Site visit inspection report on compliance with HTA minimum standards

Weston General Hospital

HTA licensing number 30013

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**

30 January 2014

Summary of inspection findings

A site visit inspection of Weston General Hospital (the establishment) was carried out by the HTA on 30 January 2014.

The HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation. Following an agreement between the Home Office and the HTA, this inspection also covered police holdings stored at the establishment.

The establishment was found to have met the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. However, some shortfalls were found in relation to the governance and quality standards. These shortfalls included the absence of formal training for hospital porters who transfer bodies to the mortuary, lack of documented risk assessments relating to mortuary activities and the absence of a documented procedure to report HTA Reportable Incidents (HTARI) to the HTA. The establishment had addressed a minor shortfall relating to its coding and traceability system, which had been identified during the previous inspection.

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

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 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

Weston General Hospital undertakes coronial and consented adult post mortem PM examinations, including high risk PM examinations, but does not undertake perinatal or forensic PM examinations. Staff based at the hospital take consent for perinatal PM examinations which are undertaken at another HTA licensed establishment.

A site visit inspection of the establishment was undertaken on 30 January 2014. This was the third routine HTA inspection and included interviews with: the Head of Histopathology (DI); the Mortuary Manager\Anatomical Pathology Technologist (APT); Bereavement Office staff and midwives who take consent or support clinical staff who take consent for adult and perinatal PM examinations; and a coroner's officer.

The mortuary is staffed by an APT who is also the Mortuary Manager. PM examinations are undertaken only when he is on site. A medical laboratory technician (MLA) based in the Pathology Laboratory, who has been trained in mortuary practices, assists the APT as required. When the APT is on leave, the MLA also takes responsibility for admission and release of bodies. The MLA also acts as a 'circulator' when high risk PM examinations are undertaken.

The mortuary has storage capacity for 28 bodies, including four spaces which can be used as an isolation fridge or as a freezer. The refrigeration units are linked to a local alarm system and also to the hospital switchboard. The set point for the fridge alarm is 5^0C. The PM room has two down draft PM tables. The premises are fit for purpose, though they have not been refurbished for twelve years. Contingency arrangements are in place with local funeral directors for storage of bodies as part of an escalation plan in the event that additional storage is required. Tissue blocks and slides are stored either in the mortuary or in the histology laboratory (depending on how recent a case is and/or whether it is a forensic case.

Bodies of the deceased are brought from the hospital to the mortuary by hospital porters accompanied by nursing staff. All bodies received into the mortuary are tagged, and bodies from the community are labelled with an additional mortuary unique number. Mortuary staff provide training to funeral directors and ambulance service personnel, who bring bodies in from the community out of hours. On-site security personnel alert porters who accompany these agencies when bodies are admitted into the mortuary. The following working day mortuary staff check the bodies and details entered into the mortuary register to ensure they are correct. The mortuary has a system to alert staff of same or similar names. Funeral directors have to make an appointment before they come to the mortuary to collect bodies.

In 2013, pathologists based at Weston General Hospital undertook around 60 PM examinations on behalf of the Coroner for West Somerset. No hospital consented PM examination was undertaken in 2013. Evisceration of a body only takes place after the pathologist identifies and completes an external examination of the body. Some of the pathologists also undertake PM examinations at Flax Bourton Public mortuary (HTA licensing no 12536) on behalf of the Avon Coroner. Tissues removed by the pathologists during PM examinations at both sites are transferred to the establishment's Pathology laboratory for processing. The laboratory also stores tissue samples retained by an independent Home Office Pathologist for police purposes. Pathologists who retain tissue from PM examinations undertaken at Flax Bourton mortuary are responsible for transporting these to the laboratory. Organs or tissues are occasionally transported to other hospitals by the hospital contracted courier for specialist examination.

Biomedical scientists at the pathology laboratory enter details of PM tissue samples that come into the laboratory, including blocks and slides, onto the Telepath laboratory computer system and on a computer spreadsheet which is shared with staff in the mortuary. The coroner's administration staff inform the mortuary when the Coroner's authority to retain material has ceased and instruct the laboratory to dispose of retained tissues in accordance with the wishes of the next of kin. Sensitive disposal of tissue takes place at the mortuary where the tissues, including fetal tissues, are packaged and disposed of separately. Staff update the computer spreadsheet once disposal has been completed. Regular audits of this spreadsheet are undertaken to ensure that tissues are not retained without consent once the authority of the Coroner ceases.

Staff based at the Bereavement office provide support for clinical staff who take consent. Midwives are involved in the consent process for perinatal PM examinations and use the recently developed Sudden and Neonatal Death Society (SANDS) forms. Relatives are provided with a Trust booklet which provides information on PM examinations and the options for retention or disposal of organs and tissue. The booklet explains why a pathologist may wish to keep organs or tissues indefinitely and the uses to which these organs or tissues may be put; it states that consent is required to keep organs or tissues.

During the inspection, a document review was carried out. The documents reviewed included standard operating procedures (SOPs) relating to admission and release of bodies, PM examinations, policies such as the consent policy, escalation plan for body storage, complaints policy, serious incident policy and management of incidents and agreements with

third parties. Computer records used to track tissues removed during PM examinations and disposal records were also reviewed.

An audit trail was undertaken of a body stored at the mortuary. Details in the mortuary register, name and identity tags were checked; no discrepancies were noted. Tissues removed during two Coroner's PM examinations, including a whole brain, were traced from the mortuary to the histopathology laboratory. Written records, next of kin wishes regarding disposal/retention of tissue, computer records (spread sheet for tracking tissue) and disposal records were audited – there were no discrepancies. A completed consent form for an adult PM examination was also reviewed.

Under s39 of the Human Tissue Act 2004 ('the Act'), relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings were reviewed by HTA at its site visit inspection. The HTA inspectors were accompanied by an observer from the Home Office. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the Act.

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**

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Formal training is not provided for hospital porters who are responsible for bringing bodies to the mortuary. This lack of formal training increases the risk that porters will not comply with mortuary procedures for handling bodies, including identification and labelling of bodies and the use of mortuary trolleys to transfer bodies into the fridges. Porters may also be unaware of the requirement to report mortuary related incidents internally and to the HTA.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The Trust has a formal incident reporting system for local incidents as well as a serious incident policy which covers investigation and corrective actions to be taken. However, The establishment does not have a documented procedure for reporting HTA reportable incidents (HTARIs) to the HTA and staff do not have sufficient knowledge of the categories of incidents which have to be reported.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment does not undertake formal assessment of the risks to bodies and tissues; for example, the risk that a body could be released without all tissue being returned in accordance with wishes of the next of kin or that the wrong body is released. The lack of formal risk assessments, including those which cover HTARI reportable categories, increases the risk of a serious incident occurring.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to consider including the current procedure for taking consent for perinatal PM examinations and the role played by midwives in the Trust's consent policy. The family wishes form used by the Coroner for West Somerset includes the standard options to dispose of tissues. The DI may wish to explore with the Coroner whether the form could be revised to include explanatory text which outlines the scheduled purposes for which tissues could be used if the family consent to its retention.
2.	GQ2	The DI is advised to ensure that the procedural and premises audit of the mortuary which was scheduled to take place in December 2013 is completed as soon as practicable.
3.	GQ3	The DI is advised to consider making arrangements for staff, including mortuary staff and staff based at bereavement services who provide support to clinical staff who take consent, to attend professional meetings in order to ensure that they are aware of any changes to practices.
4.	GQ6	Details of the deceased, including the name, hospital identification number and date of birth, are entered in the mortuary register when bodies are admitted from within the hospital. Bodies from the community are given a unique number. These numbers are not used in the laboratory computer system or in other spreadsheets. The DI is advised to consider simplifying the numbering system by using a a running mortuary number which can also be used as an identifier in the computer systems used by the laboratory. Bereavement Services give relatives a release request form with the name of the deceased which is conter-signed by relatives and used by funeral directors who collect the body. The DI is advised to consider additional information that could be included on the form ie; date of birth relating to the deceased to ensure correct identification and reduce the risk of release of the wrong body. Mortuary staff and funeral directors jointly identify bodies using all ID labels, before they are released from the mortuary.The DI is also advised to consider updating the 'Release of Bodies' SOP to list the number of point of identification which must be used before a body is released from the mortuary.
5.	PFE2	The DI is advised to consider implementing an annual schedule for monitoring

		airflow in the PM room where high risk examinations also take place. The DI is also advised to consider reviewing the personall protective equipment used by staff when undertaking high risk PM examinations to ensure that the equipment used is sufficient to reduce any health and safety risks to staff.
6.	PFE3	The establishment has a detailed escalation plan in the event that storage space in the mortuary is full. The plan includes contacting local funeral directors, placing bodies in trays which are then placed in the bottom section of the fridges to avoid the need to use the PM room for emergency storage. The DI is advised to also consider putting in place a contingency arrangement with another licensed establishment for storage of bodies in the event that it is needed.
7.	D1	The Mortuary Manager packages blocks, slides and foetal tissue for disposal. The DI is advised to consider documenting this process so that other members of staff can undertake this task.

Concluding comments

There were several areas of good practice. There is good communication between the DI, mortuary staff and laboratory staff who are responsible for tracking tissues. The Mortuary Manager attends regular formal minuted meetings with the DI and other pathology staff where mortuary activities are discussed. Mortuary staff undertake several audits, including weekly body audits and a regular audit of tissue recorded on the spreadsheet.

The induction programme for all doctors who work at Weston General includes a comprehensive training programme - 'Death certification - getting it right' - which covers seeking consent for PM examinations, the requirements of the Human Tissue Act 2004, the hierarchy of consent and the scheduled purposes under the Act.

The establishment has robust system in place to trace bodies, tissues, blocks and slides. Regular audits are undertaken to ensure that tissues retained only following the consent of family members.

There are areas of practice that require improvement, including three minor shortfalls and the HTA has given advice to the Designated Individual on a range of issues.

The HTA requires that the Designated Individual addresses the shortfalls 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 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: 24 February 2014

Report returned from DI: 10 March 2014

Final report issued: 14 March 2014

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: 22 August 2014

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
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent.

- Refresher training is available (e.g. annually).
- Attendance at consent training is documented.
- If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

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

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

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

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

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

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.