



Health Department
Directorate of Service Policy and Planning

Health Planning and Quality Division
St Andrew's House
Regent Road
Edinburgh EH1 3DG

Telephone: 0131-244 2420
Fax: 0131-244 2989
Will.scott@scotland.gsi.gov.uk
<http://www.scotland.gov.uk>

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REVIEW GROUP ON RETENTION OF ORGANS AT POST-MORTEM: CONSULTATION ON REPORT ON PHASE 3

The Minister for Health and Community Care announced today that he is publishing on a consultative basis the report on the Phase 3 work of the Review Group on Retention of Organs at Post-Mortem. While comments on the generality of the report's contents are welcome, there are a number of specific aspects of the report's recommendations which the Review Group itself suggested should be the subject of consultation. In publishing the report, the Minister indicated he would welcome comments on these points, which are set out in the remainder of this letter.

Standard Authorisation Forms and Information Leaflets

In further developing the standard authorisation forms, the Review Group has taken account of the comments received during the consultation process on its Phase 2 report, and has included proposed standard information leaflets and authorisation forms as Appendix 3 of its Phase 3 report. Since these forms will be used across NHSScotland, the Executive believes it is essential that consultation on them should be as widespread and thorough as possible, so that all those who have already given a great deal of thought to this subject can have an opportunity of contributing to the final product. There are a number of issues related to the forms on which the Executive wishes to canvas views.

In paragraph 74 of its November 2001 report, the Review Group concluded that that once a properly informed decision had been made to authorise a post-mortem examination, any interests in the prepared blocks and slides should pass to the hospital authority, who could then retain and use them for proper study and research purposes. This would suggest that the forms ought to provide for authorisation of the use of the medical record for purposes of medical education, training, audit and research, making no distinction between any of these purposes. The forms have been drafted on that basis. There is a feeling, however, especially amongst the family support groups, that research raises different concerns than do medical education, training and audit. The Review Group therefore wished (paragraph 64 of Phase 3 report) there to be consultation on whether the forms should provide for separate and specific authorisation of the *research* use of blocks and slides kept as part of the medical record. Since it is essential that the forms command the support of both relatives and health professionals, the Executive would welcome views on this point.

Paediatric Form

The child form provides for the signature of both parents when authorisation has been given. Where only one parent or guardian is present to give authorisation, the Review Group felt (paragraph 72) that it would normally be sufficient to proceed, but that enquiries should be made as to whether the absent parent would be likely to object. If it appeared likely that there would be disagreement, then ordinarily the post-mortem examination would not take place until such time as further enquiries were made or legal advice taken. In a situation where both parents were present, but could not agree on whether to authorise the post-mortem examination, it should not go ahead. The Executive would be particularly interested to receive comments on this approach. These issues are also covered in more detail in the Executive's consultation paper on new hospital post-mortem examination legislation for Scotland, since the decision on this point may need to be reflected in statute.

The Review Group also had concerns (paragraph 84) about cases where the child who had died was under the guardianship of a local authority. Under the proposed arrangements, the local authority would be *in loco parentis* and therefore able to authorise a hospital post-mortem examination on the child. The Review Group took the view that a local authority should not give such authorisation without first consulting the parents, and that if one or both parents objected, the post-mortem examination should not go ahead. Is this the approach which the Executive should adopt?

Genetic information

The Review Group considered (paragraph 81) whether there was a need to include in the forms a section allowing specific authorisation of genetic testing, partly because of the implications that would have for the present or future health of other members of the family, but also as a reflection of concerns about the possibility of genetic information becoming available when it is either not wanted or might be looked on as confidential. The Review Group decided on balance not to include such a section in the form, on the grounds that *any* post-mortem examination has the potential to reveal diseases or conditions with implications for the family, and this would be masked if genetic testing was to be singled out. However it is recognised that genetic information can be different, and the Executive would welcome views on whether the forms should provide for specific authorisation of genetic testing.

Patients' Relationships

When a person is admitted to hospital, the Review Group felt it would be appropriate (paragraph 82) for that person to nominate someone to speak on his or her behalf, and therefore reflect the individual's views accurately should the issue of a hospital post-mortem examination arise. Where no nominated person exists, the Review Group felt (paragraph 83) that the hierarchy set out in the Adults with Incapacity (Scotland) Act 2000 and the Mental Health (Care and Treatment) (Scotland) Act 2003 should be used. The Executive would welcome views on this. These issues are also discussed in the Executive's Consultation Paper on new legislation for hospital post-mortem examinations.

Piloting of Forms

The design of both the adult and paediatric authorisation forms and information leaflets is now being worked up, and the fully-designed versions will be piloted, through focus groups which will include

parent or family support groups, pathologists and staff from Intensive Care Units. It is essential that the forms command the support of both relatives and health professionals and take full account of the practical needs of families and hospital staff. To complement the work of these focus groups, the Executive would also welcome comments from as wide a range of individuals and organisations as possible. Copies of the fully-designed version of the form should be requested from the contact given at the end of this letter, or through the Review Group's website.

Procurator Fiscal Post-Mortem Examinations: Research on Retained Organs and Tissues

Relatives are able through the hospital post-mortem examination forms to authorise the use of tissue blocks and slides for education, research or clinical audit purposes. The Review Group believes (paragraph 135) that the same opportunity should be available to families in situations where the post-mortem examination is carried out on the instruction of the Fiscal, since the importance of research following Fiscal post-mortem examination cases is generally accepted. There is at present no formal mechanism for seeking such authorisation, and the Review Group has therefore devised authorisation forms which would allow relatives to do so, either before or after the examination (paragraph 141). Comments on the effectiveness of this form would be welcomed. Is it likely to avoid causing unnecessary additional distress to families while meeting the needs of research?

There are a number of practical issues which need to be resolved if this process of authorisation is to work properly. There is the question of who should approach the family. The Review Group recommends (paragraph 143) that the best person would be a dedicated Bereavement Officer, but no such category of staff exist at present. The report suggests this is not something which staff in Area Fiscal Offices could be expected to do, though it does say that the forms provided by Area Fiscal Offices need to acknowledge the existence of the option of authorisation. To help minimise the distress to families, should it be someone with whom they have already had contact, such as a police administration officer or a mortuary technician? If so, what sort of additional training would need to be provided, and by whom? Or should the task of approaching the families fall to the researchers themselves, since they will best be able to explain the nature of the research? This solution would clearly have implications for the research centres. Is the answer to these questions the same whether the approach takes place before the post-mortem examination instructed by the Fiscal, or after the Fiscal has indicated that the tissue blocks and slides retained from the examination as part of the medical record are no longer required for his or her purposes?

In undertaking discussion of these forms with the family, where should that discussion take place? Should the person seeking authorisation be expected to visit the family? If some neutral ground is thought preferable, where might that be located? Should the person seeking authorisation contact the family first by telephone, to find out if it would be acceptable to post the form to them, supplemented, if preferred, by communication with the contact person? Is there a role for the pathologist in this supplementary process?

The Review Group also considered (paragraph 145) the implications in cases of non-accidental injury where the person whose authorisation would otherwise be sought, for research or other purposes, is suspected of being implicated in a death thought to be criminal or unnatural. It might be argued that such a person should not be allowed to thwart the undertaking of research by refusing to give authorisation. Such an approach would, however, run counter to the general basis of the Review Group's approach, which rests on a general commitment to the rights of the family. The Executive

would therefore welcome comments on this issue, in particular whether there are any specific circumstances in which research could be allowed to go ahead without authorisation.

Cases to be Reported to the Procurator Fiscal

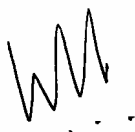
The Review Group discussed (paragraph 156) whether the list of deaths which should to be reported to the Fiscal ought to be included in statute, since that would make them easier to find and would assist medical and other professionals in knowing which cases the Fiscal needs to investigate. However, this would fix the list and would make it difficult to amend when new categories emerged or other changes had to be made. The Review Group therefore decided not to recommend that the list be included in legislation, but recommended that some other way be found to make this information publicly available and readily accessible. The Executive would welcome suggestions on ways in which this could be achieved.

Arrangements for Submitting Comments

The Annex to this letter shows the list of individuals and organisations who are being included in the consultation process. As with the Review Group's previous report, the Executive has tried to make the consultation process as inclusive as possible. Should you feel that there are others who should be added to the list, please contact Ms Cheryl Paris at the address above (telephone 0131-244 2946, fax 0131-244 2898, or by e-mail cheryl.paris@scotland.gsi.gov.uk) and she will arrange for the person or body suggested to receive a copy of the report and the consultation letter. Ms Paris should also be contacted if additional copies of the report, or copies of the authorisation forms, are being requested. The report can also be viewed at <http://www.show.scot.nhs.uk/scotorgrev>.

Comments should reach Ms Paris by **Friday 27 February 2004**, which is also the closing date for the consultation on the proposals for new legislation in Scotland on hospital post-mortem examinations.

Yours sincerely



W S SCOTT

List of Organisations Being Consulted

Action for Sick Children
Action of Churches Together in Scotland
Africa Centre Scotland
Agency for Inter-faith Relations Churches Together in Scotland
Asian Concern
Asian Welfare Association
Associated Presbyterian Churches of Scotland
Association for Children with Heart Disorders (Parent Support Group)
Association of Clinical Pathologists
Baptist Union of Scotland
Bangladesh Welfare Council
British Medical Association Scottish Office
British Paediatric Pathology, Scottish Branch
Church of Scotland
Citizens Advice Scotland
Commission for Racial Equality
Conference of Scotland Council of Christians and Jews
Crown Office (Edinburgh)
CRUSE Bereavement Care
Department of Forensic Medicine & Science, University of Glasgow
Department of General Practice, Edinburgh University
Department of Health, London
Department of Pathology, Western Infirmary, Glasgow
Ethics & Advisory Committee, Royal College of Paediatrics & Child Health
Evangelical Alliance Scotland Faculty of Advocates (Edinburgh)
The Free Church of Scotland
The Free Presbyterian Church of Scotland
General Medical Council
Health & Community Care Committee, Scottish Parliament
Hospital Chaplains Association
Human Organs Inquiry, Northern Ireland
Justice for the Innocents (Parent Support Group)
Law Society of Scotland
Local Health Councils
Local Research Ethics Committees
Medical & Dental Defence Union of Scotland
Medical Research Council
MRC Social & Public Sciences Unit, University of Glasgow
National Association of Funeral Directors
Neuropathology Department, University of Edinburgh
NHS Quality Improvement Scotland
NHS Trust Chief Executives
NHS Trust Medical Directors
Office of the Chief Rabbi
The Patients Association
Procurator Fiscals Society

Professor D Pounder, Ninewells Hospital & Medical School
Reformed Presbyterian Church of Scotland
Reform of Synagogues of Great Britain
Religious Society of Friends (Quakers)
Retained Organs Commission
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Nursing, Scottish Branch
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Pathologists (Scotland)
Royal College of Physicians & Surgeons of Glasgow
Royal College of Physicians of Edinburgh
Royal College of Surgeons of Edinburgh
Scottish Association of Health Councils
Scottish Committee, Royal College of Pathologists
Scottish Cot Death Trust (Parent Support Group)
Scottish Council for Voluntary Organisations: Voluntary Sector Health Network
Scottish Deans of Medical Schools
Scottish Episcopal Church
Scottish Ethnic Social & Cultural Organisation Council
Scottish Inter-Faith Council
Scottish Law Commission
Scottish Medico-legal Society
Scottish Neonatal Consultants' Group
Scottish Organisation Relation to the Retention of Organs (SORRO) (Parent Support Group)
Scottish Partnership Forum
Scottish Regional Council, Institute of Biomedical Sciences
Stillbirth and Neonatal Death Society (SANDS) (Parent Support Group)
Strathclyde Police
UK Central Council for Nursing, Midwifery & Health Visiting
United Free Church of Scotland

Individual members of the public, family support groups and the health professionals who requested a copy.