

Statement on the Human Tissue Bill

Executive summary

The Academy of Medical Sciences would like to comment on the Human Tissue Bill. While there are proposals in this Bill that we welcome, the Academy has some serious concerns and wishes to suggest some amendments and clarifications.

The Academy is concerned that the Bill attempts to license, monitor and regulate through a regime that is more detailed and of wider scope than is desirable or necessary for the protection of patients and of the public. In doing so it:

- will criminalise activity that is part of normal and proper clinical, pathological and research practice
- ignores certain practicalities of clinical medicine and pathology, including the management of patients with inherited disorders;
- fails to give proper consideration to the public and patient benefits of research and weigh these against the risks;
- gives the proposed Human Tissue Authority powers to determine legally binding standards without oversight from Parliament;
- fails to provide the clarity in the law, despite that being one of its prime objectives (this Bill is opaque and difficult to understand as presently drafted, even with the Explanatory Notes).

The Academy believes that, as a consequence, the Bill, as presently drafted, could have a detrimental effect on public health, clinical practice and research activity in England and Wales. Similar concerns have been expressed by other organisations.

A summary of the amendments and clarifications to the Bill that the Academy recommends is below. More detailed comment can be found in the sections entitled: ‘Amendments’ and ‘Clarifications’ later in this document.

Amendment one: blocks, slides and surplus material from surgical operations

The Academy recommends that blocks and slides, and indeed surplus material obtained from surgical operations should be excluded from this Bill. Furthermore, the Academy recommends that the proposals and criminal sanctions discussed in the Bill should be applicable only to human material removed at autopsy, and that procedures for regulating surgically-acquired material be subject to a further period of consultation.

If this is not possible, then the Academy would strongly advise that Part 2 of Schedule 1 should contain a new category, as is set out in amendment two.

Amendment two: public health and epidemiological research

The Academy believes that the Bill, as currently drafted, would have a highly detrimental effect on public health and epidemiological research. Therefore, the Academy recommends that Part 2 Schedule 1 paragraph 13 of the Bill should be amended as is set out below:

13. Epidemiological Research using remnant samples. This can be defined as ‘Research based upon samples remaining after a clinical test has been performed in which the subject will not be contacted or identified other than for record linkage purposes’. This would then cover blood, urine, biopsy samples and surgical specimens.

Moreover, there is also the problem of work which refines diagnostic practice, which also would be classified as ‘research’ under this Bill. Therefore, the Academy recommends that Part 2 Schedule 1 paragraph 13 should include, this and might read:

Epidemiological and diagnostic research using remnant samples

Amendment three: Coroners rules

The Academy recommends that the Clause 9 be modified to take account of the existing Coroners Rules.

Points of clarification one: Human Tissue Authority composition

The Academy recommends that the wording of Schedule 2.1(2) be changed to include the need for individuals to serve on the Human Tissue Authority with ‘*appropriate expertise in the use of human tissues for research*’.

Points of clarification two: existing collections, DNA analysis and morphological research

The Academy recommends that it be made absolutely clear that DNA analysis of existing collections of tissue held up to date immediately before the day in which Section 1 comes into force be exempt from the Bill.

Furthermore, the current drafting of the section on existing tissues raises problems for morphological research, which is part of many disciplines since it is included in ‘*anatomical examination*’ for ‘*anatomical purposes*’. The Academy recommends that this should be redrafted to encompass this concern, and also to make other non-morphological methods, such as chemical analysis of tissues, possible.

The Academy would like to see a much more rigorous definition of what is meant by ‘*DNA analysis*’.

Point of clarification three: ‘appropriate consent’

The Academy recommends that ‘appropriate consent’ be clearly defined. Furthermore, the Academy recommends that further thought be given to who can give consent, the settlement of disputes where these arise, who should be responsible for the seeking of consent and how this consent is then recorded so that it is easily accessible to all who need it. The Academy also recommends that the Bill be modified to protect the pathologist or research worker, in the event that consent obtained by a third party and accepted by the pathologist/researcher in

good faith turns out to have been obtained inappropriately. In addition the Academy recommends that Schedule 1 should separate '*removal and retention*' of tissues from the '*uses*' to which they are put, both from the viewpoint of consent and of punishment.

Point of clarification four: Education and training which is incidental to diagnosis and research

The Academy would ask that the terms '*incidental to diagnosis*' be further defined.

Point of clarification five: licensing

The Academy recommends that the licensing arrangements be modified to take account of the scale and number of tissue collections in the country.

Amendments

Blocks, slides and surplus material from surgical operations

One major concern is that the Bill makes no distinction between human material retained at autopsy and that obtained through surgical operation and other clinical procedures on living patients. Insofar as is known, there have been no problems with human material obtained through surgical operation etc. like those found at Alder Hey and elsewhere. Thus, while the Academy supports the proposals that refer to organs and tissues retained at autopsy, and agrees that there should be sanctions against those who transgress, it cannot agree that the same laws and sanctions should apply to tissues obtained through surgical operations etc. on living patients. Education, training and indeed research on surplus tissues obtained at surgical operation have long been the tradition in this country. Therefore, the Academy contests strongly the inclusion of such tissues as part of this Bill. A good deal of pathological work, which refines and improves diagnosis, depends upon procedures such as staining a few sections of tissue that have been taken from many anonymised cases of say, prostatic cancer. Such work cannot be described as audit or quality control, and must therefore be classified as research. We cannot believe that the Bill means to limit such work by making it subject to consent.

The Retained Organs Commission (ROC), as part of its consultation process, issued a separate consultation document on Blocks and Tissues. It was the Academy's understanding that such materials were to be treated totally separately from human material retained at autopsy. The Academy response to this consultation is available from: www.acmedsci.ac.uk

Therefore the Academy recommends that blocks and slides, and indeed surplus material obtained from surgical operations should be excluded from this Bill. Furthermore, the Academy recommends that the proposals and criminal sanctions discussed in the Bill should be applicable only to human material removed at autopsy, and that procedures for regulating surgically-acquired material be subject to a further period of consultation.

If this is not possible, then the Academy would strongly advise that Part 2 Schedule 1 Paragraph 13 should contain a new category as is set out in amendment two.

It may be that pre-legislative consultation would have avoided this inclusion; but the Academy is most concerned that, should the Bill be passed in its current form, then it will criminalise activity that is part of normal and proper clinical, pathological and research practice.

Public health and epidemiological research

The Academy is extremely concerned about the nature of consent as far as it will affect public health and epidemiological research. Specifically, the concern affects epidemiological and public health research using remnant samples. This can be defined as 'research based upon samples remaining after a clinical test has been performed in which the subject will not be contacted or identified other than for record linkage purposes'. This would then cover blood, urine, biopsy samples and surgical specimens. The proposed amendment (see below) recognises the reality that this kind of research is, in principle, no different from public health monitoring or clinical audit. Determining the proportion of women attending antenatal clinics who are hepatitis B positive or HIV positive is an example of 'public health monitoring'. This, in principle, is no different from determining the proportion of people with and without heart disease who are Chlamydia positive to see if Chlamydia infection may be a cause of heart disease. However, under the Bill, as it is currently drafted, this would be classified as

epidemiological research. There is surely no logical reason why one should be done without the other.

The Academy believes that the bill, as currently drafted, would have a highly detrimental effect on public health and epidemiological research. Therefore, the Academy recommends that Part 2 of Schedule 1 of the Bill should be amended as is set out below:

13 Epidemiological Research using remnant samples. This can be defined as 'Research based upon samples remaining after a clinical test has been performed in which the subject will not be contacted or identified other than for record linkage purposes'. This would then cover blood, urine, biopsy samples and surgical specimens.

Moreover, there is the problem of work that refines diagnostic practice, which also would be classified as 'research' under this Bill. Therefore, the Academy recommends that Part 2 Schedule 1 paragraph 13 should include, this and might read:

Epidemiological and diagnostic research using remnant samples

Coroners rules

Clause 9 note 26 states that organs and tissues may only be retained with the 'consent of the Coroner', yet Rules 9 and 12 of the Coroners Rules (1984) oblige the pathologist to retain such tissues if they are material to the cause of death. There is no mention of consent, only the time that such tissues may be retained. Thus pathologists will be subject to conflicting advice.

The Academy recommends that the Clause 9 be modified to take account of the existing Coroners Rules.

Clarifications

Human Tissue Authority composition

The Academy is concerned about the membership of any Human Tissue Authority. The Bill is not specific about who should be represented on the Authority, and we would be anxious that individuals with extensive experience of the use of human tissues in research be invited to join.

Therefore Academy recommends that the wording of Schedule 2.1(2) be changed to include the need for individuals to serve on the Human Tissue Authority with 'appropriate expertise in the use of human tissues for research'.

Existing collections, DNA analysis and morphological research

A major concern of the Academy has been the status of existing collections and their use for research. We welcome the clear statement in Section 7 (1) and (2) that the purposes listed in Section 1 and in Schedule 1 will be allowable without appropriate consent on all tissues held up to date immediately before the day in which Section 1 comes into force. This is a measure which the Academy pressed for in its response to the ROC consultation paper on Blocks and Slides, see the Academy website: www.acmedsci.ac.uk

However, Sections 46 and 47 of the Bill cause especial concern. In Section 46 it is difficult to understand whether or not it will be an offence to analyse any human DNA in existing

collections without qualifying consent. Section 47 states what purposes human DNA can be analysed without consent. Schedule 5 discusses analysis of DNA for scheduled purposes for relevant material, which we would assume includes tissues retained after surgical operation. It states that: '*this paragraph applies where the results of an analysis of DNA are to be used for a purpose which is specified in Schedule 1 and that the analysis should be regarded as being the subject of qualifying consent if the use of the relevant material for the specified purpose is authorised under section 1(1) or (7)*'. Section 7 deals with existing holdings, and it is by no means clear whether or not this means that qualifying consent is or is not needed for the analysis of DNA in pre-existing collections.

The Academy recommends that it be made absolutely clear that DNA analysis of existing collections of tissue held up to date immediately before the day in which Section 1 comes into force be exempt from the Bill.

Furthermore, the current drafting of the section on existing tissues raises problems for morphological research, which is part of many disciplines since it is included in '*anatomical examination*' for '*anatomical purposes*'. The Academy recommends that this should be redrafted to encompass this concern, and also to make other non-morphological methods, such as chemical analysis of tissues, possible.

The Bill is not specific about what '*DNA analysis*' means. Stated as badly as this, it would include any sort of genetic analysis on material *in situ* in sections from paraffin-embedded tissues, such as FISH to determine interphase cytogenetics or gene copy number; any sort of generic DNA or indeed mitochondrial DNA fingerprinting of stored tissues - in fact any genetic manipulation of the patient's DNA. Moreover, it apparently would allow work on RNA, without consent, from which much information about DNA can now be obtained

The Academy would like to see a much more rigorous definition of what is meant by '*DNA analysis*'.

'Appropriate consent'

Under the Bill, consent will be required for research to be carried out on surgical or cytological material acquired during therapeutic or diagnostic procedures. However, the Bill is especially opaque about the nature of any consent that will be required for research.

Unless consent is generic, and applies to all conceivable types of research that could be carried out on donated tissues, then any consent will be meaningless and researchers will need to re-visit patients or their relatives to acquire consent for procedures that were not previously envisaged. Clause 5 subsection 1 indicates that where there is consent to use material for one purpose, then it may not be used for another. Does this apply only to different activities listed in Schedule 1? Will generic consent allowed to apply to all these activities?

Moreover, in what terms will generic consent for research purposes be couched? It is impossible to envision the future research purposes to which human tissues might be put, and in no circumstances do we want to revert to the situation where researchers are having to return repeatedly to the patient or his/her relatives to acquire further consent.

In Section 4 '*Nominated Representatives*' where '*one or more persons*' are appointed, what is to be done if there is disagreement between those two persons? This is not addressed, nor is the problem of adults who lack the capacity to consent. The Academy is also surprised at the apparent omission of grandparents from the list of qualifying relationships.

Moreover, there is much ambiguity about who should obtain consent. The Explanatory Notes, paragraph 77, states that '*NHS Pathology Services should therefore be meeting these*

(consent) standards or be in the process of complying'. This would be largely impossible, since pathologists are not in a position to seek consent. It has to be the individual who is responsible for the removal of tissue from a living person, who is usually the clinician caring for the patient. This should be made clear.

There is no mention in the Bill of how consent will be recorded: the scale of this exercise is enormous, with over three million solid tissue samples and some 30 million blood samples being processed by the NHS from living patients every year. Some thought has to go into how this will be done.

The sanctions and penalties in the Bill only appear to apply to those individuals such as pathologists or research workers who perform the activities listed in Schedule 1, whereas it is assumed that those who seek consent, or give consent, are outside the law. This assumes that those seeking consent, which should be the clinician responsible for the care of the patient, or giving consent – the coroner – have done so appropriately and have explained fully the implications of the examination to be carried out. This is often not the case and if such consent or explanation is not fully explicit, leading to a complaint, then the pathologist or research worker will receive the sanction. This is not appropriate.

The Academy is also concerned that Schedule 1 refers to the '*removal and retention*' of tissue, for example at autopsy and also '*the uses*' of that retained tissue in education, training or research. This implies that each requires (a) the same level of consent and (b) will carry the same punitive sanctions. The Academy believes that this also is not appropriate.

The Academy recommends that '*appropriate consent*' be defined with the above issues in mind; that further thought be given to who can give consent, to the settlement of disputes where these arise, who should be responsible for the seeking of consent and how this consent is then recorded so that it is easily accessible to all who need it. The Academy also recommends that the Bill be modified to protect the pathologist or research worker should consent be inappropriately obtained or given. We would also recommend that Schedule 1 should separate '*removal and retention*' of tissues from the '*uses*' to which they are put, both from the viewpoint of consent and of punishment.

Education and training which is incidental to diagnosis or treatment

In Schedule 1 - Part 1 we are concerned about the precise meaning of '*education or training which is incidental to medical diagnosis or treatment*'? Does this refer to education or training before medical diagnosis has been made (that is, where a trainee pathologist views a slide before a diagnosis is reached in consultation with a senior pathologist); or to the use of slides which have been made for diagnostic purposes - and which it appears it will be permissible to store and use for clinical audit, public health monitoring and quality assurance purposes without consent - after that diagnosis is made? Often, in cytology, the diagnosis may not be confirmed for some time afterwards – when can that sample then be used for training?

The Academy would ask that the terms '*incidental to diagnosis*' be further defined.

Licensing

It is clear that under the Bill, some form of licensing of institutions which house tissue collections will be required. The Academy would request that such licensing arrangements are reasonable and that further consideration be made to the scale of the matter. For example, Paragraph 81 of the Explanatory Notes appears to show that the drafters think that there are only about 5 tissue banks for research in England and Wales. In fact, most teaching

hospitals and research institutes would have each have in excess of five such banks. The scale is really quite enormous, and as such must be taken into account.

The Academy would therefore recommend that the licensing arrangements be modified to take account of the scale and number of tissue collections in the country.

Professor Nicholas Wright, FMedSci
On behalf of the Academy of Medical Sciences
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