HTA
Human Tissue Authority

Strategy: Year Two

2016-2019

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Introduction from the Chair

This is the second year of our current three-year Strategy, where against a backdrop of scientific, economic and political change, our core purpose remains undiminished – to ensure that human tissue and organs are used safely and ethically, and with proper consent. When this purpose is delivered, confidence of the public is maintained in the good work the professionals in our sectors undertake.

Four guiding principles drive this Strategy and reside at the heart of all we do:

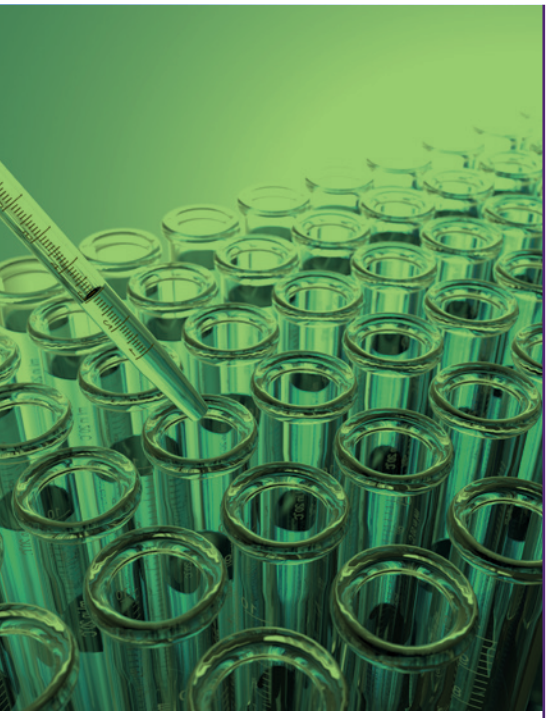
- **Consent** – and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- **Dignity** – is paramount in the treatment of human tissue and bodies.
- **Quality** – must underpin the management of human tissue and bodies.
- **Honesty and openness** – are the foundation of communications in matters pertaining to the use of human tissue and bodies.

Our four principles, which are core to our regulatory work, are also set out in our new Codes of Practice that will be implemented in the current year

The four principles, core to our regulatory work, are also set out in our new Codes of Practice that will be implemented in the current year. The way we licence and inspect establishments seeks to focus our resources on the areas of greatest risk. Our primary approach is to ensure compliance and drive higher standards. We work with establishments and the public via our regular engagement groups, through consultation, and by seeking feedback through enquiries and our website. We provide specific guidance and support to licence holders on how to meet the high quality standards the public expect. And when a more serious intervention is required, we will take robust regulatory action.

In many of the areas where we regulate, there are new products and scientific advances that were simply not contemplated at the time the Human Tissue Act was formulated. This year alone, cryopreservation, body farms and synthetic organ development all became emerging areas where the HTA has no statutory remit to regulate, but areas where we will use our principles as a framework to guide professionals and assure the public. While these activities remain outside of our formal regulation, the challenge for the HTA is to continue to maintain the confidence of professionals and public in the use of human tissue.

Sharmila Nebhrajani, OBE
Chair



About the HTA

The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health.

We were established under the Human Tissue Act 2004 (HT Act) – which covers England, Wales and Northern Ireland – to regulate activities relating to the removal, storage, use and disposal of human tissue. The HTA also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

Our overall purpose is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

We have a role in maintaining professional confidence – by assuring that human material being used by professionals has been obtained with proper consent and is managed with appropriate dignity and care.

We also have a statutory function to inform the public, professionals and the Secretary of State for Health about issues within our remit.

We meet our requirement to inform professionals by providing guidance, including through our Codes of Practice, updated versions of which will be launched in April 2017. We also meet our requirement to inform the public by providing information, to help them to make informed decisions.

We license organisations that store and use tissue for purposes such as research, human application, organ transplantation, post-mortem examination, teaching, and public exhibitions.

We license approximately 860 premises and publish standards that they must meet on:

- consent;
- governance and quality systems (including traceability);
- premises;
- facilities and equipment; and
- disposal of human tissue.

To ensure that these standards are maintained and that appropriate procedures are followed, we inspect these licensed premises periodically, and receive data updates via compliance reports between inspections.

The HTA regulates through an independent assessment process, the donation of solid organs from living people. We ensure that valid consent is given for organ donation and that no coercion takes place or reward is sought or offered. We fulfil a similar role for living donation of bone marrow and

peripheral blood stem cells from children and adults who lack the capacity to give consent.

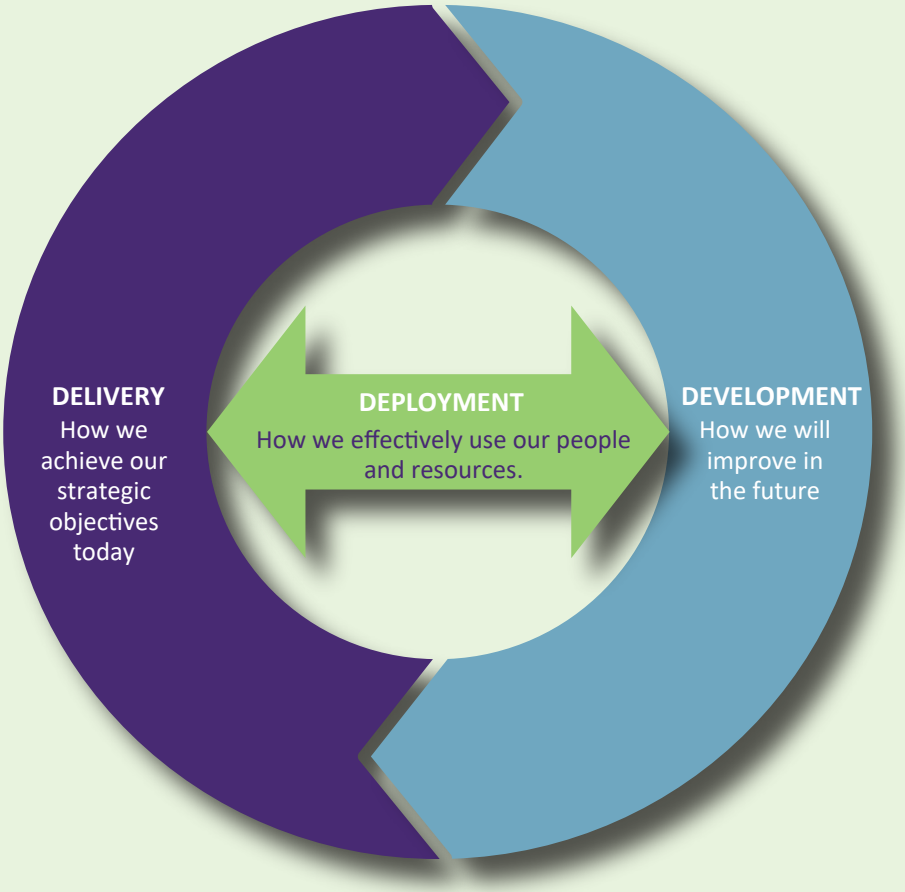
As well as licensing under the HT Act, the HTA is the Competent Authority for European Union (EU) Directives. We are responsible for the EU:

- **Tissue and Cells Directives (EUTCDs)** – To ensure the quality and safety of human tissue and cells used for patient treatment.
- **Organ Donation Directive (EUODD)** – To ensure the quality and safety of organs intended for transplantation.

In 2017, we will be bringing into force two new EU Directives, which amend and implement areas of the EUTCDs, with respect to the coding, important and export of human tissues and cells in the human application sector.

All of our activity is directed towards ensuring compliance with these standards. In this second year of our three-year Strategy, our key activities will be grouped into three themes:

- **Delivery** – How we achieve our strategic objectives today;
- **Development** – How we will improve in the future; and
- **Deployment** – How we effectively use our people and resources.



Our strategic approach

Protecting public and professional confidence requires us to protect the foundations on which confidence is built. We believe that confidence is maintained if the core principles contained within the HT Act are adhered to. These principles are:

- **Consent** – and the wishes of the donor (or in some cases, their representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- **Dignity** – is paramount in the treatment of human tissue and bodies.
- **Quality** – must underpin the management of human tissue and bodies.
- **Honesty and openness** – are the foundation of communications in matters pertaining to the use of human tissue and bodies.

These principles underpin the HTA's regulatory framework. Applying these principles provides public protection by reducing the risk of harms, such as:

- the transmission of disease in organ transplantation;
- compromised patient safety where tissue is used for human application; and
- distress which may be caused to the families of the deceased.

All of these harms have the potential to damage public confidence.
While the HTA has an influential role in promoting cultural change and good practice, public confidence cannot be safeguarded by the HTA alone. It is implicit within these principles that public confidence is also dependent on individuals and organisations undertaking activities within the HTA's remit to act within professional standards.

Our strategic approach to achieve adherence to these principles is based on right-touch regulation. This means being clear on the risks that we are regulating, being proportionate and targeted in regulating those risks, taking into account the role of professional bodies and other regulators, and using the minimum necessary regulatory force to achieve compliance and improvement.

Effective communication is also critical to our strategic approach to ensure that professionals can readily access advice and guidance from us, and that the public is clear on what they should expect from us and the areas we regulate. How we do this in our daily operation is described in the **Delivery** section of this Strategy.

The HTA has never been an organisation to stand still, and is continuously looking for ways it can enhance public confidence and better target our regulation. The **Development** section of the Strategy describes the focus for this continuous improvement over the remainder of this strategic period.

Neither **Delivery** nor **Development** is possible without resources. The **Deployment** section of the Strategy describes how we lead, manage and develop the HTA's people, how we raise and use our finances and our plans for accommodation and other key assets.

DELIVERY

To deliver the right mix of activity to maintain public and professional confidence

DEVELOPMENT

To make the right investment to continuously improve delivery

DEPLOYMENT

To make the most effective use of people and resources in pursuit of our goals

Delivery – to deliver the right mix of activity to maintain public and professional confidence

Our aim at the HTA is to be a **right-touch** regulator.

This means we primarily focus our regulation on establishments that carry out activities that involve an inherently greater risk to public confidence if standards are not maintained, and establishments that we assess as being at the greatest risk of non-compliance.

We license establishments – as required by legislation – to a set of standards, which are aligned with our principles, and designed to promote public confidence. Assurance that those standards are being met is achieved through a variety of mechanisms, including inspections, reporting requirements and the provision of advice and guidance.

We also continue to embed the principles of better regulation in our work, both day-to-day and specifically by:

- reducing our regulatory burden where possible (you can see the HTA Burden Reduction Plan on our website here);
- ensuring there is even greater transparency around the impact of regulation on business; and
- reporting against the Government's Business Impact Target (BIT).

HTA inspections – Inspections take place in each sector – according to the legislative requirements – and the regulatory risk of each sector, as well as the risk specific to each establishment. We work with establishments to schedule inspections at mutually convenient times. We recognise the significant level of compliance and transparency across our sectors, and believe that this approach enables us to reduce the burden of the inspection without increasing the risk of non-compliance.

We also undertake non-routine inspections, both announced and unannounced, when we have information which indicates that a site visit is required, for example if we receive intelligence on non-compliance, or from our analysis of data received from compliance reports between inspections.

Reporting requirements – We do place reporting requirements on licensed establishments, to inform us of incidents and events posing the highest risk to public confidence and patient safety. This allows us to take appropriate action, should things go wrong, and to ensure that any lessons learnt can be shared across the system.

Some examples of how experience is shared can be seen in some of our recent reports, including:

- Regulation of the Post Mortem Sector 2014-16: What we have learned;
- Research sector review: July 2016; and
- Anatomy sector compliance updates review: 2015/16.

You can read more on our website here.

Our regulation focuses on establishments that carry out activities that involve an inherently greater risk to public confidence if standards are not maintained, and establishments that we assess as being at the greatest risk of non-compliance

Advice and guidance – We have a statutory duty to provide advice and guidance to establishments. We place a great emphasis on this, so we can work with establishments to achieve compliance in partnership, rather than dealing solely with non-compliance. This approach has enabled us to develop strong links with representatives in each sector that we regulate. It means we are able to engage with them about issues across the sector, and gain a better understanding of the challenges they face and this in turn informs our regulatory policy development. Similarly, it gives them a better understanding of our requirements. It also means that we only use significant regulatory action when it is appropriate and in the public interest.

Living donation assessment – Under the HT Act, it is an offence for a reward to be sought or offered for a human organ or tissue for transplantation. The Act also provides independent protection to donors, in the rare cases where a donor is pressured to act against his or her wishes. The living donation assessment acts as a deterrent to donors and recipients entering the living donation programme with reward as a motivation. The system relies on donor and recipient interviews, undertaken by a group of independent and accredited assessors. They are predominantly volunteers who we train, accredit and support in order to fulfil our statutory functions, and to whom we offer our thanks and appreciation. Complex cases are reviewed by panels, made up of HTA Authority Members.

Communicating with professionals and the public – We have structured communication with professionals, the public, and our strategic partners to ensure that there is confidence in HTA regulation and in the services being regulated. Our approach is to provide relevant, high quality information, available on demand to these groups via our website, and to target information to specific audiences via a range of other channels. We involve these groups to ensure we make decisions that reflect, as far as is possible, the operational realities faced by professionals and the concerns of the public.

The groups, which report to the Authority include:

- the Stakeholder Group;
- the Histopathology Working Group; and
- the Transplantation Advisory Group.

They are made up of stakeholders, Authority Members and Executive staff. They are used to seek stakeholder views and advise the HTA on the impact of its regulatory activity.

We also provide the public with the information that they need to understand what they should expect from the services we regulate, and to allow them to make informed decisions about using these services.

This work is underpinned and directed by a programme of monitoring and evaluation, to ensure our messages are up to date, relevant, and meaningful for the audience – addressing their interests and any concerns.

Working with other regulators – Many HTA licensed establishments are also regulated or accredited by other bodies. The HTA recognises the impact that this can have on an establishment, so structured collaborative working with other

bodies is also an important feature of our strategic approach to minimise regulatory burdens. The HTA has bilateral agreements with:

- the Care Quality Commission;
- the Health Research Authority;
- the Human Fertilisation and Embryology Authority;
- the Medicines and Healthcare products Regulatory Agency; and
- the United Kingdom Accreditation Service.

Objectives for 2017/18

Our Delivery objectives remain, to:

- Deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to public confidence.
- Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- Deliver effective regulation of living donation.
- Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.
- Maintain our strategic relationships with other regulators operating in the health sector.

In the remaining period covered by this Strategy, we will:

- Undertake and publish reports on a programme of site visits and inspections which meet the aims of the HTA, and licensed establishments, and which provide assurance to the public that standards are being maintained.
- Take a proportionate approach to our regulation, and ensure that where there are shortfalls against standards, these are rectified within agreed timescales.
- Ensure decisions on living organ donation cases meet agreed service standards in a way that provides the necessary protections.
- Engage with, and involve, the public and professional stakeholders in our work, seeking feedback and comment using a wide variety of channels on and offline.
- Conduct a public evaluation to measure what areas of our work the public are most interested in being involved in, and why.

Development – To make the right investment to continuously improve delivery

To ensure that the HTA's regulatory approach remains relevant, we actively prepare for the future. We do this through our development activities, which seek to ensure public confidence will be maintained as new and innovative uses of human tissue emerge.

We see innovation across all the sectors we regulate and keep abreast of developments to inform our policy work, which often involves working with other organisations. Our Human Application sector is rapidly developing and the pace of change requires us to be agile in our response to policy and regulatory questions. We work closely with the Medicines and Healthcare products Regulatory Agency and other regulators on the Regulatory Advice Service on Regenerative Medicine (RASRM). We expect enquiries to the RASRM from those developing Advance Therapy Medicinal Products (ATMPs), as well as other novel therapies using human tissues and cells, to increase in coming years.

Where an innovative tissue use or new business model is unregulated and where there is the need for an authoritative voice on the issues, we will provide advice and guidance to both the public and professionals when we believe we are best placed to do so. In the coming year we expect to issue such guidance on cryopreservation and taphonomy.

Over the next two years, we will continue to improve our systems and processes to allow us to do more with the resources we have.

Our overarching aim is to maintain public confidence, and we recognise there is more we can do directly in this area. This includes both work we can undertake alone – such as a greater ongoing dialogue with the public – and work in partnership, with other regulators and public-facing bodies.

We will continue to work to produce better public-focussed information that reaches a wider audience, and responds to what the public have told us is important to them – involving people where we can.

Over the next two years, the HTA will take a positive role in discussions and debates on the future of regulation in the health sector, most notably in the post-Brexit environment. We will ensure we reflect our experience of regulating our diverse sectors in submissions and dialogue that will inform negotiating positions. We will be available to offer advice and guidance to colleagues across government and beyond as and when it is needed.

Where an innovative tissue use or new business model is unregulated and where there is the need for an authoritative voice on the issues, we will provide advice and guidance to both the public and professionals when we believe we are best placed to do so

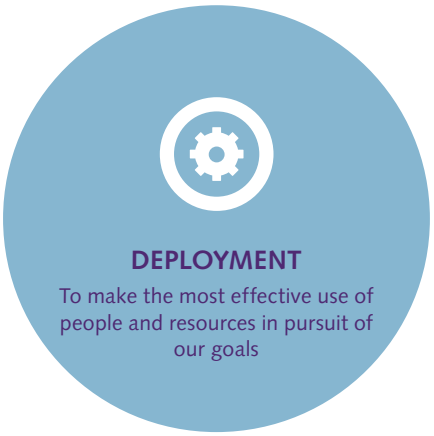
Objectives for 2017/18

Our Development objectives remain, to:

- Reduce regulatory burdens where risks to public confidence are lowest.
- Make it clearer how to achieve compliance with new and existing regulatory requirements.
- Make continuous improvements to our systems and processes to minimise wasted or duplicated effort.
- Take opportunities to better inform and involve the public.

In the remaining period covered by the Strategy, we will:

- Continue to develop our approach to engaging with licensed establishments to increase compliance (previously referred to as Designated Individual engagement).
- Undertake a comprehensive assessment of risk across the human application sector and amend our processes as necessary (in addition to our standard risk assessment across all sectors).
- Based on the outcome of our independent enquiries audit, and the work undertaken by the enquiries improvement project, refine our processes to improve further the timeliness and quality of enquiry responses.
- Implement the EU Directives on Coding and Import / Export, working with establishments to ensure as smooth a transition as possible.
- Carry out a content review of the public information on our website, and continue to develop new material – with input from the public – which is widely shared; this is to improve public understanding of what we do, and what we expect from those we regulate.
- Continue to upgrade and develop our Customer Relationship Management (CRM) system, website, and online portal to better meet our business needs.



Deployment – To make the most effective use of people and resources in pursuit of our goals

Deployment underpins both our Delivery and Development activity; it is the choices we make about how we best manage our people and resources.

Our staff – The people who work at the HTA are our most important asset. Our staff are fundamental to our ability to achieve our overall goals, and to continue to improve.

Last year, in recognition of this, we updated our People Strategy, which complements the overall Strategy, and sets out how we will lead and manage people – including how we support their professional and personal development.

Through this strategic approach, we promote an organisational culture that values our staff and creates an environment where they are encouraged to increase their knowledge skills and expertise. We look for opportunities to promote staff retention, reduce turnover and retain essential skills in HTA. The People Strategy also describes the need for the right working environment and business technology to support delivery.

People we work with – We also recognise that individuals fulfilling roles set out in legislation – Designated Individuals, Independent Assessors and Accredited Assessors – are important resources that we draw on in pursuit of our goals, through working collaboratively.

Resources – The HTA is funded through fees from licensed establishments and Grant-inAid from the Department of Health. Our approach is to manage our finances in order to ensure the continued financial viability of the HTA, whilst providing good value for licence fee-payers and the taxpayer. We continue to control accommodation costs by sharing office space in order to minimise the impact of rental costs on licence fees, and have an arrangement with the Human Fertilisation and Embryology Authority to share a Director of Resources, and a Head of Finance and Resources.

Deployment underpins both our Delivery and Development activity; it is the choices we make about how we best manage our people and resources

Objectives for 2017/18

Our Deployment objectives remain, to:

- Manage and develop our people in line with the People Strategy.
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money.
- Provide a suitable working environment and effective business technology.

In the remaining period covered by the Strategy, we will:

- Deliver on the commitments in the People Strategy, in line with its associated road map, which includes a commitment to consult staff on emerging issues and relative priorities.
- Ensure the best use of office space to control accommodation costs, through:
  - the promotion of flexible working;
  - efficient use of existing space; and by
  - ensuring each team can effectively manage their own areas.
- Undertake a re-tendering exercise for our IT support services.
- Provide opportunities for HTA staff and Authority Members to come together to encourage greater understanding of shared goals and priorities.

RECAP: OUR PRINCIPLES

- Consent and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- Dignity is paramount in the treatment of human tissue and bodies.
- Quality must underpin the management of human tissue and bodies.
- Honesty are the foundation of communications in matters pertaining to the use of human tissue and bodies.

The principles underpin the HTA's regulatory framework.

Accountability

The Authority's primary role is to ensure that the HTA's statutory responsibilities are met and discharged effectively

The Authority – the HTA's non-executive board – is made-up of a Chair and eleven Members:

- nine are appointed by the Secretary of State for Health;
- one is appointed by the Welsh Minister of Social Services and Public Health; and
- one is appointed by the Minister of Health in Northern Ireland.

The Authority is made up of both lay and professional Members and currently includes an organ donor and a transplant recipient. The professional Members of our board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial and public sector experience.

The Authority's primary role is to ensure that the HTA's statutory responsibilities are met and discharged effectively. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an Executive, which is responsible for the delivery of these responsibilities on a day-to-day basis.

While the Executive implements this Strategy by way of business plans, there are a number of mechanisms in place by which the Authority steers, scrutinises and reviews performance.

The Authority holds five board meetings per year, one of which is in

public and combined with an annual conference. These meetings provide the opportunity to assess a range of management information and more detailed reports on progress against elements of the Strategy. They also allow the Authority to hold the Executive to account for the HTA's performance.

Standing items reported to the Authority include:

- **Chief Executive's report** – to provide an overall assessment of the HTA's performance and strategic risks.
- **Delivery report** – to provide assurance on the delivery of regulatory activities.
- **Development report** – to provide assurance on the delivery of development activities.
- **Deployment report** – to provide an update on the deployment of resources.

The board meetings, supplemented by a strategic development event, also provide the main means by which the Authority sets the direction on issues of strategic importance that emerge over the course of the year.

The Authority is supported in its work by two standing committees:

- Audit and Risk Assurance Committee; and
- Remuneration Committee.

The Executive also holds quarterly accountability meetings with the Department of Health to review progress with delivery of key performance indicators and the management of strategic risks.

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Human Tissue Authority

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