Site visit inspection report on compliance with HTA licensing standards

George Eliot Hospital

HTA licensing number 12171

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem 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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

12 October 2017

Summary of inspection findings

This is the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017.

Although the HTA found that George Eliot Hospital had met the majority of the HTA's standards, eight minor shortfalls and seven major shortfalls were found against the Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment standards. These related to the policy and training for hospital (consented) post mortem examinations; information for relatives; standard operating procedures; audits; competency assessments; incident reporting; risk assessments; traceability of histology slides; alarm testing; equipment and personal protective equipment.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out in the mortuary located at George Eliot Hospital NHS Trust (the establishment). The mortuary and bereavement service is managed by the Older Adults, Stroke and Medicine Directorate. The DI is a consultant physician and the Medical Director for the Trust. The Corporate Licence Holder contact is the Chief Executive of the Trust. In summary, the establishment is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes), and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment undertakes approximately 250 PM examinations per year, the majority of which are conducted for HM Coroner for North Warwickshire. A very small number of hospital ('consented') PM examinations were carried out by the establishment (only one in the last three years). These are now, in addition to high-risk and forensic cases, transferred to another licensed establishment. However, consent for adult hospital (consented) PM examinations is sought by clinicians who have undertaken PM consent training. Training is provided annually by the DI for junior doctors as part of their induction and for permanent clinicians at all grades (see shortfall against C2(a)). Consent for perinatal and paediatric cases is undertaken on site by specially trained clinicians and two bereavement midwives; these cases are routinely sent to another HTA-licensed establishment for PM examination (see shortfall against C2(a)). Consent forms for adult hospital (consented) PM examinations are based on the HTA's model consent form. The consent form used for paediatric/perinatal cases is provided by the referring establishment and based on the SANDs consent form (see Advice item 5), therefore both forms are fully compliant with statutory and regulatory requirements.

The establishment has 55 refrigerated body spaces and five freezer spaces for the storage of bodies. This includes spaces for 'super' bariatric and bariatric bodies. None of the fridges are 'double-ended' for direct access in to the PM room and are kept locked at all times. There are dedicated fridge spaces for paediatric/perinatal cases and pregnancy remains.

Key fob access is required for the external door in to the body store, as well as a standard key/thumb lock. In addition, there is a spy hole in this door to visually verify who is requesting access prior to the door being opened. This door is predominantly used by funeral directors (see Advice item 32). Hospital bodies are admitted to the mortuary via a second external access door, closer to the main hospital building. There is only a key/thumb lock securing this door (see Advice item 33). There is CCTV monitoring within the body store only (see Advice item 31).

The PM service is predominantly fulfilled by one Consultant Histopathologist who conducts PM examinations, once or twice per week. The service is covered by two other Consultant

Histopathologists in her absence. All the histopathologists are based at another licensed establishment. PM tissue is recorded in a dedicated book and a ‘Retained Specimen Proforma’ is completed for each case (see Advice item 15). Specimens are taken to the pathology reception at the establishment by mortuary staff and sent to University Hospitals Coventry and Warwickshire (UHCW) for processing; blocks and slides are then returned to the mortuary at the establishment.The slides are examined by the pathologist at the mortuary using a dedicated microscope. Disposal instructions for all PM tissue is dealt with by the establishment (see Advice item 29).

The mortuary is staffed by the Mortuary and Bereavement Manager and a Senior Anatomical Pathology Technologist (APT), both are fully qualified APTs (see shortfall against GQ3(c)). There is a reciprical arrangement with APT staff from the Surgical Skills Centre at UHCW for additional staff, if required.

Porters transfer and admit all hospital bodies and the majority of community bodies in to the mortuary. Bodies are transferred from the wards using a concealment trolley to a mortuary access door used for this purpose. The porters complete the ‘Porter Register’ for each body admitted to the mortuary. This register and the mortuary register is completed by the mortuary staff when patient identification checks are undertaken as soon as possible on the day, or the next working day if the body was admitted out of hours, using the ‘Notification of Death’ sheet transferred with each body. The details of each body are written next to the fridge number on the whiteboard in blue dry wipe pen. Once a body has been checked by the mortuary staff the details are written in black pen to denote the appropriate body and identification checks have been completed. Training in mortuary practice is provided by the mortuary staff to the porters (see Advice item 22). Perinatal cases, pregnancy remains and their associated documentation are transferred to the mortuary by the porters in working hours. There is a separate mortuary register for these cases.

Community bodies are brought in to the mortuary via an area predominantly used by service vehicles and staff. Mortuary staff work on-call and are responsible for admitting certain Coroner’s Cases, for example, road traffic accident victims. All community bodies are admitted to the mortuary using a specific form for this purpose, completed by the funeral director (see Advice item 26).

The mortuary’s PM suite contains three down-draught PM tables and two dissection benches. The pathologist and APTs carry out identification checks of bodies prior to the external examination and evisceration of a body. Each table is colour coded to correspond to the colour of the organ bowl used for that table and a ‘one-at-a-time’ system is used to avoid mix-up of organs and tissue samples removed during PM examination. The PM suite is showing some signs of wear and does require some work to address this (see shortfall against PFE3(a)).

Description of inspection activities undertaken

The establishment has been licensed by the HTA since October 2007. Previous routine site visit inspections took place in March 2010 and December 2013. This report describes the third routine site visit inspection in October 2017. Formal interviews were conducted with the DI, Mortuary and Bereavement Manager, Senior APT, Portering staff, Coroner's Officer, Consultant Histopathologist and PM examination consent seekers (adult and perinatal). A visual inspection of the mortuary, including the body store, PM room and viewing suite was also conducted.

A traceability audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for three adult bodies (two hospital and one community) and one perinatal body. A minor anomaly was found; the body stored in the freezer only had two identifers on the identification bands (see Advice item 26). In addition, an initial audit of three PM examination cases where histology had been taken, were conducted. The inspection team visited the pathology reception to review records and specimens in storage, to establish the relatives' wishes for the tissue and if these had been complied with. All the records indicated this was correct in each case, however, specimen documentation showed the amount of slides generated from the PM tissue blocks were not recorded (see shortfall against T1(g)). Further audits were conducted of stored tissue and records for hospital (consented) and Coroner's PM cases (see Advice item 38).

Inspection findings

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

Advice and guidance was given to the DI to further improve practices following the last inspection in 2013. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The 'Policy for Consent to Treatment, Examination or Post Mortem' (GOV/POL/39) does not contain accurate information that reflects the requirements of the HTA's Codes of Practice, the HT Act 2004, or correct referencing to documents and external guidance. For example: i) Section 5.11.3: (Regarding the retention of tissues outside the Coroner's remit), 'the person who is named by the Coroner as the next of kin should be contacted for such consent'. For consent to be appropriate and valid under the HT Act 2004, consent must be obtained in accordance with the 'hierarchy of qualifying relationships'. Although the hierarchy is mentioned in section 5.11.3, this statement does not reflect this. ii) Section 5.11.13: 'Tissue made into blocks and slides from hospital post mortems are retained as part of the patients medical record in line with guidelines published by the Royal College of Pathologists (RcPath): "The retention and storage of pathological records and archives" (4th edition 2009). 'Any material requires consent for its continued retention, and while tissue is held within the medical record it can be used for other purposes such as clinical audit'. This is correct for tissue from the living. Consent is required for the retention of tissue from the deceased and for specified (scheduled) purposes outlined in the HT Act 2004 ,e.g. clinical audit. In addition, the RcPath guidelines were superceded in 2015. iii) Section 5.11.8 refers to the consent form used to record paediatric/perinatal consented PM examinations 'Consent to a Post Mortem Examination on a Baby'. The consent form currently used by the establishment is called 'Consent Form for Post Mortem Examination of a Baby or Child', from the establishment where these cases are transferred to. iv) Section 5.11.10 references the 'HT Act 2006' v) Section 5.11.9 refers to the use of PM tissue in research and genetic testing. Specific consent is required for these purposes for tissue from the deceased. In addition, this section refers to	**Major**

	‘residual tissue archived after diagnostic examination’ and ‘provided the excess tissue was not collected for that purpose, this tissue can be used without patient identifiable information’. This is applicable to tissue from the living only. vi) Appendix D, does not refer to the correct version of the adult PM consent form (‘Consent for Post Mortem Examination of an Adult’). The form currently in use is ‘Consent to a Hospital Post Mortem Examination of an Adult’. In addition the reference to the consent information leaflet is incorrect (‘A Guide to Post Mortem Examination of an Adult). The leaflet currently in use is ‘A Guide to Post Mortem Care of an Adult’ (see shortfall C1(c)). This is also the case in appendix F and it is out of date. The ‘Consent for Post Mortem Examination’ section of the consent policy requires a thorough review to ensure the information it contains is accurate (see Advice iem 2).	

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.	The consent information leaflet 'A Guide to Post Mortem Care of an Adult' does not reflect the information provided in the consent form currently used by the establishment, the HTA's Codes of Practice or the HT Act 2004. The information provided is incorrect, conflicting and misleading. Examples include, but are not limited to: i) Paragraph one, page 8, states that tissue and fluid samples **will** be taken; this should state '**with your consent** samples of tissue and fluid can be taken'. Consent is required to retain any PM tissues, including those for medical record. ii) Paragraph three, implies that tissue kept for medical record, can also be used for certain scheduled purposes defined in the HT Act. Further evidence of this is documented in paragraph one, page 10. Consent is required for tissue from the deceased to be used for all scheduled purposes defined in the HT Act 2004. iii) Paragraph seven, page 9, states that the hospital will retain tissue taken at post mortem, particularly if they have been made into blocks and slides. There is no indication that consent needs to be obtained for this. iv) Paragraph one, page 11, contradicts the section of the form that explains tissues are taken in cassettes (therefore no wet tissue trimmings) and states that these trimmings may be stored. All wet trimming should be disposed of as clinical waste. v) Paragraph two, states that tissue blocks are kept indefinitely, which implies for no specified purpose. vi) Paragraph three, states the 'next of kin' can decide what happens to retained tissue, other than tissue samples prepared for examination under a microscope (see Advice item 1). This leaflet requires a thorough review to ensure the information it contains is accurate and reflects the HT Act 2004 and the HTA's codes of practice.	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	i) The presentation used by the DI for annual consent training for adult consented PM examinations does not refer to the consent form currently in use by the establishment. The consent form in the presentation clearly refers to blocks and slides being kept indefinitely as part of the medical record and may also be used for medical education and audit. The training material is misleading clinicians expected to seek valid and appropriate consent. The HTA had been assured by the previous DI the training material had been updated following the last inspection. ii) Training for paediatric/perinatal consent seeking has been undertaken by clinicians and bereavement midwives but this is not regularly refreshed (see Advice item 7).	**Major**
d) Competency is assessed and maintained	There are no competency assessments for any staff who undertake PM examination consent.	**Major**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Mortuary SOPs do not always accurately reflect current practice and in some cases do not contain sufficient detail. Examples include, but are not limited to: i) SOP (M-REC-001), 'Deceased Patient Reception and Storage', Section 1.1 does not state that the name of the body is entered in to the 'incoming book'. In addition, it does not include how many or what identifiers can be used to identify bodies on admission. ii) SOP (M-REC-002), 'Deceased patient's with Same or Similar Names', only refers to the surname being the same. Similar first and surnames should also be flagged and included in the SOP. Although documented in the SOP, same/similar names are not highlighted in the register (see advice item 27). iii) SOP (M-REC-003) 'Booking in to the Mortuary Register', contains the 'Proforma for Patients Brought in Dead at George Eliot Hospital'. This form is different from the form actually in use, 'Local Authority Deceased Patient's Form'. iv) SOP (M-REC-005) 'Deceased Patient Release', does not specify what identifiers are required on release of a body. v) SOP (M-AUT-001) 'Preparation of Deceased Patient for Post Mortem Examination', states that three identifiers should be checked when a body is removed from the fridge for PM examination. However, the SOP indicates that body identification is only checked against the Coroner's authority for post mortem, after the body has been transferred to the post mortem table. All SOPs require review to provide assurance they detail correct practices and procedures for mortuary tasks.	**Minor**
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	There is no formal document governance system for SOPs or departmental forms. Although SOPs are ratified by the HTA Committee, they are not regularly reviewed by someone other than the author. There are no page numbers and the version number stated on the front of the SOPs do not always match the version number documented on the back. In addition, the SOP (M-REC-001), 'Deceased Patient Reception and Storage', has not been reviewed for four years.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The current schedule of audits does not contain enough audits and the frequency of audits is insufficient, including those in relation to bodies, tissues and traceability. For example, the audit for collection and storage of specimens undertaken in June 2014, is scheduled again for June 2018 (see Advice item 21).	**Minor**
b) Audit findings document who is responsible for follow-up actions and the time frame for completing these.	Two audits have been conducted so far for 2017. Not all audit findings are reflected in the conclusions or recommedations of the audits. For example, the audit 'Specimen Receipt Storage and Disposal' (MO-AU05-17), highlights the absence of specimen numbers and mortuary documentation stating the wrong HTA licence number. The audit 'Transport of Samples and Documentation' (MO-AU06-17) recommends that blocks and slides should be counted on return and documented. These anomalies were also highlighted by the inspection team during the inspection.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Mortuary staff are not regularly assessed to ensure competency in mortuary tasks is maintained.	**Major**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Mortuary staff and porters are not fully aware of HTA reportable incidents (HTARIs). There are currently two SOPs for staff to follow, these should be amalgamated to avoid duplication and reviewed to reference the correct information, including all HTARI categories and how HTARIs should be reported. A review of the incident log and mortuary meeting minutes highlighted four incidents that should have been reported to the HTA. (See advice item 23).	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The risk assessments are predominantly related to health and safety matters. There are some risk assessments in relation to some licensed activities and the potential risks to the deceased and tissue (see Advice item 24).	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The number of slides generated from tissue blocks at UHCW are not recorded in mortuary documentation on return to Geroge Eliot Hospital (see advice item 10).	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Fridge and freezer alarms are not regularly tested to ensure they will trigger when temperatures deviate from expected ranges.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The post mortem tables are showing areas of rust and the tile flooring is showing signs of wear, including cracking of the grout. This compromises the mortuary staff's ability to clean and decontaminate the PM room sufficiently. *The Trust has identified these issues and there is a plan in place to refurbish the PM room in January 2018.*	**Major**
d) Staff have access to necessary PPE	Mortuary staff and pathologists are not face fitted for the disposable masks available for use in the PM room.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to avoid using the term 'next of kin' (NOK) in all consent documentation and procedures, when consent is required from a person in the highest qualifying relationship to a deceased. For example, in the 'Policy for Consent to Treatment, Examination or Post Mortem' (GOV/POL/39) and 'A Guide to Post Mortem Care of an Adult'.
2.	C1(a)	The DI is advised to update the 'Policy for Consent to Treatment, Examination or Post Mortem' (GOV/POL/39) to ensure it refers to the HTA's new codes of practice and any other guidance, ensuring any information reproduced in the policy is accurate and in-line with the HTA's Codes of Practice and the requirements of the HT Act 2004.
3.	C1(f)	Relatives are instructed to contact the Bereavement Centre 'no later than 12 hours prior to the planned start time' of the PM examination. However, the planned start time is not documented on the consent form for relatives to refer to. At the next opportunity, the DI is advised to include a section in the consent form to record this.
4.	C1(g)	At the next opportunity, the DI is advised to include page numbers, a review date and version number on the adult hospital (consented) PM forms.
5.	C1(g)	The paediatric/perinatal consent form in use refers to the HTA's old 'Code of Practice 3: Post Mortem Examination' (2009). The DI is advised to liaise with the referring establishment to ensure they are using the most recent version of the consent form.
6.	C2(b)	The DI is advised to record who attends the annual PM consent training for adults and adopt a system to ensure permanent clinicians refresh their training at least every two years.
7.	C2(b)	Refresher training for paediatric/perinatal consent seeking should be formally scheduled (at least every two years) and the attendance of staff should be recorded to ensure they continue to undertake regular training in this area.
8.	GQ1(a)	The DI is advised to ensure that only one Quality Manual is in use for the mortuary and regularly reviewed.
9.	GQ1(a)	The DI is advised to review all departmental SOPs to ensure they reflect current practice, contain clear information and include correct referencing to other documents.
10.	GQ1(a)	The mortuary manager is advised to develop an SOP for the process of transferring PM specimens to UHCW, their subsequent return, collection and storage. This should include follow-up procedures (in case specimens are not returned), the checking and recording of blocks and slides and the completion of documentation.
11.	GQ1(a)	The DI is advised to ensure that all SOPs contain the same standard information, for example, references to other relevant SOPs or risk assessments. SOPs that do not provide a reference to a risk assessment(s) could indicate the procedure has not been appropriately risk assessed. For

		example the SOP (M-REC-005) 'Deceased Patient Release' does not refer to an associated risk assessment.
12.	GQ1(a)	SOPs consistently refer to 'The Human Tissue Authority Code of Practice for the Removal, Storage and Disposal of Human Organs and Tissue'. This is not a HTA document and the DI is advised to remove this reference from SOPs.
13.	GQ1(a)	Although bodies are checked on release by both members of mortuary staff (the majority of time), the DI is advised to document what additional checks are undertaken when bodies with same/similar names are released. This will help mitigate the risk of releasing a wrong body.
14.	GQ1(a)	The DI may wish to consider implementing a standardised release form for funeral directors to use that will contain the required three identifiers when releasing bodies, including full name, date of birth and address of the deceased.
15.	GQ1(a)	The 'Retained Specimen Proforma – GEH Mortuary' can detail three different HTA licence numbers. These forms should be updated to display the correct licence number for the establishment (No.12171) to avoid confusion.
16.	GQ1(a)	The mortuary manager maintains oversight of any potential long stayers in the mortuary and is aware of the HTA's advice to freeze bodies in storage after 30 days. The mortuary manager is advised to document this procedure in to an SOP that other staff can refer to in her absence.
17.	GQ1(c)	The families permission should be obtained for any invasive procedures, for example, removal of pacemakers for cremation. This could be discussed and the outcome recorded when the families contact bereavement services.
18.	GQ1(e)	The DI is advised to ensure staff sign SOPs relevant to the mortuary practices they undertake, to acknowledge they have read and understood them. For example, porters should sign SOP (M-GEN-008) 'Use of hydraulic Lift/Trolley' and all staff (including pathologists) should sign the HTARI SOP.
19.	GQ1(g)	The DI is advised to have relevant Persons Designated (PDs) register for the portal via the HTA website. This will ensure that HTARIs are reported in the absence of the DI and within five working days of discovery.
20.	GQ1(h)	As the mortuary and bereavement service work closely together, the mortuary manager is advised to introduce regular minuted meetings to ensure relevant information is shared and recorded.
21.	GQ2(a)	The DI is advised to implement a regular documented audit of all PM tissue in storage (hospital (consented) and Coroner's cases), ensuring these are regularly reviewed, followed-up and appropriately dealt with.
22.	GQ3(a)	Porters should undertake regular refresher training in mortuary practice which is recorded and should include: - the potential risks to the deceased during transfer into refrigerated storage. - HTA reportable incidents - Sign off of key SOPs relevant to the tasks they undertake and equipment they use.

23.	GQ5(a)	The DI is advised to ensure that he, and all staff working under the licence, are aware of the HTARI categories and reports any incidents within five days of discovery.
24.	GQ6(a)	The DI is advised to ensure that the licensed activities outlined in GQ1 and the HTARI categories are risk assessed to provide a comprehensive set of risk assessments. In particular, risks to the dignity and integrity of bodies and stored tissue should be covered. In addition, it is important that they contain sufficient and correct information. For example, referring to the HTA's updated Codes of Practice and where the use of PPE is required, the type of PPE to be used should be stated, or a reference to an SOP which contains that information. The HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) provides guidance and information in relation to risk assessments.
25.	T1(b)	Currently, bodies admitted to the mortuary are written in to the mortuary register in date order. The DI may wish to consider introducing the use of a sequential 'mortuary register' number, allocated to each body as they are entered in to the mortuary register. This number can be used as an additional identifier for bodies while in the care of the mortuary (written on paperwork and the body store whiteboard) and help with traceability and filing of mortuary paperwork.
26.	T1(a)	The DI is advised to ensure that all bodies admitted to the mortuary, including those bodies returning from other establishments are identified using three identifiers, one being unique.
27.	T1(d)	The DI is advised to highlight bodies with same/similar names in the mortuary register, on fridge/freezer doors and the body store whiteboard using signs or magnets, as a visual cue to alert staff. This method can also be used for other important information. For example, 'Danger of Infection', 'Pacemaker' or 'Tissue Retained'.
28.	T1(g)	Records of PM tissue taken for histology and toxicology, and their subsequent traceability is in paper format recorded on different forms. The DI is advised to develop an electronic record where this information can be held centrally, easily referred to and audited.
29.	T2(d)	Although the disposal method and date of disposal are recorded on specimen paperwork, the mortuary manager is advised to include this information in the SOP (M-AUT-006) 'Disposing of Samples for Histology and Toxicology'.
30.	PFE1(b)	The mortuary manager is advised to risk assess the body store and ancillary areas to help with appropriately demarcating these as 'clean' and 'transitional' areas. The Health and Safety Executive (HSE) document 'Safe Working and Prevention of Infection in Mortuaries and Post Mortem Rooms' provides helpful information in relation to this.
31.	PFE1(d)	The DI is advised to establish if there is external CCTV coverage of the mortuary access doors and explore options with the Trust in relation to this, if these areas are not monitored. This will provide further assurance of security for the mortuary in the event of any incidents.

32.	PFE1(d)	The DI may wish to consider options to better conceal the external access doors to the mortuary to prevent the dignity of bodies being compromised during admission and release procedures.
33.	PFE1(d)	The DI is advised to add a magnetic lock to the second door to ensure that the mortuary remains secure when the key/thumb lock is unlocked.
34.	PFE1(e)	The door between the body store and PM room is kept closed but is not routinely locked during PM sessions. The mortuary manager is advised to keep this door locked during PM sessions to prevent unauthorised or unintentional access, compromising the dignity and respect of the bodies during PM examination.
35.	PFE3(f)	The mortuary fridges and freezers are regularly serviced (annually) but a review of the break down records indicate a number of engineer call-outs in the last 12 months. The mortuary manager is advised to monitor these closely to identify any significant issues. The DI may wish to consider escalating this to the Trust's risk register if required.
36.	N/A	The mortuary staff may wish to consider using a sign on the viewing room door when viewings are in progress to alert other athorised staff that a viewing is in progress when they access the mortuary.
37.	N/A	The DI is advised to display updated HTA licences, detailing the name of the correct DI.
38.	N/A	Following the inspection in 2013, the HTA advised the establishment to audit the retained tissues and consent forms from hospital (consented) PM examinations to assure themselves that sufficient consent was in place for their continued retention. Following this inspection, all tissues that are being stored for hospital consented and Coroner's cases were audited to confirm the purposes for which they are being stored for, and if they are being used for that purpose. The results of the audit were submitted to the HTA for review and the HTA has given advice on the results of that audit. . The DI is advised to consider if it is appropriate to continue storing other tissue that is not being used for the purpose for which it had been retained, for example, teaching or research, or if disposal of these tissues would be more appropriate. The DI is advised to have a process in place for the regular audit and review of tissue retained from Coroner's cases for civil or legal proceedings to ensure that each case is considered on an individual basis, that there is a documented reason for retaining tissue and that tissue is not retained for longer than necessary. The rationale for the disposal of any tissues should be recorded, including the date and method of disposal.

Concluding comments

The mortuary team appear enthusiastic and conscientious, demonstrating a high level of compassion and care for the work they undertake. They are supported by a DI and senior management team who recognise the importance and significance of mortuary practice.

There are areas of strength and good practice:

- The paediatric mortuary register contains a section for the transfer and return of post mortem cases from the referring establishment;
- PM tables are colour-coded to correspond with the colour of the organ bowl used for that table;
- The use of a different coloured white board pen to denote that identification and body checks have been completed;
- The premises are clean, tidy and well organized;
- The mortuary team have good working relationships with service users.

There are a number of areas of practice that require improvement, including seven major shortfalls and eight minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes 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: 08/11/17

Report returned from DI: No redactions or comments on factual accuracy received.

Final report issued: 11/12/17

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: 04 May 2018

Appendix 1: HTA licensing standards

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

Consent
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice. b) There is a documented standard operating procedure (SOP) detailing the consent process. *Guidance* *This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.* c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice. *Guidance* *Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.* d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

Guidance

Refresher training should be available (for example annually).

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

Guidance

SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.

Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

Guidance

For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.

However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

Guidance

These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

As a minimum, the schedule should include a range of vertical and horizontal audits

checking compliance with documented procedures, the completion of records and traceability.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

Guidance

Staff should be made aware of the outcomes of audits and where improvements have been identified.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

Guidance

Audits of stored tissue should include samples held under the authority of the police, where applicable.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.

APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

Assessment of competence should include the standard of APTs' reconstruction work.

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

Guidance: attendance by staff at training events should be recorded.

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.

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

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

Guidance

HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.

Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances

change. Staff should be involved in the risk assessment process.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary.

Guidance

The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

Guidance

Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

Guidance

Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment forthese cases.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

Guidance

Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.

Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.

d) The method and date of disposal are recorded.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

a) The premises are clean and well maintained.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Storage arrangements ensure the dignity of the deceased.

Guidance

Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

Guidance

Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

Guidance

There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.

Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.

Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.

Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities

forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements

with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

Guidance

COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.

d) Staff have access to necessary PPE.

Guidance

Where face masks should be worn, they should be face fitted.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

Guidance

This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.

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.