Site visit inspection report on compliance with HTA minimum standards

Wrightington Hospital

HTA licensing number 12487

Licensed under the Human Tissue Act 2004 for the

- **carrying out of an anatomical examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation;**
- **storage of a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose; and**
- **storage of an anatomical specimen**

01 December 2016

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Wrightington Hospital had met most of the HTA standards, one minor shortfall was identified against standard GQ7 (risk assessments).

Particular examples of strengths and good practice are included in the concluding comments section of the report. The establishment has also been provided with advice about areas that could be improved further.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report describes the second site visit inspection of Wrightington Hospital ('the establishment'), where the 'Bioskills Laboratory' ('the laboratory') is located. The establishment has been licensed by the HTA since 2007 and imports fresh frozen specimens (upper limb specimens and, occasionally, lower limb specimens) for use in surgical skills training. The DI is a senior Consultant Orthopaedic Surgeon and Head of the Unit. The Corporate Licence Holder is the Wrightington, Wigan and Leigh NHS Trust. The laboratory manager is a Person Designated (PD) and other staff working under the licence include a Bioskills Technician and a HTA Policy Co-ordinator and Research Manager. A further PD is another Consultant Orthopaedic Surgeon, who is the Research and Governance Lead for the Upper Limb Unit at Wrightington Hospital.

The laboratory hosts up to 50 courses each year. Course delegates are qualified doctors, who either take part in practical training in the laboratory, or observe procedures, via video link, in a lecture theatre within the same building. Staff do not seek consent from tissue donors as the cadaveric specimens are imported from either the Anatomy Gifts Registry (AGR) or Life Legacy, which are both based in the USA. Details of the consent forms are held at the AGR laboratory and are checked by staff to ensure suitable consent has been obtained. Before working with the specimens, all course delegates are required to read SOPs and to attend a meeting where work with human tissue, risk of contact with infectious

material, use of personal protective equipment (PPE), the taking of images and respect for donors is discussed. A formal code of conduct is not in place but course delegates are required to sign a ‘disclaimer’, which primarily covers the risks of injury but also forbids the making of images. Course demonstrators are qualified surgeons who work at the Wrightington Hospital and delegates are supervised at all times. The training room has 11 tables and each group of delegates are assigned a table with at least one member of staff.

The establishment currently receives only body parts but they may consider the use of whole bodies in the future. Specimens are ordered one month in advance of the course and are delivered by a contracted courier to the establishment, where they are stored in allocated freezers prior to their use. The area of receipt is in a secluded part of the hospital and CCTV cameras are in place. Staff members are notified when the specimen has left Manchester airport and sign for the delivery on receipt. The delivery note and unique identification (ID) number of each specimen are checked against the records and details are recorded in a paper register. The establishment uses the same unique ID number generated by the supplier for traceability purposes. Where two upper limbs are supplied from the same donor, the ID number is used but the specimens are additionally labelled with an ‘L’ or an ‘R’ to denote ‘left’ and ‘right’.

Specimens are stored in -30^{o}C freezers until ready for use. Twenty-four hours before their planned use, specimens are thawed by being placed in a fridge or in containers kept at room temperature. There are three -30^{o}C freezers and two fridges at the establishment. Freezer and fridge temperatures are monitored daily but temperatures are not recorded (see Advice, item 13). Freezers are alarmed, with a call out system that contacts the person on call when the temperature deviates outside of the range +/-10^{o}C. The alarm system is not routinely tested to ensure the call-out procedure is functioning correctly (see Advice, item 13). There is restricted access to storage areas and freezers are double-locked with a key. Staff also use a key to access both the storage area and the laboratory. Courses often take place out of hours and at weekends. At least two members of staff are present throughout the course and there is a lone working policy in place.

Specimens are placed in either two yellow or two orange biohazard bags to thaw. The unique ID number, found on unwrapping the specimen, is placed between the two bags, ensuring visibility. The outside bag is labelled with the unique ID number using an indelible marker pen. All specimens are refrozen after use and may be re-used several times before disposal. In preparation for being refrozen, specimens are placed back into their biohazard bags and a patient ID band label is attached to the outside of the bag and secured with a cable tie. Specimens for disposal are collected from the freezers and placed in wheeled biohazard bins. Porters move the bins to a secure holding area at the Wrightington Hospital site, ready to be collected for incineration by a contracted courier. As specimens for disposal are placed in yellow biohazard bags, it is not possible to easily identify those for disposal and specimens still to be used in courses, some of which are also held in yellow biohazard bags (see Advice, item 15). The establishment does not loan out the specimens. Audits are carried out every six months or annually by establishment staff but full details of specimens in traceability audits are not recorded (see Advice, item 7).

During the inspection, the HTA completed a traceability audit involving five specimens stored in the -30^{o}C freezers. In three cases, frozen specimens were chosen at random and the unique ID numbers and specimen details were compared with the details held in records. The consent, donor testing, transportation and location records for these cases were also reviewed. A minor discrepancy was found in the labelling of one specimen (see Advice, item 8) and was corrected immediately. For the remaining two specimens, a reverse traceability audit was carried out by selecting them from records and tracing them to their storage

locations, examining their associated records. Although, no discrepancies were found, one limb had been stored in the freezer since 2012 (see Advice, item 14).

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	Although some assessments are in place for health and safety risks, there are no documented risk assessments for practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice (see Advice, item 10)	Minor

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	N/A	The establishment is making plans for a new surgical training laboratory, which is expected to be completed in 2018. Although there will be a change of premises, the new laboratory will remain on the Wrightington Hospital site. The new laboratory will continue with similar staffing and governance arrangements. Building on discussions during the inspection, the DI is advised to fill in and submit a new licensing application.
2.	GQ1	Staff and delegates are expected to follow SOPs but there is no system in place for the DI to be assured that staff and delegates have read and understood the SOPs. The DI is advised to implement a suitable system; for example, a signing-off procedure.
3.	GQ1	To improve the overall standard of controlled documents, and ensure that they can be easily followed, the DI is advised to:

		• number pages • review the document control information to ensure consistency and accuracy. For example, in SOP 02 ('The disposal of human tissue by incineration'), the 'effective date' is stated as '3.10.2017' but the 'review date' is stated as 'Oct 17'.
4.	GQ1	Although SOPs are in place, not all contain the step-by-step detail that would allow new staff to carry out the activity. An SOP should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained. People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices; however, the author of an SOP should not also be the only person who reviews it. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements.
5.	GQ1	During the review of documents, several minor discrepancies were noted; for example, typographical errors and inconsistencies in terminology. The DI is advised to review the content of all documents for completeness, accuracy and legibility, perhaps including them in the audit schedule. Including documents in audits would may help to identify any discrepancies. Several documents make reference to a 'HTA Research Licence', which the establishment does not hold.
6.	GQ2	Although audits are undertaken, the DI is advised to document an audit schedule, detailing all audits that are planned to take place throughout the year.
7.	GQ2	Although audits are being carried out in some detail, the findings are only briefly summarised, which limits their usefulness. The DI is advised to consider making better use of documented audit evidence to include more detail and derive greater benefit from the results. Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be

		recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work. Some establishments may be able to make use of existing in-house expertise or services.
8.	GQ5	All specimens and records were traceable but one minor discrepancy was found in the labelling of a specimen. Identification details were found with the specimen itself but not on the outside of the bag or in between the two bags, as in the standard operating procedure. Staff labelled the bag with the correct unique ID number immediately.The DI is advised to ensure a consistent labelling process is in place.
9.	GQ5	Traceability is maintained using paper records. The inspection team were told that these were intermittently scanned and saved as an electronic record but no recent evidence of this approach was seen during the inspection. The DI is advised to move to an electronic records system, which would be more reliable, ensure consistency, be more easily updated and could regularly be backed-up on a routine basis. The development of a newer and larger laboratory provides an ideal opportunity to reflect on the limitations and risks of the current system, and to scope future requirements.
10.	GQ7	All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our standards. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining. Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including: • loss of or damage to specimens; • loss of traceability; • receiving specimens without appropriate consent documentation; • storage of specimens and contingency arrangements; • transport of specimens to and from the establishment;

		• security arrangements. Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident. By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.
11.	PFE1	Two external doors have notable air gaps at floor level, which could compromise security and protections from vermin. The DI is advised to discuss this matter, and how best to resolve it, with the relevant hospital department.
12.	PFE2	As well as being fit for purpose, equipment should be able to be cleaned. Since the previous inspection, wooden laboratory stools have been replaced by stools that have a plastic seat and a chromium-plated steel base. The chromium plating has deteriorated on these stools and the bases have become corroded with rust. The rusted surfaces will reduce the effectiveness of cleaning and decontamination, and the DI is advised to consider whether these stools can be therefore be suitably repaired, covered or replaced.
13.	PFE3	Although the establishment's storage areas and freezers are alarmed, and their temperature monitored, the establishment does not record daily temperatures. Documented temperature monitoring allows establishments to easily visualise and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regularly tested and manually challenged periodically to ensure that they are operating as expected. Signs should be added to freezers to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum temperatures.
14.	D1	During the traceability audit, one specimen was found to have been stored in the freezer since 2012. The DI is advised to develop a policy that clarifies the maximum length of time specimens should be stored at the establishment before disposal.
15.	D2	Due to a change in local disposal arrangements, there has been a change in the colour of bags used for containing waste. There is currently a risk that specimens stored in yellow bags for use may be confused with specimens in yellow bags for disposal. As well as ensuring that new disposal requirements are implemented,

		and staff are following them, the DI is advised to consider how best to mitigate this risk of confusion.

Concluding comments

During the inspection, it was observed that there was good communication between staff and good practice in relation to the sourcing of cadaveric material was noted. Staff from the establishment had also visited laboratory facilities in the USA, and their experiences of practices there will inform the planning of the new Bioskills Laboratory at the Wrightington Hospital.

There are some areas of practice that require improvement, including one minor shortfall in relation to risk assessments. To make further improvements, the HTA has given advice to the Designated Individual with regards to documents, audits, traceability, risk assessments, premises, equipment, storage arrangements and disposal.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended time frames within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 20 December 2016

Report returned from DI: 13 January 2016

Final report issued: 17 January 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 28 February 2017

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Independent interpreters are available when appropriate • Information is available in suitable formats
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all licensable activities • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system
GQ2 There is a documented system of quality management and audit
• A document control system, covering all documented policies and standard operating procedures (SOPs).

- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the bodies / body parts were acquired, the uses to which the bodies / body parts were put, when the bodies / body parts were transferred and to whom

GQ6 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose • Policies in place to review and maintain the safety of staff, authorised visitors and students • Where appropriate, policies are in place to ensure that the premises are of a standard (and maintained to that standard) that ensures the dignity of deceased persons • The premises have sufficient space for procedures to be carried out safely and efficiently • Policies are in place to ensure that the premises are secure and confidentiality is maintained
PFE 2 Environmental controls are in place to avoid potential contamination
• Appropriate separation of relevant material • Air classification system and maintenance of air quality, including control and monitoring of environmental conditions • Documented cleaning and decontamination procedures • Staff are provided with appropriate protective equipment and facilities that minimise risk of contamination
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• Relevant material, consumables and records are stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings • Critical storage conditions are monitored and recorded • System to deal with emergencies on 24 hour basis
PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation • A system is in place to ensure that traceability of relevant material is maintained during transportation • Records of transportation and delivery • Records are kept of transfer agreements with recipients of relevant material • Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored
• Records of calibration, validation and maintenance, including any agreements with maintenance companies • Users have access to instructions for equipment and receive training in use and maintenance where appropriate • Staff aware of how to report an equipment problem • Contingency plan for equipment failure

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• Documented disposal policy • Policy is made available to the public • Compliance with health and safety recommendations
D2 The reason for disposal and the methods used are carefully documented
• Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal • Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.