samples. It sets out arrangements for the retention, storage, use and release of residual newborn blood spots and related information and communication requirements. It has been updated to reflect current guidance in relation to information and governance concerning the use of biological specimens for research, while at the same time safeguarding the newborn blood spot screening programme, which is of major public health importance to the lives of children and their families.

The original code of practice was developed by an expert group, including parent representatives, and in consultation with legal and other experts, to reflect policies and laws regarding the use of human biological material, genetic testing and confidentiality of data. It drew on existing models for similar collections internationally as well as wider literature on use of biological samples for research and genetic testing [1,2,3,4,5,6].

This revised code of practice considers updated guidance from the Royal College of Pathologists, the Human Tissue Authority, the Medical Research Council and the Health Research Authority [7,8,9,10,11]. The code of practice gives guidance to the Directors of Newborn Screening Laboratories, who are the custodians of the blood spot samples during and after the screening process. This code of practice will be made available to members of the public and to health professionals through parent

information materials and relevant professional documents. Information on the use of residual newborn blood spots will be made publically available. This code of practice will be reviewed periodically, taking into account any changes in legislation or relevant ethical and practice guidance.

Retention

Failure to diagnose an affected child through screening may require investigation by re-testing of the original blood spots and is part of quality assurance. The newborn blood spot screening programme requires laboratories to retain all residual newborn blood spot cards for 5 years as part of quality assurance[1]. Following this retention period, residual newborn blood spot cards will no longer be available and should be destroyed by the laboratory within 12 months. The screening results form part of the child's medical record and will be kept in line with records management guidance [12].

Note that this retention guidance is currently under review. Screening laboratories are requested not to destroy any residual newborn blood spot cards and shall be notified directly when the outcome of the review has been reached.

[1] The 5 year retention period begins from date of receipt of the blood spot sample in the laboratory.

Storage

Storage of residual newborn blood spots should comply with current legislation and good practice guidance including the Royal College of Pathologists, Human Tissue Authority and Medical Research Council [7,8,9,10].

Stored residual newborn blood spots should be physically separated from personal information including the NHS number but keep the laboratory identification. This is already in place in Wales, and will be enabled following the introduction of a new blood spot card design in England and Northern Ireland. Linkage of residual newborn blood spots to personal information will only be possible through the laboratory identification or card serial number. This linkage will be carried out only by individuals authorised by the Directors of Newborn Screening Laboratories.

Uses

Residual newborn blood spots may be used for testing with parental consent and on request of the child's clinician acting on behalf of the family, should a clinical need arise.

Residual newborn blood spots may be used for audit, training, improvement and development of laboratory methods relevant to screening, public health monitoring and other uses as allowed under the provisions of the Human Tissue Act 2004 [8].

Residual newborn blood spots or screening data may be used for research, without seeking individual consent, if the identifiers have been removed from samples and data before they are given to researchers[2], and if the research has research ethics committee approval, is compliant with relevant legislation [8,13,14] and any research requirements of the Human Tissue Authority and Health Research Authority [8,11,15].

Very occasionally, research may involve contacting parents or their children, inviting them to take part. In these circumstances, parents and/or their children will be informed about this research and allowed time to decide whether or not to accept such an invitation. At the time that the newborn blood spot sample is taken, parents will be asked whether they are happy to be contacted with such future invitations. Their response will be recorded on the card. This information should be stored by the laboratory in a retrievable form and checked before contact is made with the family.

All research projects must be approved by a research ethics committee and be subject to peer review to make sure that the research is of high quality.

The independent Antenatal and Newborn Screening Research Advisory Committee (hosted by Public Health England) must also approve any research projects that use data or samples from newborn blood spot screening.

When releasing residual newborn blood spots for research or audit, the laboratory should ensure that one spot is retained for quality assurance/clinical purposes.

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[2] Samples and data may be anonymised (the link between the identity of the child and samples/data is permanently removed) or de-identified (the laboratory retains a link between the identity of the child and samples/data but the researcher does not receive this link). Where, in exceptional circumstances, the researchers felt there was a clinical reason to feedback information to a family this could be done via the laboratory. This possibility would have been part of the research ethics committee/Antenatal and Newborn Research Advisory Committee application.

Release

Residual newborn blood spots may be released for uses as specified above.

Forensic purposes

Appropriate legal permission (written court order or by instruction of a Coroner) is required for the release of residual newborn blood spots from specific dead or missing people for forensic purposes. This access should be carefully controlled. Directors of Newborn Screening Laboratories may wish to liaise with the legal and governance department within their own Trusts/Health Boards when such requests are received. Samples from individuals who are alive and not missing should rarely be released for this purpose since alternatives are available – this would also require legal permission (written court order or by instruction of a Coroner). Directors of Newborn Screening Laboratories may wish to check such applications with their Trust/Health Board's legal and governance department.

Return to parents/carers

Residual newborn blood spots will not be returned to parents/carers as they contain sensitive/genetic information about the mother and father as well as the child (including paternity).

Commercial uses

Newborn screening laboratories are not permitted to sell, or grant exclusive access to, residual newborn blood spots to commercial organisations. Some commercial partnerships may be required to develop screening methods that may benefit the screening service and public health more generally but access to residual newborn blood spots for this purpose must be checked with the Antenatal and Newborn Research Advisory Committee and local information governance leads before release.

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