

Academy of Medical Sciences

Response to the Retained Organs Commission Consultation Document on:

- Unclaimed and unidentifiable organs and tissue
- A possible regulatory framework

This response was prepared by a working group chaired by Professor Ian Lauder FMedSci. The other members were Professor Peter Furness, Professor David Graham FMedSci, Professor John Harris FMedSci and Professor Nick Wright FMedSci. The response has been endorsed by the Council of the Academy.

General observations and principal comments:

- 1) **A distinction must be made between post mortem tissue and human material which is “left over” after surgical resections, biopsy or blood sampling.** Tissues from living patients which are ‘surplus’ to diagnostic requirements very rarely have the emotional associations of post mortem tissue and there is sound evidence that the public does not regard such samples in the same way. For example, in a recent analysis of events at the Peterborough Tissue Bank, 99% of 2,026 patients gave informed consent in response to a request for transfer of such surplus tissue *to commercial organisations*. It was clear that the level of approval of surplus tissue being used for the good of all in a non-commercial setting would have been even higher. We must respect the rights of the tiny minority, but we must not ignore the wishes of the vast majority.

If procedures designed to satisfy the emotional requirements of handling post mortem tissue were to be applied to all human tissue the result would be disastrous for teaching and research. This would work against the common good and hence damage the very individuals the regulations are attempting to protect.

With respect, we observe that the constitution, membership and experience of the Retained Organ Commission is appropriate only to the question of post mortem tissue. In terms of importance, the Commission should realise that post mortem tissue is used in teaching and research to a much smaller extent than “surplus” tissue.

If (contrary to our recommendations below) it is deemed necessary to have a single “human tissue authority” responsible for oversight of all types of human biological material then it will be vital that this authority recognises the distinction between these two types of material. The composition of such an authority would need to include people with relevant expertise.

- 2) The main trend in biomedical ethics in recent years has been patient centred, emphasising individual autonomy and rights.¹ We fully appreciate and agree wholeheartedly with the need to respect individual rights and desires, which has been the focus of the Retained Organ Commission's approach to the problem since its inception. However, **there is a real danger that if we focus *exclusively* on the rights of individuals we may lose sight of that mass of**

¹ However, it is notable that in that branch of bioethics which is concerned with environmental matters rather than medicine, the reverse is true. In environmental ethics the common good, or preservation of the ecosystem, is the main beneficiary and the exercise of individual autonomy (i.e. individuals choosing to pollute or use natural resources) is regarded as the main threat.

individual rights which constitutes the common good. The result would be damage to all, including the few individuals whose rights are supposedly being upheld.

The National Health Service was originally conceived and still exists for the common good, principally in the form of providing good health care but also in providing research intended to improve that health care.

Using human tissue for teaching, quality control and research is central to the work of the National Health Service on behalf of the common good. We are concerned that in the aftermath of the traumatic events at Alder Hey, hard cases may make bad law. Regulations designed to eliminate *any possible* future infringement of individual wishes risk damaging the good of all, both by blocking valuable work and by utilising resources which would otherwise be available for the benefit of all – including the individuals whose protection is being sought.

Regulation is undoubtedly required, but the more restrictive and bureaucratic the regulation, the more it will inhibit work done for the common good.

For example, we note that some of the proposals under discussion – such as “reverent disposal” of tiny quantities of blood or small groups of individual cells – can only have been made on the basis of a belief in an *absolute* requirement to support an individual right (to control what happens to biological material). There is no discussion of the practical consequences, which include the use of resources to satisfy such proposals; resources which would otherwise be available for work directly towards the common good. **Sensible balances must be struck. This may be impossible on first attempt, especially in the current climate; there must be a mechanism for review and revision.**

Any ‘right’ is meaningless unless someone or some body undertakes the obligation to guarantee that right. In the case of the NHS, the individual right to health care is guaranteed by society. Those individuals who exercise their right to the health care provided by the NHS are also members of society, so they have at least some level of obligation to facilitate the continuing function and improvement of the NHS, as far as is reasonable and within their capacity.

We believe that the majority of people, understanding the possibility of giving benefit to society - benefit to the NHS from which they themselves derive benefit - would make an altruistic rather than a selfish decision. Such a socially responsible decision should be chosen, not enforced, and some may have good reasons not to give consent. **However, we believe that where individual wishes are not known and cannot reasonably be ascertained, by default any possibility of supporting the common good should become a major factor in deciding the most appropriate course of action.** If this is not accepted, the Retained Organs Commission risks damaging the rights of many individual patients, now and in the future.

- 3) As noted above, to perform religious ceremonies for the disposal of sub-microgram amounts of tissue would be absurd. The logical extension of this would be to consider the same for sharps boxes, sanitary towels, and soiled bandages. We are firmly of the belief that small tissue samples deserve less rigorous regulation than whole organs. For this and many other reasons outlined below we believe that **microscope slides and tissue blocks, as well as banks of frozen biopsies, used for examinations where fixation is a technical disadvantage, should be retained as part of the medical record.** Disposal of these important specimens should be avoided wherever possible.
- 4) Many of the remaining problems in this area result from members of the public having an incomplete understanding of how human tissues are – indeed, must – be used for the good of everyone. We note that the commission has proceeded with commendable efficiency through most of its “aims” as identified in Annex 4. The notable exception appears to be item 7, **“To restore public confidence in the post mortem system and to improve public understanding**

of the need for retention of organs and tissues". Indeed, we are not aware of any initiative from the Commission directed solely towards this aim.

It may be that this apparent lack of effort is actually a consequence of the subject being difficult to promote in the public communication media. If so, this provides an argument for redoubled effort. We have no doubt that the Retained Organs Commission will not lack well qualified volunteers to assist it in this work, if it merely asks for such support. We contribute one specific suggestion in our response below; the opening of pathology museums to schools and the public as an educational resource.

General comments on Section V, a framework for regulation.

- 5) In the introductory text in this section, the descriptions of archives seem not to distinguish between organs, tissue, blocks and slides. Furthermore, 'acute surgical and medical treatment' is mentioned, suggesting that regulation of all these components is included in the discussion. Issues relating to material from surgical resections are mixed with the discussion of post mortem tissue, and in some cases it is not clear which is being discussed. **Absolute clarity is needed here, since as we noted in our previous comments, very different levels of public concern apply. If regulations designed for whole major organs are applied to all human biological material the result would be farcical, and would damage patient care.**
- 6) In the section relating to the ethical basis of regulation, the issue of whether a relative who does not want to know the details of post mortem procedures can be considered as providing "informed consent" is not discussed. As before, in such circumstances we believe that any possibility of providing benefit for the whole of society should be the deciding factor. Relatives in Scotland have clearly expressed the view that collections of human organs should be retained if they can be used for ethically approved research.
- 7) The document does not consider all possible regulatory frameworks, and indeed much of the text suggests that a decision has already been made to establish a Human Tissue Authority. We are concerned that this will result in excessive bureaucracy and hence waste resources which could be used for the good of all. **We note that much of the proposed work of this Authority seems to duplicate that of existing bodies, notably the existing NHS Research Ethics Committees. We see no reason why these existing ethics committees should not be given responsibility for the oversight of local collections of post-mortem tissue.** Research Ethics Committees already take responsibility for safeguarding living patients when experimental interventions are planned upon their bodies. **We find it difficult to understand why a higher standard of supervision could be required to protect the tissues of the dead than is accepted as protection for the intact bodies of the living.**
- 8) Another mechanism of scrutiny that is not mentioned is examination by the public. Since Alder Hey most pathology museums have closed, but in the past some have been open to the public. This is still the case in other countries; we commend the work of the Virchow museum at the Charité Hospital in Berlin, which is open to the public and where parties of schoolchildren are educated. Surely this is the ultimate test of what is acceptable to the public. It demonstrates that nothing is being hidden and it also assists in educating the public about the benefits of studying human tissue, which is one of the Retained Organs Commission's stated aims. **We therefore suggest that the Retained Organ Commission should encourage museums to be re-assembled and made available as an educational resource - for all.** A museum which is open to the public should require little regulation; it is open for inspection every day.

With reference to the specific questions:

Principles (Paragraph 16)

1. *Are there any other ethical principles which should inform all action proposed in relation to retained organs or are those set out above both right and sufficient?*

The ethical principles set out are right, but not sufficient. An intention to provide benefit for the whole of society is surely an important ethical principle. There is no mention of the role of post mortem examination and the use of human tissue in the good of all, in terms of improving the health service. The issue of public benefit always needs to be considered in the context of use of post mortem material even if it is judged of lesser importance than personal family “rights”.

To carry out a consented post mortem requires altruism not only from the relatives who give consent but also from the doctors, who, (for the good of all) must invest time in requesting appropriate consent. They do this despite the fact that the investigation is quite likely to reveal their diagnostic errors. This altruism should be explicitly recognised. There is good evidence that the precipitate drop in numbers of ‘consent’ autopsies carried out since January 2000 is due much more to a reduction in the number of autopsies requested than the proportion where consent is given.

Type of material to be included (Paragraph 17)

2. *Would it be helpful to identify and define a new term such as “human material” to refer to body parts (including whole bodies in the case of pre-term and still-born babies), organs, part organs, tissue and other substances “taken” from the body during post mortem examinations. Should such a definition include or exclude:*

- *standard tissue blocks, which might be excluded on the basis that such blocks are made by replacing a large proportion (60% to 80%) of the human material in the blocks with paraffin wax and that such blocks are relatively small (although even standard blocks may contain whole or substantial parts of organs from small babies)?*
- *slides, which might be excluded on the basis that these contain a tiny amount of material which has been chemically changed even more than tissue blocks?*
- *bodily fluids and other self-regenerating material such as small amounts of skin, hair, teeth and nail clippings?*
- *other exclusions set out in paragraph 18 ?*

If (contrary to our advice) a decision is made to consider **all** material of human origin within the same regulatory framework for handling and disposal, then the use of a more generic term such as “human material” will be appropriate. This term is generally taken to include all samples of human origin including both organised tissue and body fluids, hair, teeth, nail clippings, urine, even faeces, which contain DNA; to imply otherwise invites misunderstanding.

To exclude bodily fluids on the basis that they are “self-regenerating” is not appropriate after death and, for example, would take the retention of post mortem blood samples outside any regulatory system. Since the present and future possibilities for research which might arise from storage of blood samples are high on the ethical agenda, some of the proposed separations of human material are artificially inflexible.

Current experience suggests that there is a natural and sensible split between organs and part organs (major tissue in the McLean² definition) on the one hand, and blocks and slides on the other. Relatives can understand and accept the separation between these items. **We strongly believe that blocks and slides can be excluded from this process and could be taken to be part of the medical record. Along with blocks and slides we would also exclude banks of frozen biopsies, used for examinations where fixation is a technical disadvantage.** It would in any event be

² McLean Report – Independent Review Group on Retention of Organs at Post Mortem – Final Report, issued November 2001.

completely impractical to return all materials to the body, as performing a post mortem examination inevitably results in blood and other body fluids passing into the drainage system. If fluids are to be included in the list of retained human items, the fact that some fluids are inevitably lost during the process of post mortem needs to be explicit.

The status of transplanted organs, originally provided as a gift by others, needs to be made explicit.

The reasons for retaining organs and tissue (Paragraphs 20-21)

3. *Is the Commission right to believe that respectful use of retained organs and tissue, following properly informed consent in the context of knowledge and understanding of what is involved, is an important outcome for many relatives and families? Are there any other factors relating to the value of organ retention which the Commission needs to be aware of?*

We believe that this is indeed an important outcome for relatives. As indicated in item 3 of our general comments, we believe that the Retained Organs Commission has a major contribution to make in publicising the benefits of post mortem practice, alongside the efforts of the medical profession in this direction. It is important for families to understand that they have an opportunity to contribute in this way to the public good.

SECTION IV:

RESPECTFUL USE AND DISPOSAL OF UNCLAIMED AND UNIDENTIFIABLE ORGANS AND TISSUE

Unidentifiable material taken between 1961 and March 2000 (Paragraph 33)

4. *How should the unidentifiable organs, tissue and other material from before March 2000 be dealt with? Should it all be reverently disposed of or should it be carefully reviewed and some retention authorized on the basis of the potential contribution made to teaching and research?*

By today's standards, unless specifically consented (usually as part of a defined research project, e.g. brain donations in dementia research), all material retained before 2000 is judged to be of questionable consent status. There seems to be little benefit in subdividing material retained prior to 2000 on the basis of unclear legislative steps.

The potential future contribution of individual tissue samples to teaching and research is impossible to predict. This question assumes that such prediction is possible; but the Commission itself has already quoted examples of the use of tissues from the 1919 influenza epidemic and the investigation of the origins of CJD. We could provide many other examples. We are confident that similar problems will arise in the future, and if the Retained Organs Commission has caused relevant specimens to be destroyed, investigation will be blocked.

For material that has not been reclaimed by relatives, we therefore view the introduction of a policy of **automatic** disposal as harmful to public interest and the evidence suggests this is not what relatives want. Rather, **archival material should be reviewed and its retention should be encouraged because there is always a possibility that it may be useful in ethically regulated work towards improving human health by research or education.**

5. *In particular should*

- *research material now anonymised but where there is evidence that ethical approval was given for the research on the basis that the consent of relatives or families be obtained,*
- *anonymised slides used for QA, audit or teaching purposes which the Commission has already concluded should be kept for as long as they are useful -*

also be retained?

We assume that this question relates only to post-mortem tissue.

Once again, it should be permissible to retain samples for as long as they are **possibly** useful, unless there is positive evidence that this would be contrary to the wishes of the donor or relatives.

Any approval or consent for the original use implies that the donors looked favourably on use for the common good. To destroy them would undoubtedly be contrary to the common good, therefore probably contrary to the wishes of the donors, had those wishes been known in detail. As noted in our general comments, where there is uncertainty then potential to benefit all should be a major deciding factor.

It is important that arguments for destruction should be carefully reasoned and not based simply on perceived hostility to past pathology practice.

(Paragraph 34)

6. *Should unidentifiable blocks used for control purposes continue to be used for such purposes? If not some Trusts may have no source of material for controls – does this matter?*

This certainly does matter! Unidentifiable samples for control purposes must remain available if the NHS laboratory services are to continue to function, at least until such time as appropriate consented material becomes available. The loss of such material would damage patient care and the rights of the individuals the ROC is attempting to protect would be compromised.

Unidentifiable material taken since March 2000 (Paragraph 35)

7. *Is it the case that there are no separate use/ disposal/ return issues in respect of unidentifiable material taken since March 2000?*

We are not aware of any such issues in relation to post mortem tissue, unless there has been an error, because since March 2000 post-mortem tissue should not have been deliberately anonymised without consent for use for the common good, at least in some form. Our response to Question 5 then becomes relevant; **such consent provides evidence of goodwill towards use for the common good; forced disposal would be against the common good and hence unethical.**

For the future we note a tension between the work of the Retained Organs Commission and the advice from other sections of the Department of Health in relation to research using human tissue, where *irreversible* anonymisation of samples is recommended wherever practical. This recommendation appears to have been made without consideration of the fact that it makes it impossible subsequently to follow the wishes of relatives (or patients). Such wishes may change, as is recognised by Department of Health guidance on consent.

Unclaimed Material (Paragraphs 36 – 39)

We first note that when the ROC says that NHS resources have been ‘stretched’ it is being euphemistic; resources have been ‘used’. ‘Stretching’ limited resources in one direction inevitably means ‘contraction’ in another.

8. *Has there been sufficient publicity to ensure that all those who might want to know what happened following a relative’s or family member’s post mortem will have made inquiries?*

We believe sufficient publicity has been given. We note that in Scotland the renewed advertising campaign has been deliberately low-key following research which suggested that there was a possibility of doing more harm than good by continued reminders. Reminders may produce unnecessary distress to grieving individuals who have already made enquiries; some will regard such publicity as evidence that hospitals are still hiding something. The renewed Scottish advertising campaign has elicited only a few new enquiries. Attempts to undertake “cold calling” to

seek retrospective consent for the retention and use of archival material has been actively discouraged by family support groups in Scotland and is contrary to standard advice given by research ethics committees.

9. *If not, should further use or disposal of organs and tissue be embargoed and further publicity be given? And if so, for how long a period?*

Whether or not a decision is made to seek further publicity, there should be no embargo on further use of material provided that use is ethically approved. To do so would be contrary to the common good. Clear central guidance is needed on this issue so that a consistent, country wide approach can be adopted by ethical committees. This is the position adopted by the Scottish Executive in the light of advice given by parents' groups. If there is to be further publicity, it is clear that any disposal of archival organs and tissue should be postponed until the end of such a campaign.

10. *Should special efforts be made to alert members of ethnic minority groups to the possibility of organ retention?*

Discussions with relevant ethnic groups suggest that further efforts are not required. It seems likely that those ethnic minorities who are averse to these practices did not consent to hospital post mortems in the first place. However this constraint will not apply to medico-legal post mortems performed before 2001, so it may be appropriate to exercise additional care when using material from this source. Such advice is within the remit of research ethics committees.

(Paragraph 40-41)

11. *In general terms, is it acceptable to continue to use for respectful and beneficial purposes organs and tissue about which no inquiry has been made by relatives?*

We view the continued use of post mortem organs and tissue as vital for medical research and the continued functioning of NHS laboratories, all for the common good. Its use is entirely acceptable provided that the work is ethically approved. As explained in our general comments, we strongly believe that the *possibility* of benefit for the good of all should be the major factor in deciding what to do when individual wishes are not known. We should assume altruism unless there is evidence to the contrary.

Unclaimed material taken before 1961 (Paragraph 42)

12. *Should this material be reviewed and, if useful, retained? If so, should such a review be carried out straight away or be delayed either until the regulatory framework is in place (see Section V) or until a specified period has passed (see paragraph 37 above)?*

There is no question but that this material should be retained if it is useful, or if it might *become* useful (as for questions 4-6). Much of it is unique and will never be seen again in current practice. The question should be what is the justification for *disposal*, not what is the justification for retention. The older the material, the more likely it is to be of a type which cannot be replaced or provided from any other source.

Unclaimed material taken between 1961 and March 2000 (Paragraph 43)

13. *If there is evidence that the material was taken with informed consent, should it not be disposed of until the use for which consent was given has been completed? Should it then be disposed of respectfully? Or should such material simply be periodically reviewed and disposed of respectfully when it could not provide further benefit?*

If material was taken with informed consent for research, the ethical imperative is to pursue such research and a new directive to dispose of such material could be viewed as unethical. These samples have been given for the benefit of the public; if there is a possibility that the public may obtain further benefit from their use or study (in ethically approved projects), where is the ethical justification for their destruction? It should be permissible to retain tissues obtained with informed consent until no **possible** future use can be envisaged. As noted above, the future value of such samples can be difficult or impossible to predict. *'When it could not provide further benefit'* is an absolute statement which will probably never be satisfied with certainty.

14. *Should the lack of inquiries from relatives be considered to equate to consent or to "lack of objection"?*

For work which is directed to benefit the common good (and which has no possibility of harming the tissue donor, as she/he is dead) a lack of inquiries should be taken to represent implied consent, which should be sufficient to permit non-controversial uses which are clearly intended for the benefit of society. We should assume altruism unless there is evidence to the contrary.

Work which may affect living relatives (such as genetic studies on identifiable samples) requires separate consideration, but such questions are within the remit of research ethics committees.

15. *Does the possibility that some of the material was taken without informed consent but relatives have since died or are too distressed to make inquiries suggest that all unclaimed material should be disposed of except that for which there was evidence of consent?*

Disposal at the present time cannot by definition provide comfort to dead relatives, or to those who are 'too distressed to make enquiry' as they will not know of its disposal. Therefore we believe that the balance of benefit shifts to the public good if use can be made of it. Disposal in these circumstances would be a pointless exercise, wasting resources which might otherwise provide real benefit for patients.

16. *Should material which can be identified as having been taken from members of religious groups which require bodily completeness at the time of the funeral be disposed of appropriately in the absence of positive evidence of relatives' consent?*

This is not considered a practical proposal. The ethnicity of samples may sometimes be recorded, but ethnicity cannot be assumed to equate to a specific religion. Identification as belonging to a specific *religious* group can rarely be made with confidence unless the matter has been discussed with the relatives, whereupon the appropriate course of action should be obvious and will probably have already been taken.

17. *Should the utility of such material be taken into account in determining whether or not unclaimed material should be disposed of? In particular should such material only be disposed of if it was clearly irrelevant to present purposes? Such a proposition might be based on the determination that the value of the material to society outweighed the possibility of individual offence being caused by its retention.*

For reasons explained in our general comments above, we believe that wherever there is no known objection it should be permissible to retain material which has **any possible** future ethical use for the good of all. The *future* usefulness of archived samples cannot be predicted, certainly not merely on the basis of relevance 'to present purposes'.

There is no justification for wholesale disposal of unclaimed material. Such destruction will not expiate past practices which are now considered blameworthy.

18. *Should there be any special consideration given to material of particular historical or scientific significance?*

Only in so far that the arguments for retention are even stronger. Again, consideration of the good of all should be emphasized.

Unclaimed Material taken since March 2000 (Paragraphs 45-46)

19. *Should any further measures be introduced to ensure that organs and tissue are in future only retained for good cause and with properly informed consent? Should an exception be made in respect of blocks and slides?*

We are alarmed to note the suggestion that blocks and slides should NOT be retained. Review of historic blocks and slides is essential from time to time, especially as medical knowledge advances. This is important both for general public health and sometimes for the particular family. It is also pertinent to point out that almost by definition the benefits of review of a particular case may become evident only after some considerable time has elapsed. As medical knowledge advances it is common to be asked to re-examine post mortem blocks and slides which may have been retained for decades, in the expectation that review of the archival case may establish with certainty a particular diagnosis in a living family member. In cases of sudden death in childhood, later review of blocks and slides is extremely important if a second death occurs in the family. Once again, such a proposal seeks to provide absolute protection of some individual rights but in so doing would inflict much more serious damage on others.

Recognition of these imperatives in Scotland has led to a resolution that blocks and slides are to be clearly assigned to the medical record in future (provided that initial consent for retention of such material was provided in the setting of the hospital post mortem) and therefore their status is unlikely to be questioned subsequently by the families. This measure enables the cause of death to be reviewed and verified in the light of new information or advances in medicine, and to be subjected to audit to ensure that post mortems are performed to a high medical standard.

Disposal Issues (Paragraphs 47-49)

20. *Are the requirements for respectful or reverent disposal correctly identified? When should the additional measures be used?*

Current post mortem consent forms list a range of disposal options and allow families to choose. Present experience suggests that funeral directors, bereavement counsellors and pathology departments are working well together in adhering faithfully to the logical conclusions of such choices.

However, during post mortem some blood and fluid will enter the drainage system. Tiny fragments of tissue will inevitably be thrown away in the process of preparing microscope slides. 'Respectful disposal' cannot sensibly be arranged for such material.

For reasons given in our general comments, it may be appropriate to avoid mixing post mortem tissue and "surplus" tissue from surgical resections during disposal.

21. *Is incineration at hospitals or designated clinical waste disposal sites ever appropriate for human material? e.g. cotton 'waste' from operating theatres which might have very small amounts of human tissue still adhering to it.*

We first note that this question mixes issues relating to surgical waste and post mortem tissue, which for reasons given above we consider to be invalid.

However, it illustrates that **a sensible limiting point is required. To pretend there is an absolute requirement could lead to absurd ceremonial for the disposal of individual cells. We suggest**

that a practical and appropriate limiting point would be fragments of solid human tissue any larger than those in a conventional histology block. We should remember that normal physiological processes result in each adult shedding several grams of tissue every day.

A lower limiting point may be appropriate for the smaller samples produced at paediatric post mortem.

The only appropriate response is that incineration is the safe and practical mode of disposal for such material, though it may be kept separate from other types of waste.

The Retained Organs Commission does not seem to have addressed the problem of disposing of infected human material which already poses hospitals with enormous disposal problems. **In practical terms incineration must continue.**

22. In respect of organs and tissue removed in the past should disposal always be accompanied by a ceremonial element? Is the same type of ceremony appropriate for all material, or might different procedures be appropriate depending on (for example) whether the material concerned was a whole organ or a slide? If so, on what basis should the distinction be made?

We believe that a simple, single, multi-faith ceremony is appropriate for post-mortem material above the limiting point discussed in our answer to question 21, though we note with sadness that any ceremony is likely to offend some. **The prospect of a ceremony for the disposal of a microscope slide containing less than one microgram of tissue seems absurd.**

23. In respect of material removed in the future, when relatives should have had an opportunity to express their views, should the same considerations apply or would a specific ceremonial element only be appropriate if, having been informed of this potential element, it was requested by relatives?

In the absence of a specific request from relatives the simplest of arrangements are appropriate provided they are compatible with confidentiality, respect and safety. We should comply with the wishes of relatives wherever possible and practical, though relatives should assume responsibility for carrying out anything beyond a simple ceremony.

If consent has been given to produce blocks and slides, these should be retained as part of the medical record.

24. Should all human material removed in the future be disposed of in future by cremation or burial at a cemetery if relatives wish it? Who should pay for the additional costs involved?

This should be permissible for any material above the limiting point discussed in the answer to question 21. However, the National Health Service cannot afford to pay for every possible request so we believe that the costs of separate cremation or burial should be borne by relatives.

There may be a case for providing financial help for relatives' arrangements in the context of medico-legal autopsies where the family had little or no say in the process. Central funding would assist in this regard.

In the case of fetuses, where the parents do not wish to make arrangements themselves these should be sent individually to the crematorium.

It should be made clear to parents that there may be no ashes resulting from such a cremation, even from many full term babies. Cremated organs will rarely yield any ashes for relatives to reclaim.

Paragraph 50

25. *How should the conflicting requirements for reverent disposal of different religious faiths be met in relation to unidentifiable organs and tissue?*

If organs are unidentifiable then conflicting requirements cannot possibly be resolved. A simple multi-faith service is the best that can be achieved. Cremation would be the preferred method of disposal.

Options for disposal (Paragraph 51-52)

26. *Should crematoria/cemeteries be asked to make special arrangements for disposal of unidentifiable or unclaimed material? This would probably require a change in the law. Would this be justified for what might be a “one-off” event?*

If we are referring only to post mortem material above a certain size (as discussed above) then disposal at a crematorium is probably preferable. However we believe that wherever possible such material should continue to be retained because of its potential benefit for the good of all, as discussed above. We would therefore hope that the amount of material requiring disposal would be small.

Concerns about the disposal of large volumes surely arise only if surgically resected tissues from living patients are included. For reasons given above we firmly believe these specimens deserve completely separate consideration. It is extremely unusual, even since Alder Hey, for living patients to express any concern about the manner of disposal of resected diseased tissue.

The phrase in this question ‘*for what might be a “one-off” event*’ contrasts with the earlier comment about possible ‘*round the clock working*’ (p. 23). This emphasises the lack of clear distinction in the consultation document between post-mortem and surgical specimens.

27. *Should special arrangements be made to introduce new NHS disposal arrangements?*

On the understanding that this document is exclusively about post mortem tissue, we anticipate that the amount of tissue to be disposed of in the future will be small and therefore new facilities will not be needed.

28. *How should attendance of relatives at reverent disposal ceremonies be facilitated?*

This depends on the individual situation involved. Such ceremonies could be held at defined times, where relatives can be invited to attend if they wish. It would be better if they were held at a crematorium.

As noted above, relatives should be informed beforehand that incineration / cremation of many specimens will leave little or no residue or ash.

SECTION V:

A FRAMEWORK FOR THE REGULATION OF COLLECTIONS OF HUMAN BODY PARTS.

The ethical basis for regulation (Paragraphs 63-65)

29. *Should these values be used to govern the activities and day-to-day regulation of collections of human organs and tissue?*

Yes. However we note that although the ethical importance of ‘doing good through medical research’ is mentioned in paragraph 65, this (or any other mention of the common good) is completely absent from the list in Paragraph 64.

Furthermore **we should enhance the status of item (a) (any formally expressed opinions which the deceased recorded prior to death)**. We consider it perverse that even if an individual expresses and records clear wishes that his or her tissues should be available for transplantation or research, these wishes can be over-ridden by relatives, or may be ignored if the relatives are not available to confirm their agreement.

The legal profession does not permit relatives to alter the last will and testament if they find its contents distressing, unless its contents are illegal. At present there is legal uncertainty about ownership of a human body after death – but its ownership is never questioned before death. If legal ownership of a dead body becomes possible, then it surely follows that the previous owner should enjoy full rights to control its use and disposal, just as with other property. To remove this right, or to hand it to others, would be unjustifiable intrusion by the state.

The Royal College of Pathologists has recently recommended that **the NHS should encourage all patients to record explicitly their wishes in relation to a variety of matters, including involvement in teaching, the use of tissues removed at operations, organ donation and post-mortem procedures.**³ We commend some such approach, which should cover the whole population. An alternative might be a questionnaire with every set of electoral papers. It would place the decisions where they rightfully belong, and in doing so would relieve relatives of a responsibility to take potentially agonising decisions, which they may later regret, at a time of great distress.

Statutory Regulation (Paragraphs 66-67)

30. *Should there be a formal statutory-based system with a regulatory authority with statutory powers?*

We note that the text provided by the Retained Organ Commission elsewhere clearly answers this question in the affirmative. **For reasons given in our general comments above we have grave reservations about this move, and suggest that local ethics committees are better placed to undertake supervision.** Despite this we find ourselves obliged to answer questions on the assumption that such a body will be created. These answers should not be taken to indicate that we agree to its creation.

If such a body is established then considerable effort should be made to minimize bureaucracy. Bureaucracy will use the resources of hospitals and universities and thereby limit their potential for doing other work intended for the public good.

31. *What sanctions should apply to keeping an unlicensed/unregulated collection or to breach of conditions laid down by the Act or associated Regulations?*

We believe that the General Medical Council and the employing authorities already have sufficient power, in the form of the usual professional disciplinary procedures, to regulate collections at the present time and in the future. Decisions of Research Ethics Committees are already effectively enforced in this way. Custodians of collections are currently answerable to these authorities who can impose punitive sanctions and/or penalties if necessary.

(Paragraphs 68-71)

32. *Should there be a formal licensing system or a more informal registration procedure – or a mixture of both according to the size, duration and significance of the collection? Should it have an inspectorate function?*

³ Transitional guidelines to facilitate changes in procedures for handling 'surplus' and archival material from human biological samples. 2001. Royal College of Pathologists. <http://www.rcpath.org/activities/publications/transitional.html>

We note again that the text provided by the Retained Organs Commission answers its own question by assuming that a licensing system is required - see Paragraph 76.

In conformity with our previous comments we believe that informal registration is preferable wherever possible.

In practice, collections used for research will already be registered with a Local Research Ethics Committee and it would be simple to require all collections to do the same.

Inspection should be carried out when deemed necessary on the basis of the content and use of a collection rather than at regular pre-defined intervals. Procedures designed for high-turnover research collections will be absurd if applied to static teaching collections, especially if they are open to the public.

An interim voluntary authority (Paragraphs 72-73)

33. *Should the Commission recommend the establishment of an interim voluntary regulatory authority until the proposed new legislation comes into force? Should it have an Inspectorate function?*

It is likely that there would be merit in piloting a voluntary scheme prior to legislation, otherwise unforeseen problems will be extremely difficult to correct. **However, we note again that this question pre-supposes the establishment of an authority. It would be better to pilot possible approaches, including our suggestion of passing responsibility to local research ethics committees.**

A Human Tissue Authority (HTA) (Paragraphs 74-76)

34. *To restore public confidence, should the Human Tissue Authority enjoy direct and independent licensing powers similar to those of the organizations referred to in paragraph 75?*

It is difficult to answer this question in the absence of clear functional division between an HTA and research ethics committees.

However, despite the seriousness of the problems in relation to post-mortem human tissue **we cannot accept that the ethical difficulties here are of the same complexity as those posed by modern developments in human fertility and embryology. We prefer the concept of registration and occasional inspection, preferably by local research ethics committees**, in order to minimize bureaucratic waste of resources.

35. *What should be the balance of membership between professional and lay members?*

Probably equal; but we believe the selection process is more important than this balance. It is vital that all members should clearly understand the processes involved in post mortem practice and the importance of retaining tissue and organs from post mortems for diagnostic as well as other purposes. Informed public bodies such as the Alzheimer's Research Trust, the Multiple Sclerosis Society and the Parkinson's Disease Society should be represented among the lay members.

If (against our advice) an Authority is also empowered to consider the use of tissues from living individuals then its composition should heavily reflect this requirement, because tissues from living individuals are used in teaching and research far more than post mortem tissues.

Scope of an HTA (paragraph 78)

36. *Should collections consisting exclusively of blocks and slides be excluded from an HTA's remit? Should that remit include surgical specimens generally or only when they were in mixed collections?*

The collection of blocks and slides should be outside the Human Tissue Authority's remit.

As discussed repeatedly above, **surgical specimens and post mortem tissues deserve completely separate consideration.**

Conditions for grant or withdrawal of licence / registration (Paragraph 79)

What criteria should be applied in relation to consent to collections made between 1961 and 2000?

Option (ii) - absence of any evidence of any overriding objection to material being taken. In the absence of such objection then potential to advance the common good should be the main consideration.

Historical collections (Paragraph 79)

38. *Should there be no requirement for evidence of consent in relation to material collected prior to 1961? But should positive evidence that the individual concerned objected – or that relatives objected – be taken into account? An example of this might be the O'Neill Giant.*

In relation to samples form prior to 1961, where there was no requirement for consent, objections from relatives should be taken into account; but only if those relatives are old enough to remember the individual's death. Recorded objections from the individual concerned (as in the case of the O'Neill giant) should be accorded greater weight than objections from relatives.

Paragraph 80

39. *Should the consideration of individual collections pre-dating the 1961 Human Tissue Act be left for an interim HTA to address on a case-by-case basis?*

We believe that an interim HTA should act merely as a source of advice in relation to this material.

Paragraph 81-82

40. *Are there purposes and related conditions under which it should not be permissible to keep or use collections of human material? Should this be subject to separate consultation by the interim HTA as part of the process of developing its function and approach?*

We believe that the most authoritative, thorough and logical discussion of what constitutes “ethical use” in relation to human tissue remains that published by the Nuffield Council on Bioethics in 1995, even though this document has been superseded in other respects. We believe that the principles explained in this document should be used to test whether the purposes and related conditions are permissible.

Division of use in the way proposed is not practical. Collections made primarily for educational purposes are often immensely valuable for research; for example, the Royal College of Surgeons has actively facilitated the use of its collection for research. But each research project will need separate consideration. The parallel with the current duties of Local Research Ethics Committees in approving specific research projects is obvious and supports our argument that LRECs should be involved.

We believe that ‘education’ should be interpreted as broadly as possible. As noted above, the aims of the Retained Organs Commission would be well served if we follow the example of other countries and use pathology museums, with care, for the education of the general public, including school children.

41. *Should the license grant be indefinite – but subject to periodic review – or for a set time, subject to renewal – or be limited by purpose? (Similar conditions apply to registration).*

Again we would wish to minimize bureaucracy because of its adverse impact on the limited resources available for the common good. For this reason licences or registration should be granted for an indefinite period unless there is a specific reason for review.

42. *How frequently should collections be inspected and what qualifications and experience should the inspectors have?*

The frequency of inspections would depend heavily on the nature and use of the collections and a Human Tissue Authority (or a Local Research Ethics Committee) should be empowered to decide when they are needed. We suggest the inspectors should work only in teams of one lay and one professional person. They should have a thorough knowledge of acquisition, storage, documentation, safety, ethical and legal issues relating to human post mortem material. The process of inspection should be designed to minimise extra work and disruption for the organisation being inspected; again, bureaucratic preparatory work would waste resources which could be better employed elsewhere.

43. *What legal powers should the inspectors have? Should they be able to compel dispersal and/or disposal of collections in certain circumstances?*

We strongly believe that the inspectors should report back to the Human Tissue Authority (or LREC). They should inspect, not be judge and jury. Powers for immediate action by inspectors should not extend beyond an order to cease work and/or remove from public display; even these are probably not needed as there are other mechanisms available to prevent extreme abuses. A route for appeal against decisions should be available.

44. *On what grounds should licenses or registration be withdrawn – and what appeals process should be established?*

Unethical use, as defined by the Nuffield Council of Bioethics (1995) and interpreted by the Local Research Ethics Committee, should be the principal consideration. We would hope that in most circumstances the requirement imposed after such an offence would be changes in procedure, management or location rather than destruction or dispersal of the collection.

45. *To whom will licenses be granted – individuals, groups or corporations?*

Approval (not licenses) should be granted to institutions unless there are exceptional circumstances. The individual responsible for the day-to-day management of the collection should however be clearly identified.

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