

Human Tissue Authority

Our year in numbers 2018 - 2019



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Introduction

This document summarises inspection and licensing data and regulatory activity undertaken by the Human Tissue Authority (HTA) from the 2018/19 business year.

It can be read in conjunction with our [Annual Report and Accounts 2018/19](#), and the more detailed activity reported via the [various working groups and Committees](#) published on the HTA website.

The HTA was established in 2005, and is an Executive Non-Departmental Public Body, more commonly referred to as an arms-length body (ALB), sponsored by the Department of Health and Social Care.

We regulate organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. We also give approval for organ and bone marrow donations from living people.

We separate our approach to regulating and licensing establishments into six distinct sectors:

- Anatomy
- Human Application
- Organ Donation and Transplantation (living and deceased)
- Post Mortem
- Public Display
- Research

You can read previous annual reviews on our website.

For more information on the work of the Authority, please see our [Business Plan 2019 - 2020](#) and [Strategy 2019 - 2022](#).

Our goals

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

- The Human Tissue Act 2004 (and associated Regulations).
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).
- The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).

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.

How we achieve our goals

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004.
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).
- We license organisations involved in organ donation and transplantation as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended).
- We monitor and inspect or audit organisations to ensure they comply with the requirements of the legislation and our standards.
- We use our powers to take regulatory action where we identify non-compliance.
- We assess living organ donations to ensure donors are protected from duress or coercion, and that no reward is offered or given.
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit.
- We monitor developments relating to activities within our remit and advise Government on related issues.

Performance

The HTA is funded through licence fees and grant-in-aid from the Department of Health and Social Care. We are aware of the budget constraints faced by many of our licensed establishments and remain committed to living within our means and keeping costs low.

Performance indicators 2018/19

Performance Indicators	Target 2018/19	Performance 2018/19	Target 2017/18	Performance 2017/18
Undertake a risk-based inspection/audit programme	200 site visits	222 site visits	210 site visits	240 site visits
Take appropriate action for all regulatory non-compliance	100% of (CAPAs ¹) implemented within 28 days	72%	100% of (CAPAs ¹) implemented within 28 days	77%
Make appropriately evidence decisions to agreed quality standard	100% of living donation non-panel cases turned around within 5 working days	100%	100% of living donation non-panel cases turned around within 5 working days	100%
Respond to enquiries in a timely way	95% of enquiries answered within 10 working days	95%	95% of enquiries answered within 10 working days	96%
Reduce attrition rates through improved selection and targeted measures to retain staff	Attrition rate to be no more than 18%	20%	Attrition rate to be no more than 18%	23%

¹ Corrective and Preventative Action plan

Financial summary position as at 31 March 2019

We have generated the income needed to cover the cost of licensable activities and delivered within the budget set for the year. We have a comprehensive fees model that enables us to set our fees according to the regulatory workload and allocate our costs according to our activities as set out in legislation.

	2018/19	2017/18
Income		
Licence fees	£3,654,000	£3,296,000
From devolved Governments	£131,000	£130,000
Revenue grant-in-aid	£703,000	£800,000
Other income ¹	£572,000	£458,000
Expenditure		
Staff costs	£2,901,000	£2,827,000
General Administrative and non-cash costs	£2,086,000	£1,779,000
Surplus(defecit) for the year	£73,000	£78,000

¹ Other income is made up predominantly of rental income from NHS Resolution and seconded staff cost.

Licensing

The Human Tissue Act prescribes certain activities that can only be undertaken by a licensed establishment. The establishments we license must adhere to our standards, which align to our core principles.

Licensing applications received

Sector	Applications received
Human Application	159
Post Mortem	86
Research	71
Public Display	6
Anatomy	17
Organ Donation and Transplantation	25
Total	364

Licensing applications and variations

Sector	Standalone and hub	Satellite	Total
Human Application	132	49	181
Post Mortem	178	71	249
Research	165	152	317
Public Display	15	6	21
Anatomy	38	12	50
Organ Donation and Transplantation	35	0	35
Removal	1	0	1
Total	564	290	854

Inspections and audits

We conduct site visits of licensed establishments in order to assess whether our standards are being maintained. We schedule inspections based on a number of factors, including the legislative requirements, and according to the risk of the activities being carried out. We welcome the significant degree of trust that the vast majority of our licensed establishments have in us, as demonstrated by their openness and willingness to improve, which we believe is a key factor in the high level of compliance we see. As a result we only use significant regulatory action when it is appropriate and in the public interest.

Inspections/audits by sector from inspection

Type	Human Application	Post Mortem	Research	Public Display	Anatomy	ODT	Total
Routine	68	48	23	4	3	11	157
Satellite	2	0	0	0	0	0	2
Non-routine	0	0	0	0	0	0	0
LAAV ¹	2	1	5	0	1	2	11
CAPA ² follow up	2	3	0	0	0	0	5
Total	74	52	28	4	4	13	175

Site visits

Type	Human Application	Post Mortem	Research	Public Display	Anatomy	ODT	Total
Routine	68	48	23	4	3	11	157
Satellite	18	12	15	1	2	0	48
Non routine	0	0	0	0	0	0	0
LAAV ¹	2	1	5	0	1	2	11
CAPA ² follow up	2	4	0	0	0	0	6
Total	90	65	43	5	6	13	222

¹Licence Application Assessment Visit

²Corrective and Preventative Action plan

Shortfalls found during inspection/audit

Sector	Total	With Shortfalls	% with Shortfalls
Human Application	68	66	97.1%
Post Mortem	48	46	95.8%
Research	23	21	91.3%
Public Display	4	1	25.0%
Anatomy	3	2	66.7%
Organ Donation and Transplantation	11	5	45.5%
Total	157	141	89.8%

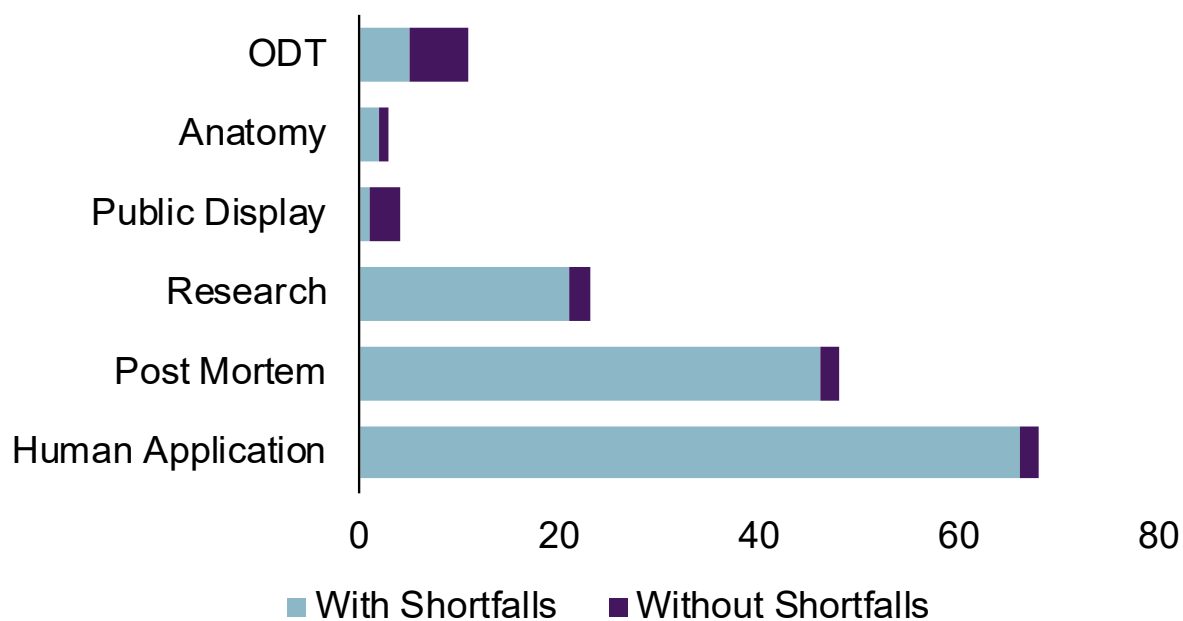


Fig 1. Inspections/audits with and without shortfalls by sector

Breakdown of shortfalls

Sector	Minor	Major	Major (cumulative)	Critical	Critical (cumulative)	Total
Human Application	445	35	13	2	0	495
Post Mortem	376	126	6	3	0	511
Research	108	25	2	0	0	135
Public Display	2	0	0	0	0	2
Anatomy	8	2	0	0	0	10
Organ Donation and Transplantation	10	0	0	0	0	10
Total	949	188	21	5	0	1163

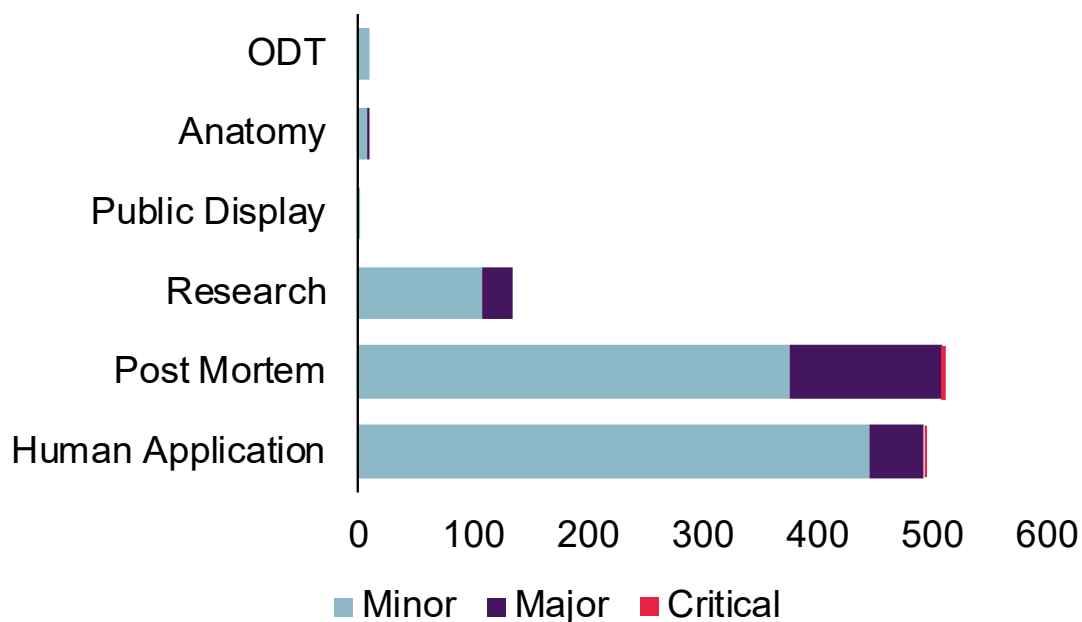


Fig 2. Breakdown of shortfalls

Reportable incidents

We require incidents and events which pose the highest risk to public confidence and patient safety to be reported to us by licensed establishments. This reporting, along with issues and complaints about licensed establishments that are raised with us by third parties, allows us to take action if required.



116

HTA reportable incidents in the post mortem sector



323

Serious adverse events or reactions in the Human Application sector

Serious adverse events and reactions in the Organ Donation and Transplantation sector

2018/19	Serious Adverse Events (SAE)	Serious Adverse Reactions (SAR)
Q1	6	9
Q2	2	2
Q3	13	10
Q4	12	8

Living donation

The HTA maintains a system to ensure that donations of organs or tissue for transplantation from living people are given without coercion or reward. The system relies on donor and recipient interviews, undertaken by a group of independent and accredited assessors. They are predominantly volunteers whom we train, accredit and support in order to fulfil our statutory functions. Complex cases are reviewed by panels, made up of HTA Authority members.

Number of living donor transplants

Organ type	Directed	Paired/pooled	Non directed altruistic (NDAD)	Directed Altruistic (DAD)
Kidney	860	220	95	12
Liver	30	0	4	0
Small Bowel	1	0	0	0
Total			1222	

Cases approved by HTA panel

Organ type	Directed	Paired/pooled	Non directed altruistic (NDAD)	Directed Altruistic (DAD)
Kidney	1	220	95	2
Liver	0	0	4	0
Small Bowel	0	0	0	0
Total			322	



128

Number of Independent Assessors (IA)



71

Bone marrow/PBSC¹ approvals



50

Number of Accredited Assessors (AAs)

¹Peripheral blood stem cells

Website and enquiries

We provide advice and guidance to both the public and professionals, and recognise the value in supporting establishments to comply, rather than dealing solely with non-compliance. We publish a range of Codes of Practice and sector specific advice and guidance, as well as answering individual enquiries from establishments and members of the public. We share learning gained from inspections, incident reports and compliance updates through our newsletters and publications.

General Enquiries

2018/19	Q1	Q2	Q3	Q4	2018/19 total
From public about body donation	400	460	386	378	1624
Other general enquiries	445	460	361	455	1721
Total enquiries	845	920	747	833	3345
Website	196	235	207	208	846
Phone or emailed enquiry	649	685	540	625	2499

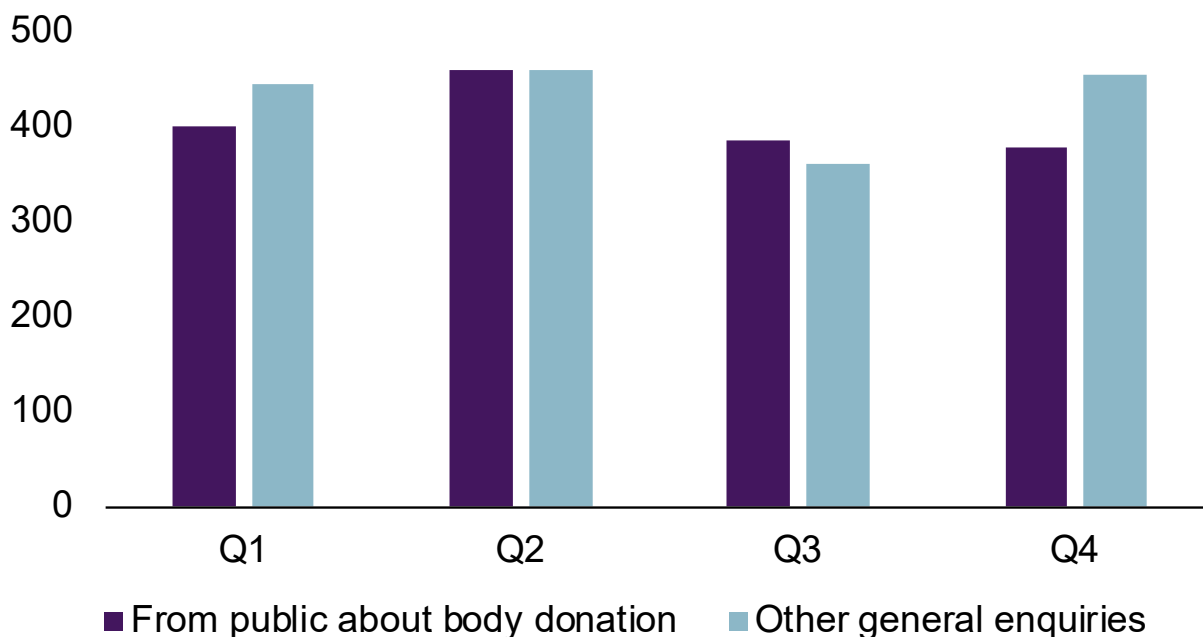


Fig 3. Number of enquiries by topic

Homepage visits

2018/19	Q1	Q2	Q3	Q4	2018/19 total
Page visits	13,987	14,828	15,155	16,603	60,573

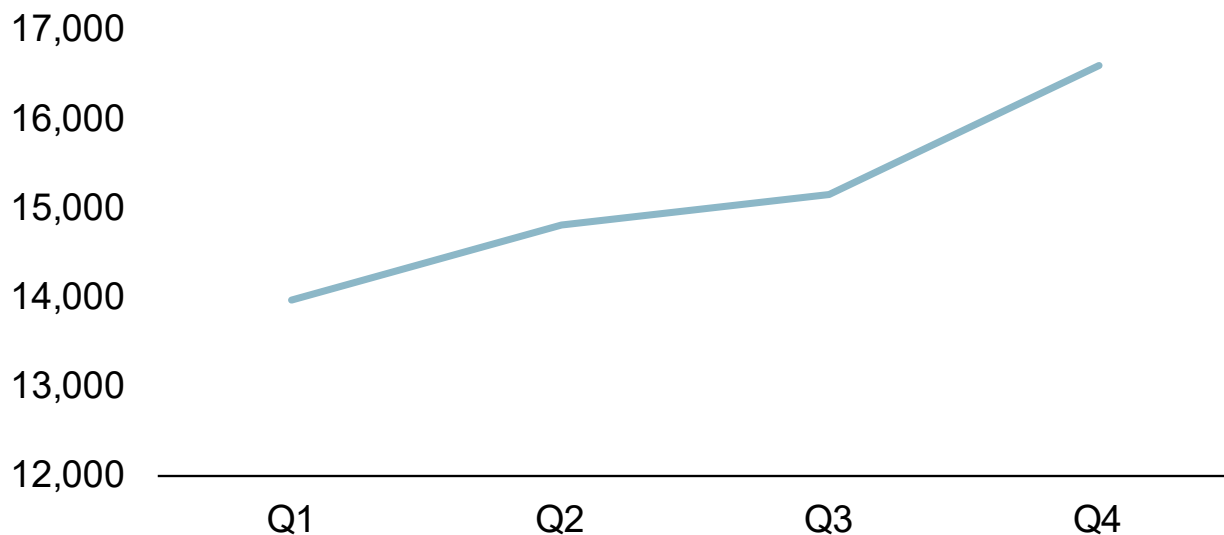


Fig 4. Homepage visits per quarter

Most visited pages

Page title	Page link	Page views
Donating your body	https://www.hta.gov.uk/donating-your-body	100,900
Medical schools list	https://www.hta.gov.uk/medical-schools	52,450
HTA Codes of Practice	https://www.hta.gov.uk/hta-codes-practice-and-standards-0	29,802
Body donation FAQs	https://www.hta.gov.uk/faqs/body-donation	22,856
Human Tissue Act 2004	https://www.hta.gov.uk/policies/human-tissue-act-2004	20,162

HTA people and licence contacts

Our people



Licence contacts



Feedback on the HTA

Inspection feedback

“Open, transparent, honest, and very approachable. Made the whole experience a pleasant one. The members of the inspection team were courteous and demonstrated professionalism.”

“Excellent inspection team – very approachable and friendly and put us all at ease.”

Public confidence

“I just wanted to say that I think your website is fantastic and you have made such a great job at explaining complex matters in a simple but detailed way.” (Email)

“I’ve followed you - you’re doing wonderful things for UK medicine and training.” (Twitter)

Stakeholders

“Really important piece of work showing public support for greater data sharing with biobanks. Thanks @IpsosMORI @HTA_UK.” (Twitter)

“Jules was FANTASTIC today, thank you for your ongoing support.” (Twitter)

Annual conference feedback

“Very enjoyable and informative day.”

“Really enjoyed the whole event!”

“It was a very informative and well organised day. Thank you.”

Customer service

“HTA_UK what an amazing website you’ve got! Thank you and keep up the good work! (Twitter)”

“A big thanks to @HTA_UK head of regulation who took time to speak to me this morning & gave some excellent advice.” (Twitter)

“I have been looking at the cord blood section, in particular, it has been so very helpful for my husband and I in making our decision on cord blood banking. So I just wanted to say thank you and keep up the good work!”

Feedback has been shortened and edited for the sake of clarity and brevity.

Follow us and feedback

Get in touch

Join our public panel - www.hta.gov.uk/join-our-public-panel

Read and comment on the new HTA blogs - www.hta.gov.uk/blog

Follow us on social media:

- Twitter - www.twitter.com/HTA_UK
- Facebook - www.facebook.com/HumanTissueAuthority

Keep up to date with the HTA

See all recent inspection reports - www.hta.gov.uk/news/see-our-latest-inspection-reports

You can sign up to receive alerts when establishments receive their latest inspection reports. Simply find the establishment you wish to be alerted on, and click the 'Sign up to receive updates on this establishment' button on their profile page - www.hta.gov.uk/establishments

Sign up to our newsletters - www.hta.gov.uk/newsletter/signup



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