HTA
Human Tissue Authority

Strategy

2016-2019

Contents

Introduction from the Chair

This is a full programme of development work for 2016/17 and beyond and we will continue to draw on the wisdom and practical insight from you, our stakeholders to help us with this work.

This is an exciting time for the HTA. The pace of scientific advance seems ever quicker and the potential for new developments and therapies for patients often comes from quite unexpected quarters.

The HTA's challenge is to make sure not only that we regulate well now, but can also continually adapt, where possible, to reflect future innovation. This is not only a challenge but an opportunity too; an opportunity to find ways to adapt our regulatory model to protect the public. It will also help us to foster the innovation and creative thinking from which new scientific insights and cures will emerge.

This Strategy describes how we balance these challenges and opportunities. It identifies new business priorities as well as setting out the blueprint for an organisational model capable of delivering them. The 2016/19 Strategy describes how we will deliver our day to day operations, develop targeted regulation to sustain public confidence and deploy our most valuable asset, our expert staff.

We know the HTA continues to be recognised as an effective, expert regulator. We have overseen significant improvements in the practices of hospitals, mortuaries, research organisations and others. Our remit and responsibilities have continued to grow as we take on new legislation from the EU. We now licence over 850 premises and inspect or audit around 180 of them every year. This delivery will continue. But we will strengthen our expertise by keeping abreast – ahead if we can – of the rapidly developing scientific landscape.

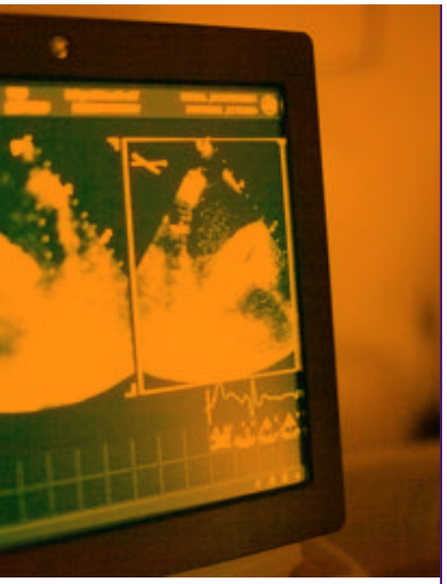
In the coming year, several important projects will help us:

- We will implement our revised Codes of Practice and Standards. This will introduce new working practices that reflect the high standards we expect institutions to meet.
- We will implement the EU Directives on Coding and Import in the UK. This will ensure that traceability, quality and safety of tissue for human application remains high, even when crossing borders.
- We will continue to refine our regulatory model to focus on reducing burden where risks to public confidence are the lowest
- We will conduct a root and branch review of our fees structure.

This is a full programme of development work for 2016/17 and beyond and we will continue to draw on the wisdom and practical insight from you, our stakeholders to help us with this work.

In order to deliver our programme of work we have restructured and redefined the responsibilities of our highly capable executive team. They will work with our dedicated non- executive board that combines both sector skills and lay experience, to steer the HTA through the period of this plan.

Successful regulation really is a team sport. My thanks to our "team"; our Board, especially those who retired this year after many years in service to the HTA; our staff for the truly important work they do and finally to you, our partners, who ensure standards are as high as they can be in providing vital services to patients and the public.



Introduction to the HTA Strategy

The HTA is an Executive Non-Departmental Public Body (ENDPB) 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.

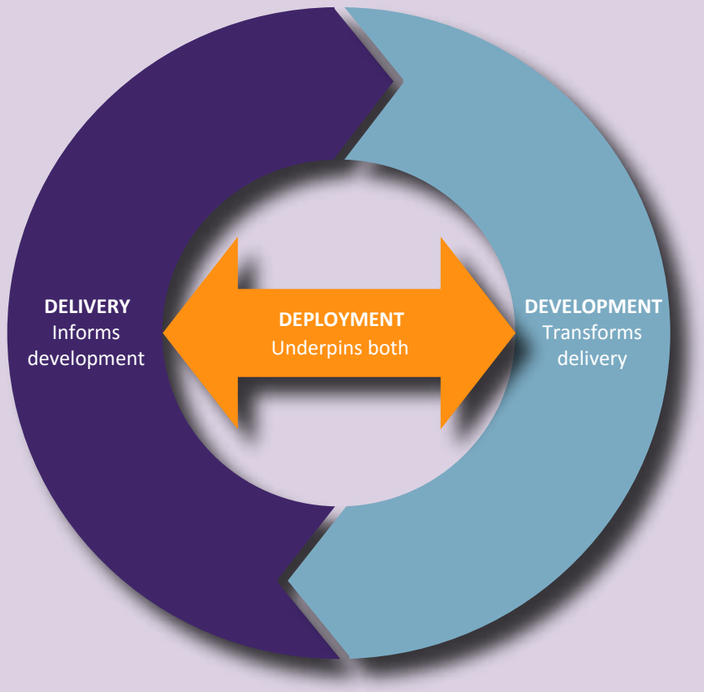
Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

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

The HTA is respected, trusted and influential in matter within, and closely associated, with its remit. Professionals and the public can have confidence because the HTA ensures that appropriate standards are maintained.

All of our activity is directed towards these ends. Our strategy sets out:

- **Delivery**; how we achieve this today
- **Development**; how we will improve in the future
- **Deployment**; how we use our people and resources.



About the HTA

The HTA has a number of statutory functions in England, Wales and Northern Ireland. We inform the public, professionals and the Secretary of State for Health about issues within our remit.

We meet this requirement for professionals by providing guidance, including Codes of Practice, and for the public by providing information to help them 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 850 premises and currently publish Standards that they must meet on: consent; governance and quality systems (including traceability); premises, facilities and equipment; and disposal. We also inspect organisations to check that they maintain high standards and follow appropriate procedures.

As well as licensing under the HT Act, the HTA is the Competent Authority in the UK responsible for ensuring the quality and safety of human tissue and cells used for patient treatment. We ensure compliance with the European Union Tissue and Cells Directives (EUTCDs). We are also the UK's Competent Authority for the European Union Organ Donation Directive (EUODD), ensuring the quality and safety of organs intended for transplantation.

The HTA also regulates, through an independent assessment process, the donation of solid organs from living people. We make sure that valid consent has been given and that no 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 consent. The HTA regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

The Authority – the HTA's non-executive board – is made up of a Chair and eleven Members: nine appointed by the Secretary of State for Health; one appointed by the Welsh Minister; and one by the Minister in Northern Ireland. The Authority combines both lay and professional Members and includes an organ donor and a transplant recipient.

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

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 Human Tissue Act are adhered to. These principles are:

- **Consent** and the wishes of the donor, or where appropriate, their nominated representatives or relatives, have primacy when removing, storing and using human tissue
- **Dignity** should be paramount in the treatment of human tissue and bodies
- **Quality** should underpin the management of human tissue and bodies
- **Honesty and openness** should be the foundation of communications in matters pertaining to the use of human tissue and bodies

The 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 or distress 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 acitivities within the HTA's remit to act within professional standards.

Our strategic approach to achieve adherence to these principles is founded on **right-touch regulation**. This means being clear on the risks 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 services we regulate. How we do this in our daily operation is described in the **Delivery** section of the 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 next three years.

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

The HTA aims to be a **right-touch** regulator which complies with the principles of better regulation, and supports the Government's aims with regard to deregulation.

That means that we focus our regulation on those establishments which carry out activities with inherently greater risk to public confidence if standards are not maintained, and those which we have assessed as being at the greatest risk of non-compliance. This approach means that we target our resources at those areas which have the greatest impact on our overall goal.

We undertake **licensing** as required by legislation to a set of licensing standards, which are aligned with our principles and designed to promote public confidence. Assurance that standards are being met is achieved through a variety of mechanisms.

HTA **inspections** take place in each sector according to the legislative requirements and the regulatory risk in that sector, as well as the risk specific to each establishment. The HTA's current approach is to work with an establishment to schedule an inspection at a mutually convenient time. 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 do, however, have a right of entry to licensed establishments (except those in the transplantation sector) and, where we believe it is justified to do so, will conduct a short-notice or unannounced inspection.

We also 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 lessons learnt can be shared.

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

The living donation assessment regulatory framework acts as a deterrent to donors and recipients entering the living donation programme with reward as a motivation. It also provides independent protection to donors, to avoid the rare cases where a donor is pressured to act against his or her wishes. The system relies on **donor and recipient interviews** undertaken by a group of independent and accredited assessors who are predominantly volunteers who we train, accredit and support in order to fulfil our statutory functions.

Our approach is to ensure that relevant, high quality information is available on demand to these groups via our website and to target information to specific audiences via a range of channels.

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

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.

Our Delivery objectives for 2016-2019 are to continue:

- 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
- to 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
- to deliver effective regulation of living donation
- to 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
- to maintain our strategic relationships with other regulators operating in the health sector

In the period covered by the 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
- ensure that, where there are shortfalls against standards, these are rectified within agreed timescales
- reach decisions on living organ donation cases to agreed service standards and in a way which provides the necessary protections
- provide high quality responses to enquiries from professionals and the public
- actively communicate with the public and professional stakeholders about matters within our remit using a wide variety of channels
- seek to exert influence in Europe and internationally in matters relating to the regulation of organ donation and transplantation and tissues and cells for human application

Development – to make the right investment to continuously improve delivery

The HTA has always been active in seeking ways it can advance public confidence and better target its regulation.

Over recent years, the Government has introduced a range of measures which place obligations on regulators to reduce regulatory burdens and to support innovation and economic growth. There is undeniably a tension between reducing regulatory burdens and the delivery of statutory duties which protect public confidence. The HTA will manage these tensions by maintaining right-touch regulation focussed on risk while simultaneously identifying opportunities for **reducing regulatory burdens** and potentially, the costs of compliance where risks are lower. There are also opportunities for **clarifying compliance requirements**, whether these are new or existing requirements. As there is no review of the human tissue legislation currently planned, any such changes will take place within the constraints of the current legislation.

Early in the period covered by this Strategy, the Department of Health will publish the findings from the Triennial Review of the HTA undertaken during 2015. Our response to the recommendations from the Review will also be built into our development programme.

Over the last five years, the HTA has made significant efficiency savings. Although we actively seek opportunities to reduce our costs, the scope for cost savings is now more limited than it was. Our focus for the next three years will be to look for ways of **improving systems and processes** to allow us to do more with the resources we have. Our licensing and inspection review (completed in 2015) identified a range of targets for improvement.

As all of our activity is aimed at maintaining public confidence, there is also more we can do directly in pursuit of **improving public confidence,** both alone and in partnership with other regulators and public-facing bodies. Our aims in this regard are to produce better public-focussed information which reaches a wider audience. There is also more we can do to involve the public in informing and assuring our regulatory approach and the decisions we make.

Our Development objectives for 2016-2019 are 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
- take opportunities to better inform and involve the public

There is also more we can do to involve the public in informing and assuring our regulatory approach and the decisions we make.

In the period covered by the strategy, we will:

- build on the outcomes of the licensing and inspection review and other known improvement targets to produce an HTA Development programme. Potential projects within this programme will be judged on their contribution towards Development objectives and will include:
  - introduction of the EU Coding and Import Directives
  - introduction of revised Human Tissue Act licensing standards
  - review of the Human Application inspection cycle to better target risk
  - Designated Individual Development
  - review of the inspection process
  - Independent and Accredited Assessor Development
- refine our processes to further improve the timeliness and quality of enquiry responses
- work with partners to develop and more widely communicate public-facing information which improves understanding of what we do, what to expect from those we regulate, and which promotes informed consent. Examples are likely to include:
  - Summary guides to the HTA Codes of Practice
  - Public guides to the research, body and brain donation
- improve arrangements for the public to inform and assure our regulatory approach
- seek further opportunities to collaborate with others to reduce regulatory burdens, clarify regulatory pathways and involve the public
- act on the recommendations of the Triennial Review of the HTA (due to report in 2016)
- undertake a fundamental review of our fees structure to ensure it remains sufficiently aligned with our regulatory activity
- strengthen our arrangements for horizon scanning and accessing external expertise, in particular on scientific trends and developments, to better inform policy development and strategic planning
- actively seek opportunities to reflect and shape thinking on the future of regulation in the health sector
- continue to upgrade and develop our Customer Relationship Management (CRM) system, website and portal to better meet business needs

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

Underpinning both delivery and development activity are the choices we make about how we best manage our people and resources.

The people working at the HTA are our most important asset and are fundamental to our ability to achieve our overall goal. In recognition of how critical our people are, we have developed a **People Strategy** which complements the overall strategy. The People Strategy sets out how we will lead and manage people and support their professional and personal development. We aim to ensure we have skilled and motivated people who we retain for longer, are proud to work at the HTA and are committed to achieving our organisational objectives. The People Strategy also describes the need for the **right working environment and business technology** to support delivery.

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.

The HTA is funded through fees from licensed establishments and grant-in-aid from the Department of Health. Our approach is to manage our finances to **ensure the continued financial viability of the HTA** while providing good value for licence fee-payers and the taxpayer. We will seek to control accommodation costs by sharing office space in order to minimise the impact of rental costs on licence fees.

Our Deployment objectives for 2016-2019 are:

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

In the period covered by the strategy, we will:

- deliver the People Strategy in line with its associated road map, including consulting staff on emerging issues and relative priorities
- consult stakeholders annually on the setting of licence fees
- ensure best use of office space to control accommodation costs
- undertake a retendering exercise for our IT support services

RECAP: OUR PRINCIPLES

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The principles underpin the HTA's regulatory framework.

Accountability

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 four board meetings per year, one of which is in public and combined with an annual conference.

The Authority holds four 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.

The board meetings, supplemented by two strategic development events, also provide the main means by which we set 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: the Audit and Risk Assurance Committee and the Remuneration Committee. In addition, ad hoc groups are created where significant input is required from Authority Members on major development or change issues.

There are three further standing groups, which report back to the Authority – the Stakeholder Group; the Histopathology Working Group; and the Transplantation Advisory Group – each comprising stakeholders, Authority Members and Executive staff. These groups are used to seek stakeholder views and advise the HTA on the impact of its regulatory activity.

Strategic performance review

This report provides updates on progress against a set of key performance indicators (KPIs) which collectively give an indication of the health of the business. The Authority monitors progress using a 'traffic light' system, whereby each indicator is assessed as red, amber or green. The Executive provides more detailed briefing on remedial action being taken on objectives where the traffic light is showing either red or amber. The strategic performance review framework, including KPIs for 2016/17 is available in the business plan.

Financial report

This report provides the Authority with assurances on the management of financial resources. The report provides commentary on the overall financial position, income and expenditure variances, forecast outturns, financial performance and financial risks.

Strategic risk register

The risk register is reviewed monthly by the Executive and changes are highlighted at each Authority meeting. An overview of the key risks facing the organisation is included, so the Authority can assure itself that risks are being identified and managed appropriately.

Other regular reporting

In addition, the Authority receives a number of quarterly reports which provide summary information relating to aspects of the HTA's core operations. These reports are the Regulatory Activity Report, the Living Donation Activity Report and the Communications Evaluation Report, all of which improve the Authority's ability to bring strategic oversight to the work of the HTA.

All of these reports are published on the HTA website as part of the Authority's meeting papers.

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