Comhairle na nDochtúirí Leighis
Medical Council

Anatomy Department Inspection

National University of Ireland, Galway.

Date of inspection: 28 November 2024

License holder: Professor Peter Dockery

Inspection team:

Professor Claire Smith, Inspector of Anatomy for the Medical Council

Mr. Graham Knowles, Medical Council, Education and Training Committee member

Ms. Aoise O'Reilly, Undergraduate Professional Development Manager, Medical Council

The Medical Council are the licensing authority for the practicing of Anatomy in Ireland as set out in Section 106 of the Medical Practitioners Act 2007. In 2015, the Council published the Code of Practice for Anatomical Examinations. Code was designed to help safeguard public confidence in the practice of Anatomy in Ireland and support continuous development in licensed places whilst awaiting updated legislation in Human Tissue Bill.

At each inspection visit, the Inspector of Anatomy is supported by a non-medical member of the Medical Council (with no background in Anatomy or Pathology to ensure appropriate lay representation), as the Council have delegated decision making powers to its Education and Training Committee, the non-medical member on this occasion was a Committee member. As well as a member of the Medical Council Executive. The Medical Council's Code of Practice for Anatomical Examination provides the framework for the inspections of Anatomy Departments.

SECTION 1 – ORGANISATIONAL CAPACITY AND CAPABILITY

1. LICENSING, AUTHORITY, RESPONSIBILITY AND ACCOUNTABILITY

Anatomical Examination must only be practised in institutions where there is a lead individual holding a license issued by the Medical Council at its discretion. That lead individual holding the license should have appropriate experience and documented delegated authority from the Chief Executive (or equivalent) to practise Anatomical Examination in line with licensing requirements, this Code of Practice and any recommendations arising from inspections conducted with reference to this Code and under S106 of the Medical Practitioners Act 2007.

The lead individual holding the license is responsible for the practice of Anatomical Examination at the institution. Since the lead individual holds the license for the institution, he/she is also accountable to the institution and should provide regular reports on the practice of Anatomical Examination at the institution, which should be noted at the level of the Chief Executive (or equivalent) and the Board (or equivalent). The lead individual holding the license must make the required annual returns to the Medical Council under S106 of the Medical Practitioners Act 2007.

If an institution wishes to change the lead individual holding the license, it must seek the approval of the Medical Council. Wherein a license is issued by the Medical Council to a lead individual at an institution, all staff/individuals of the institution who practise Anatomical Examination therein under the supervision of the lead individual are also licensed under the terms of Section 106 of the Medical Practitioners Act 2007. To give effect to this, the lead individual holding the license should have a system and documentation in place to ensure appropriate training, delegation of responsibility and accountability for these individuals.

Findings:
The lead individual (Professor Peter Dockery) continues to be deemed suitable. Professor Dockery has held the license since 2014. Professor Dockery undertook a PhD in Anatomy in 1986, becoming Professor of Anatomy National University of Ireland, Galway 2005. He is currently Vice Head of the School of Medicine. He has an established international research profile, and is engaged with the activities of professional societies that support the development of sector best practice. The anatomy team met during the inspection were aware of the license requirements and their delegated responsibilities. Anatomy staff include Professors (3), Lecturers (8), Chief Technical Officer (1), Senior Technical Officer (3), Administrator (1), Teaching Assistants/Anatomy Demonstrators (6).

Annual Anatomical Returns have been provided as required.

2. GOVERNANCE AND QUALITY SYSTEMS

All aspects of Anatomical Examination should be governed by documented, controlled and monitored policies and procedures that form part of the institution's overall governance process.

There should be a systematic record management system that ensures data protection, confidentiality and has suitable provision for data back-up.

There should be a documented internal audit system, with an appropriate schedule and accountability.

Staff should be appropriately qualified and trained for their work and should show care and respect for the donors' remains in their charge at all times. They should undergo documented continuing professional development and have regular documented appraisals and personal development plans. This may form part of the annual performance management and development appraisals.

Risk assessments of the practices and processes related to Anatomical Examination should be in place, including processes to escalate knowledge of risk upward through the institution as appropriate. These risk assessments should be documented and reviewed regularly and they should be readily available to all staff, who should be aware of their content.

Procedures should be in place to ensure investigation of and response to adverse events. Staff should be able to use incident reporting systems and corrective / preventative action should be taken where necessary.

Findings:
The inspection team met with several members of the anatomy team (Academic, Professional Services and Technical). There is clear strategic leadership of the unit (Professor Dockery), and all members of the team met demonstrated a clear understanding of their role in relation to Anatomical Examination, Research, Education and Training using human tissue. The team demonstrated working well together, with a clear aim to ensure dignity and respect of human

tissue. Within the team the dedicated role of Anatomical Donor Programme Manager takes a lead role in supporting families with donation. One Lecturer is also designated the Academic in Charge of the Dissecting room, delineating clear responsibility for human tissue. An Anatomical Governance Board exists that meets regularly to review requests for use of donor material and laboratory provision.
Staff are supported, and take part in standard University training (Data Protection, Health and Safety, etc.) that supports them in their role within anatomy. Staff undertake appraisals, through the University. In addition staff are engaged as appropriate in sector wide professional groups that support them in the role.

The staff demonstrated a systematic record management system that ensured data protection, confidentiality, and has suitable provision for data back-up. Physical copies of donor forms are held in a dedicated locked storage room in fire proof cabinets. An electronic database holds current records. The digital back-ups of these are managed by the University. But also with local back-up provision. The record management includes the digitalisation of historical written documents. The staff also explained how donor details are checked at different points to reduce the potential for human error. Staff are aware of incident reporting.

Standard Operating Procedures are in place, and are combined with Risk Assessments. With the new Human Tissue Act these will need further development. Related to this, the inspection team received a detailed booklet, that in many ways forms an 'Anatomy Quality Manual'. Alongside the development of the Standard Operating Procedures, it might be helpful for the institution to consider developing this into a single source of truth as a document updated on an annual basis, that can be provided to new staff.

Last internal Audit: The audit is carried out each year after the cessation of teaching at the end of Semester II. The audit involves a full check of all anatomical specimens held by Anatomy. Previous audits were completed June 2023 and November 2024.

SECTION 2 - RECOMMENDED PRACTICES

1. CONSENT

Appropriate consent: This can only be given by the donor, in writing, in the presence of at least one witness who attests their signature. A model consent form has been prepared for use throughout Ireland (see appendices). The individual making the donation must be aged 18 years or older and have capacity to consent.
Informed consent: Full and clear information should be provided to a person wishing to donate his/her body for Anatomical Examination, to allow the potential donor with capacity to make a voluntary, informed decision. This information should include the nature of the activities for which the body can be used and the length of time it, or its parts can be retained.
Explicit duration of consent: The duration of time that the donor consents to his /her body being used for anatomical examination should be specified in the consent.
Withdrawal of consent: Consent may be withdrawn by the donor at any time before his/her death, in writing, to the institution that his/her body had been offered. Staff involved in seeking consent should receive appropriate training and support.

In order for lawful Anatomical Examination to take place, the Medical Certificate of the Cause of Death [MCCD] must be signed and the death must be registered. A body may be removed to a receiving institution and embalmed or otherwise preserved before the donor's death has been registered, but Anatomical Examination should not take place until it has been registered. A copy of the MCCD and death registration should be kept at the receiving institution.

Findings:
The National University of Ireland, Galway has a donation catchment area of the West and Northwest of Ireland. Consent is obtained by using an adapted model consent form published as an appendix to the Code of Practice for Anatomical Examination. This consent form meets all of the recommendations within the Code of Practice. There is an information booklet for potential donors and their families, ensuring informed consent. The consent form clearly details requests that relate to the duration of consent, for example the ability to consent to retention of body parts. The unit receives donors using 'older' consent forms that have been completed. The unit applies a rule of 'consent not given' for components such as retention of body parts, and the use of images, where these were not options on older forms. This is an appropriate, and sector wide used approach.

Changes in the required Medical Certificate of the Cause of Death [MCCD] have been adopted by the unit, and they are working on developing efficient process to support this. The unit is also in the process of obtaining the Death Registration Certificates for all donors.

2. PREMISES, FACILITIES AND EQUIPMENT

As set out in Section 1, the lead individual holding the license should have appropriate and documented delegated authority from the Chief Executive (or equivalent) to practice Anatomical Examination in line with licensing requirements, this Code of Practice and any recommendations arising from inspections.

Premises: A risk assessment should be carried out and documented to ensure that the premises at which Anatomical Examination is carried out and where bodies and body parts are stored are secure, fit for purpose and ensure the confidentiality and dignity of the donors. The premises should have sufficient space for procedures to be carried out and measures should be in place to prevent unauthorised access. There should be documented cleaning and decontamination procedures and appropriate environmental controls (e.g. air-handling) in place.
Facilities: There should be sufficient storage capacity for the required bodies and body parts. The storage conditions should be monitored, recorded and action taken if required, to ensure the dignity of the deceased and the integrity and traceability of their remains. Documented contingency plans should be in place, in the event of storage facilities being rendered unsuitable.
Equipment: All equipment should be subject to recommended validation, calibration and maintenance. The condition of the equipment should be monitored and documented. Users should be trained in the use of the equipment, have access to relevant instruction manuals and understand how to report equipment problems.

Findings:
The premises are located on the National University of Ireland, Galway campus. The Anatomy facility moved to its current location in 2019. The inspection team took a tour from both the entry route used by a donor and the route through which students access the facility. Both enable secure and controlled access. Access for staff is via dedicated electronic cards. Visitors are required to sign in. Students present their electronic cards to a member of staff that are digitally read.

The facility has CCTV on the external aspect (provided by the University). A recommendation would be to test how long the CCTV recording lasts for, the extent of the recording, and if the facility needed to access the footage, how they go about this. This will help the facility to establish

this process within their standard operating procedures and to evaluate if the coverage is sufficient.

The laboratory spaces remain in good order, and is well maintained. The facility and staff are supported by University estate provision/processes, for example the monitoring of the CCTV, Fridge/Freezer temperatures and the formaldehyde levels. The embalming and preparation area remains up to date and suitable for the receiving, preparation and storage of donors. This includes a downdraft embalming table, a 6- 4 bay body fridge and a 1- 4 bay -20^{C} freezer. The facility uses a mix of traditional embalming and soft fix methods as suitable. The preparation area is fitted with a fume hood for the mixing of chemicals and a gravity fed embalming system. Suitable Personal Protection Equipment is provided.

The facility has a contingency plan, so that in the event that donors are required to be moved from the Human Biology Building it would be to the previous Anatomy Building which retains a mortuary and the previous dissection room which has ventilation. This Building is included under the University's Anatomy Licence.

A number of specimens in jars are located at the Clinical Science Institute on the University Hospital Galway campus (The Professor John Kennedy Museum of Pathology). This site was not visited during this inspection. At the 2019 inspection concern was raised as to if these specimens would fall under the Inspector's Jurisdiction with the Human Tissue Act. Once the Human Tissue Act commences, clarification will be provided as to whether an inspection by the Inspector of Anatomy is required.

3. RECORD KEEPING / TRACEABILITY

The license holder is responsible for a donor's body and body parts from its acceptance for Anatomical Examination until the burial, cremation, disposal or return to the family. All places where Anatomical Examination is carried out should keep records in a permanent and secure form for each body / body part / tissue in their possession. These records should be held on the premises that the body was first received and on any other premises to which the body / parts / tissues have been transferred. All records must be available for inspection and review. Records should be kept after the disposal of a body / body parts / tissues and maintained in line with a documented Records Management Policy.

A unique code should be assigned to each donation and to each of the products derived from it. The labelling of specimens should be robust to enable traceability of specimens at all times.

A register of donated bodies and parts / tissues derived from them should be kept and an audit trail maintained, including the consent obtained, when and where the body was accepted, the uses to which any specimen was put, when and where any material was transferred and to whom.

Records of delivery and transportation should be kept and a system put in place to ensure traceability of bodies / parts / tissues during transport. Records of service level agreements with undertakers, transport companies / couriers should be kept together with records of agreements with recipients of bodies / parts/ tissues.

Findings:

Donors are brought into the facility and are assigned a unique identifier. From this point forward this is what is used as their reference. Any human tissue that is removed from the donor is tagged

with the same identifier. Only the core anatomy members of staff have access to enable the join up of the identifier and the individual's identity.

Retained parts are stored in appropriate containers and are recorded via a dedicated system. This includes a photographic record to assist with specimen management. Bones are stored in the facility and are audited annually.

During the inspection and audit of a number of donors, body parts, and historical material was undertaken. The audit trail was quickly provided, with no issues identified.

Funeral provision has been provided by a dedicated service. This is now at the end of contract and a tender process, supported by the University, is in process.

Donors arrive in their coffins; the coffins are stored by the University until the donors are returned to them.

4. SENSITIVE DISPOSAL

Processes should be in place to inform donors and their relatives how remains will be sensitively disposed of after use and who will be responsible for any associated costs. Staff should be familiar with the basic legal requirements, the institutions own arrangements and the options available for those wanting to make their own arrangements for disposal. This information should be available in writing.

It is best practice to retain tissue removed from a cadaver during the course of anatomical examination for disposal with it. Body parts retained after disposal of the body and any tissue removed from the parts may be disposed of as clinical waste, and 'best practice' is to cremate or bury such tissue.

The date, method and reason for disposal should be recorded.

Findings:

The options regarding disposal are clearly provided in the information pack, so donors and families can select the option they wish. At the time of disposal contact is made with the donors next of kin. Arrangements include the option for burial in the University Plot in Bohermore Cemetery, Galway City. Another option is private burial. Donors may also select cremation.

Each year a non-denominational commemoration service is held for families, staff, and students.

5. LOAN / TRANSFER OF CADAVERIC MATERIAL

Given the dependence on generous donation, it is recognised that situations may arise where cadaveric material is loaned or transferred between license holders. Bodies / body parts / tissues should only be loaned / transferred for the purposes for which consent was given.

The loan or transfer of bodies / body parts / tissues should be between license holders only and should be kept on licensed premises only.

A loan should be for a defined period and subject to a written, signed agreement, a copy of

which should be kept by both parties. The agreement should indicate the material covered by it, where the material will be held, the purpose and timespan of the loan. While the material is on loan, it will remain the responsibility of the lending institution and should be returned to it upon expiration of the loan period.

If a body / body part is transferred to another institution, the documents pertaining to the donation should be transferred with the material and the institution making the transfer should keep a record of it. The institution receiving the transfer will be responsible for the disposal of the material in line with the provisions of the consent.

Findings:
No loans are currently in place.

6. USE OF IMAGES

Suitable practices should be put in place to ensure that the dignity of the deceased is maintained at all times and the inappropriate use of images is prevented.

Findings:
The consent form has an option to provide consent stating that the donor would not be identifiable. The code of conduct clearly states that no mobile phones, cameras or other equipment is permitted without prior agreement. A procedure is in place that details photography in the facility.

7. CHARGING

Whilst a human body / part / tissue cannot be sold, charges may be applied to cover any costs incurred in preparing and transporting them for use by other license holders. These charges should fairly and transparently reflect the costs involved.

Findings:
The facility do not charge for access or use of human tissue. They impose reasonable charges for the use of the facility and for the involvement of staff, and any specialist equipment.

8. IMPORT AND EXPORT

Frozen body parts are imported (mainly from the USA) into Ireland for Anatomical Examination. In addition, there may be benefits in collaborating with Northern Ireland in sourcing bodies for Anatomical Examination. Although this importation falls outside of the Anatomy Act 1832, once within the Republic of Ireland, human material to be used for Anatomical Examination falls under the jurisdiction of the Anatomy Act 1832 and the role of the Medical Council. As such, it can only be used by license holders.

The possible misuse of imported material for Anatomical Examination poses a considerable reputational risk to the Medical Council and Anatomy Sector. Imported bodies should be obtained, transported, used and disposed of by license holders in accordance with the consent given by the person from whom it came. License holders should be able to demonstrate to the Medical Council that the requisite consent is in place. License holders should also be able to demonstrate that the required material is not available from within Ireland.

Fresh-frozen cadaveric material poses a number of health and safety risks not associated with

embalmed cadaveric material. License holders should therefore ensure that their premises, staff and practices are equipped to deal with the use of fresh-frozen material. License holders should, as far as possible, satisfy themselves that donor material has been screened for transmissible disease, e.g. hepatitis B, hepatitis C, meningitis, tuberculosis, prion disease and HIV and be accompanied by certification from an accredited / licensed laboratory to that effect.

Cadaveric material for export, should be obtained, used, transported and stored in accordance with the consent that has been given. Donors should be provided with adequate information to indicate that their bodies / body parts / tissues may be exported. The donor should be provided with information to indicate whether or not the remains will be repatriated and within what timeframe.

Findings:
No Import or Export takes place.

Other comments
None

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