Site visit inspection report on compliance with HTA minimum standards

Alder Hey Children's NHS Foundation Trust

HTA licensing number 12213

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**

15 December 2015

Summary of inspection findings

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

Alder Hey Children's NHS Foundation Trust (the establishment) was found to have met all HTA standards.

Since the last inspection, the establishment has moved to a new hospital building adjacent to the facility previously used. At the time of inspection, the building had been occupied for less than three months and had not been handed over to the Trust by the PFI contracted builders. Newly installed equipment was still being validated and staff were working through a schedule of review of governance documentation, revising as necessary to reflect the differences in process resulting from the change in location and infrastructure.

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 (DI), 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

Alder Hey Children's NHS Foundation Trust (the establishment) is a tertiary referral centre providing specialist hospital services for children. In October 2015, Alder Hey Children's Hospital (AHCH) moved to a new hospital building which incorporates a purpose-built mortuary facility and related pathology services. At the time of inspection, some elements of governance documentation were being revised to reflect process changes resulting from the move. Some recently installed equipment was still being validated.

The establishment performs approximately 250 paediatric and perinatal post mortem (PM) examinations per annum. This total consists of referrals from nine surrounding coronial districts, consented perinatal and paediatric PM examinations from within AHCH, forensic PM examinations and referrals from seven other hospitals within a wider geographical area. As the hospital does not have a maternity unit, products of conception are not received from within the AHCH, but may be received into the histopathology laboratory from referring centres. High-risk PM examinations are referred to another specialist hospital within the area.

Qualified mortuary staff receive all bodies or specimens into the mortuary and are on call for this purpose when required out of hours. The procedure for cases referred from other hospitals or received from the wards at AHCH for coronial or consented PM examination

involves identity being checked using the hospital wristband attached to the body, and reference to clinical notes and referral paperwork.

When the establishment receives a body following a death in the community, formal identification of the deceased is carried out by the accompanying police officer and family, and a wristband is then printed by establishment staff and attached.

In all cases, mortuary staff then add details of the deceased into a mortuary register and electronic software system, which allocates a unique, sequential, body number. For cases transferred from wards at AHCH, details are also recorded in a separate “Hospital Register” to record traceability, which includes the time of transfer from ward to mortuary in addition to name, date and hospital number.

The establishment has 15 storage spaces, ten of these refrigerated, and a further five spaces which can be converted to freezer storage. There is a separate storage refrigerator for fetuses. All refrigerators and freezers are monitored and alarmed via a web-based proprietary temperature monitoring system. At the time of inspection this had only recently been installed and staff were comparing the temperatures recorded daily using the digital readouts on the storage units with those shown by hand held thermometers, as a way of checking that calibration had been carried out properly during installation. The alarm sounds locally, and currently also alerts the Trust building management service as well as an external monitoring company. There is an on-call rota for staff in the event of an alarm sounding out of hours and plans are in place to simplify the monitoring procedure, to alert only the external monitoring company in the event of an alarm event out of office hours. Following sign-off by the installers, alarms will be tested quarterly.

Having been newly installed, equipment is still under warranty, and in due course preventative maintenance will be carried out by the Trust’s building management service, with specialist engineers being called in where necessary. The establishment has a contingency arrangement in place in case of equipment failure or when full capacity is approached.

When a PM examination is authorised by the coroner, or consented to by the bereaved family, the pathology department software system allocates a unique PM examination number (N number). The N number is printed on labels which are used to label documentation, sample pots, tissue blocks and slides, and any subsequent reports relating to that PM examination. A bar-code is also generated, but the establishment does not yet use bar-code readers to track samples and documents.

Coronial authority for PM examination is faxed to the establishment. Consent for PM examination for deaths occurring within AHCH is sought by trained consultant clinicians or a specialist nurse. Pathologists from the establishment have also visited referral centres to train staff there in the requirements for consent for a PM examination. Referral centres use consent documentation supplied by the establishment.

During the PM examination, the pathologist, or assisting anatomical pathology technologist (APT) completes a form detailing the tissue retained for examination. Tissues blocks are placed into pre-printed cassettes in the PM examination room and sent to the laboratory, accompanied by the appropriate form detailing the tissues retained and any specialist stains required. This information is entered onto the electronic record within the mortuary and updated by laboratory staff following production of slides.

Subsequently, the electronic case record is updated with details of slides being transferred for examination, either within the department or to external specialists, and their subsequent

return. Details of storage location of those tissues for which consent to store has been received are also recorded within the electronic record as is the date and reason for disposal when tissues are disposed of. Tissue storage is subject to periodic audit or inventory and there is a system of vertical and horizontal audits within the mortuary and laboratory covering documentation and processes.

Body release is carried out only by qualified APTs. When bodies or specimens are returned to referring hospitals, the establishment tracks receipt by use of a faxback form.

The wishes of relatives for return, retention or disposal of tissue samples retained following PM examination are collated by designated administration staff and entered onto two spread sheets; one for coronial cases and one for hospital, consented, cases. The electronic database is also updated with triggers for disposal. Periodically, laboratory staff compile a disposal list and blocks and slides are sensitively disposed of by incineration, with records updated to reflect this. The establishment uses a system of library card inserts to indicate where stored samples have been disposed, to facilitate audit of that procedure. AHCH is not involved in disposal of fetal tissue; all such tissue is returned to referring hospitals.

Organs retained during forensic PM examination may be held for a short period while fixing takes place, before collection by the police for transfer to the reporting pathologist. Blocks and slides retained following forensic PM examinations are stored at the establishment and there are procedures in place for periodically checking with the relevant police forces as to the continuation of their authority. Where police authority has ended, relatives' instructions are sought from the appropriate coroner and the establishment has systems in place to request these and follow up where necessary.

This inspection was the third inspection of the establishment. It was a non-routine inspection, scheduled as a result of the establishment having moved to a new facility. It comprised a visual inspection of the body store, PM examination room and histopathology laboratory as well as a review of relevant updated documentation and discussions with key staff. The HTA also visited the archive store of research samples. These research samples were existing holdings collected before the HT Act came into force.

In addition, an audit of traceability was carried out:

- Two bodies were located within the body store and identity details compared with those held within the hospital and mortuary registers. The appropriate coronial authority for PM examination and hospital consent documentation were also reviewed. Details of tissue samples retained at PM examination for each case were reviewed and compared with the corresponding electronic record.
- One fetus was located within the fetus storage unit and identity details checked as before against the paper and electronic register.

Other than the consent form in one case not having been fully completed with contact details in the event of a change of mind, no discrepancies were found. Staff explained that as the consent form related to a referred case, the time limit for change of mind expired before transfer to the establishment. Advice has been provided below regarding this.

- For two cases where tissue had been retained during PM examination, the relevant tissue retention record forms were reviewed, together with the forms detailing family instructions. Relevant authorities for PM examination were reviewed and the records were traced through the laboratory database and blocks located in store.
- Blocks relating to another case were located in store and the records traced back through the laboratory to the original consent for retention.

No discrepancies were found and it was noted that for one case, where disposal was to take place in January 2016, the appropriate marker was entered on the corresponding spread sheet.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to ensure that Service Level Agreements (SLA) entered into with other Trusts referring cases for PM examination oblige the referring establishment to ensure that consent is sought only by trained staff. The HTA notes that the DI feels this requirement was in previous versions of the SLA, but does not appear to have been included in recent updates of the SLA. The HTA also notes that establishment staff have carried out consent training, and refresher training, for staff at referring Trusts, but as that training is cascaded within those Trusts, establishment staff have no practical way of checking that consent has been sought by trained staff and rely on the consent forms received having been completed correctly.
2.	C2	The DI is advised to clarify with referral centres their procedures permitting consent givers to withdraw consent within defined time limits. He is also advised to periodically audit consent forms to ensure that the appropriate section of the consent form has been completed. By doing so the DI will help to assure staff at the establishment that consent for PM examination remains valid.
3.	GQ1	The DI is advised to review and update the Standard Operating Procedure (SOP) used by bereavement staff when facilitating viewing of the deceased by relatives to ensure it fully details the identifiers to be checked and the documentation these should be checked against. The HTA notes that trained mortuary staff are involved in all identification procedures required for receipt and release of bodies, viewings during working hours and PM examinations. Viewings out of hours take place very occasionally; in many cases the bereavement staff will have had dealings with the deceased and family immediately following death. The HTA also notes that mortuary staff have trained bereavement staff on out of hours viewing procedures. By ensuring that bereavement staff have clear guidance on identification procedures to be used the DI will help to mitigate the risk of errors in this procedure.
4.	GQ8	The DI is advised to risk assess the procedures for receipt of cases referred from elsewhere for PM examination, with particular reference to the risk of consent not being obtained in line with the HTA Code of Practice on Consent.

		Reference is made to the advice given above under standards C1 and C2.
5.	PFE1	The DI is advised to extend the intercom system used by funeral directors to notify establishment staff of their arrival at the establishment to a point within the PM examination room. The HTA notes that the current arrangement means that when staff are working in the PM examination room for several hours, they are unaware of the arrival of funeral directors, which has resulted in delays in the admission process. In addition, in several instances body transport vehicles have remained parked for extended periods outside the establishment in view of staff occupying neighbouring buildings, presenting a potential risk to the dignity of the deceased.
6.	PFE2, GQ8	The DI is advised to risk assess the likelihood of staff carrying out known or unknown high risk PM examinations in order to inform the decision on whether respirator equipment for staff is to be purchased. The HTA notes that prior to the establishment relocating to the new facility, respirator equipment was available, but had never been used as all high risk cases were referred elsewhere.
7.	PFE2	The DI is advised to ensure that records of equipment validation and calibration, together with maintenance records, are retained within the department. The HTA notes that equipment had only recently been installed and that relevant calibration and validation certification will be delivered to the department when the new hospital building is handed over to the Trust by the builders. By ensuring that such certification is retained within the department and that records of preventative maintenance or repairs carried out are similarly maintained, the DI will be able to assure himself of the continued suitability of the facilities for carrying out licensable activities.
8.	N/A	The DI is advised to appoint a Person Designated (PD) to oversee the activity of removal of tissue from the deceased in the Accident and Emergency department at the establishment, in cases involving the Sudden Death in Infancy (SUDI) protocol. The HTA notes that the licence covers the whole of the Alder Hey Children's Hospital site, but that no PD has been appointed. By appointing a PD and arranging regular update meetings with that person, the DI will be able to assure himself that licensable activity being carried out elsewhere within the hospital is being carried out under appropriate governance and will be advised in the event of any incident relating to that activity.

Concluding comments

The HTA noted various examples of good practice at the establishment.

- There is a close working relationship between staff carrying out the licensable activity, and good communication between staff working in the mortuary and the laboratory.
- The establishment offers consent training to staff at referring hospitals and pathologists make themselves available for consultation with referring centres where necessary.

- The establishment has set up robust procedures to record wishes of relatives for disposal of tissue retained at PM examination. This involves the use of two separate spread sheets and electronic markers used within the mortuary and laboratory database software.

- Staff seek updates on a regular basis from the coroner and local police forces in relation to blocks and slides held under their authorities.

- There is a comprehensive schedule of audits and these include examination audits of staff carrying out procedures against specific SOPs.

The HTA has given advice to the DI with respect to some elements of documentation, risk assessment, and equipment maintenance records, and the appointment of a PD in the Accident and Emergency department.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 4 January 2016

Report returned from DI: 8 January 2016

Final report issued: 12 January 2016

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.