Site visit inspection report on compliance with HTA minimum standards

The London Welbeck Hospital

Proposed HTA licensing number 22676

Application to be licensed for the

- **procurement and testing of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

1st August 2019

Summary of inspection findings

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

Although the HTA found that The London Welbeck Hospital (the establishment) had met the majority of the HTA standards, seven minor shortfalls were found in relation to governance and quality system standards and premises, facilities and equipment standards. The shortfalls relate to the standard operating procedures (SOPs), the agreement with the courier company, the record retention times, the recording of batch records of material coming into contact with tissue, the procedure for reporting of serious adverse events and reactions, and the risk assessments for procedures and premises.

The HTA's regulatory requirements

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

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

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

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

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

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

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

Proposed licensable activities to be carried out by the establishment

'E' = Establishment has applied for a licence to carry out this activity.

'TPA' = Third party agreement; the establishment has applied for a licence to carry out this activity but another establishment (unlicensed) will carry out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Other; Adipose (ATMP)	**E**		**TPA**				

Background to the establishment and description of inspection activities undertaken

The establishment has applied to be licensed for the procurement and testing of adipose tissue under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). This was a licence application assessment visit to assess whether the establishment meets the required HTA standards.

Based at the establishment, the company LifePlus Clinics Ltd. proposes to procure adipose tissue as starting material for an autologous Advanced Therapy Medicinal Product (ATMP).

The proposed Licence Holder (LH) is The London Welbeck Hospital, the proposed Corporate Licence Holder contact (CLHc) is the Director of The London Welbeck Hospital, and the proposed DI is the Quality Manager of LifePlus Clinics Ltd.

Donors will be identified by orthopaedic surgeons who will refer them to the establishment where they have an initial consultation with a consultant plastic surgeon who will provide information on the risks and expected benefits of the treatment, and who will take the medical and social history. Donors will also receive an information leaflet about adipose tissue procurement. Consent will subsequently be taken by the consultant plastic surgeon for the procurement of tissue and the taking of blood samples for mandatory serological tests. Blood for serological testing will be taken within 30 days of the procedure to determine patient suitability and then again on the day of procurement for the mandatory serology testing. The testing will be undertaken at an accredited testing laboratory under a third party agreement.

The testing laboratory will be responsible for the courier transport of the blood samples from the establishment to the laboratory.

For the harvest of adipose tissue, a theatre nurse will label syringes with the patient's name, date of birth, a unique donation number and the Single European Code - Donation Identification Sequence. In theatre, approximately 20 millilitres of adipose tissue will be aseptically harvested by a consultant plastic surgeon using standard liposuction technique.

All syringes containing tissue will be packed in a validated transport box provided by the manufacturer and shipped on cold packs with a temperature logger and a 'Starting Material Tracking Form' to the London-based ATMP manufacturer who is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). The transport is carried out by a courier company according to the terms of an agreement with the establishment.

Each tissue procurement is listed in a procurement index form. All medical notes and procurement records are held securely in an access-controlled storage room on site in the form of paper copies.

The inspection included discussions with the proposed DI, the proposed CLHc, the hospital's clinical manager, the Medical Director of LifePlus Clinics Ltd., and the Chief Executive Officer of LifePlus Clinics Ltd. A visual inspection of one consultation room, the document storage room and the theatre facilities was carried out. The third party agreements and the documents for all licensable activities were reviewed.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	The establishment does not have SOPs in place for some procedures. Examples include: - an SOP that details how serology results are received, who can review them and how they can be followed up; - an SOP that details how the establishment notifies the manufacturing team in case any procedural deviations or potential quality issues with the starting material are identified. The SOP for adipose tissue procurement lacks sufficient detail to ensure procedures are carried out consistently. For example, it does not detail that syringes containing tissue should be packed in a plastic bag before placing them in the transport box. The SOP also states that liposuction is carried out using saline, but staff stated that they will use a sodium lactate solution.	**Minor**
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	The third party agreement between the establishment and the courier company has no clause that states that the courier will notify the establishment of any serious events within 24 hours.	**Minor**

GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells. i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.	The establishment's quality manual states that patient records are archived for 30 years and processing records are archived for 10 years. However, the quality manual does not specify that records need to be archived for those periods "after the use, expiry or disposal of tissues and / or cells".	**Minor**
j) Records are kept of products and material coming into contact with the tissues and / or cells.	The establishment's SOPs and policies do not state the requirement to document the batch number and expiry dates of reagents and materials coming into contact with tissues.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The establishment has no procedures in place for the reporting of serious adverse events and reactions in the absence of the DI.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes.	The establishment has not risk assessed the transport of starting material by taxi if the courier is unavailable. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	The DI has documented how the PFE standards will be met. However, no risk assessment looking at the premises where licensable activities will take place has been carried out. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1d	Currently the proposed DI writes, reviews and authorises the quality manual and the SOPs. He is advised to identify suitable reviewers to ensure the documentation reflects current practices. During the inspection some documents were still in draft format and not version controlled. The DI is advised to ensure the final versions of the documents are version controlled.
2.	GQ1s	The proposed DI should ensure that the agreement between the establishment and the ATMP manufacturer clearly sets out who takes responsibility for the transport of the tissue to the manufacturer, as currently the establishment is responsible for the courier but the transport boxes are provided, and validated, by the manufacturer.
3.	GQ2a	The proposed DI is advised to refer to the correct legislation in the agreements, quality manual and relevant documents.
4.	GQ2b	The establishment has procedures in place for conducting the internal audit and the proposed DI drafted a list of activities he intends to audit. The proposed DI is advised to ensure a schedule for the audit is in place before the licensable activities commence.
5.	GQ2c	The proposed DI is advised to identify an independent auditor who is not involved in the licensable activities but has expertise in auditing against HTA standards.
6.	GQ4f	The proposed DI is advised to include a field in the medical and social history questionnaire for documenting the donor's travel history. The DI is also advised to ensure that up-to-date information on worldwide disease outbreaks is available to medical staff assessing the donors.

7.	GQ4j	The proposed DI is advised to amend the procurement/operation note to include a field for batch numbers and expiry dates of reagents and materials coming into contact with tissue.
8.	GQ5b	The proposed DI is advised to identify a contact person at the testing laboratory responsible for the serology testing who can provide advice to the establishment as required.
9.	GQ7a, c	The proposed DI is advised to provide examples of serious adverse events and reactions in the quality manual and SOP.
10.	PFE4h	The validation of the transport boxes was carried out by the manufacturer 11 years ago, and the boxes have been in use for the same number of years. The proposed DI is advised to risk assess the use of those boxes, and decide whether a re-validation of the boxes is required.
11.	-	Currently the agreement with the ATMP manufacturer states that the licensable activities are carried out between two HTA-licensed establishments. The proposed DI is advised to review the agreement so it reflects that the manufacturer's activities are regulated by the MHRA. The proposed DI is further advised to review the agreement with the manufacturer to include the provision that the manufacturer is responsible for retaining their manufacturer's license and to inform the establishment immediately if the licence is suspended.

Concluding comments

The proposed DI has strong links to the manufacturing team. The work at the establishment is supported by experienced senior personnel across the organisation.

There are a number of areas of practice that require improvement, including seven minor shortfalls relating to the governance and quality system standards, and risk assessments of procedures and the premises. The HTA has given advice to the proposed DI with respect to improving the governance and quality system, a risk assessment of the transport boxes, and the agreement with the ATMP manufacturer.

The HTA requires that the proposed DI 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: 29th August 2019

Report returned from DI: 10th September 2019

Final report issued: 13th September 2019

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: 3rd October 2019

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.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.

b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.

g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.

f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.

Appendix 2: Classification of the level of shortfall (HA)

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 direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   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.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and

safety of the tissues and cells.

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 and, which can be addressed by further development by the establishment.

   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 review or at the time of the next inspection.

   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.