Code of Practice for the Retention and Storage of Residual Newborn Blood Spots

Background to recommendations

Newborn blood spot screening programmes are highly effective public health programmes, which have enabled earlier treatment and prevented life-long disability. Blood spots left over once screening tests have been completed (‘residual’ newborn blood spots) have also provided a valuable research resource. Testing of residual newborn blood spot cards, which may have been stored for many years, has allowed molecular genetic diagnosis, carrier testing and prenatal diagnosis for at-risk relatives of individuals who may have died many years previously of suspected genetic conditions and for whom the blood spot is the only remaining sample. They 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. It is important to enable this to continue.

This code of practice sets out arrangements for the retention, storage, use and release of residual newborn blood spots and related information and communication requirements. It has been established to reflect current thinking 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. It 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 has drawn on existing models for similar collections internationally as well as a wider literature on use of biological samples for research and genetic testing. The 1999 statement of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science is currently under review and this code of practice will be incorporated into new guidance anticipated in 2005.

The code of practice gives broad guidance to the Directors of Newborn Screening Laboratories, who together with their respective Departments of Health, are the custodians of the blood spot samples during and after the immediate screening procedure. The UK Newborn Screening Programme Centre will make this code of practice available to members of the public and to health professionals through its website. The Programme Centre will include information on the use of blood spots as part of its annual report to the Programme Centre Board to which it is accountable. The Programme Centre Board is in turn accountable to the UK Health Departments. The Programme Centre Board will review the code of practice periodically, taking into account any interim changes in legislation or ethical perspectives.

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Public Health England is responsible for the NHS Screening Programmes
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 management. All newborn blood spots will be retained for a minimum of five years as part of quality management. Retention thereafter will depend on the resources and requirements of the screening laboratory and/or health department.

Storage

Conditions for storage should adhere to standard operating procedures to be developed by the Programme Centre in partnership with the UK Newborn Screening Laboratory Network and other appropriate laboratory networks. These will specify the storage conditions required to maintain appropriate specimen quality, to provide security of access and to retrieve filter paper cards efficiently. In the longer term, conformity with these standard operating procedures will be included in the accreditation of a newborn screening laboratory. Resources to comply with these standard operating procedures will be incorporated into the commissioning process.

Blood spot cards stored after the immediate testing and quality assurance period will be physically separated from personal information including the NHS number but will keep the laboratory identification. Linkage of blood spot cards to personal information will only be possible through the laboratory identification. This linkage will be carried out only by authorised individuals.

Existing holdings, at the time the Human Tissue Act came into effect, are exempt. The legislation for Scotland is under revision at the time of writing.

Uses

Residual newborn blood spots may be used for testing on request of the child’s doctor acting on behalf of the family, should the baby or another family member become ill.

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.

Residual newborn blood spots may also be used for research where the samples have been anonymised and the research project has ethical approval, as outlined in the Human Tissue Act and in MRC Guidance, without individual informed consent.

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 of the initial heel prick, parents may choose not to be contacted with such future invitations (see page 24).

All research projects should have been approved by an ethics committee and be subject to peer review to ensure that the research is of high quality.
Release

Residual newborn blood spots may be released for uses as specified above. An appropriate legal permission (court order) is required for the release of residual newborn blood spots from specific dead or missing people for forensic purposes. Samples from individuals who are alive and not missing should not be released for this purpose since alternatives are available.

An appropriate legal permission (court order) is required for the release of residual newborn blood spots from deceased children for the purposes of establishing maternity or paternity. Samples from individuals who are alive should not be released for this purpose since alternatives are available.

Newborn screening laboratories may not 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. These arrangements will be subject to scrutiny by the Programme Centre Board and documented in the Programme Centre’s annual report.

Literature supporting this Code of Practice