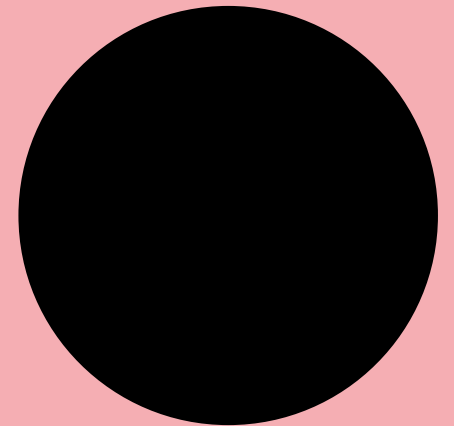
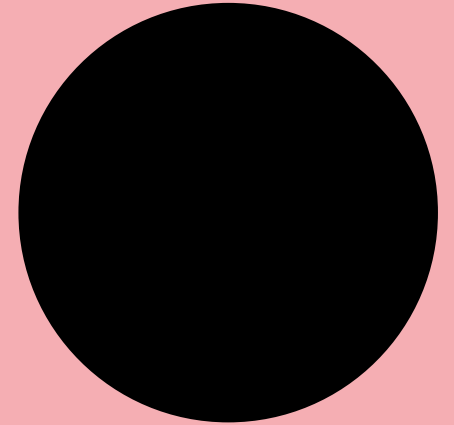


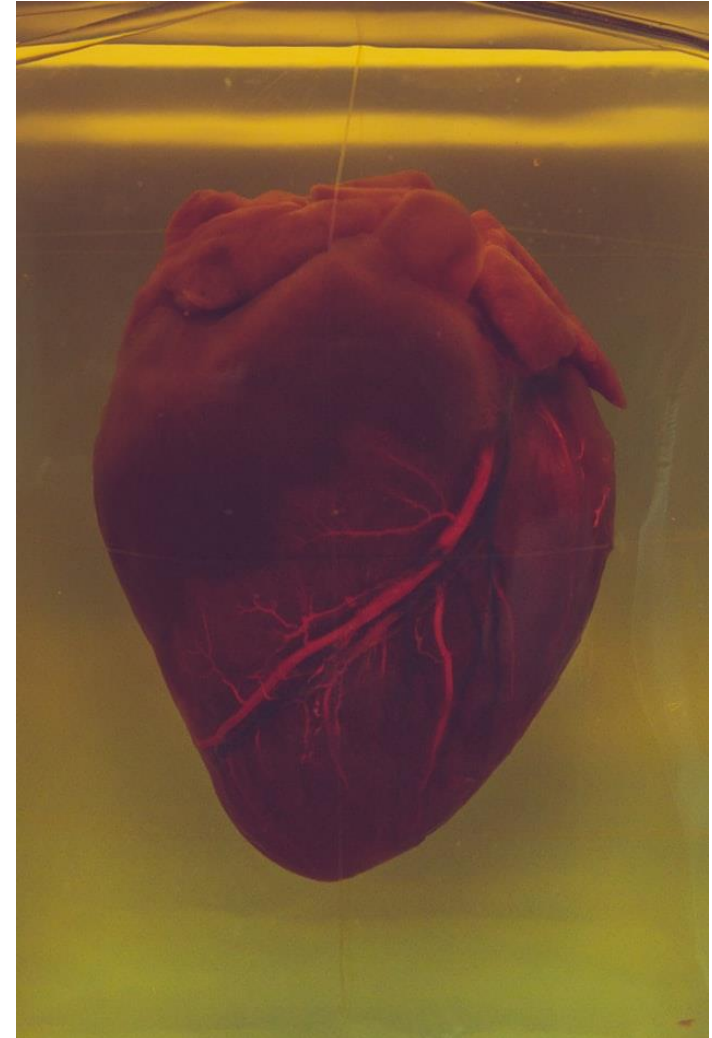


Human Tissue Authority (HTA): 2020 Professional Evaluation



Contents

03	Background
04	Research objectives
05	Executive summary
07	Who we spoke to
10	The HTA's performance against its key metrics
14	Evaluating knowledge and perceptions
22	Evaluating the HTA's regulatory role
29	Evaluating fees and payments
33	Evaluating engagement and communication
37	Future priorities to consider
41	Conclusions and recommendations
44	Contact details

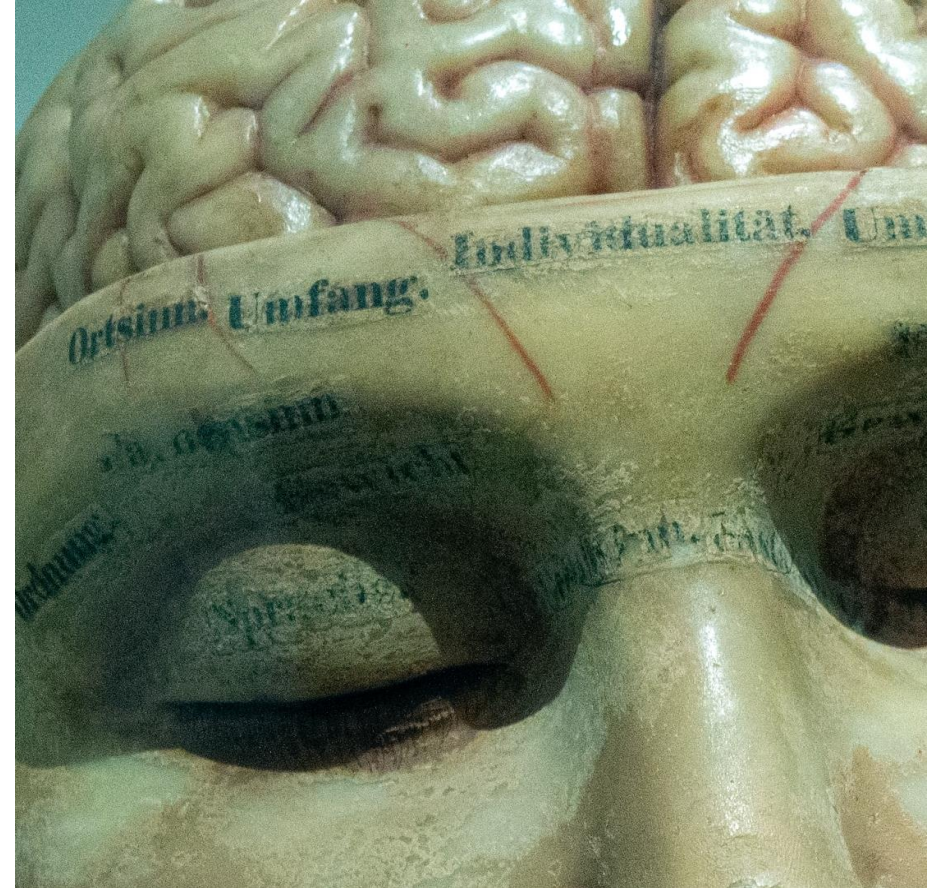


Background

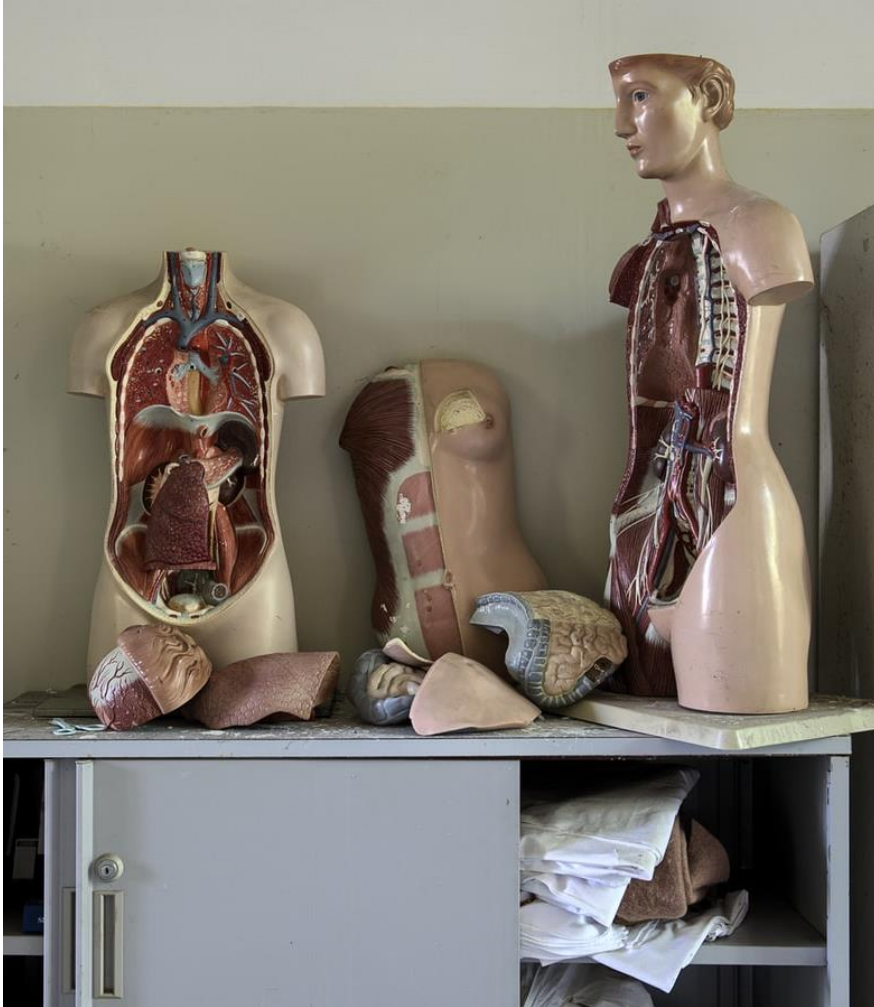
The Human Tissue Authority (HTA) is the regulator for organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. In addition to this, it provides approval for organ and bone marrow donations from living people. To create an environment of trust among the public and professionals, the HTA is responsible for regulating stakeholders across the sectors above to ensure the safe and ethical use of human organs and tissue.

Stakeholder feedback is crucial to understanding the effectiveness of the HTA's regulation and identifying opportunities to adapt or expand on its regulatory approach. Evidence to suggest how the HTA's engagement is evaluated also means that the regulator can continuously consider how it communicates with stakeholders in a way that builds and maintains trust.

Although the HTA consulted with the public in 2016, a full professional stakeholder evaluation of this sort has not been conducted since 2013. The outcome of the professional evaluation will therefore be important in providing a robust update on the sentiments of regulated organisations towards the HTA. This will inform any review to the current regulatory approach and engagement strategies so that they that are fit for purpose.



Research objectives



The HTA commissioned Savanta ComRes to undertake this research with its stakeholders; the overarching objective being to remain a right-touch regulator, and to ensure public and professional confidence in organisations that work with human bodies, body parts, organs and tissue.

Specifically, the core objectives were to:

- 1. Gauge awareness, knowledge and understanding of the HTA's licensing requirements**, including the role of key regulatory contacts and confidence of the organisations in maintaining standards;
- 2. Assess experiences of the HTA's regulatory oversight**, including pre-inspection, inspection/audit, contact with the HTA and its publications and guidance;
- 3. Measure awareness, knowledge and understanding of the HTA's strategy**, including its expectations of them as organisations and vice-versa; what licensed establishments expect from the HTA;
- 4. Examine the perceived value and potential burden of oversight**, focusing particularly on value for money, burdensome experiences and how the HTA might add value through its work;
- 5. Evaluate the potential impact of the regulatory model on innovation at licensed establishments.**

Executive summary



Evaluating stakeholders' knowledge and perceptions of the HTA

The HTA scores highly against its key metrics; knowledge (96%), confidence in regulation (94%) and favourability (87%). Knowledge of the HTA commonly pertains to its statutory requirements; under half (43%) say they know 'very well' what the HTA does, although it should be noted that just knowing 'a fair amount' appears sufficient in maintaining effective relationships. Favourable impressions appear primarily driven by perceptions of the HTA's professionalism in terms of being an effective and thorough regulator,, and its perceived helpfulness in providing guidance and advice.



Evaluating the HTA's regulatory role

Reflecting broader favourability levels, having 'a great deal' of confidence in the HTA as a regulator is more prevalent than in 2013 (57% vs. 49%) alongside perceptions of the body as authoritative and effective. The most notable changes stakeholders have identified in recent years are more thorough regulation and the HTA appearing more supportive and accessible as a body. The vast majority (at least nine in ten) deem the HTA effective in fulfilling its regulatory responsibilities, including producing codes of practice and overseeing guidance around consent. This is helping to improve the quality and standards of stakeholders' procedures and the revised codes of practice and standards is considered to have had an impact for most (66%). Whilst many say the level of regulation is reasonable and standards are easy to comply with, some stakeholders indicate there is scope to make inspections shorter and more focussed to reduce burden on their sector. Some think the HTA could be more flexible in its approach, such as in its expectations of information collected from donors. Others suggest that this process require clarity, particularly in interpreting guidance for collecting consent.



Evaluating fees and payments

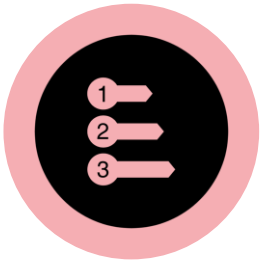
There appears to be no clear consensus regarding fees and payments – many stakeholders lack the knowledge, particularly in the Organ donation and transplantation sector. Whilst most don't express strong sentiments, some do suggest a 'one-size-fits all' payment model can be imbalanced and that fees could be reviewed based on level of engagement and risk for each organisation. This is particularly prevalent in sectors such as Public display where levels of engagement vary widely.

Executive Summary



Evaluating communication and engagement with the HTA

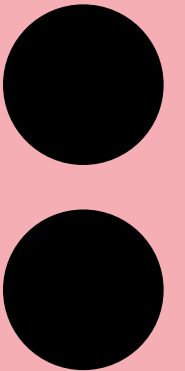
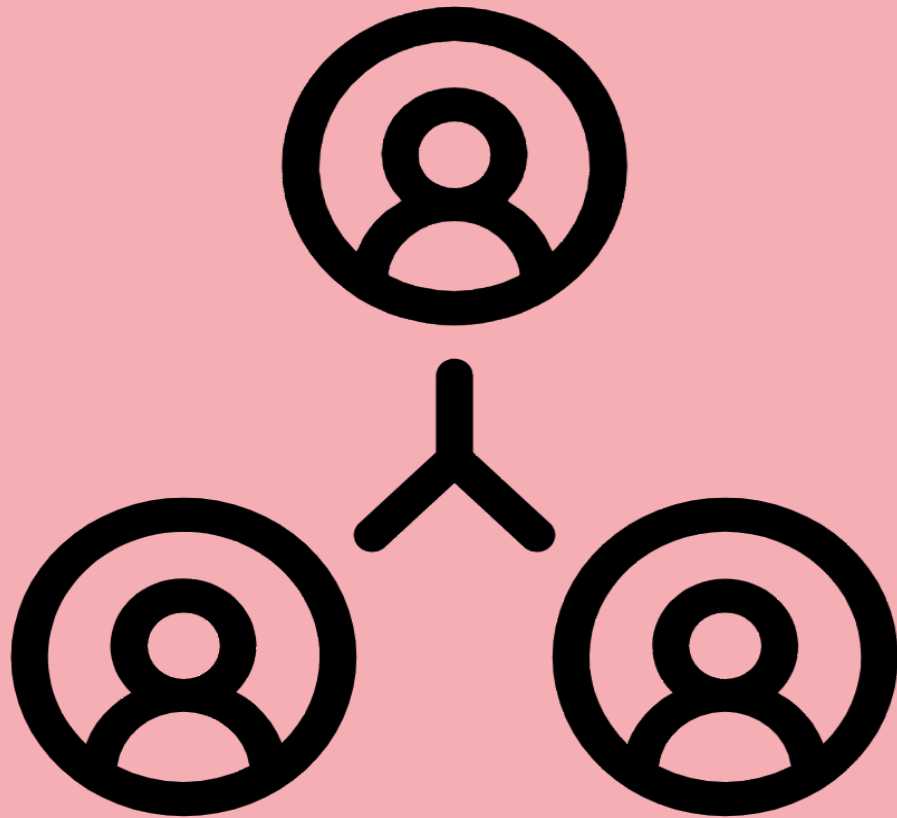
Whilst communication is rated as good by most (78%) stakeholders, this metric has decreased since 2013, although not problematically so; fewer say it has been very good (35% vs. 46%) - but on the whole, evaluations have been positive. The most common forms of interaction with the HTA are through the website, emails or newsletters and bulletins – all of which are considered useful by most stakeholders. For instance, more than eight in ten consider the website effective (82%). The slight decrease in those saying communication is very good could be a reflection of the views of those who have either been receiving less personal contact or who describe waiting too long for a response to know if their feedback has been taken into account. In this context, a few stakeholders cite frustrations with regards to direct inquiries they have made and would like to see more timely feedback from the HTA. Many stakeholders provide further suggestions for how the HTA could improve its engagement with them, which include sector-specific communication, better filtering, navigation and signposting to new developments and guidance relevant to them.



Future priorities for the HTA to consider

Alongside suggestions mentioned for better engagement and right touch regulation, stakeholders provide a variety of suggestions for what that they think the HTA could focus on in the longer term. The most common themes that emerge include a desire for clearer guidance that allows less room for interpretation, streamlining inspections to reduce burden on their sector, promoting more training opportunities online and offline, and offering more examples of best practice. In addition, a few stakeholders suggested that it is important for the HTA to continue with any public engagement exercises, especially those which promote awareness on changes to the organ donation consent procedures. This would be in accordance with the HTA's objective to maintain trust among the public and professionals. Across various sectors, suggestions are also made with reference to the need for guidance around new developments and emerging technologies such as stem cell therapy. Beyond these suggestions, it is positive to note that the majority of stakeholders (60%) say the HTA does not need to do anything to improve its relationship with them; a testament to the continued success since the last evaluation to maintain positive levels of favourability and trust among its stakeholders.

Who we spoke to



Methodology

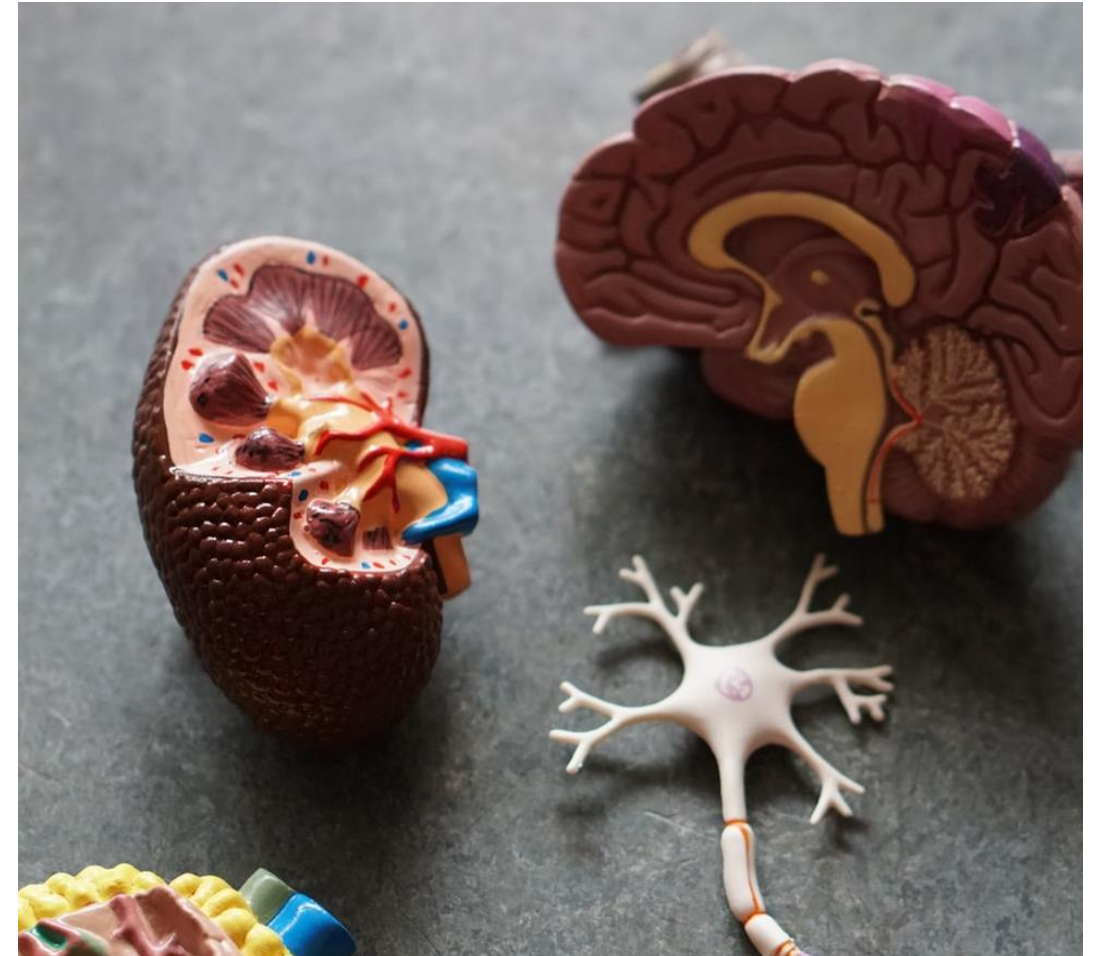
The evaluation was conducted in two phases:

1. A ten-minute online survey of HTA stakeholders:

- Savanta ComRes interviewed 518 stakeholders between 17th February and 9th March 2020;
- 518 individuals out of a total sample of 3,028 contacts provided by the HTA responded to the survey, amounting to a response rate of 17.1%;

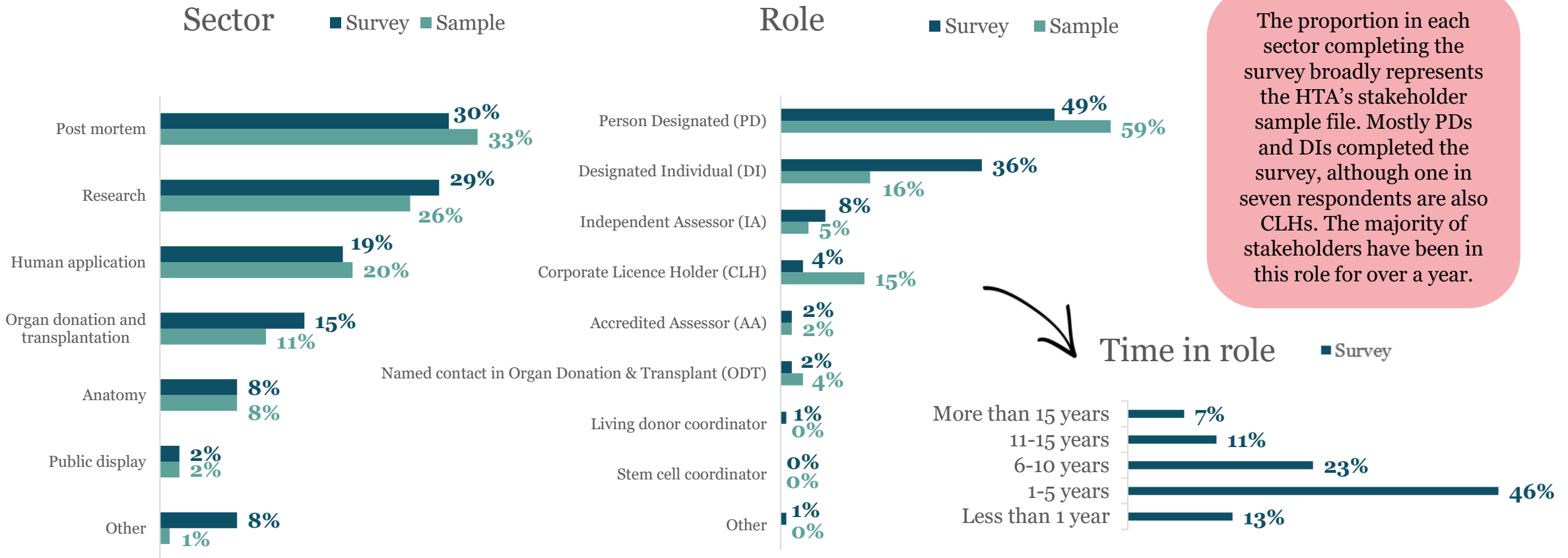
2. 30 in-depth semi-structured telephone interviews :

- Stakeholders were given an opportunity to opt in for telephone interviews at the end of the online survey
- Savanta ComRes then booked and conducted interviews with 30 of these individuals between 12th March and 16th April 2020;
- 5 interviews were conducted among each sector group;
- Interviews each lasted half an hour and were designed to explore and discuss stakeholder evaluations of the HTA in greater depth and detail.



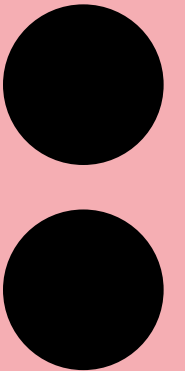
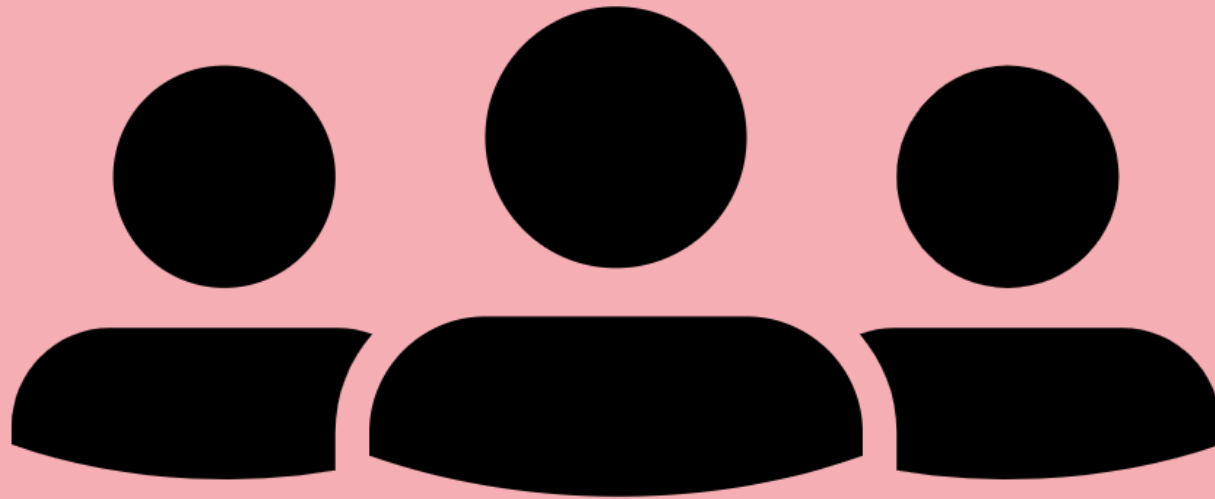
A mixture of sectors and roles participated in the survey, broadly representing the HTA's stakeholder sample file

The HTA provided a sample file containing the email addresses of its stakeholders. Each received an email from Savanta ComRes inviting them to take part in the evaluation with an individual link to the survey. To provide an accurate picture of survey respondents, we allowed stakeholders to select multiple roles and sectors in the survey. Data are unweighted and represent a natural fall-out of those participating, a breakdown of which is shown below.



9 IQ1A. Please specify your relationship with the HTA. Base: All survey respondents (n=518); All stakeholders in the sample file (3,028)
 IQ3A. In which sectors do you work? Base: All survey respondents (n=518); All stakeholders in the sample (3,028)
 IQ2. How long have you been working in this role? Base: All survey respondents (n=518)

The HTA's performance against its key metrics



The vast majority of stakeholders rate the HTA positively against key metrics including knowledge, confidence, communications and advocacy



Knowledge of the HTA:

NET: Fair amount or more 96%

NET: Just a little or less 4%



Communications with the HTA:

NET: Good 78%

NET: Poor 3%



Confidence in the HTA as a regulator:

NET: Fair amount or more 94%

NET: Not very much or less 3%



Describing the HTA:

NET: Speak highly 69%

NET: Be critical 3%



Favourability towards the HTA:

NET: Favourable 87%

NET: Unfavourable 2%

In the upcoming sections of the report, we will explore some of these metrics in more detail. For instance, the report will note where and why some stakeholders have suggested improvements for the HTA's communication strategies. In addition, we'll explore the influence of having either a 'fair' or 'good' knowledge of the HTA.

Survey findings indicate stakeholders do not hold strong positive or negative views regarding HTA fees and payments



Enough info about how HTA fees are calculated:

NET: Agree 29%

NET: Disagree 15%

NET: Don't Know / No opinion 33%



Fees change too much year to year:

NET: Agree 10%

NET: Disagree 11%

NET: Don't Know / No opinion 41%



Fees charged are about right:

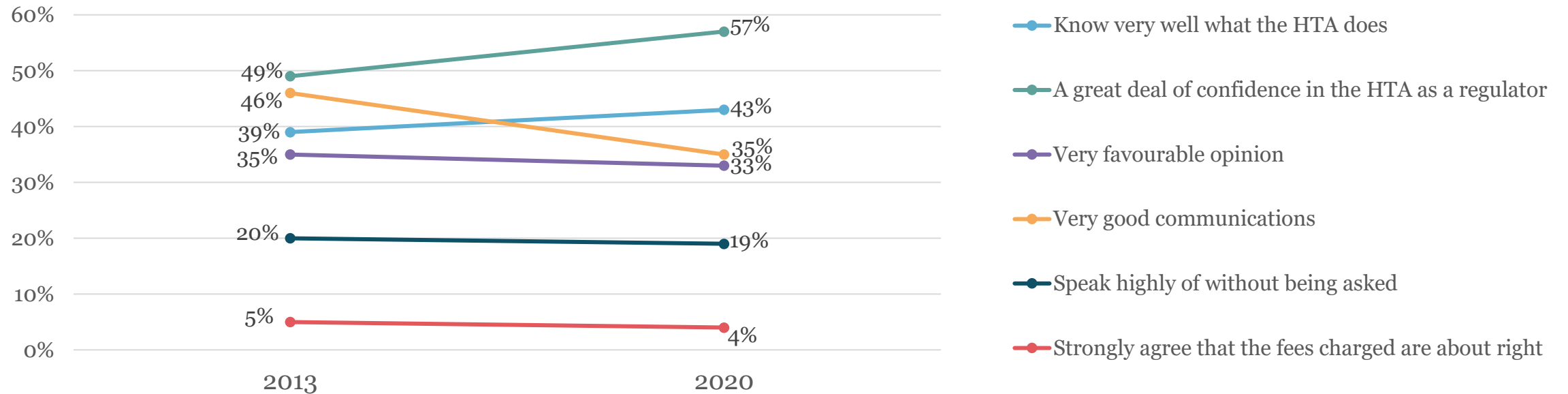
NET: Agree 23%

NET: Disagree 11%

NET: Don't Know / No opinion 36%

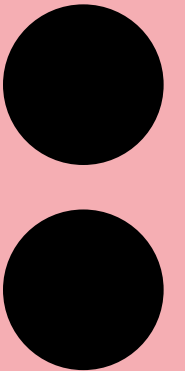
There appears to be **no clear consensus** in stakeholders' attitudes to HTA fees and payments. A plurality tend to say they neither agree nor disagree, don't know or have no opinion to whether the charges are right or if they change too much year on year. Variance by sector and insights from the qualitative interviews around what is driving such responses will be discussed later in the report.

Since 2013, high levels of confidence in the HTA as a regulator and knowledge of what the HTA does have increased while fewer stakeholders appear to rate communication as being ‘very good’



The high scores across most metrics seen on the previous two slides demonstrate that the HTA is positively viewed by its stakeholders for the most part. To go beyond this, we have considered on this slide **to what extent stakeholders rate the HTA at the top band of each of these metrics and observed any change over time**. Comparing data from 2020 to previous data collected in 2013¹, it appears that a greater proportion of stakeholders now hold ‘a great deal’ of confidence in the HTA as a regulator (57% vs. 49%) demonstrating progress against this metric. Meanwhile, a minority still consider themselves very favourable towards the HTA; a metric which largely remains unchanged. With greater confidence, it may be expected that stakeholders would have greater knowledge of what the regulator does. Indeed, this metric has improved slightly, although appears broadly consistent with 2013 (43% vs. 39%). The lesser proportion rating communications as very good (46% vs. 35%) signal an area for further investigation in this report.

Evaluating knowledge and perceptions



Almost all stakeholders think they know what the HTA does and have at least a basic familiarity through their engagements with the regulator

How well do you think you know what the HTA does?

NET: A fair amount or more 96%; NET: Just a little or less 4%

The overwhelming majority (96%) of HTA stakeholders surveyed say they know a fair amount or more about what the HTA does, including more than two in five (43%) reporting that they know what the HTA does very well. This finding was further evidenced through interviews with stakeholders. Those in Anatomy, Post mortem, Research, and Human application sectors were particularly likely to describe themselves as “fairly familiar” or “very familiar” with the HTA in their current role.

Some who are very familiar reference the longevity of working in their current role or sector. They suggest this accumulation of knowledge over time has given them a deep understanding of the HTA’s strategy and awareness of its licencing requirements.

In contrast, *none* of those belonging to Public display and Organ donation and transplantation sectors described themselves as being very familiar in interviews, with some explaining they have only had limited interactions with the regulator.

Among those just describing themselves as fairly familiar are stakeholders who are still learning about the different elements of the HTA’s overarching role. They tend to have a basic degree of familiarity with its statutory requirements, typically gained through the few interactions they have had with the regulator for reports and inspections. These stakeholders are also more likely to have a knowledge HTA’s work within their sector only.

*“Very familiar – I was involved in tissue into the UK before the HTA was in existence.”
Human application, CLH*

A **basic knowledge** of what the HTA does appears to be **sufficient in maintaining an effective relationship** with the regulator. A large majority express favourable opinions of the regulator regardless of if they say they know ‘very well’ or ‘a fair amount’ about what it does (95% and 85% respectively).

*“I’m familiar with what I need to do within the HTA in that submitting reports, assessing donors [...] As to what they do around other areas, I have absolutely no idea to be honest.”
Organ donation and transplantation, IA*

The extent to which stakeholders understand what the HTA does is largely consistent across sectors; a majority think they know at least a fair amount



Knowledge of the HTA

By sector, ranked descending by % NET Fair amount or more



Anatomy:

NET: Fair amount or more 100%*; NET: Just a little or less 0%*



Research:

NET: Fair amount or more 99%; NET: Just a little or less 1%



Organ donation and transplantation:

NET: Fair amount or more 98%; NET: Just a little or less 3%



Post mortem:

NET: Fair amount or more 97%; NET: Just a little or less 3%



Human application:

NET: Fair amount or more 95%; NET: Just a little or less 5%



Public display:

NET: Fair amount or more 83%*; NET: Just a little or less 17%*

At least 95% of stakeholders in all sectors say they know a fair amount or more about what the HTA does, with the exception of the public display sector (83%*). Public display is the smallest sector both in terms of number of stakeholders overall, and the number completing the survey (12) meaning the figure is indicative only, and could explain the fluctuation.

“I think the authority itself and the work it covers is not widely understood in the general public, until one finds themselves in receipt of that, or involved in that work.”

Organ donation and transplantation, IA

A few stakeholders interviewed sporadically note that **public understanding of the HTA is limited and suggest working to increase this**. Suggestions of how to do this are discussed later on in the report.

Interviews and survey data suggest stakeholders are aware of the HTA's statutory requirements; they often make unprompted references to these and also rate them as highly important activities for the HTA

“Well, the Human Tissue Act came about after there were various awful incidents where organs were being taken from children without the parents knowing, tissues were being kept and perhaps being used for research without, again. So I would say consent, and [...] their core role is really to uphold the Human Tissue Act as it translates into UK law.”
Human application, PD

“One of their core roles, obviously, is to do with inspections and making sure that everybody is adhering to the rules and regulations.”
Anatomy, DI

“They're a regulator to make sure that people work with human tissue appropriately and with consent.”
Research, PD

When describing their understanding of the HTA's core role, many interviewees reference its licensing requirements, importance in ensuring compliance with the law, and that individuals follow regulations. Many also referenced the HTA's role in providing “guidance” or setting out “guidelines”. This demonstrates a **strong association** between the HTA and its **statutory requirements** as a regulator.

Some interviewees were also able to reference specific elements of these requirements including the Human Tissue Act or related EU directives. Others highlighted the HTA's role in undertaking inspections. Some stakeholders also spoke of the importance of “consent” and highlighted “ethical” considerations in relation to the HTA's core role, suggesting that appropriate ethical guidance as an area of particular interest for them.

Strong associations with the HTA and its statutory requirements are also evidenced in the survey data. Almost all think the producing codes of practice (99%) and inspecting organisations to ensure good standards and appropriate procedures (98%) are important activities for the HTA. This is also the case with regards to public duties such as giving advice and guidance (97%) and ensuring dignity and respect for the deceased (97%).

NET: Important

1. Producing codes of practice **99%**
2. Overseeing the consent requirements of the Human Tissue Act **99%**
3. Inspecting organisations to ensure good standards and appropriate procedures **98%**
4. Ensuring dignity and respect for the deceased **97%**
5. Giving advice and guidance **97%**

FQ5. How important, if at all, do you think each of the following activities are for the HTA? Base: All respondents (n=518)

Telephone interview Q7. Can you please describe what you consider the HTA's core role to be? Interviewees unsure of the HTA's role were provided with the following description: *The HTA was created by Parliament as an arms'-length body of the Department of Health and Social Care. The HTA regulate organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. They also give approval for organ and bone marrow donations from living people. The HTA do not promote organ, tissue, or body donation, their role is to ensure that when it takes place, it is lawful.*

Alongside being ‘necessary’, stakeholders also associate the HTA with being ‘helpful’, ‘respectful’ and ‘thorough’

When asked to provide the first words or phrases that spring to mind when they think of the HTA, interviewees provided a wide array of responses, although there were some common themes across many of the interviews.

Positively, across different sectors many stakeholders highlight positive traits they associate with the HTA, using words like “helpful”, “ethical”, “thorough”, “respectful”, and “guidance”. A smaller number of interviewees use language such as “difficult”, “inflexible” and “contradictory” which seem to relate to a minority of negative experiences in interpreting guidance or in communicating with the HTA.

*“I’ve never found them overly onerous or anything like that. They’ve always been there to help.”
Research, DI*

Others think of the HTA’s regulatory role, mentioning words like “necessary”, “regulatory”, and “regulation”.

*“‘Necessary’ is an absolute, that there needs to be an authority governing this area, the areas of the HTA, because of the very nature of the sensitivities.”
Post mortem, CLH*

standards important informative consistent guidance law
information advice don't understand regulation frustrating regulatory body formal
directive ethical helpful website regulatory
inflexible fast regulatory
efficient detailed necessary Human Tissue Act specific formalised
comprehensive useful necessary human application
positive not widely known good reputation
bureaucracy tissue
complex authoritative human tissue thorough cells
consistency human remains tissue
organised transparent professional respectful not straightforward unclear
close eye difficult information source do the job
statutory instrument live donations clear help
contradictory regulations safety
reassuring awareness

Stakeholders mostly hold positive and balanced impressions of the HTA, often as a result of its professionalism, good engagement and helpful guidance

How favourable or unfavourable is your overall opinion of the HTA?

NET: Favourable 87%; NET: Unfavourable 2%

"[HTA have] always been really helpful, very, very thoughtful, you know, and not impatient if I feel I'm sort of asking something that seems a little bit obvious." Organ donation and transplantation, AA

"It's having that, you know, the help and the reassurance that what you're doing in day-to-day life is being done properly and that's based on the guidance that's produced and based on the feedback that you get from the HTA." Research, DI

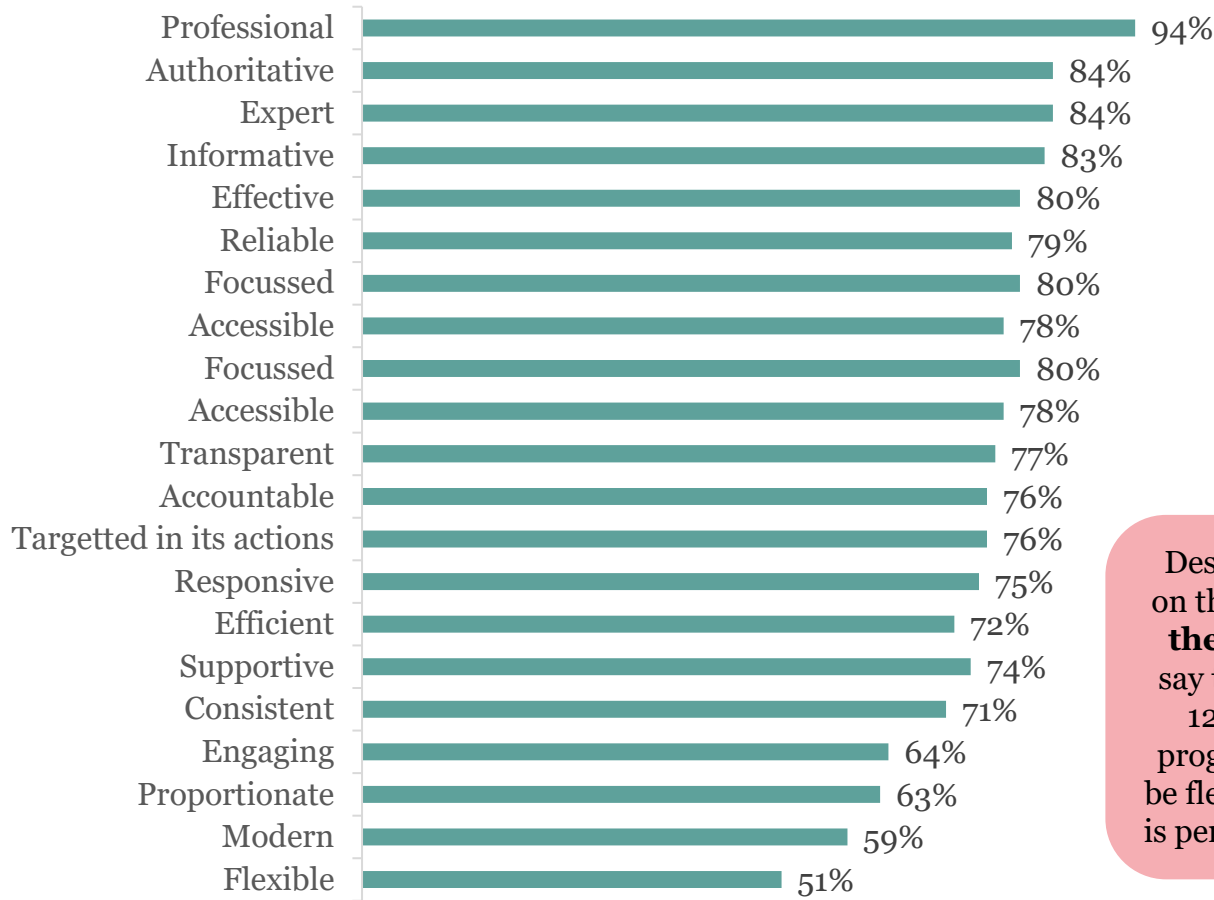
As seen on the previous slide, many stakeholders interviewed made favourable top-of-mind associations with the HTA. This is further evidenced by the close to nine in ten (87%) of those surveyed who also say they hold a favourable opinion of the regulator, compared to just 2% who possess an unfavourable opinion. Examples of **positive engagements** with the HTA identified by interviewees often tend to **reference** helpful and timely **guidance, good audits and inspections**, and noting the thorough and professional nature of their work.

Whilst 33% rate the HTA very favourably, **54% say they are mainly favourable**. Investigating this further in interviews, most gave balanced descriptions of the HTA which were broadly positive or neutral. A minority noted a few challenging experiences they had encountered that relate to engagement. For instance, one individual reported their perceptions of the HTA worsened due to what they perceived to be a high staff turnover as it left them feeling as if they didn't have a designated contact. Another described the length of time it took the HTA to respond to their query as "frustrating". However, judging from the largely positive feedback these appear as one-off personal experiences and not a broader reflection of the overall work of the HTA.

"When I've eventually got to talk to somebody, they've been extremely helpful. But the process getting a reply is tedious. I'm still waiting for a reply on something for about six months, it's not critical but it would be nice to tidy something up." Post mortem, DI

The view that the HTA is authoritative and effective is more prevalent now than in 2013 although a minority suggest its approach can be inflexible

Descriptions of the HTA



Positive descriptions of the HTA are evidenced through the survey data. Only a small minority (12% or less) of all stakeholders disagree that each of the attributes tested on the left can be used to describe the HTA. Stakeholders are most likely to agree that the HTA is ‘professional’ (94%). This is near identical to the proportion in 2013 (93%); a positive given the length of time that has passed since this was measured. More than four in five (84%) stakeholders agree that the HTA is ‘authoritative’, which is **significantly higher than in 2013** (76%). Significantly more stakeholders also agree the HTA is ‘effective’ in 2020 than in 2013 (80% vs. 74%). These shifts may reflect the increase in perceived confidence stakeholders have in the HTA as a regulator broadly.

Despite the few challenging experiences mentioned on the previous slide, **three quarters (75%) agree the HTA is responsive**. However just half (51%) say the same about the regulator being flexible, with 12% disagreeing. Regardless, the HTA has made progress since 2013 where only 43% considered it to be flexible. A few acknowledged in interviews that this is perhaps expected given the HTA is a statutory body.

“They seem professional and thorough, but they’re not very flexible in their approach.”
Public display, DI

Favourability levels are broadly high and consistent by sector but a larger than average proportion of those in Independent Assessors roles suggest the HTA could be more flexible in its inspections



Favourability towards the HTA

By sector, ranked descending by % NET Favourable



Anatomy:

NET: Favourable 98%*; NET: Unfavourable 0%*



Research:

NET: Favourable 92%; NET: Unfavourable 2%



Human application:

NET: Favourable 89%; NET: Unfavourable 3%



Organ donation and transplantation:

NET: Favourable 86%; NET: Unfavourable 0%



Post mortem:

NET: Favourable 84%; NET: Unfavourable 1%



Public display:

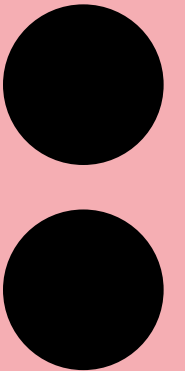
NET: Favourable 83%*; NET: Unfavourable 0%*

The vast majority of stakeholders in each sector have a favourable impression of the HTA, with just 8 of those surveyed indicating they are unfavourable. The latter of which consists of stakeholders who sit within Human application, Post mortem and Research sectors.

No stakeholders in the Organ donation transplantation sector indicate they are unfavourable towards the HTA (84% are favourable). However it seems that those in **Independent Assessor roles** who sit across this and other sectors are twice as likely than the average stakeholder to **disagree the HTA is flexible** (28%* vs. 12%). It seems from interviews that this can be a result of misalignment between different expectations around levels of details required in reports. For instance, one stakeholder references an instruction from the HTA that they conduct mental health assessments with donors but that they did not feel clear about the scope of this, who should be conducting them and what the outcomes would be.

“The clinicians expect the HTA to provide guidance; the HTA expect clinicians to find guidance elsewhere but they won't be explicit about that. That's why they don't get ten out of ten. .” Organ donation and transplantation, IA

Evaluating the HTA's regulatory role



A vast majority appear confident in the HTA as a regulator, some express uncertainty but this more often relates to regulation outside of their sector

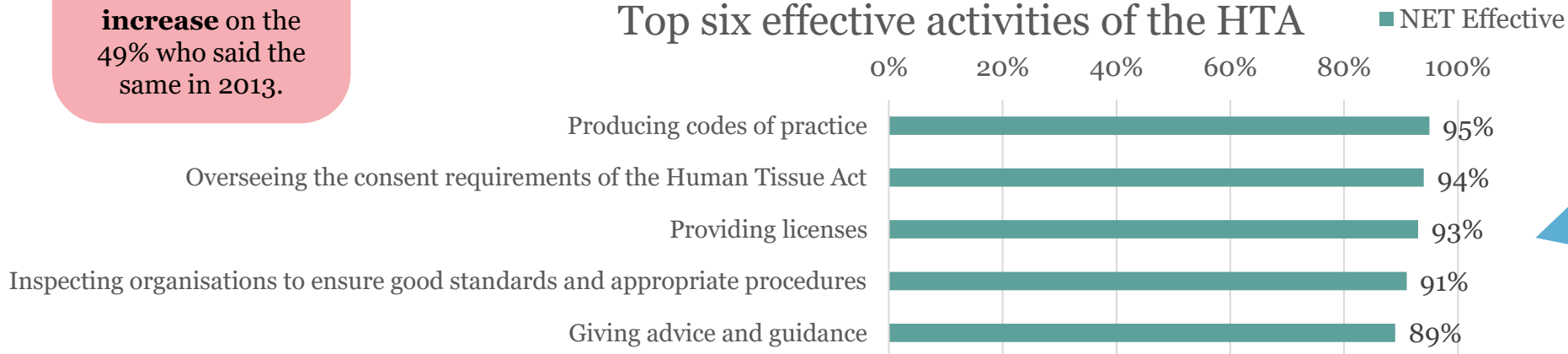
To what extent, if at all, do you have confidence in the HTA as a regulator of the removal, storage, use and disposal of human tissue?
NET: A fair amount or more 94%; NET: Not very much or less 3%

Almost all (94%) stakeholders express at least a fair amount of confidence in the HTA as a regulator. Over half (57%) hold **a great deal of confidence** which reflects an **increase** on the 49% who said the same in 2013.

The high levels of confidence in the HTA as a regulator are reflected in a **large proportion** of stakeholders **deeming activities related to its statutory role as effective**. In interviews, a few stakeholders noted suggestions for improvements, although all indicate they have confidence in the HTA, on balance. Some interviewees expressed uncertainty about the HTA's effectiveness outside of their sector which is perhaps unsurprising. Judging from the testimonials given in interviews, the current approach appears to be fit for purpose in **helping to improve the quality** and standards of procedures dealing with human tissue.

"We deal with many other registries and some of them don't even have a national competent authority, like the HTA [...] We've visited a few countries to do a few audits. So, it's only when you visit these registries and you perform the audits when you found a few gaps, that's when you're grateful that you have the HTA." Human application, DI

Top six effective activities of the HTA



"I think they are effective. I think, certainly they've changed the face of, obviously my sector of research, for the better." Research, DI

More than nine in ten across all sectors express confidence in the HTA as a regulator, particularly those in Anatomy and Research sectors



Confidence in the HTA

By sector, ranked descending by % NET Fair amount or more



Anatomy:

NET: Fair amount or more 100%; NET: Not very much or less 0%



Public display:

NET: Fair amount or more 100%*; NET: Not very much or less 0%*



Human application:

NET: Fair amount or more 96%; NET: Not very much or less 2%



Post mortem:

NET: Fair amount or more 95%; NET: Not very much or less 4%



Research:

NET: Fair amount or more 95%; NET: Not very much or less 3%



Organ donation and transplantation:

NET: Fair amount or more 91%; NET: Not very much or less 3%

Judging by survey data, at least nine in ten stakeholders in all sectors have at least a fair amount of confidence in the HTA as a regulator. A majority of those in **Research and Anatomy sectors** express a **great deal of confidence** (61% and 64%* respectively) perhaps reflecting some of the feedback noted around a perceived improvement in stringent processes and guidance.

The slight variation in confidence in the HTA by sector was also reflected in interviews, with many who described themselves as being extremely confident in its approach to regulation. **Some variation** to this was particularly evident among **Post mortem stakeholders**. For instance, two interviewees in this sector were uncertain with regards to the process for assessing risk or consent grey areas which may indicate a need for **further clarity** from the HTA.

“Some [incidents] are quite a lot more serious than others. and the information isn't clear on what they're doing in each particular case.” Post mortem, CLH

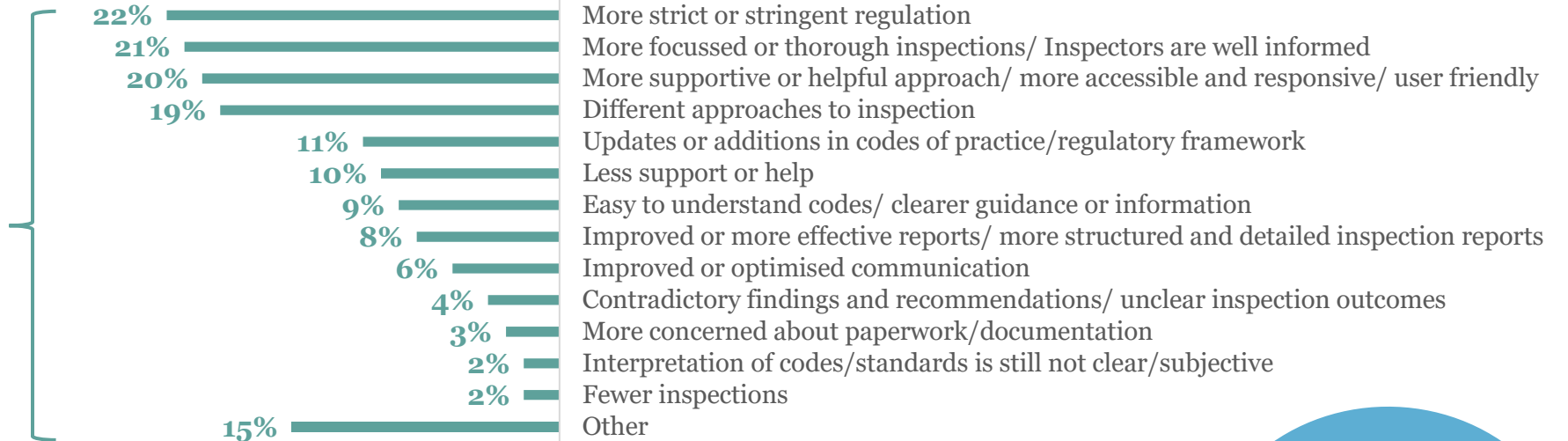
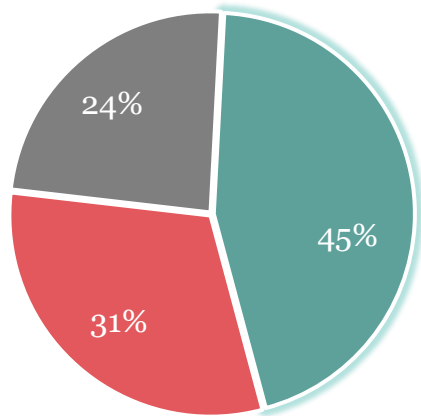
“I wouldn't say that [the issue of post-mortem consent for babies] has been particularly ever picked up, even though I've raised them.” Post mortem, PD

More stringent regulation, focused inspections and supportive staff are the most noticeable differences in the HTA's regulatory approach, according to those stakeholders who have noticed a change in the last few years

Noticed changes in the HTA's regulatory approach over the last few years

Among those who have noticed these

■ Yes ■ No ■ Don't know



Under half of those surveyed (45%) note a change to the HTA's regulatory approach in recent years. Whilst it is not clear from the data why this is, the fact that some stakeholders only have minimal interactions with the HTA would suggest they may not have enough exposure to notice an obvious change. Those who have noticed a change in its approach are most likely to cite stricter regulation and more focused inspections (22% and 21%). This could link back to the **rise in confidence in the HTA as a regulator** between 2013 and 2020. Many of those interviewed, particularly those from Research sector, note that the processes have improved as **inspectors** themselves are **more authoritative and able to give clear guidance**.

"[In] the last five years, I think they've definitely upped their game and [and] really tightened up."
Public display, PD

"We've found the inspectors much more helpful. I think they have a very clear understanding of what the remit is, what the law is."
Research, DI

The scope of the HTA's regulation is considered as reasonable by a majority of stakeholders, although just under a fifth say the overall level is too much in the sense of being proportionate and not too overburdensome



Positive perceptions of the HTA's level of regulation and its reasonableness underpin broader levels of confidence. **Four in five (80%) survey respondents say the level of regulation is about right**, in the sense of being proportionate and not overly burdensome. This contrasts the fifth (17%) saying there's too much and 1% too little.

A majority of stakeholders consider HTA's inspections reasonable in relation to aspects such as the scope and frequency (*right table*) indicating it has been **successful at being a right touch regulator**. Whilst this view is consistent across sector, almost a third (30%) suggest it is ineffective at reducing burden on their sector (*bottom chart*). Although representing a minority, it should be noted that **all eight respondents** who hold **unfavourable views** of the HTA **also consider the level of regulation to be too much**. It may therefore be beneficial for the HTA to consider ways of minimising the burden in the interest of maintaining trust among a few of its less engaged stakeholders.

HTA's effectiveness at reducing burden on your sector

NET: Effective 53%

NET: Ineffective 30%



Evaluating aspects of regulation

Ranked descending by % NET Reasonable

Advice and support provided by the HTA:
NET: Reasonable 85%; NET: Unreasonable 8%

Frequency of inspection:
NET: Reasonable 85%; NET: Unreasonable 4%

Time spent on site:
NET: Reasonable 83%; NET: Unreasonable 3%

Scope of the inspection:
NET: Reasonable 81%; NET: Unreasonable 6%

Corrective and Preventative Action Plans:
NET: Reasonable 79%; NET: Unreasonable 6%

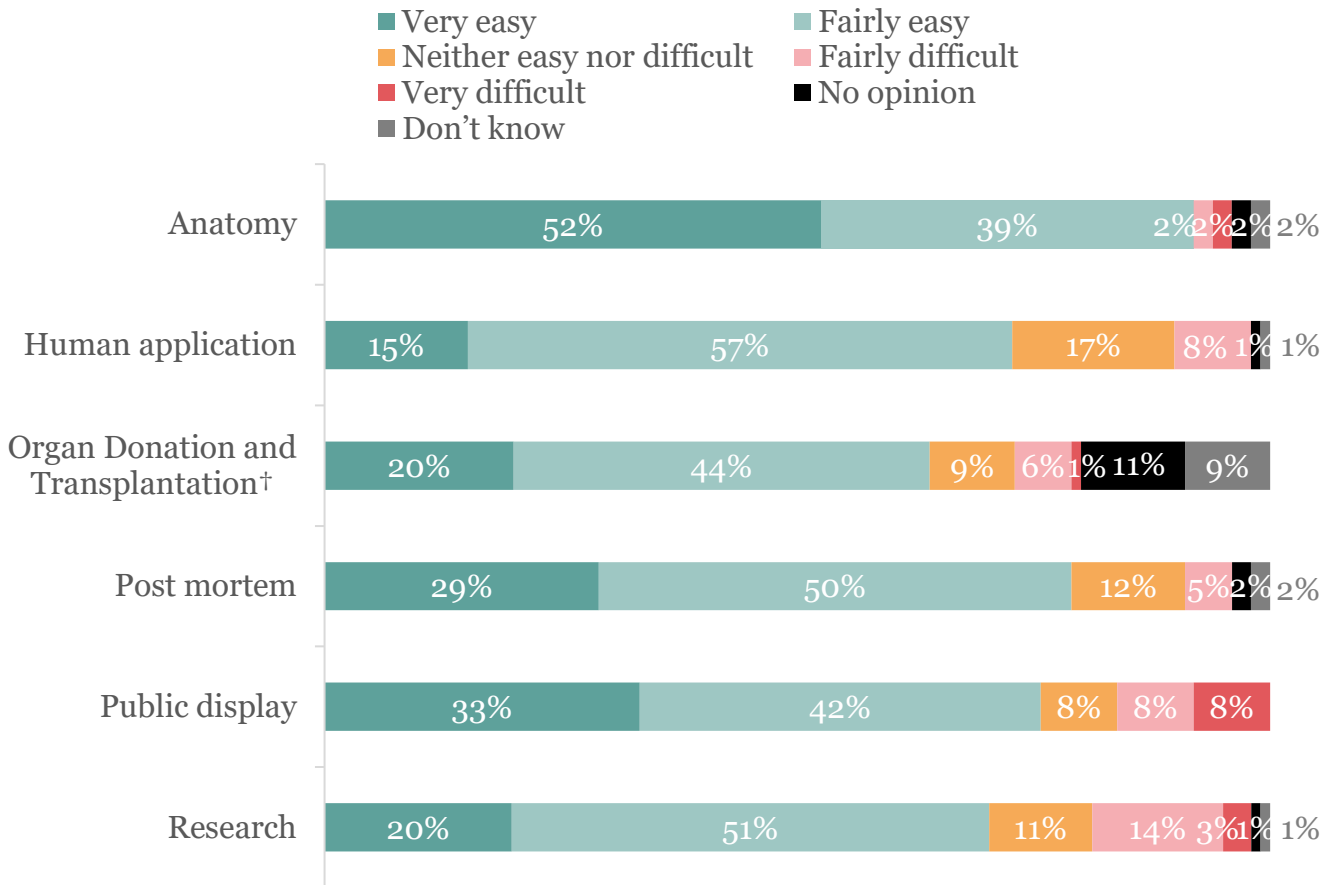
Notice periods for routine inspections:
NET: Reasonable 79%; NET: Unreasonable 4%

Interaction with you prior to inspection:
NET: Reasonable 77%; NET: Unreasonable 4%

Compared to other regulatory bodies:
NET: Reasonable 73%; NET: Unreasonable 4%

Most stakeholders suggest it is easy to know how to comply with the HTA's standards in their sector although a few suggest a need for greater clarity

Ease of complying with HTA's standards or criteria



A majority of all stakeholders suggest it is **easy to know how to comply** with the HTA's standards in their sector. This is especially the case for nine in ten (91%) Anatomy sector survey respondents.

Overall, the vast majority of interviewees when asked about the ease of understanding HTA standards or criteria described them as “straightforward” or “easy” to understand, or making reference to the “excellent website” as a resource. **Only a few** interviewees said that the standards or criteria are not easy to understand, with one describing them as **too “vague”** and another as “contradictory/inconsistent” in certain places. These seem to relate to wider issues that these interviewees discussed around **interpretation of guidance around consent processes**. Those in the research sector are most likely to say it is difficult to understand what is required of them to comply with HTA standards (16%). An example of Research sector difficulties emerged in the telephone interviews, with one stakeholder who stated that “sometimes its challenging” in reference to a specific **“traceability standard”** that needed greater clarification from the HTA.

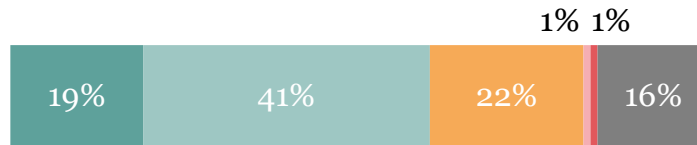
Meanwhile although fewer (64%) Organ donation and transplantation stakeholders say they find it easy to comply with HTA's criteria than other sectors this appears to stem from greater uncertainty than a lack of clarity. In interviews, whilst this point didn't come through, there was some apparent **disparity around ‘tests’ to govern people's understanding**. One stakeholder mentioned they had done this whilst another suggested the HTA should be more proactive in offering tests.

The revised codes of practice and standards appear to have largely had a positive impact on the tangible usage of the guidance in practice

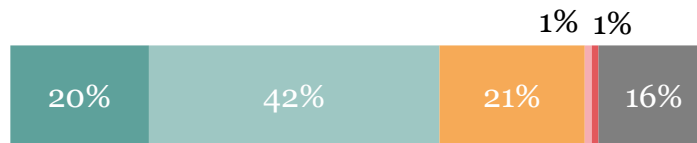
2017 vs. 2009 codes of practice and standards

■ Strongly agree ■ Tend to agree ■ Neither agree nor disagree ■ Tend to disagree ■ Strongly disagree ■ Don't know

The 2017 Codes of Practice and Standards are more useful to me and my organisation than the 2009 Codes of Practice



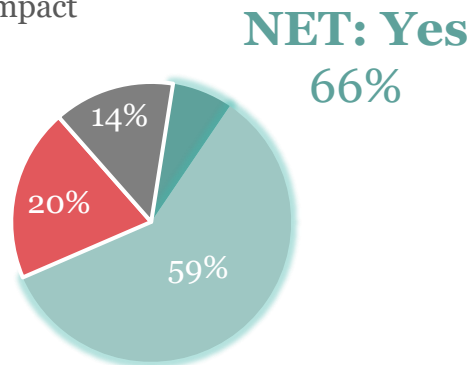
The 2017 Codes of Practice and Standards are easier to understand than the 2009 Codes of Practice



The majority of stakeholders working in the Anatomy, Post mortem, Public display, and Research sectors agree that the 2017 codes are **more useful (60%) and easier to understand (61%)** than the 2009 codes. These sentiments are reflected in the responses of telephone interviewees with a few outlining how the new codes have been improvement, such as the **inclusion of scenarios** and not being too wordy which is making them more tangible. The fact that they are online is also considered a strong positive in terms of ease of access.. Saying this, a few suggestions around improvements are still cited, such as a reference guide as it is not “a light read”, **more working examples and clarity.**

Impact of the HTA’s revised Codes of Practice and Standards

- Yes, a significant impact
- Yes, some impact
- No impact
- Don't know

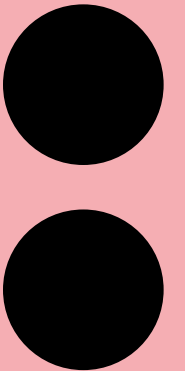


“I like the sections. It's easier to use for staff training. We can just take chunks of it.”
Anatomy, DI

“Some of them weren't a direct match [or] weren't entirely clear [like] showing that you've got sufficient electronic back up and storage, or words like 'sufficient' or 'adequate’” Research, DI

Others have not noticed much change at all and even among those who say there is an improvement, some view the changes as relatively minor and not overly significant. However for the most part, it appears that the majority (66%) consider the revised codes to have had an impact albeit not always a significant one.

Evaluating fees and payments



The vast majority of stakeholders think it is important for the HTA to provide value for money for the tax payer - and most consider the regulator effective in doing so, with some variation by sector

Providing value for money for the tax payer

NET: Important 82%



NET: Effective 58%



Eight in ten (82%) consider it important that the HTA provides value for money for the tax payer. Whilst a majority (58%) think it is effective in doing so, there is some **variation by sector**. This appears to be a result of varying degrees of exposure to how fees are calculated; an area which will be discussed in more detail on the following slide.

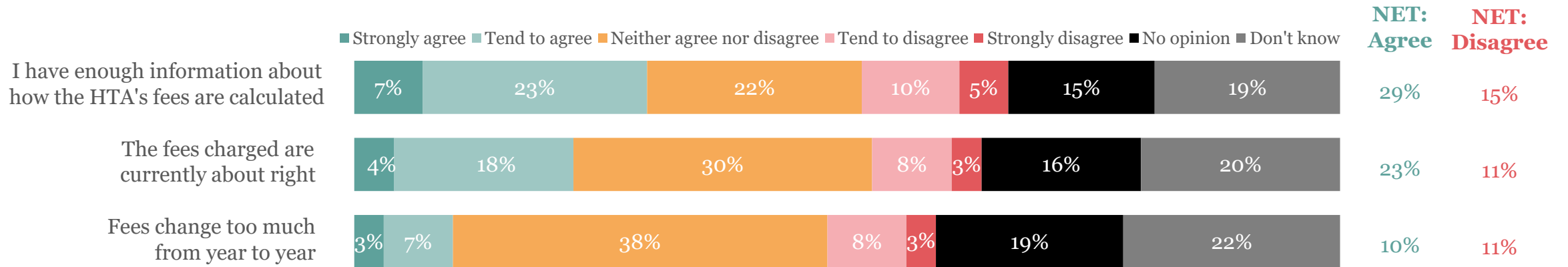
Stakeholders in the **Human application** sector are **more likely** than other sectors to say the HTA is effective at providing value for money with seven in ten (70%) reporting this. A high proportion of **other sectors** say that they **don't know** which is likely to be a reflection of their lack of involvement in fees and payments (39% Organ donation and transplantation; 39% Research; 45%* Anatomy). **Post mortem** sector stakeholders, although only a minority (13%), are more likely than average to suggest the HTA is **ineffective** in providing value for money. Whilst some interviewees tend to say they don't know or don't get involved, others suggested that fees can feel imbalanced in comparison to other stakeholders who require more regulation, which is perhaps where the perceived lack of value for money stems from.

"We get exactly the same inspections as a neighboring borough that's got [more] failings and we pay exactly the same fee."
Post mortem, DI

Views are largely mixed with most stakeholders not expressing strong sentiments either way with regards to the HTA's fees and payments

A majority (62%) of stakeholders say they feel fairly or very well informed about the fees charged by the HTA and how to pay them. Despite this, it is apparent through further exploration of the survey and interview data that many stakeholders may still be unclear or dissatisfied with the current charges.

The survey data indicates no clear consensus around whether the current fees charged are about right despite little outright disagreement. Around a quarter (24%) say they are but this is superseded by the sum proportion of stakeholders that neither agree nor disagree (30%), hold no opinion (16%) or don't know (20%). A similar trend can also be seen in regards to whether or not the fees change too much year on year.

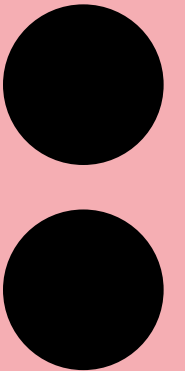
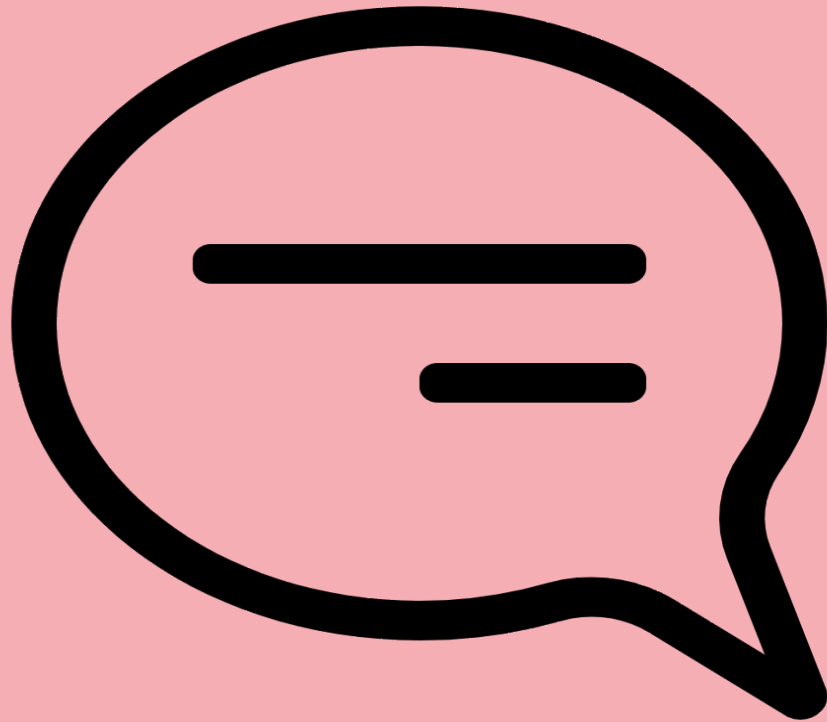


On the subject of the HTA's fees and payments, most interviewees closely reflected the survey data, displaying a mixture of attitudes around this topic. The explanation many stakeholders who were unsure gave was often the same; that they **do not handle HTA fees and payments**. Some noted that internal finance departments or other individuals handled these. This is particularly true of **Organ donation and transplantation interviewees**, as all of those interviewed displayed some level of uncertainty about the fees and struggled to provide a view of how reasonable they were. Others who displayed more **neutral attitudes** towards fees or showed general agreement tended to acknowledge that they were **as they would expect** and that they do not have too much control over this. Those who disagreed often explained this was due to the fixed pricing structure that did not take into account risk or the level of engagement needed. On the whole, most stakeholders don't appear to have strong sentiments either way and acknowledge that a set fee is the easiest model for the HTA.

"I work for a business, so obviously I wish the cost was cheaper, but I understand why they are where they are. I have no idea how they're calculated."
Research, DI

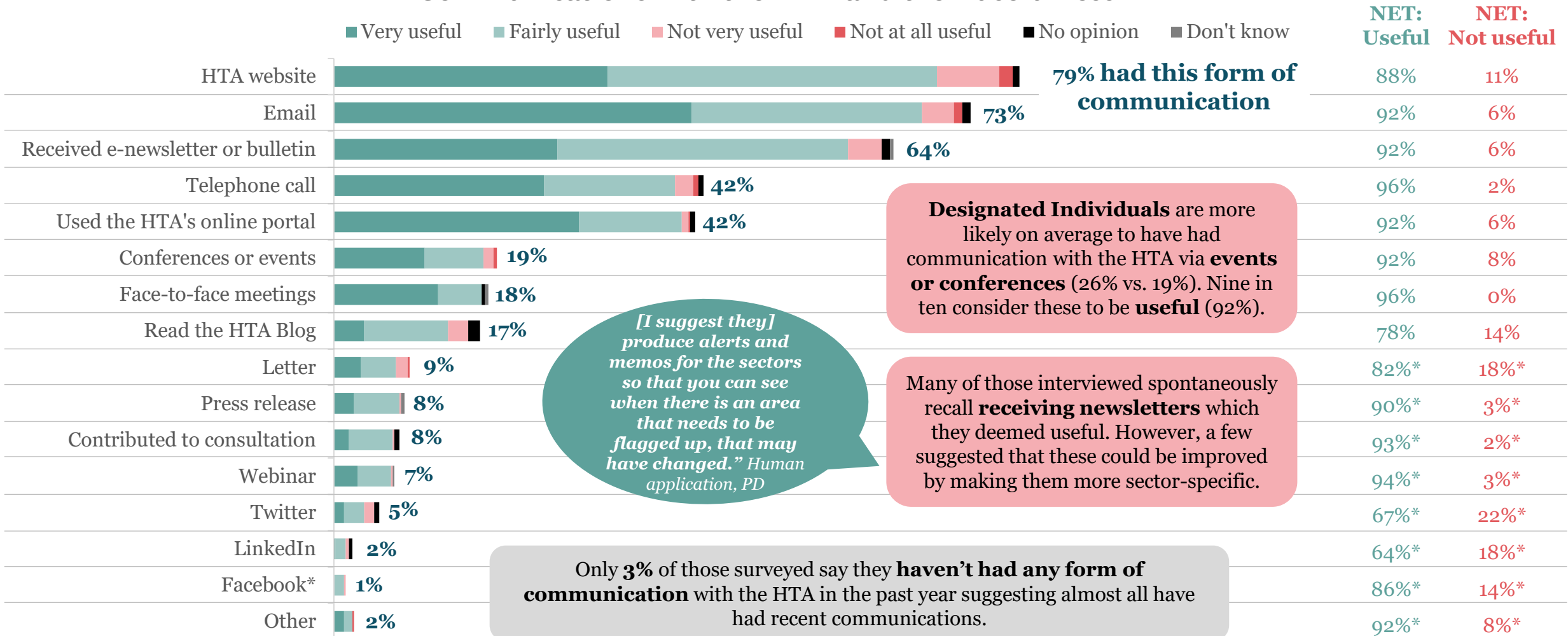
FPQ1. To what extent, if at all, do you agree or disagree with each of the following descriptions about the HTA's fees and payments? Base: All respondents (n=518)
Telephone interview Q11. Thinking about the HTA's fees and payments, how reasonable or not do you think the HTA's fees are?

Evaluating engagement and communication



The three most common forms of communication with or from the HTA are via the website, email or e-newsletters. While a clear majority consider all forms to be useful, one in ten say the HTA website is *not* useful

Communications with the HTA and their usefulness



Most stakeholders consider their communications with the HTA to be good; more sector specific resources are suggested by some, as are quicker responses for those who have experienced long wait times

Overall, how would you rate your communications with the HTA?

NET: Good 78%; NET: Poor 3%

Around **eight in ten** consider the HTA's communications to be **good** (78%). This is positive and a testament to the good engagement the HTA has with its stakeholders for the most part. A **smaller proportion** describe communications as **very good** (35%) compared to 2013 (46%) flagging this as an area to consider going forward, in maintaining effective engagement.

Qualitative interviews with stakeholders suggest a mixture of engagement patterns, with some citing limited communications with the HTA; a **once or twice a year** regarding inspections or fees and payments, or when they have an incident. There is fairly consistent praise of the advice and guidance HTA provides. Most describe it as "useful" and some even stress how "vital" or "very important" it is for them or their organisation. Positive evaluations are given most frequently by stakeholders that have been able to reach a **designated point of contact** at the HTA who can provide direct guidance. A minority say they have not had this and this has been a challenge – judging by the widely positive feedback, a potential focus may need to be on **personal communication**.

"Sometimes have found it most useful to bypass official channels [...] if I'm struggling or I can't get hold of my DI I have called directly and then I've spoken to Inspection Managers in the past and that was extremely helpful. Just to go straight to the person and get the answer was much more easy and straight forward."
Post mortem, PD

In citing areas for potential improvements, stakeholders most often recommend that the HTA provides **more sector-specific guidance in its communications**, such as in conferences and events, website navigation, and in the newsletters that are sent out. An example of why this could be useful was given by an interviewee who felt that important clinical guidance could be lost amidst other updates and important changes required to the way they work could be communicated more clearly. Another point of feedback that was mentioned by a few interviewees was around the **timeliness of responses**. Some across all sectors referenced times when they were waiting for the HTA to follow-up regarding an issue or query they raised, although this is not a consistent finding.

Other than this feedback, **general engagement** with the HTA has been evaluated positively. **Many suggest the HTA has been responsive** in emails and calls – whilst online portals and the website are considered effective for submitting information. A **majority** of stakeholders surveyed believe the **HTA keeps them well informed** about all of the key areas tested in the survey: forthcoming changes (76%); its work (81%); why it takes decisions (67%); and fees (62%).

A majority of all sectors rate the HTA's communication as good and submitting information as easy, whilst a few cite improvements to the website to make it easier to navigate for specific documents or information



Communications with the HTA

By sector, ranked descending by % NET Good



Anatomy:

NET: Good 84%*; NET: Poor 2%*



Post mortem:

NET: Good 84%; NET: Poor 3%



Public display:

NET: Good 83%*; NET: Poor 0%*



Research:

NET: Good 80%; NET: Poor 3%



Organ donation and transplantation:

NET: Good 78%; NET: Poor 0%



Human application:

NET: Good 74%; NET: Poor 6%

At least **three in four** stakeholders in each sector rate their communications with the HTA as **good**. Across all sectors, very few respondents rate their communications as poor, representing positive evaluations across different stakeholders.

In investigating different stakeholders' experiences submitting information to the HTA, **compliance updates** are most commonly **deemed easy** (64%) as is pre and post inspection information (58% and 59% respectively). Just over half deem **annual activity submissions** easy (50%) and, notably, a **fifth of Human Application** stakeholders (18%) say it is **difficult** to do.



82%
of all rate the HTA's website provision as effective

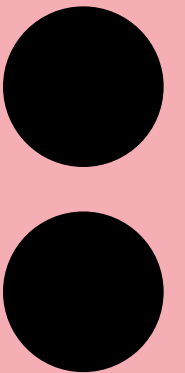
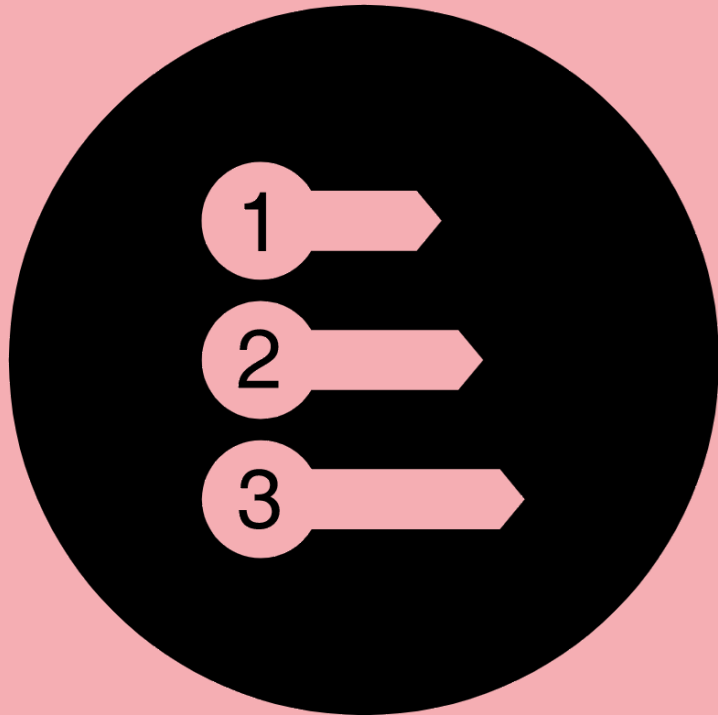
A **majority consider the website** effective but one in seven (13%) consider it ineffective, rising to around a fifth among those in Human Application and Research sectors (23% and 18% respectively).

Interviewees suggested that slightly **better navigation to relevant information** would help some to use the website more effectively. Indeed, the most common unprompted response when asked how communication could be improved in the survey is 'improved or more dynamic web reporting system/ improved website and search/navigation/indexing' (26 respondents).

"There's a document that I knew was on the website [...] I would type in a search word, and thousands of documents would come up."

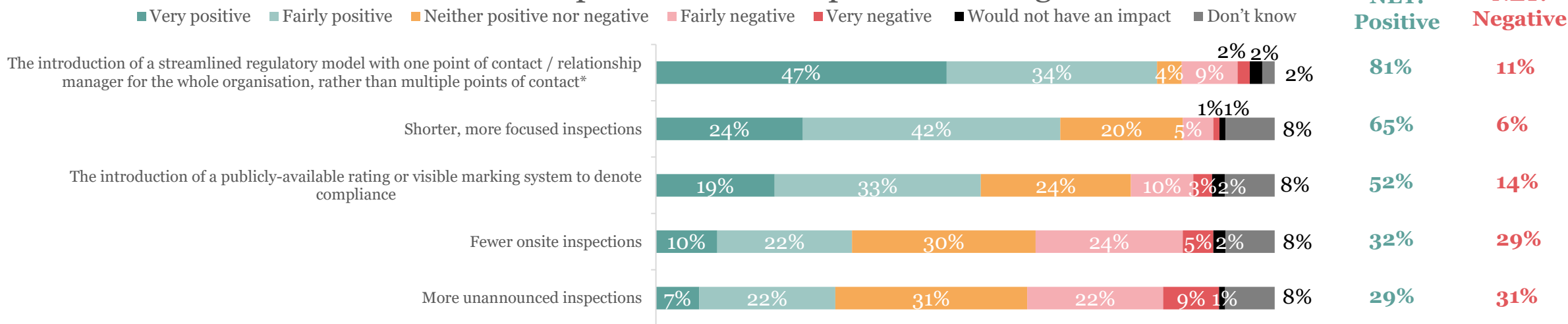
Human application, DI

Future priorities to consider



Of the potential regulatory changes tested, shorter, more focused inspections would be most likely to have positive impact. Nearly half* of those working in multiple sectors also say the introduction of a streamlined regulatory model would have a ‘very’ positive impact

Impact and value of potential changes



The HTA asked stakeholders to rate a number of potential changes in terms of the impact they could have. There is **greater consensus** around **streamlining the regulatory model** having a positive impact, and **shorter inspections**. Stakeholders appear more divided regarding the frequency of inspections and how planned out these should be versus being unannounced. There is a fair degree of **variance by sector**.

It is interesting to note that all 8 respondents who indicate unfavourable impressions of the HTA say that fewer on-site inspections would have a positive impact. However, given the lack of consensus around this change, it may be something for the HTA to consider carefully before implementing. Meanwhile, those in Research (43%), Human Application (38%), Anatomy (39%*) and Public Display (50%*) are all more likely than average (31%) to say **unannounced inspections** would have a negative impact. Interviews suggest overburdening practices could risk **discouraging displays in museums and innovation in research**.

“Museums can find it difficult to operate and have limited funding. If regulations are overly onerous then museums won’t do it. If HTA wants the public display of remains to be on display at museums, they need to ensure it’s not too onerous.”
Public display, PD

A mixture of suggestions are given on what the HTA should focus on over the next few years; notably training opportunities and sharing best practice

Although they provide largely positive evaluations around current communications, stakeholders interviewed were keen to offer a variety of suggestions about how the HTA could **improve its engagement** with them. The most common suggestion made by interviewees is **more communication around training opportunities**, with other suggestions often including **more examples of best practice in promoting clearer and up to date guidance** that leaves less room for interpretation. This aligns with the most common suggestions made according to the survey data regarding areas for the HTA to focus on. Although the majority think otherwise, **26% of those in research say the HTA is ineffective in sharing best practice**, suggesting this may be an especially useful item to consider for this group. In addition, as highlighted earlier, some mentioned sector-specific newsletters would be beneficial. A few also suggest they would find more face-to-face contact with HTA representatives helpful as they prefer this to email communication, and more organised gatherings of stakeholders in similar roles.

*“It would be quite useful to do an interactive course on being a designated individual and what is expected.”
Post mortem, DI*

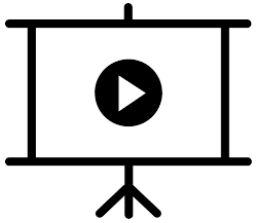
“I'd be much more interested in looking at examples of best practice than where licenses have failed - seeing whether there's anything on there that we can adopt, see whether there are things that apply to our situation.” Research, DI



There are a mixture of viewpoints on whether the HTA takes into account the feedback of stakeholders and their organisations. A few stakeholders provide examples of exercises where they felt the HTA had listened to them, such as roundtables or recent consultations. Such activities would like to be seen more often in the future. However, many of those interviewed expressed that they genuinely **did not know if the HTA takes their views and feedback into account**, with some outlining they aren't sure if anything was done following their input. This is perhaps an area of feedback that the HTA may wish to take forward, utilising the findings from the stakeholder evaluation to communicate back to stakeholders around how their views may lead to changes. As some have suggested that the timeliness of responses has been an issue, it may be beneficial in encouraging more trust and better engagement to **consider including timescales** when feeding back to stakeholders about any actions that will be taken as a result of their input

“I think the answer is it's hard to tell. They don't seem to take on board the comments, but we don't know, because it's not shared. So we don't know if they're taking it on board.” Post mortem, DI

Other notable opportunities for the HTA suggested by stakeholders include wider education exercises, public facing activities and – for Research and Anatomy stakeholders – supporting in new technologies and innovative work



Despite three in five (60%) survey respondents saying the HTA does not need to improve its relationship with them, interviewees still have a variety of suggestions for the HTA to improve as a regulator and improve its relationship with stakeholders that tend to centre on **wider educational exercises alongside training opportunities.**

“It would be a really valuable thing if they offered face-to-face training days, or half days, rather than it all being online. Because I think a lot of questions could then be asked at that point.”

Research, PD

In the context of recommendations, a theme common that emerged from interview is the opportunity for the HTA to boost its public profile. A few described the campaign on organ donation as well-received suggesting that similar activities in the future could be effective in considering to what extent the HTA should be more public facing than it already is. A few note that **specific guidance for the public and specialists on changes to organ donor consent** would be helpful in the context of rules changing. Others suggest that the public knowing they are there may be reassuring in itself, rather than waiting for an incident to occur where they need guidance and discovering the HTA at that stage.

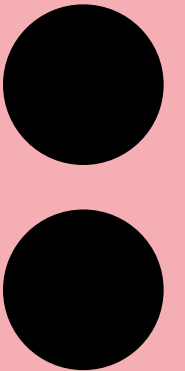
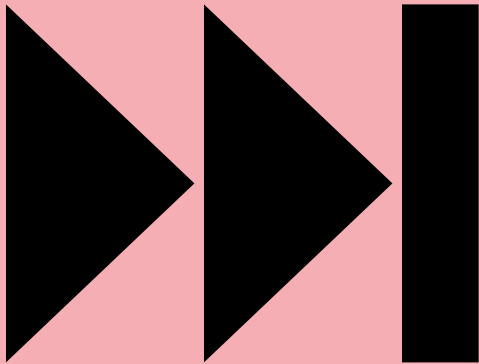
On the topic of innovation, less than half (45%) consider the HTA effective in **supporting business and innovation** whilst a similar proportion (41%) do not know. Whilst the high **proportion of uncertainty** seems to suggest a lack of awareness and communication, it does indicate a potential area for focus for the HTA. Those in Research and Private sectors may find this of particular value with a fifth (21% and 23%) regarding the HTA as ineffective in supporting business and innovation. It makes sense given the sector they work in, that **Research stakeholders** would be interested in support with new developments. This rang true in interviews, as well as with those in the **Human Application** sector who note **guidance on new stem cell therapy** should be a focus.

“I think that there needs to be a lot of focus on information to the public surrounding [presumed consent for organ harvesting for the deceased].” Organ donation and transplantation, IA

“Some of the advanced cellular therapies. It's taking off massively and people need quite a lot of help with the regulatory guidance around that.” Human application, PD

“I know they are looking at it to a certain extent but it would be useful to have some very clear guidance on [...] when you can look at RNA, for example.” Research, DI

Conclusions and recommendations



Conclusions

The HTA has maintained positive relationships with most of its stakeholders as a result of its effectiveness as a regulator and improved accessibility as a body. The fact most have heard from the HTA in the last year through is a testament to the good reach of communication across various channels.

Stakeholders demonstrate strong associations between the HTA and its statutory requirements as a regulator, and a great deal of confidence in its regulatory approach. This has seemingly been enhanced by the more thorough regulation they've seen in the last few years.

In balance with more robust regulation, stakeholders are mostly finding the standards easy to comply with. Whilst not overly burdensome, the fact some still consider the HTA inflexible suggests more can be done to reduce the burden on sectors, although this perception is less prevalent now.

Stakeholders may need to know more about how the fees are calculated or the rationale for the current price model to understand whether these provide value for money. For some, a review of the 'one size fits all' model is a priority to counter the feeling that fees can be imbalanced.

Recommendations

Uphold the HTA's strong reputation as a regulator as this is maintaining trust among professionals in the regulation of human tissue

Consider the value of regularly tracking changes to regulation noticed on an annual basis, to understand what new guidance and updates are reaching stakeholders

Discuss internally the best ways to balance rigorous regulation with being a right touch regulator; considering the scope for shorter, more focused inspections

Consider whether there is scope for a review of the current fees model or to introduce more communication around how these are calculated

Conclusions

Most deem wider engagement with the HTA to be effective but the fact some still cite some issues with the timeliness of response to inquiries suggests the regulator may need to consider its current 10-day response target.

The website, portal and newsletters are clearly useful in keeping stakeholders informed about new guidance and uploading reports. There is scope to improve signposting and navigating stakeholders to sector-specific news.

The updated codes of standard and practice are having a positive impact on the quality of procedures for storing and handling human tissue. Interpreting guidance around collecting consent can still be a challenge though.

Linked to trust, stakeholders consider it within the HTA's remit to be more public-facing; leading on educational activities and public campaigns. For example, promoting awareness of the latest law changes around organ donation.

The other key role many stakeholders consider important for the HTA to focus on is streamlining its processes; through collaboration with other organisations. Additionally, they wish to see ongoing training opportunities for each sector and updated, relevant guidance for new research pathways.

Recommendations

Consider whether there is scope to shorten the time taken to respond to inquiries; communicate back about how feedback is being actioned

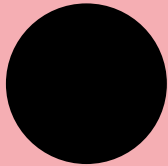
Continue to invest in the website and newsletters as successful tools for informing stakeholders; consider further signposting by sector

Continue to explore where current guidance can be expanded to give clearer instructions, including sharing best practice and including example scenarios

Consider public research, for instance, to explore awareness and comprehension of messaging around the new opt-out system for organ donation

Review priorities for the year ahead and balance this focus across guidance around new research fields, training opportunities (online and offline) and streamlining regulation

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