

The Importance of Blood and Tissue Samples

The Paediatric Liver Services at King's College Hospital, London, Birmingham Children's Hospital and St James's Hospital, Leeds are supra-regional referral services where children with liver disease are referred from all over the United Kingdom and the world. This is because liver diseases are rare in children and are better investigated and looked after in specialised centres.

The centres' aim is to continue to improve their ability to diagnose the different types of liver disease, to understand why they develop and to improve modes of treatment. This can only be achieved if we continue the search to try and understand the mechanisms leading to liver damage in different conditions and the best drugs to be given for these conditions.

In order to do this, it is essential to have access to blood samples and liver biopsy specimens which can be used at a later date when new disorders are discovered or to investigate the possible cause of liver damage in a large number of children affected by the same condition. The livers therefore store in a special bank, a small quantity of blood (half a teaspoonful) and a small piece of the liver biopsy (pinhead size) obtained from you or your child so that it is available for further investigations later on. Any blood or tissues taken will always be explained to you and you will also be asked for your consent to store these items, which will need to be made in writing. Many of the families who have a child treated at the centres will be familiar with this.

Apart from research purposes, these samples can be extremely helpful in performing more investigations without the necessity of taking further blood or biopsy when the results of other tests suggest specific conditions. Both the blood and biopsy samples are kept frozen for further studies. If the stored blood or liver biopsy is used for research, this will only be done after the study has been ethically approved by the Research Ethics Committee at the individual centre. The blood samples and biopsies are used in these studies anonymously, so that you or your child is not recognisable when the

study is published. You will be informed over the years if any discovery using stored blood or biopsy has led to a change in understanding of the disease affecting you or your child.

Your consultant or specialist nurse will be happy to discuss any aspect of this. If you decide not to participate at any time then you should discuss this with the consultants or named specialists. Your decision will not affect the care of your child.

Human Tissue Bill

Many of you will be aware of the Human Tissue Bill which was principally motivated by events at Alder Hey and Bristol but its scope is much broader than the problems highlighted by those events.

The Bill will make it a criminal offence in England, Wales and Northern Ireland to remove, store or use human bodies or store or use human organs and tissue for scheduled purposes without 'consent'. Consent is not defined on the face of the Bill. The definition of consent will be a matter of legal interpretation, ultimately for the Courts to decide (not a matter for the Human Tissue Authority that will be established to regulate activity governed by the Bill).

The scheduled purposes that the Bill regulates include, among other things, teaching, research, anatomy, hospital post-mortems, transplantation, public health monitoring, clinical audit, quality assurance and public display. Tissue includes blood, tissue blocks and slides and any other bodily material containing cells other than hair, nail, gametes or embryos.

The Bill will also make it a criminal offence throughout the UK to store material containing DNA with the intention of carrying out DNA analysis without consent.

Licensing requirements will apply to all forms of human tissue covered by the Bill. These requirements will include the need to have a licence (and to comply with any terms in that licence set by the Human

Tissue Authority) to store any tissue for any of the scheduled purposes.

CLDF is entirely supportive of the aim of the Bill to seek to ensure that the events that occurred at Alder Hey and Bristol are never repeated. We also recognise the importance of promoting public confidence and providing clarity in the requirements relating to the use of human organs and tissue.

Regrettably, the Bill in its current form is likely to be unworkable. We believe it is incoherent, contains inconsistencies and ambiguities and will create unnecessary expense and bureaucracy. CLDF believes that those aspects of the Bill that relate to tissue taken from the living in particular are likely to create a climate of fear among health practitioners and researchers, to unnecessarily impede medical research to the detriment of the public interest and will fail to achieve the clarity in the law, public confidence and public protection the Government sets out to achieve.

More time is needed for consultation and scrutiny of the aspects of the Bill dealing with tissue taken from the living. Through the Association of Medical Research Charities we are calling on the Government to remove the parts of the Bill relating to tissue taken from living persons so that the aspects relating to post-mortem tissue can proceed to the statute books and the aspects dealing with ante-mortem tissue can be given essential extra time for further public consultation and Parliamentary scrutiny. Failing that, we will be seeking certain critical modifications to the ante-mortem tissue parts of the Bill to seek to reduce the risk of problems outlined. There are also a number of steps that we feel must be taken to ensure that Parliament is able to scrutinise the Bill properly.

At present CLDF is working with other members of the Association of Medical Research Charities to present a consistent position statement as well as highlight the importance of the need for storage of tissue and blood samples.