The role of regulatory bodies in the healthcare sector

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ABSTRACT

Haematological Transplant Centres seeking certification from JACIE (the Joint Accreditation Committee of ISCT & EBMT) are required to provide evidence that they hold a licence from their...

Haematological Transplant Centres seeking certification from JACIE (the Joint Accreditation Committee of ISCT & EBMT) are required to provide evidence that they hold a licence from their Competent Authority.

The Human Tissue Authority (HTA) is the recognised Competent Authority in the United Kingdom charged with regulating and licensing transplant activities and other requirements involving Human Tissue. Competent Authorities were established in EU Member States following the 2004 EU Directive ‘on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells’ and the subsequent technical directives from 2006 and beyond. In the United Kingdom, the Directives were enshrined in local law as The Human Tissue Act 2004, and subsequent Quality & Safety Regulations and amendments which were introduced from 2007 onwards.

In Practice

From a Haematology Transplant perspective, the Regulations require an organisation (‘corporate body’) to hold a licence which allows them to procure, test, store, distribute and (if necessary) import and/or export tissues and/or cells intended for human application. The hierarchy for each licence is as follows:

Designated Individual – A Designated Individual (DI) has a key role to play in implementing the requirements of the Human Tissue Act. They are the person under whose supervision the licensed activity is authorised to be carried out. They have the primary legal responsibility under Section 18 of the Human Tissue Act to ensure:

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- that suitable practices are used in undertaking licensed activity;
- that other persons working under the licence are suitable; and
- that the conditions of the licence are complied with.

The DI might be a head of department, clinician, scientist, or manager. What is important is that it is a person who is in a position to ensure that activities are conducted properly, by people who are suitable to conduct those activities, and that all the necessary requirements are complied with.

Licence Holder – The role of Licence Holder does not impose the duties that are expected of the Designated Individual, however, they have the right to apply to the HTA to vary the licence. This enables them to substitute another person as the Designated Individual and allows the establishment to cover circumstances where the Designated Individual is unable to oversee the licensable activities. Consequently, the HTA prefers individual Licence Holders to be more senior than the Designated Individuals, such as a Medical Director or Chief Executive.

The Authority enforces the requirements of the Regulations through Codes of Practice, (for example, Consent, Research, and Donation of Allogeneic Bone Marrow & Peripheral Blood Stem Cells (PBSC)), Guidance (Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment) and a set of Standards, and by issuing Directions. These are implemented by the Designated Individual at each site.

The HTA requires the DI to submit an annual report detailing all activity for the previous 12 months in January of each year. Sites are subject to onsite inspection every two years, with inspectors requiring evidence against each standard to be submitted via SharePoint in advance. The inspectors use the Guide and the Standards to assess the evidence and the compliance of the organisation and also assess the DI’s suitability to be in post. They visit each part of the organisation and any third-parties used for licensed activities (‘scheduled purposes’). They will interview core team members and will hold a closing meeting at the end of the audit to describe their findings. Non-conformance to HTA standards results in a documented shortfall. These are graded as minor, major or critical.

- A minor shortfall does not meet the criteria for a critical or major shortfall but still shows a departure from expected standards.
- A major shortfall represents a non-critical shortfall in performing licensable activities and presents an indirect risk to the safety of donors or recipients.
- A critical shortfall poses a significant, direct risk of harm to patients or donors. This grading can result from a single critical issue or a cumulative effect of multiple "major"

shortfalls. This can lead to the HTA issuing a notice to revoke a licence, suspend activities, or impose new conditions.

Once the final report has been received, it's the DI's responsibility to determine how the identified shortfalls will be addressed and to seek the HTA's agreement on a timescale for completion of actions, through the submission of a Corrective and Preventative Action (CAPA) plan. The HTA usually expect the CAPA plan to be submitted within 14 days of the report being received by the Centre. Further regulatory action may result if the HTA cannot confirm that the CAPA plan has been effective. This can lead to the HTA issuing directions, adding conditions, suspension or revocation of a licence.

If a licence is revoked, all transplant activity must cease immediately.

In most cases, the CAPA is successful and the HTA reissue the licence.

The DI is also responsible for reporting Serious Adverse Events and Adverse Reactions (SAEARs) within 24hrs of notification. SAEs are any untoward occurrence associated with the licensed activities for tissues or cells which might lead to transmission of communicable disease, death, life-threatening, disabling or incapacitating conditions, or that might result in or prolong hospitalisation or morbidity. Sars are an unintended response, including communicable disease, in a donor or recipient of tissues or cells, which is associated with the procurement of those tissues, and which is fatal, life-threatening, disabling, incapacitating or which results in prolonged hospitalisation or morbidity. The HTA have the right to conduct an inspection if there is cause for concern from an SAEAR report.

Conclusion

Competent Authorities are a vital part of the framework of healthcare and have a rigorous programme of oversight. Although they have a regulatory enforcement role, they also act as a critical friend to the transplant centre and offer advice and guidance to ensure centres comply with regulations. Centres should forge strong relationships with their inspection teams and be open, honest and transparent in all their interactions. This will make the inspection process less onerous for the team and enable the inspectors to work more effectively. This can only serve to improve the quality of the care provided to our patients.

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