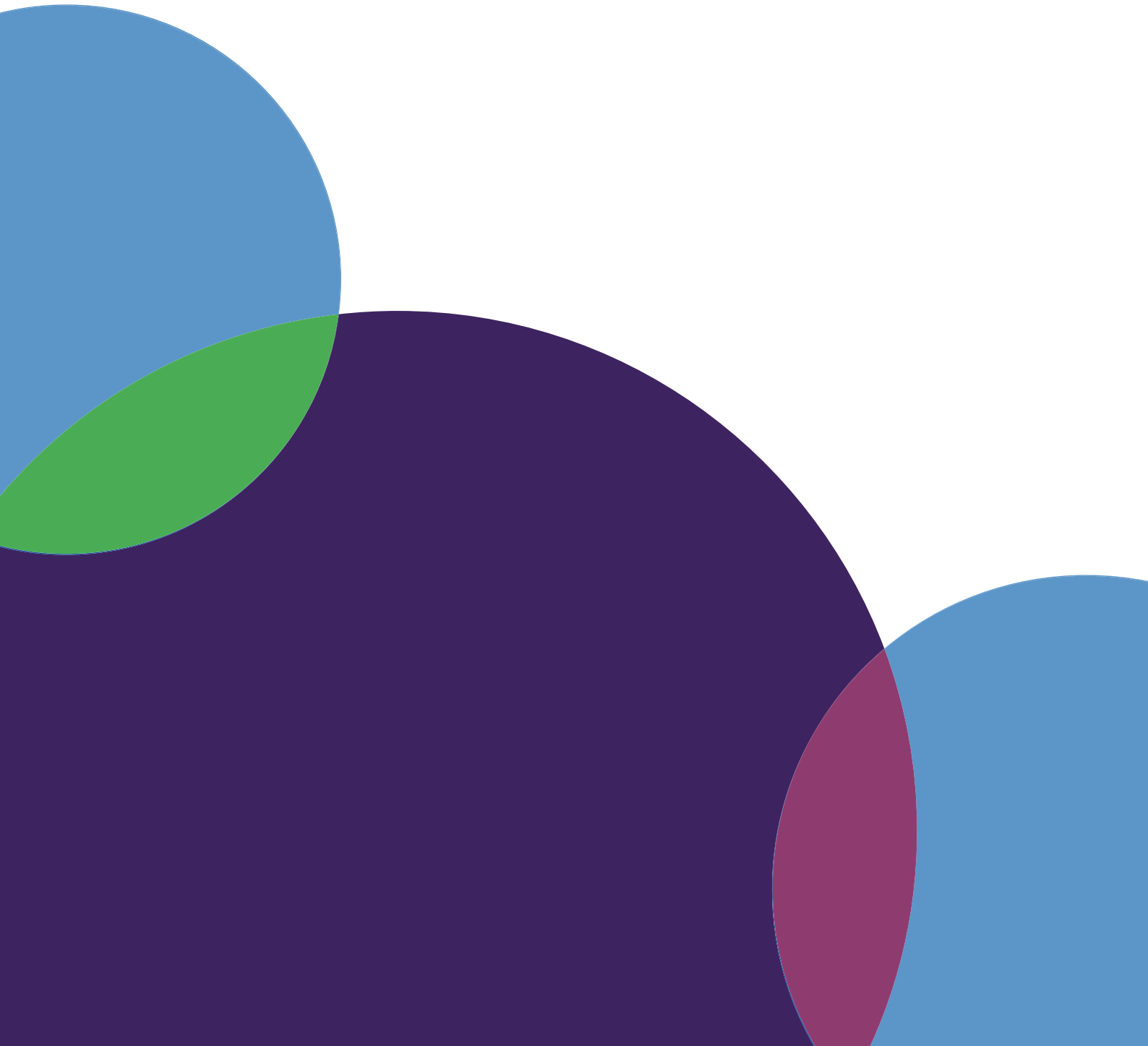
HTA
Human Tissue Authority

2023/24 review

Human Tissue Authority



A message from Lynne Berry, Chair

In recent years, improved technology and significant changes to our sectors have presented challenges and opportunities. This has resulted in us adapting our regulatory approach to ensure they do not become barriers to the use of human tissue or innovation. We have since applied our learning to help shape our approach.

In 2023/24, we set ourselves an ambitious agenda and I am proud to say we delivered real, tangible impact. We drove forward efficiencies in our regulatory approach by taking a more proportionate stance using new and updated regulatory tools. We also developed how we engage with our licensed establishments and key stakeholders to better understand their experiences and gain insights. This intel helped identify and inform our priorities, respond to the threat of human trafficking for organ removal, and support the post-mortem sector to improve management of the deceased.

This review takes a thematic approach to demonstrating a number of our achievements over the last business year. Our work shows we used our expertise and intel to guide, advise and collaborate. It also shows that we support our licensed establishments, including frontline NHS services, when delivering our regulatory work. This brought about change in our sectors and the wider system, and provides reassurance to the public that we are regulating with expert oversight.

Our values underpin our work. They are the principles that ground how we operate as an organisation and how we interact with one another, our stakeholders and licensed establishments. By taking a values-led approach, we are committed to work together and with transparency. It puts us in a strong position to oversee our sectors, address changes or inefficiencies and implement new ways of working.

I would like to thank everyone who worked with us last year. We will continue to work collaboratively to deliver on our mission to be an excellent regulator that sustains public and professional confidence, today and in the future.

Lynne Berry CBE
Chair, Human Tissue Authority

Our purpose and values

We are the statutory regulator for ensuring that the removal, storage and use of human tissue is undertaken safely, ethically and with proper consent across a variety of settings. This includes when they are used for medical treatment, education, research, public display, and are subjected to post-mortem examination. We also approve all organ donations from living people in the UK.

We use four values to deliver our work with integrity:

Collaboration

We work together to achieve a common goal while seeking and valuing diverse perspectives. We share ideas and best practice to strive for excellence.

Openness

We work transparently, with accountability for our actions and decisions. We take responsibility and remain honest.

Respect

We respect diversity, actively listen and value people's perspectives, professionalism and skills.

Excellence

We deliver excellence through expertise, leadership and collaboration. We are committed to personal and professional development and encourage a culture of learning and growth.

2023/24 highlights

2023

May

Presented 'Travel for transplantation: The good the bad and the ugly'
We worked with NHS Blood and Transplant (NHSBT) to raise awareness of human trafficking for organ removal at the annual UK Living Kidney Donor Network meeting.

June

Published an update to Code of Practice F, Part two
We updated this Code of Practice to reflect legislation introducing an 'opt-out' or deemed consent system for deceased organ and tissue donation in Northern Ireland.

Hosted colleagues from Kyoto University, Japan
We welcomed colleagues from the Center for iPS Cell Research and Application, Kyoto University and discussed the regulation of human cellular material in the UK.

Published the first of two open datasets in-year
In addition to the data we routinely publish, we committed to release additional datasets twice a year. The second group of datasets were published in September 2023.

July

Started using a shared HR service function
We began accessing a new HR function with the Care Quality Commission to deliver services, such as recruitment, to make efficiencies and help improve resilience.

Hosted members of the Western Australian Parliamentary Committee
We met parliamentarians and officials from Western Australia to discuss our role in living and deceased organ donation and the scope of offences under our legislation.

August

The UK's first womb transplant publicised our role
The transplant was performed at Imperial College and Oxford University Hospitals. Both hospitals recognised the importance of our role in approving the transplant.

Hosted a multi-agency event on organ transplantation
We hosted a roundtable discussion with various police forces and other relevant organisations to share learning about human trafficking for organ removal.

September

Attended focus groups about the Human Tissue Act (Supply of Information about Transplants) Regulations 2024 ('Regulations')
We attended DHSC-led focus group sessions with clinicians and patient groups to discuss the practical implications of reporting non-UK human organ transplants.

Deborah Bowman said farewell to the Board
We thanked Deborah for her valuable contributions as a member of our Board and her expertise in relation to bioethics, clinical ethics and medical law.

October

A healthcare group was fined for an offence under the Human Tissue Act 2004
We assisted the police with their investigation into a healthcare group, which was convicted for allowing the unauthorised storage of human tissue for research and fined £100,000.

Requirements changed for bodies laid to rest at sea
Working with stakeholders, we helped ensure DNA can be extracted from bodies before being laid to rest off the Isle of Wight. This helps match and identify body parts if they wash ashore.

Held a series of sector-focused forums
Starting in October, we led six sector-focused forums with key stakeholders. They identified current or anticipated regulatory issues and discussed solutions.

November

The Fuller Independent Inquiry reported on crimes at Maidstone and Tunbridge Wells NHS Trust
We are working to improve collaboration and drive-up standards across the sector. We will continue to fully support the inquiry as it undertakes its work.

December

New Board members joined our Authority
Mhairi Anderson, David Lock KC and Jessica Watts joined us as new Board members, bringing expertise linked to our regulated sectors and the wider system. Ellen Donovan was reappointed as the Member for Wales.

2024

January

Presented at a Metropolitan Police human trafficking conference
We worked with the police to share our role in approving cases of living organ donation and the steps we have taken in response to human trafficking for organ removal.

February

Delivered new mandatory refresher training for Independent Assessors
In collaboration with the police, we delivered training sessions for Independent Assessors to help them better identify the signs and indicators of human trafficking for organ removal.

Achieved our target number of inspections and audits
This year, we increased the number of planned inspections to 222 using the same resources. We met the target in February and exceeded it by the end of the year.

March

Prepared for upcoming Regulations about reporting non-UK human organ transplants
We worked alongside NHSBT to prepare for the Regulations. This involved developing guidance and processes to help clinicians report organ transplants that take place outside the UK.

Hosted webinars on security standards in the post-mortem sector
We held a series of webinars to ensure Designated Individuals in the post-mortem sector are aware of and vigilant about mortuary security standards.

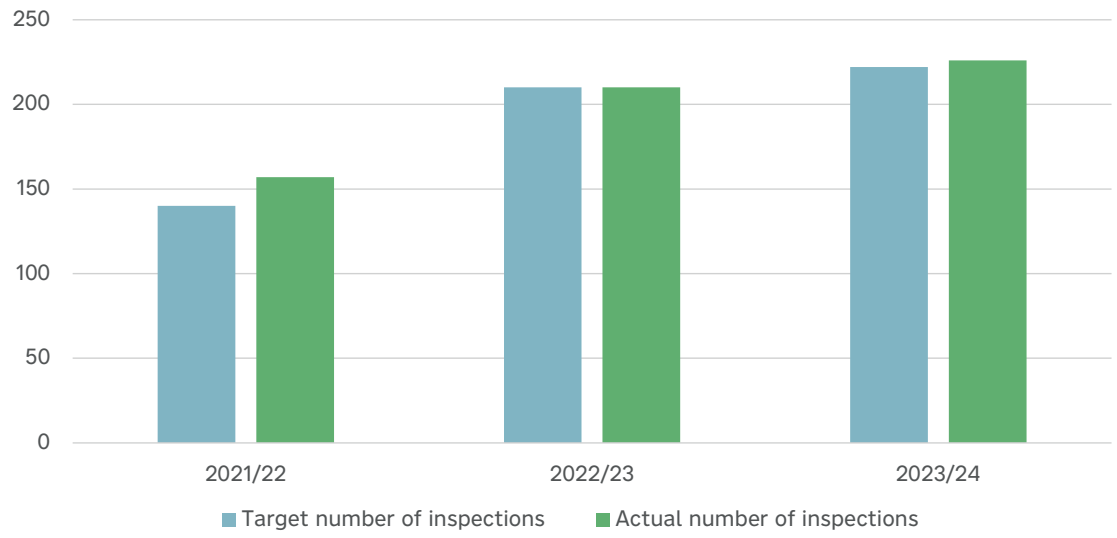
Maintaining trust in the safe use of human tissue

We work to ensure the safe and trusted use of human tissue in our regulated sectors by improving compliance, supporting innovation and developing a strong reputation as an expert regulator. When carrying out our activities, we take a pragmatic and constructive approach to regulation. As a result, our impact as a regulator is largely achieved through our core functions of licensing, inspection and providing guidance.

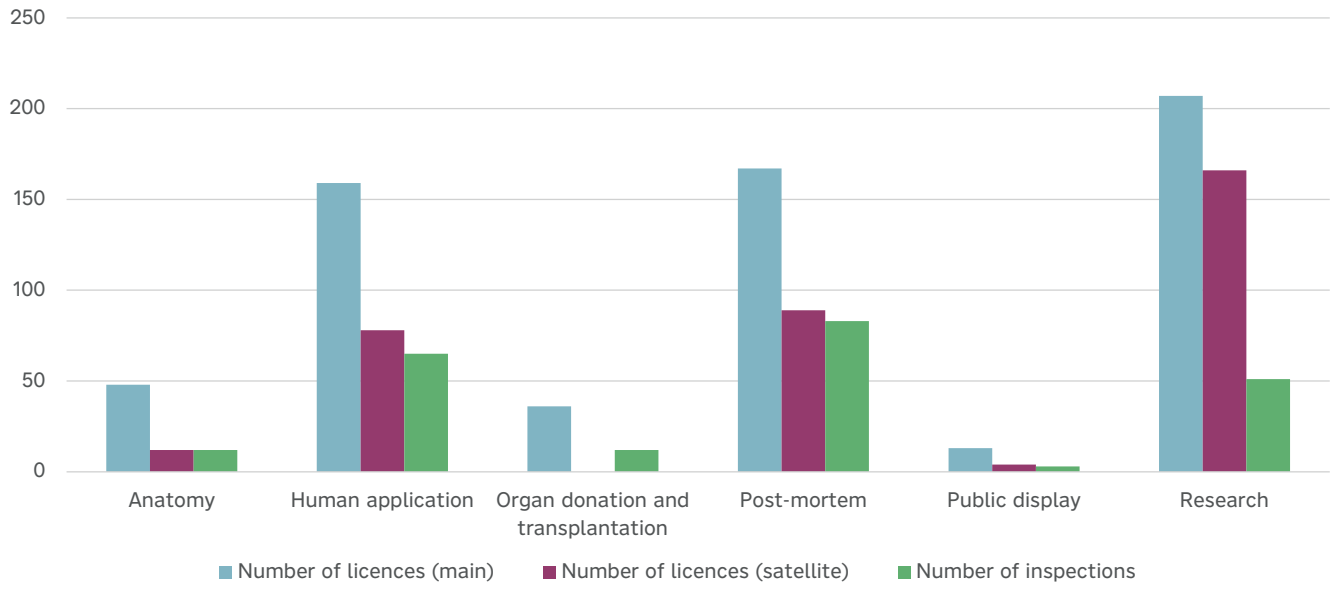
Assessing compliance

In 2023/24, we took the bold decision to broaden our regulatory oversight and carry out over 40% more inspections than we completed at the start of our strategy in 2021/22. We set a target of 222 inspections and exceeded it by taking a more risk-based and bespoke approach. Overall, we inspected 226 of all our licensed establishments – almost a quarter – using the same resource as the previous year.

Number of inspections (planned and unplanned)



Number of inspections per sector



> *… the style and process of this inspection has been much more helpful and felt less pressured than previous inspections, but with the same level of rigour, detail and honest and open reporting of findings, both adverse and positive.*

To meet the target and gauge compliance, we used a range of inspection methods that were proportionate to the anticipated risk presented – both at a sector and establishment level. In the anatomy, human application, post-mortem, public display and research sectors, methods include typical site-based inspections, themed site-based inspections, and virtual regulatory assessments (VRAs). At any point – either while planning an assessment or as a result of what we uncover – we can adapt our approach and add a site-based component (resulting in a hybrid inspection).

In the organ donation and transplantation sector, we carry out site-based audits. These involve assessing establishments against specific criteria and gathering evidence through a combination of reviews and discussions with staff.

> *Although any inspection can be stressful and time consuming, my experience on the day was good and thought provoking. The inspector was clear in her expectations and explanations and the overall effect of the process is to strive to improve services. It was a positive experience.*

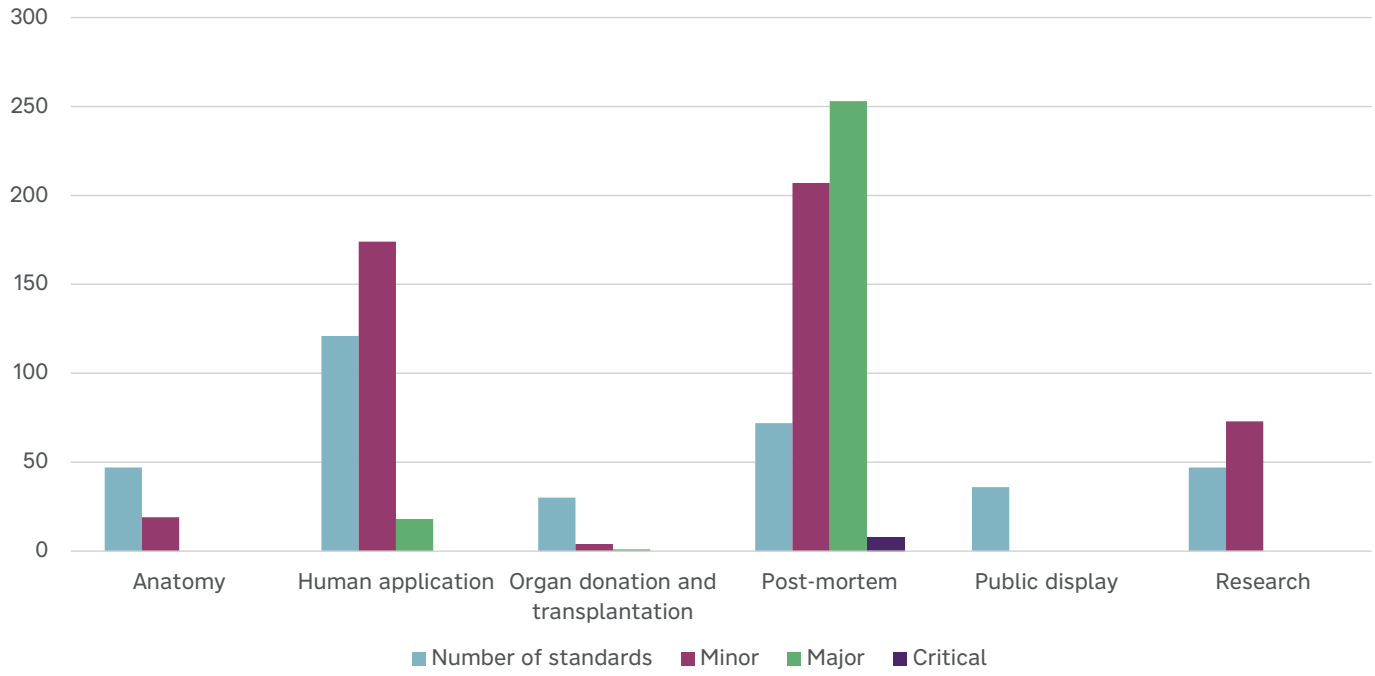
As well as assessing compliance through inspections, we also routinely use desk-based assessments to ensure establishments are compliant with licensing requirements. In 2023/24, we captured 929 updates to existing licences and assessed 35 new licence applications. We also used 182 pieces of intel to ensure establishments continued to be correctly licensed.

Shortfalls

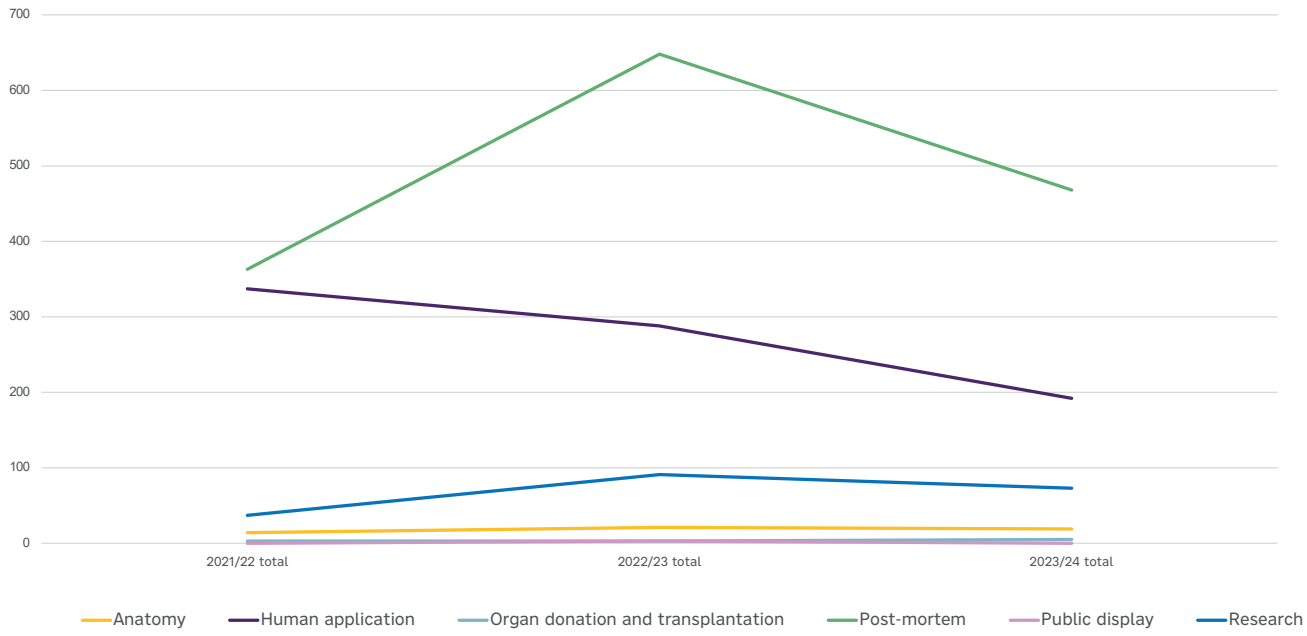
When we inspect an establishment, we assess the premises, review their records, operational policies and procedures, and observe practices. We also conduct interviews and roundtable discussions with a range of staff. By assessing establishments in this way, we can identify whether they are compliant with our standards and – where they are not met – assess the criticality of any shortfalls.

We categorise shortfalls as minor, major or critical against a total of 353 licensing standards (noting that some standards span multiple sectors). In 2023/24, we identified 757 shortfalls across 226 inspections and worked with our licensed establishments to identify the steps they needed to take to meet our standards.

Number of shortfalls per sector



Number of shortfalls per sector (2021/22 - 2023/24)



We took immediate action when we found critical shortfalls to address areas of concern. This involved being directive about what an establishment should do to correct the shortfall. Where we found major or minor shortfalls, we worked (or continue to work) with establishments to ensure they achieved full compliance in a timely manner through an agreed corrective and preventative action (CAPA) plan.

> *...improvement suggestions are common sense, pragmatic, and have improved safety. As soon as we have the conversation with the HTA it just makes sense. ... – it's a conversation, a realisation of how [things are supposed to] work.*

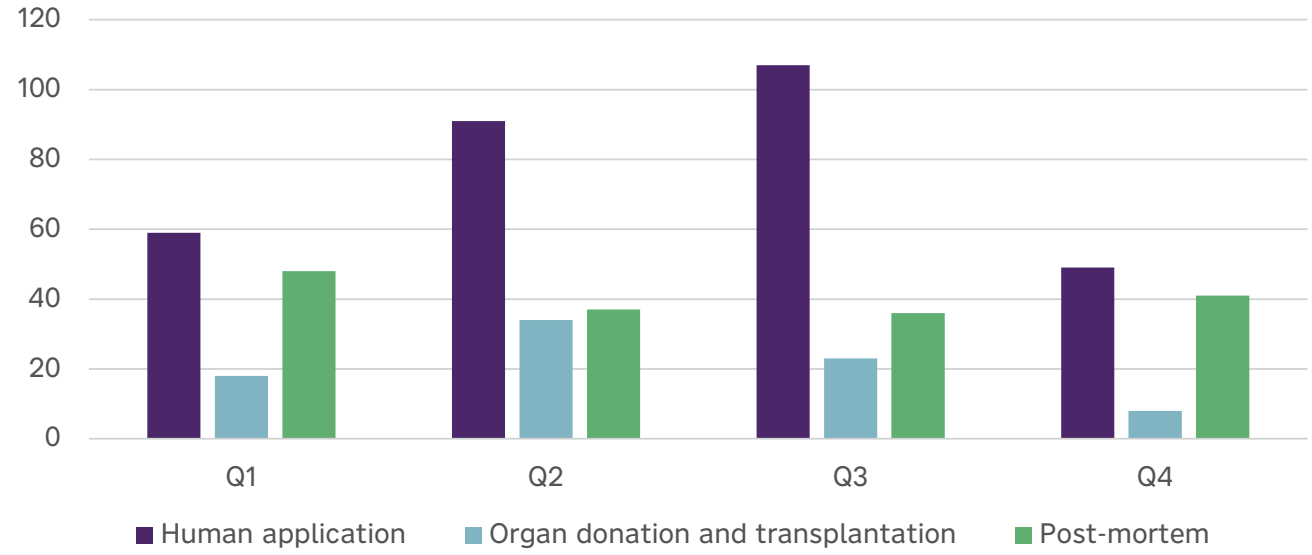
> *[The HTA] has a way [of driving up standards] that is working with the establishment rather than being antagonistic.*

Serious incidents

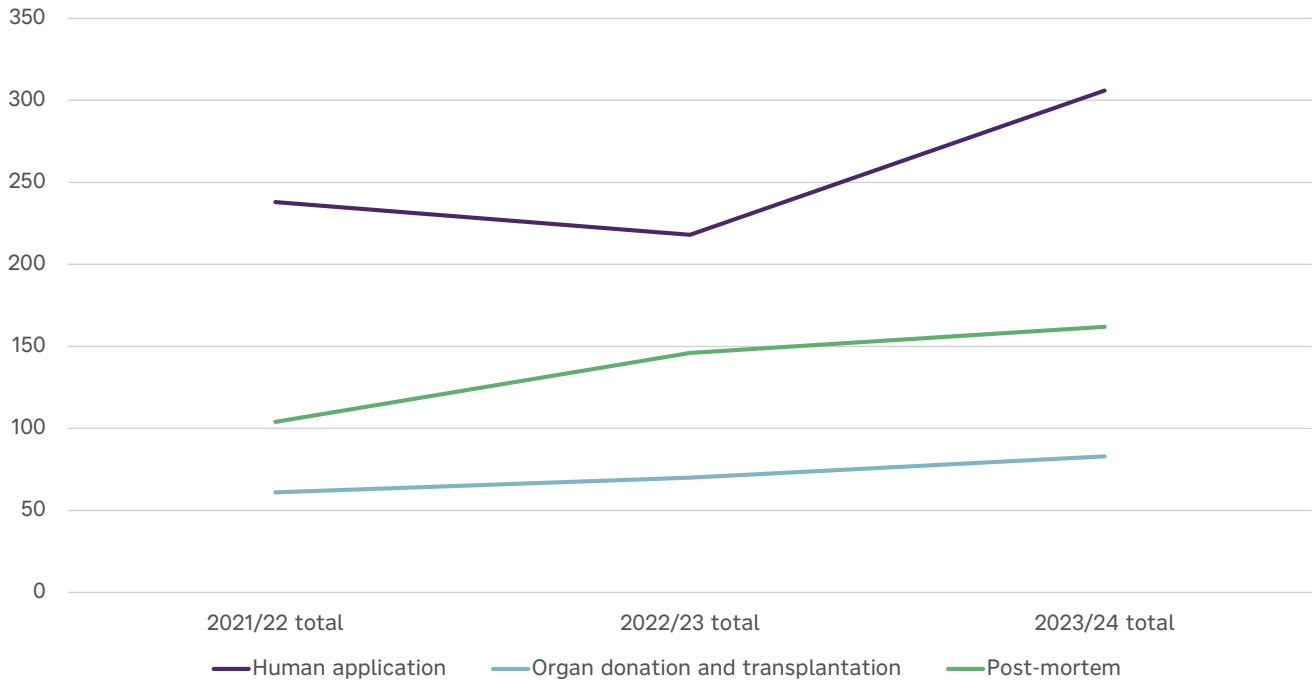
We require establishments in several sectors to report serious incidents that occur in areas covered by their licence. This is to ensure we are sighted on incidents and can ensure they are carefully investigated.

Once an incident is reported to us, we check that it meets our requirements of a reportable incident. We subsequently seek to understand what immediate actions have been taken and work with establishments to reduce the likelihood of the incident being repeated.

Number of closed incidents per sector



Number of closed incidents per sector (2021/22 - 2023/24)



In 2023/24, we were alerted to 551 reportable incidents. Our establishments reported 306 serious adverse events and reactions (SAEARs) in the human application sector, 162 HTA Reportable Incidents (HTARIs) in the post-mortem sector and 83 SAEARs in the organ donation and transplantation sector. Since the start of the strategy, the number of closed incidents across all three sectors have increased. We will continue to work with stakeholders to encourage proactive incident reporting.

> *One of the very helpful things [the HTA] do is share examples of the most common adverse incidents in that sector, and then you can carry out risk assessments to make sure that your processes are such that you would avoid having similar incidents.*

A risk-based approach

Our approach to regulation involves being attuned to the risks, taking a targeted – yet proportionate – approach, and using the necessary regulatory tools to achieve compliance and improvement.

Developing our regulatory toolkit

We developed VRAs during the Covid-19 pandemic to ensure we could continue to monitor the compliance of our licensed establishments, without needing to conduct on-site inspections. We have continued to use VRAs as an effective assessment method for lower-risk establishments and sectors, enabling us to assess more establishments.

Given the success of VRAs and their routine use within the research sector, we developed another regulatory tool that results in similar benefits using a lighter touch – 'evaluated self-assessments' (ESAs). These require lower-risk establishments to carry out an assessment against our framework and report the details within a defined timeframe. We subsequently analyse the return alongside the regulatory history of the establishment and take steps to escalate areas of non-compliance, as necessary.

Following a pilot programme, ESAs have been added to our regulatory toolkit. They help us have routine contact with establishments in a proportionate way and help establishments actively maintain compliance with our standards. ESAs also reinforce the message that responsibility for compliance lies with those undertaking regulatory activities.

Alongside developing a new regulatory method and working to reach an ambitious inspection target, we also conducted a review of our inspection regime. This involved looking at how we inspect establishments: from assessing the risks that a sector presents through to inspection and post-inspection follow-up. It also considered how we could improve the use of technology and data to support a more risk-based approach.

The review suggested models and options that could benefit how we regulate – for example, by improving how we evidence and assess compliance and strengthening the post-inspection process. These suggested areas for improvement will be tested and shaped in the coming business year, in line with our strategic priority to further enhance our approach to regulation.

Taking steps to be an efficient regulator

During 2023/24, we looked at the risks facing our sectors to help determine the best use of our regulatory tools and identify where additional efforts may be needed.

For the first time since the Covid-19 pandemic, we asked licensed establishments across our six sectors to complete a data collection exercise. The exercise sought to inform how we profile risks, as well as how we use data and intel to take a risk-based and differentiated approach to inspection. The results helped us to gain insight on the key risks at an establishment and sector level. For example, within the anatomy and research sectors, the data has been used to prioritise and plan the allocation of inspections.

Last year, we began developing a regulatory insight model to transform how we use data to regulate. The model will use information from our sectors and beyond to identify key risk areas and routinely identify emerging themes and trends across our licensed establishments and sectors. This will support our regulatory oversight and use of finite resources.

To help develop the model, we collaborated with an external consultant to map the data used to inform indicators, determine where there is potential to streamline and automate the data that we compile, and encourage data reporting to ensure that the model works. This work will continue into 2024/25 as we seek to build and test a prototype model.

Maintaining public trust and confidence

We are an effective regulator that maintains public confidence through our licensing, inspection and authorisation processes and by being open and transparent. We believe that patients and families should be confident that their tissue will be used in line with their wishes and handled with care.

We continue to adopt a regulatory approach that seeks to deter or prevent criminal breaches of human tissue legislation. This includes referring cases to the police for investigation where we consider there to have been a potential breach. While police referrals are more commonplace in relation to living organ donation, referrals are made across our sectors when necessary.

Last year, one of our referrals to the police resulted in a healthcare group being fined £100,000 after pleading guilty to the unlawful storage of human tissue. This marked a key milestone for us as it was the first criminal conviction originating from a direct referral and involved close working with the police. It was a stark reminder of the reason we were setup as a regulator[1] and that it is still pertinent today. Following the conviction, we proactively engaged with the independent healthcare sector and relevant organisations (such as professional regulators and bodies) to promote good practice among health professionals. We will continue to raise awareness of our legislation across sectors and work to amplify our message in 2024/25.

[1] Inquiries at Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) found that organs and tissue from children who had died had often been removed, stored and used without proper consent. In response, government setup an advisory group – the Retained Organs Commission – whose recommendation led to the creation of the Human Tissue Authority.

We have also taken steps to maintain trust and confidence by increasing our transparency as a regulator and ensuring that we act in accordance with our values. One way this has been achieved is by publishing more data about our operations, policies and procedures.

We published two data instalments last year. This included datasets relating to licensing, inspection, shortfalls and enquiries data from April 2017 to March 2022, as well as 2022/23. Our commitment to release this data in an accessible format will continue and builds on other data we routinely publish, such as our quarterly publication of closed incidents.

Given 2023/24 was the last year of our corporate strategy, we took steps to proactively assess our impact as an independent regulator. Understanding our impact on the sectors we regulate and the wider health system was essential in understanding how effectively we deliver our core function. It also helped inform how we respond to and manage the challenges that we face.

We appointed an external contractor to engage with our workforce, licensed establishments and other key stakeholders to determine our impact. The work showed that our oversight of the safe and ethical use of human tissue continues to be relevant in a modern world as our sectors keep pace with innovation and developments. The findings also identified how we make an impact, for example by using our expert voice, maintaining the trust of licensed establishments, and facilitating collaboration to deliver a common goal.

> *My relationship with the HTA as a DI is very different to the relationship [with another regulator]. Lots more collaborative approach with the HTA and more proactive interaction between the two.*

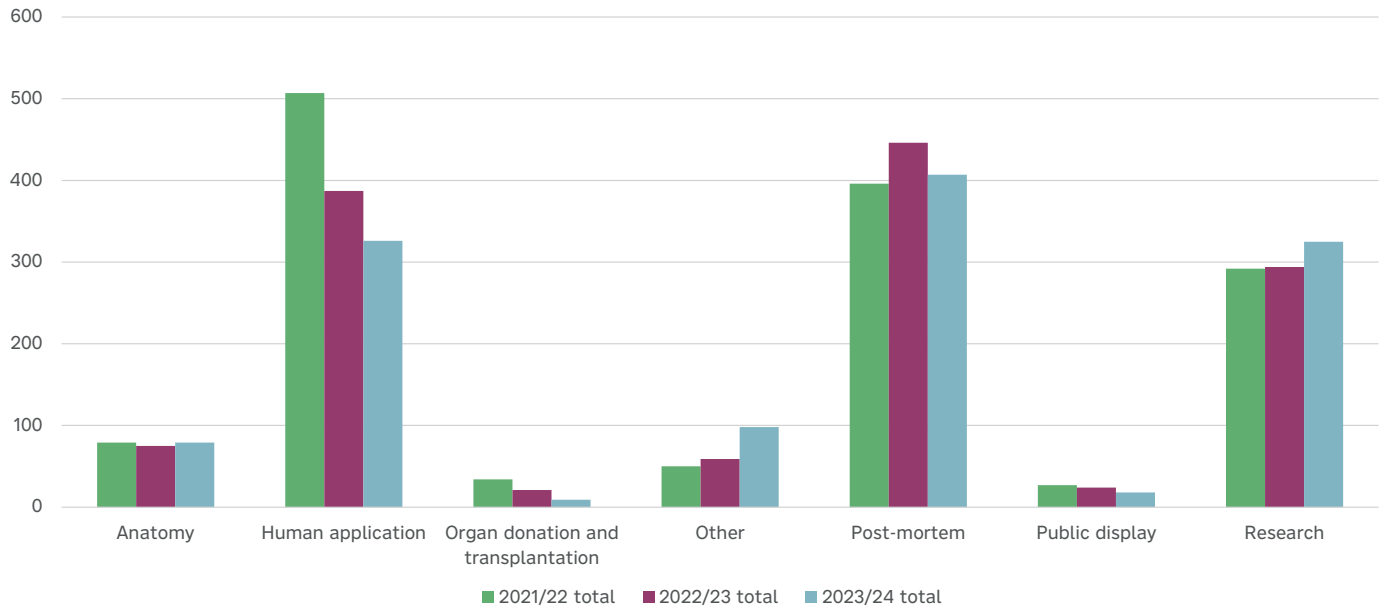
> *Certainly what they have been doing through the sector-wide collaboration is reaching out to other organisations both to gain information and to influence practice in those settings.*

These findings and opportunities for us to increase our impact have been used to inform our approach, such as the development of our 2024 to 2027 corporate strategy. They will continue to inform our work over the coming year.

Communicating with the public and professionals

Our website, social media presence and enquiries system enable us to effectively communicate with the public and professionals. We provide timely information, advice and guidance in relation to our regulated sectors and activities.

Number of general enquiries[2]



In 2023/24, we received 1,262 general enquiries. Around a third were in relation to the post-mortem sector and around half of all general enquiries involved the human application and research sectors. These three sectors have received the most general enquiries over the course of our strategy, accounting for over 80% of all enquiries each year.

We also facilitate information sharing with key stakeholders and sector representatives through our engagement events such as sector-focused forums and roundtables.

> *…providing that opportunity [to engage with other stakeholders at the forums] is quite unique because we don't really have that otherwise. The HTA convened those forums … and brought the people together into that space.*

[2] Numbers reflect enquiries received via the general enquiries email inbox. It does not include enquiries received via other routes, such as directly to inspectors (known as Regulation Managers) or alternative inboxes

> *The level of interest they show in learning about the funeral sector, that's unusual for people in arm's length bodies, but I like their collaborative approach.*

Our engagement levels with the public and professionals on a day-to-day basis enable us to tailor or promote information accordingly. For example, by amending or redirecting content on our website or increasing our presence on LinkedIn to reach our professional audience. Since the website was upgraded in 2022, engagement has continually improved.

Number of website visits in 2023/24: 354,268 (including 491,156 page views by 213,587 users)

Popular web pages in 2023/24: Pages about body donation (30,145 visits) and our Codes of Practice (15,640 visits)

Number of social media posts, views and reactions in 2023/24

Platform	Posts	Views	Likes or reactions
X	374	124,057	1,522
LinkedIn	72	34,892	734
Facebook	69	8,299	1,248

Supporting our licensed establishments to overcome challenges

As well as providing regulatory oversight and guidance to our sectors, we take an active role in supporting our establishments to ensure they deliver to a high standard and are equipped to overcome challenges.

Detecting human trafficking for organ removal

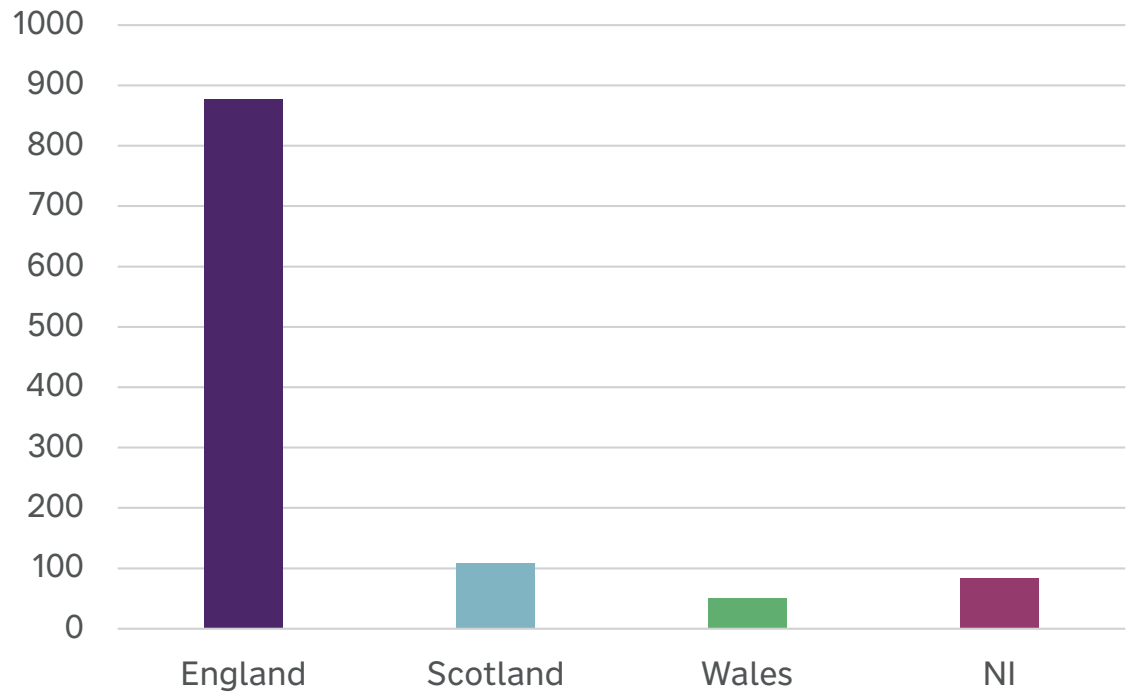
We have a unique role as a regulator where we approve all cases of living organ donation in the UK when criteria – set out in legislation – are met. To make this decision, we need to be satisfied that:

- a donor has not been or will not be given a reward for their donation
- a donor has not been coerced or experienced duress to donate, and
- a donor has provided valid consent for the removal of their organ.

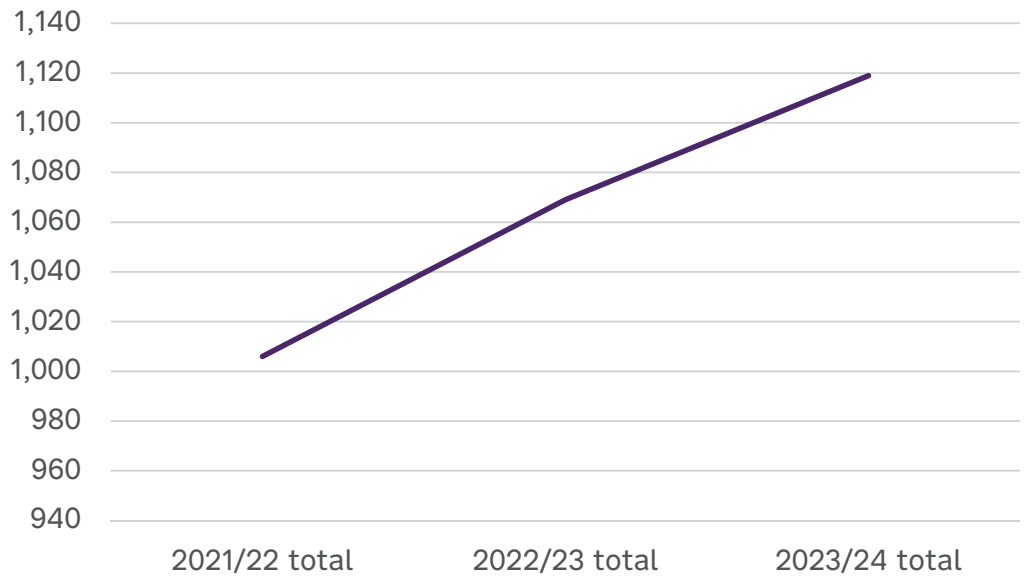
Number of approved living organ donations

In 2023/24, we approved 1,119 living organ donations. The number has steadily increased over the course of our strategy and continues to recover after the number of living organ donations reduced to 561 during 2020/21 due to the Covid-19 pandemic.

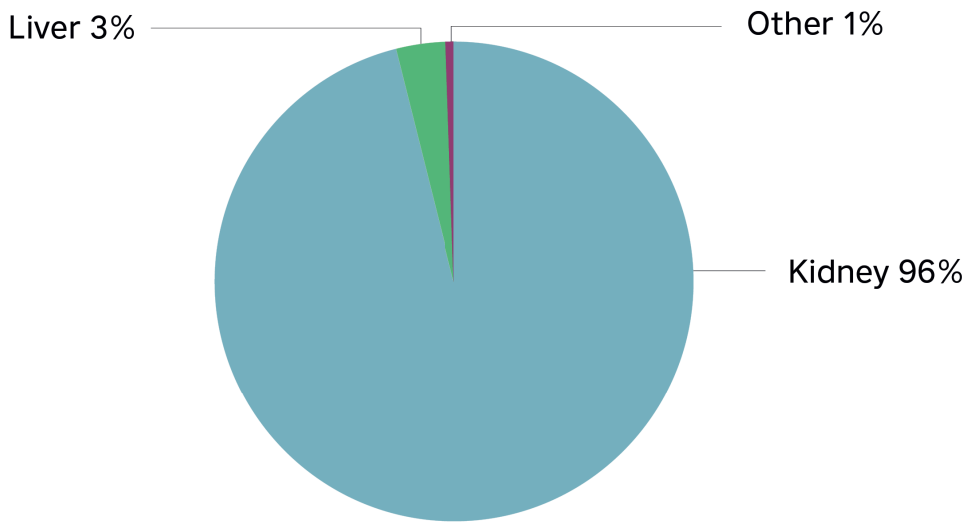
Approved living organ donations



Approved living organ donations (2021/22 - 2023/24)



Distribution of living organ donations approved in 2023/24



In March 2023, a Nigerian senator, his wife and an accomplice were convicted of bringing a man to the UK to have his kidney removed and transplanted to their daughter. This case highlighted how the landscape of living organ donation has changed.

In response, we have taken steps to play our part in building awareness and detecting the trafficking of vulnerable people for their organs. This has involved strengthening aspects of the living donation approval process to evidence the relationship between a recipient and donor – for example, by working with the sector to clarify what is considered acceptable evidence, and no longer accepting unsupported affidavits as evidence of a claimed relationship.

We have also ensured all Independent Assessors (IAs; who interview donors and recipients to explore whether legislative requirements are met on our behalf) have the information and training they need to detect human trafficking. We have done this by ensuring IAs receive mandatory refresher training to improve their knowledge and understanding of the relevant signs and indicators of human trafficking. Our guidance for IAs and clinical teams has also been updated so that it is easier to navigate.

Given we participate in the latter stages of living organ donation, we collaborated on this issue with organisations and government departments. By proactively engaging with key stakeholders, we have been able to put measures in place to detect the trafficking of vulnerable people earlier in the living organ donation process and ensure a wider system impact. An example of this includes working with UK Visas and Immigration to raise awareness of visa applications that could involve human trafficking for organ transplantation. It has also resulted in us receiving notifications of the number of relevant approved and rejected visa applications (to help ascertain the scale of the problem).

To share learning and understanding of the threat of human trafficking for organ removal, we hosted a roundtable discussion with the relevant agencies. This included NHSBT, police forces, the National Crime Agency and government departments. We have also raised awareness of the threat by presenting at events such as a human trafficking conference, which was organised and attended by the police.

To identify cases earlier in the living organ donation process, there is a need for clinical teams to have a level of professional scepticism. In a bid to assist the detection of human transplant-related crimes, government laid the Human Tissue Act (Supply of Information about Transplants) Regulations 2024 before Parliament. The Regulations provide clinicians with assurance that, under certain circumstances, they must inform us when they suspect a transplant-related crime may have taken place. Simultaneously, it also introduces a responsibility on clinicians to notify us of patients who receive an organ transplant outside the UK.

The Regulations came into force on 1 April 2024 and we developed guidance to support clinicians in response. We also collaborated with NHSBT to promote the Regulations once they were laid to help ensure clinicians were prepared.

Work on this area continues. It involves collaborating with NHSBT, tailoring our police referral process and considering the impact of the Regulations. We continue to refer suspected cases of an organ transplant-related offences to the police for investigation, to protect vulnerable people.

Driving improvements within the post-mortem sector

Part of our role is to ensure post-mortem examinations are undertaken on suitable and licensed premises with appropriate consent or under the authority of the coroner. Given the complex system for managing the deceased, the scrutiny it receives and the sensitive subject matter, the post-mortem sector continues to be a high-risk sector.

In 2023/24, we took steps to improve practices at our licensed mortuaries and a large proportion of this work has focused on improving mortuary security.

Previously, our approach involved clarifying our expectations of the post-mortem and anatomy sectors and conducting assessments to reinforce our standards. Last year, we moved to use our data and inspection methods to highlight common areas of non-compliance and take a targeted approach to improving compliance in the post-mortem sector.

> *The inspectors were very transparent about what they were doing and why – I didn't feel that there was any ulterior motive or attempt to 'catch us out' on anything. The advice and guidance was helpful and well considered.*

During the year, we conducted a data collection exercise to gain high-level insights on areas within the post-mortem sector. The results – alongside our shortfall and incident data, and the findings from the Phase 1 report of Sir Jonathan Michael's independent inquiry into Fuller's offending – confirmed further action was required to improve compliance with our security-related standards and in relation to contingency planning.

To raise awareness and vigilance of security in our licensed mortuaries, we hosted four webinars on security standards for Designated Individuals (DIs; who have a legal duty to ensure that our statutory and regulatory requirements are met). The webinars conveyed that DIs should have a well-rounded understanding of security arrangements in their mortuaries. This includes the importance of restricting, monitoring and auditing mortuary access. It also summarised the evidence we require to assure ourselves that security measures are in place to meet our standards and are suitably monitored.

> *I thought this webinar was an excellent start and I liked the holistic approach to the topic backed up by data and clear explanations. I thought it worked very well.*

Given our incident data in the post-mortem sector, we also updated our HTARI guidance to improve the quality of information provided to us. This will enable us to understand what immediate steps an establishment has taken – both in response to the incident as well as to reduce the likelihood of the incident taking place in the future. The guidance also assists establishments in deciding whether an incident is reportable and ensures they are aware of our escalation processes.

Turning the lens on ourselves, we considered how we could improve our approach to assessing security-related standards in mortuaries and our expectations of licensed establishments. This includes how we assess that an establishment is assuring themselves that they are meeting the standards (for example, by carrying out routine audits of mortuary access, and reinforcing the importance of supervising all mortuary visitors).

We will continue to focus on driving improvements in mortuary security. To help do this, we will assess and engage with the sector and support the next phase of the independent inquiry into Fuller's offending.

Changing requirements for bodies laid to rest at sea

At times, we use our expertise to assist change beyond our regulatory remit. This may be where we identify a problem or where we are asked for our advice or guidance. One example of this involved working with stakeholders to change requirements for bodies laid to rest at sea.

Occasionally, the deceased are laid to rest at sea. While weighted caskets are used, over time they can breach and bodies can wash ashore. When this occurs, the police and coroner may mount a suspicious death inquiry or cause distress to families of the deceased by asking them to identify body parts.

In a move to resolve this longstanding problem, the Marine Management Organisation led a working group that involved the HTA, the Senior Coroner for the Isle of Wight, National Crime Agency, Hampshire and Isle of Wight Constabulary and government departments. As a collective, we worked to change requirements and ensure that bodies laid to rest at The Needles site (off the Isle of Wight) from October 2023 have DNA extracted prior to being buried at sea. The DNA is subsequently held on a restricted access database for comparison to help match and identify any body parts found. Changing the burial at sea requirements ensured the wishes of those who seek a sea burial are respected. It also ensures families are not caused undue distress and that police and coroner resources may be allocated elsewhere.

Our role was important in bringing about this change. We advised on the necessary consent requirements to a group of funeral directors who have been authorised by government to obtain the relevant consent for tissue removal. While responsibility for obtaining consent continues to sit with the establishment carrying out the tissue removal, we will continue to offer our expertise by providing training on an annual basis and offering our guidance to the stakeholders involved.

Supporting innovation in the human application sector

In the human application sector, we license and inspect establishments that procure, process, store, distribute, import and export tissue for human use, or carry out donor testing. These include a range of organisations such as hospitals, stem cell laboratories and tissue banks that can use a variety of tissues and cells (such as bone, skin, heart valves and stem cells). It is a diverse sector where there has been considerable innovation and growth.

Avoiding delays in patient treatment

Under human tissue legislation, establishments are required to notify us before they start new licensable activities or vary methodologies. This is to ensure appropriate procedures and practices are safe for patients.

In 2023/24, we received 332 licence variation requests relating to patient treatment within the human application sector. While the majority were routine, seven requests were considered time-critical and prioritised as they had the potential to cause unnecessary delays to patient treatment. By collaborating at pace with establishments, we were able to rapidly authorise licence variations and enable patients to access the urgent care they needed. This included a hospital that sought to conduct urgent paediatric treatment within two weeks. To approve this time-sensitive request and expedite our assessment of their application, we met the proposed licensee to understand their needs and the planned procedure. After gaining necessary assurances, we approved the application within seven working days enabling the procedure to go ahead as scheduled.

In emergencies, we can directly authorise any person to distribute, import or export tissue for human use outside of the usual licensing framework. These unforeseen events can be brought about by factors such as a change in a patient's circumstances or the availability of highly matched human tissue.

During 2023/24, we used our powers to provide direct authorisation on four occasions. To do this, we worked closely with establishments to gain assurances about the planned treatment, ensure any risks to patient safety were appropriately considered and managed, and ensure patients were appropriately informed and provided proper consent.

By prioritising urgent requests to amend licenses or providing emergency authorisations, we continue to ensure that establishments meet legislative requirements. This proactive approach also enables the use of innovative procedures without compromising patient treatment and care.

Facilitating innovation

We use our position and expertise to support licensed establishments use the latest technologies in accordance with human tissue legislation.

In the human application sector, we do this by adapting our licensing approach to keep pace with innovation and changing clinical practices. There were previously scenarios where a licensed establishment would use a remote site to carry out licensable activity, such as exporting human tissue. Customarily, we licensed both the establishment and remote site in line with our approach in other sectors. However, this model was not practical for manufacturing Advanced Therapy Medicinal Products (ATMPs; medicines for human use that contain genes, tissues and cells). Our typical licensing approach could also lead to additional costs for the sector and undue regulatory burden.

In response to this scenario, we worked with relevant establishments in 2023/24 to find appropriate solutions. This included the introduction of 'hub and spoke' licences where a central establishment oversees activities across remote sites and removes the need to license and inspect each remote site. This approach also ensures we continue to have robust operational and regulatory oversight – for example, by inspecting the central establishment to assure ourselves that remote sites are adhering to our standards through formal agreements. This model has most recently been used to transport human cells across the UK to develop CAR T-cell therapies (a type of cancer immunotherapy treatment that uses genetically altered immune cells to locate and destroy cancer cells).

By adapting our licensing model, we have supported the sector to continue innovating life and health sciences, without compromising on our need to maintain regulatory oversight.

Working with other regulators to support innovation

The Regulatory Advice Service for Regenerative Medicines (RASRM) was set up in 2014 to provide a 'one stop shop' to access free, clear, expert advice about the regulation of regenerative medicines.

To provide this advice, we work alongside organisations such as the Medicines and Healthcare products Regulatory Agency, Human Fertilisation and Embryology Authority and Health Research Authority. Our aim is to help researchers and professionals navigate the regulatory landscape and comply with associated standards in this complex area.

In line with our commitment to be an open, supportive and accessible regulator that supports innovation, we will continue to support the field of regenerative medicine and ensure safe access to innovative therapies. We will also continue to signpost establishments within the human application sector to expert groups and others working in the field, to help facilitate best practice and support across the sector.

Looking ahead

A message from Colin Sullivan, our Chief Executive

Reflecting on our activity last year helps shape our ambitions and the development of our new corporate strategy. In 2024/25, we will continue to be a proportionate, effective and forward-looking regulator. Our values of collaboration, openness, respect and excellence will again underpin how we ensure human tissue is handled safely and with proper consent.

- **Approach to regulation:** In 2023/24, we reviewed our approach to inspections and developed a new regulatory assessment tool. We will continue to refine how we assess the risks that a sector and establishments present, and work with stakeholders and establishments to drive up compliance with our standards.

- **Use of data and information:** As well as using data to improve our approach to regulation, we will use information gathered through horizon scanning and stakeholder engagement to identify priority areas. We continue to be a transparent regulator by publishing our data to support data-driven research and help maintain public trust and confidence.

- **Building trust and confidence:** Recognising that we are not the only organisation responsible for ensuring public trust and confidence with respect to human tissue, we will continue to collaborate and use our expertise to help achieve our ambitions, meet common goals and support innovation. In 2024/25, we will also continue to support the independent inquiry into Fuller's offending and take action in light of the inquiry's findings and recommendations.

- **Being an efficient and effective public body:** In addition to developing efficiencies to continue ensuring we effectively regulate our sectors, we will also make improvements within our organisation. To help do this, we will continue to pursue collaborative opportunities where practicable to improve our systems and processes. We will also develop a renewed people strategy to improve how we value, reward and retain the best talent.

I look forward to leading the organisation through another exciting year as we deliver our strategic ambitions. I thank our excellent staff for their dedication and commitment, alongside our licensed establishments and other stakeholders for their work to help achieve the safe and trusted use of human tissue.

Dr Colin Sullivan
Chief Executive, Human Tissue Authority