The Human Tissue Authority (HTA)

Public Engagement

Qualitative Research Report

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Prepared for:

Human Tissue Authority (HTA)

Prepared by:

Research Works Limited

Regency House

The Quadrant

219a Hatfield Road

St Albans, Herts

AL1 4TB

all@researchworks.co.uk

Tel: 01727 893 159

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1. Executive Summary

The Human Tissue Authority (HTA) has commissioned research into public awareness of, and interest in, the HTA and the areas that the HTA regulates.

The research included focus groups comprised of members of the general public, and depth interviews with informed (here meaning people who had some direct experience of the areas that the HTA regulates) respondents.

Awareness of the HTA across the sample groups was practically non-existent (which is to be expect, given the sample selected, i.e. uninformed?). Some respondents had assumed that regulation existed, but thought this was likely to be part of the wider NHS remit. This lack of awareness was compounded to some extent by a lack of awareness, and understanding, of the range of issues that related to human tissue.

Once respondents were made aware of HTA, and the work it carries out, they were positive about the HTA as a regulatory body, and reassured that these sensitive issues were being properly regulated in the public interest.

The topics that provoked most interest and response were: organ donation and transplantation; post-mortem examination; and research/anatomy. Human application was not initially understood by most respondents, but once they grasped the idea, they were interested and wanted to know that this area was properly regulated. Public display was also not well understood initially, and once understood (for instance, stimulated by prompts) was seen as something of a niche area when compared to the other areas.

Generally, respondents felt that the HTA's remit covered the appropriate areas; however, there was some concern that HTA regulation did not cover individual health professionals and clinicians. Further to this, respondents wanted to know how and by whom coroners were regulated.

There was a strong distrust across the sample groups of private companies handling and using human tissue. There was equally strong disapproval of human tissue being used for cosmetic training purposes.

Overall, respondents did not feel strongly that HTA needs to promote itself to the public; they were more concerned to know that health professionals were aware of HTA, so that, if and when the areas HTA regulates became relevant to them, health professionals could inform them or signpost them to HTA.

2. Background and Research Requirement

2.1 Background

The Human Tissue Authority (HTA) is a regulator set up in 2005 to regulate organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and public display. It also gives approval for organ and bone marrow donations from living people.

The HTA was created by Parliament as an executive agency of the Department of Health, and is overseen by a board of lay and professional members appointed by the government. The interests of the public are central to the work of HTA.

The HTA has commissioned qualitative research to evaluate public awareness of the existence of HTA and, for those that are more informed, confidence in the range of responsibilities that they undertake through regulation.

2.2 Research Objectives

Human cells and tissues used for health and research purposes include skin, body parts, organs, bone, and saliva.

Bodies, organs, tissue and cells can be used for many purposes including:

- Treating patients with particular medical conditions
- Transplanting into people whose organs have failed
- Treating patients who have blood disorders like leukaemia with stem cells

- Researching causes and treatments for illnesses, such as cancer or diseases of the brain and nervous system

- Teaching students about the human body and training to develop the skills of surgeons

- Display in public, such as exhibitions and museums

- Finding out through post-mortem examination why someone has died, including examining their organs and tissue samples to determine the cause of death.

In terms of tissue and cells, the HTA's role concerns the regulation of the procurement, testing, processing, storage, distribution, import and export of tissues and cells for human application; the HTA does not regulate the medical efficacy and safety of treatments or medical devices.

The research areas highlighted for evaluation were:

Awareness among the general public of:

- HTA's existence (prompted and unprompted awareness)

- HTA's role: evaluation of the areas HTA regulate to see which – if any - the public were already aware of

- How interested the public are in the work of the HTA (both in general and in relation to areas regulated by HTA)

Confidence in the system, and in how well the HTA is perceived to be carrying out their duties generally and, amongst more informed respondents (here meaning those

who have had some experience of the issues that HTA regulates), in particular relating to:

- Consent
- Safety/safeguarding the public
- Ethics
- Does knowing about the HTA and their work make the public more confident to: donate an organ (post-mortem); donate a body (post-mortem); or donate an organ (living donation)?
- How bodies are treated in a mortuary
- How human tissue (and cells) are treated and used in research
- What are the public's expectations of regulation in the above situations?

3. Research Methodology and Sample

3.1 Methodology

Qualitative research is a method often adopted in response to a creative development brief. The open and discursive nature of qualitative questioning is a strength when exploring 'what works' (and what doesn't) when reviewing written or visual materials.

Qualitative samples are purposive and quota-driven in nature; they are designed to achieve specific outcomes. They therefore have no quantitative accuracy in terms of identifying proportions of populations holding stated views.

For these methodological reasons, it is not appropriate to present qualitative findings in terms of the numbers of respondents expressing certain views. We therefore describe the findings in qualitative terms, referring to groups within our sample e.g. younger people and giving a broad sense of the weight of views e.g. 'a majority' or 'a minority'.

3.2 Recruitment and Sample Structure

The research was qualitative; the sample groups comprised:

Six (6) extended focus group sessions with the general public (typically of two hours' duration, with 8-10 respondents in each group), made up of:

- Younger men, aged 18-30; ABC1
- Younger women, aged 18-25; C2DE

- ABC1 Men; aged 26-49; C2DE
- C2DE Women; aged 26-49; ABC1
- ABC1 Women; aged 50+; ABC1
- C2DE Men; aged 50+; C2DE

The classifications in the list above are NRS social grades. These grades are used in the UK by a number of governmental and independent organisations to segment population groups into social classes based on occupation.

Grade	**Social Class**	**Typical occupation**
A	Upper middle class	Higher managerial, administrative or professional
B	Middle class	Intermediate managerial, administrative or professional
C1	Lower middle class	Supervisory, clerical, junior managerial, administrative or professional
C2	Skilled working class	Skilled manual workers, trades
D	Working class	Semi-skilled and unskilled manual workers
E	Non-working	Casual workers, pensioners, benefit dependent

Six (6) individual depth interviews were carried out with informed respondents. These respondents comprised a mix of gender, age and life-stage. Respondent experience included: organ donation (as a recipient); core blood service user and donation; stem cell treatment; and post-mortem examination of a close relative. The sample did not include respondents with a significantly negative attitude towards HTA.

Fieldwork was carried across England throughout March and April 2017.

4 Main Findings

4.1 Awareness of HTA

Unprompted awareness

Unprompted awareness of HTA was practically non-existent among the general public groups. The one respondent who reported having heard of HTA assumed it was 'something to do with human-made stuff [bio-engineering]'. A small number of respondents 'expected' a body such as HTA to exist, though they were not specifically aware of HTA. Others assumed that regulation was part of the wider NHS remit.

> '*I'd have thought the NHS oversaw this kind of thing*.'

Among the general public groups, there were respondents who had some awareness of issues regulated by HTA (such as stem cell research) and some who reported having researched the topic; these respondents had not become aware of HTA when they had done so. **It appears that investigating areas regulated by HTA does not automatically lead members of the public to information about HTA.**

These respondents were unsure what 'public display' might mean, and needed guidance on this idea. Some had thought it might relate to post-mortem examinations, or funerals where the body could be viewed in an open casket.

Informed respondents were also unaware of HTA up to the point where they had experienced a relevant issue and, even then, understandings of HTA as an entity were fairly vague. Respondents were asked what they thought the HTA might do, they guessed/suggested HTA's responsibilities were centred around organ donation as the key area of regulation.

'*I'd heard of it, but I didn't know what they are all about really.*'

'*Was this set up to stop people abusing organs?*'

Among both sample groups, appreciation of the need for regulation only appeared in relation to specific circumstances (typically organ donation and post-mortems). Beyond these narrow circumstances, most were happy to hear about the HTA and what it does, but some respondents did not want to hear about the subject matter at all.

'For me it's all a little bit scary, for me, unless it's personal and really going to affect me or someone I know, then I would shy away from it'

Prompted awareness: HTA is a reassuring presence

When prompted (with a description of HTA), respondents were visibly reassured by the existence of HTA.

'I think it's quite good that we've got them … I know there was a scandal at some point'

Most respondents were equally reassured by the fact that a single authority regulated all aspects of human tissue issues. Some respondents assumed that regulation fell under the broader catch all term "the NHS", and was covered under their existing procedures and protocols; others simply assumed there was 'something out there' that was doing the job of upholding standards.

On reflection, some respondents were positive about regulation being independent of the wider NHS.

'*It's good that if an individual hasn't given consent that the authorities don't just take the body, they must ask the family.*'

'*Yes, when you think about it you would like to think that there was somebody regulating outside of the NHS.*'

Some respondents were notably less comfortable than others regarding the handling of people's tissue, particularly after death. Those who felt this way typically reported it as a superstition, or religious consideration. The main concern was about treatment of their own bodies, or those of relatives, after death; they wanted some reassurance that they, or their loved ones, would be treated with the appropriate dignity after death.

'*The worry is you're going to get chopped up anyway at post-mortems.*'

Respondents linked the existence of an organisation regulating the removal, storage and use of human tissue and organs, with two key ideas: response to a scandal (or a series of scandals) around improper use of human tissue in the NHS; and the buying and selling of body parts (this was not related to the health service).

The date when HTA was set up (2005) prompted a small number of respondents to remember, often vaguely, media coverage of a scandal around the removal of organs from dead babies in Liverpool.

'I would say looking at the date 2005 … it was set up after a scandal. Wasn't it children's bodies … up Liverpool way?'

Those respondents who alluded to the buying and selling of body parts (generally human organs) perceived this as a particularly important ethical issue, but did not relate this practice to the UK. From this, it was clear that the system in the UK had achieved good public confidence i.e. in being free from financial dealings of human tissue including organs.

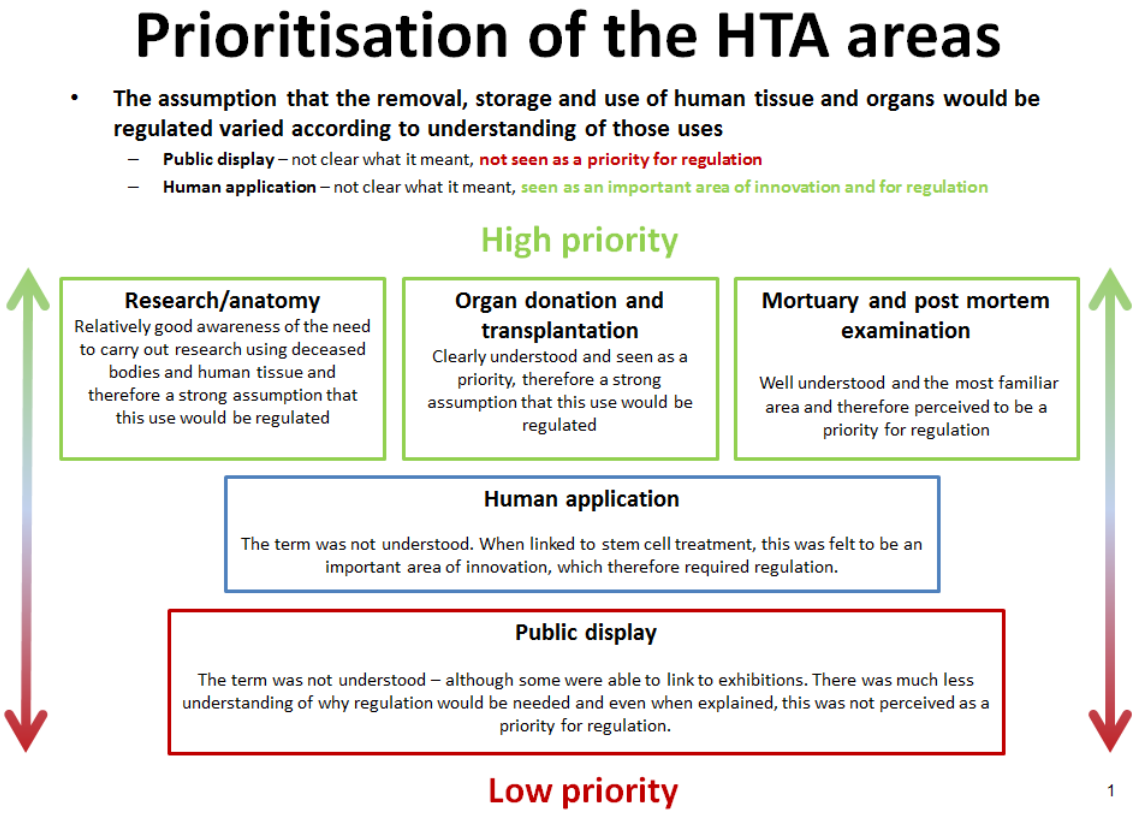
'They should be making sure that people don't buy and sell organs. It's about setting a precedent.'

Overall, there was an understanding, linked to typically vague memories of past scandals, about why there was a need for regulation of the handling of human tissue, but understanding of the range of practices and activities this regulation encompassed was extremely limited.

> '*It's reassuring to know that people dealing with tissues in all these different ways are regulated and procedures are followed.*'

> '*You hear rumours about Frankenstein stuff and what they can do with body parts, so it's good to know there is someone overseeing it all.*'

Respondents consistently assumed that HTA regulated organ donation and transplantation, for two reasons: this was the use of human tissue they tended to prioritise; and this was the practice they had heard most about.



Prioritisation of the HTA areas

4.2 Organ donation and transplantation

A number of factors were perceived as important in relation to organ donation and transplantation:

- Investigating and preventing cases that were financially driven, or coerced
- Acting quickly
- Respecting the consent of the donor, or alternatively their families (living or deceased)
- Maintaining the quality of the organ
- Ensuring that staff handling organs were fully qualified
- Ensuring that any adverse incidents were reported and learnt from

Consent was seen to be a priority issue, along with ethical considerations around sensitive handling of human tissue. Those who highlighted consent were particularly concerned that consent came from the individual donor; this was felt to be more important than the family's wishes (although respondents were able to think about consent issues from a family member's point-of-view).

> '*If someone says they don't want their organs donated we should respect their wishes.*'

> '*It's good that if an individual hasn't given consent that the authorities don't just take the body, they must ask the family.*'

Typically, respondents felt there were more issues to consider around living donors than organ donation after death.

> '*You're giving up part of your body and you would need to know how it will affect your health, your mental health, your family.*'

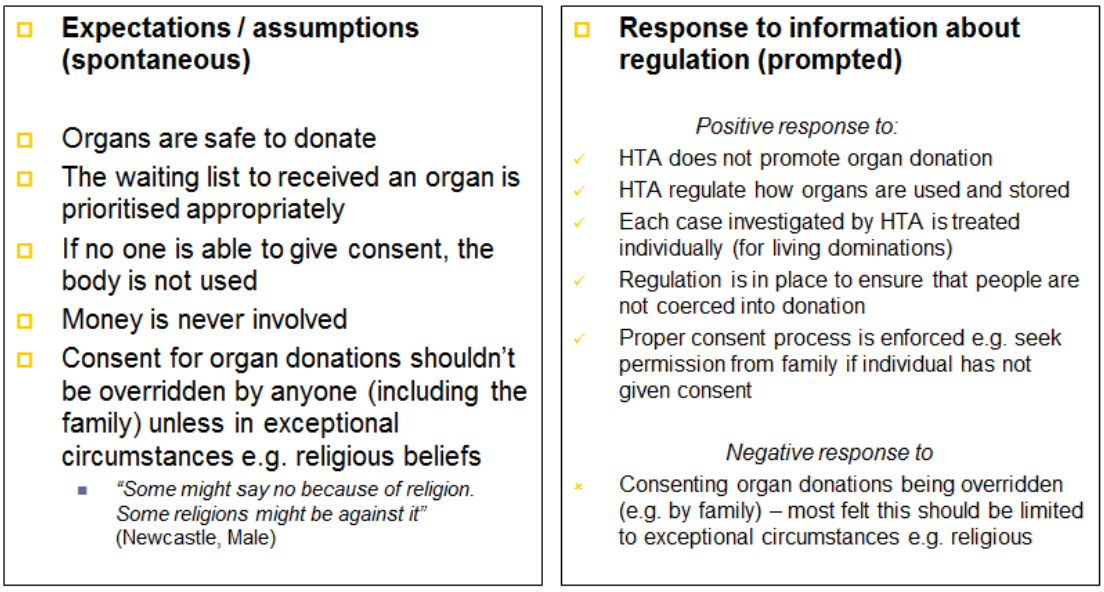
> '*There is a difference between live and deceased donations.*'

> '*If you're alive you have a choice; if you're dead it's out of your control.*'

A number of respondents felt that donation after death included ethical issues around the improper use of donated organs, or not specifically respecting the expressed wishes of the donor. The contentious area for the public is that **an individual's wishes must be respected**; overriding those wishes (even by obtaining consent from family members) was met with disapproval.

> '*To carry a donor card and then you found out they were taking your heart and all that, just to experiment on, you might not be happy with that.*'

> '*Some religions – I think it's Jehovah's Witnesses – don't allow organ donation, or blood.*'



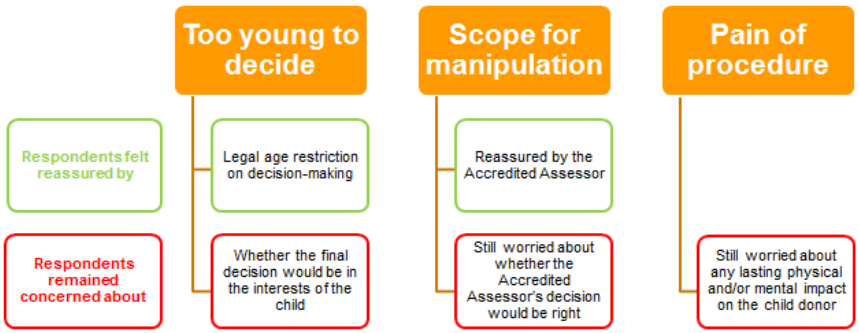
Expectations around organ donation before and after prompting

Organ donation and transplantation scenarios

The scenarios around organ donation and transplantation presented to respondents provoked a range of responses. It was clear that few respondents had considered the issues before and the topic was novel, and disturbing for some. The example of sibling bone marrow donation was quite concerning for some respondents. They clearly perceived a number of ethical issues, particularly around who, ultimately, was entitled to give consent.

Discussion Scenario - *Reactions to the sibling bone marrow donation scenario*

- ***"My eldest child wants to donate their bone marrow to their younger sibling who has cancer. My eldest child is only 5 years old. Is this legal?"***
  - Typically, it was assumed that the parents would have ultimate responsibility over the decision
  - However, not all respondents were comfortable with the parent having ultimate control
- **Key issues perceived for this scenario included:**



It was generally assumed that parents would have ultimate control over consent, but not all respondents were comfortable with this idea.

When they learned that HTA approval was required, respondents gave a range of reactions:

- some were reassured that the final decision was in the hands of independent professionals;
- others felt that this was a curtailment of parental rights;
- the involvement of the Accredited Assessor was reassuring for most; however,
- concerns remained about the fairness of a decision reached by a professional rather than the family
  - Respondents thought that the AA would have decision making power, so were concerned around the fairness of this. In reality the HTA makes the decision based on the AA's report

There were some respondents who assumed that a case as complex as this example would involve more than a decision by a professional, perhaps to the extent of having a court procedure to finalise the decision.

Broadly, in relation to the donation scenarios, the public were in agreement with HTA's decision-making. Where there was disagreement, it related to the power given to families to override an individual's consent. **There is clearly a diversity of opinion on whether the family has the right to override the wishes of a deceased person.**

> '*Once the individual has made their decision that should be respected, as long as they are of sound mind.*'

> '*What's the point in the* [consent] *form if it can be overridden?*'

Respondents were positive about HTA's response to donation scenarios where a financial incentive or coercive pressures were issues. Most felt that the regulations in place were appropriate and worked for the interests of the general public.

Discussion Scenario Topics - *Reactions to donation and transplant scenarios*

Scenario	Spontaneous views	HTA response
Financial incentive	Perceived to be financially driven and therefore suspect. Also felt to be taking advantage of the NHS	✓ Pleased with HTA's denial of the procedure
Coercion	Perceived more difficult to judge due to unknown factors (i.e. maybe she had grown close to the family)	Most felt that further confidential interviews should be had with the nanny to decipher her motives
Deceased donation	Relatively clear that the deceased individual's recorded wishes should be respected	✓ Pleased with HTA's denial of the procedure
Consent	It was largely perceived that the family should not be able to intervene where consent has been given by the individual, unless in exceptional circumstances e.g. religion	× Most felt the family were currently being granted too much power e.g. to blocking a consenting donation

Note: The HTA supplied Research Works with some case studies (partially on real examples, partially fabricated for effect) to use as examples in the focus groups on the above scenarios

There were no significant differences in the responses of the general public groups and informed respondents in relation to organ donation and transplantation.

4.3 Mortuary and post-mortem examination

In relation to post-mortem issues, most respondents were primarily concerned with maintaining dignity of the deceased and ensuring that individual or family wishes were respected.

Some respondents were clearly uncomfortable with discussing this topic, but most were reassured that post-mortem issues were regulated. **There is likely to be a section of the public that is unwilling to contemplate post-mortem issues; it might be seen as a taboo subject.**

A number of factors were perceived to be important:

- Maintaining dignity and respect for the deceased
- Maintaining confidentiality
- Where possible, respecting the wishes of the deceased
- Ensuring that those handling bodies in the mortuary and carrying out post mortem examinations were fully qualified
- Where possible, respecting family wishes
- Ensuring that incidents were reported and learnt from

It was felt to be important that personal and religious preferences were respected. This included the wishes of the deceased individuals and their families.

However, some felt that the family did not have a right to give consent for post-mortem examination.

'*What right do the family have to give consent for a post-mortem?*'

'*For me, it would be all about how the body was being handled.*'

A small number of respondents assumed that post-mortem regulation was the responsibility of the NHS rather than HTA. Most had assumed there was some regulation around this area; they felt this was to be expected, given the ethical considerations. **Some respondents wanted to know who regulated the coroner and if this was part of HTA's remit.**

There were a small number of respondents who reported incidents of post-mortem examination being carried out without specific consent. Most of these reports were second or third hand (a 'friend of a friend') but some reported more specific knowledge.

'*My cousin died of liver problems; they knew why he was going to die, but they still gave him a post mortem. It was more for their research. The family was Italian and didn't want it done, but they still carried on. They took out his liver.*'

There was some diversity of opinion in relation to adverse incidents. Some respondents felt that the family should be told in the interests of transparency; others felt that this would be too traumatic for many people. All agreed that such incidents should be responded to promptly, and learned from.

'*They should have corrected the mistake without telling the family.*'

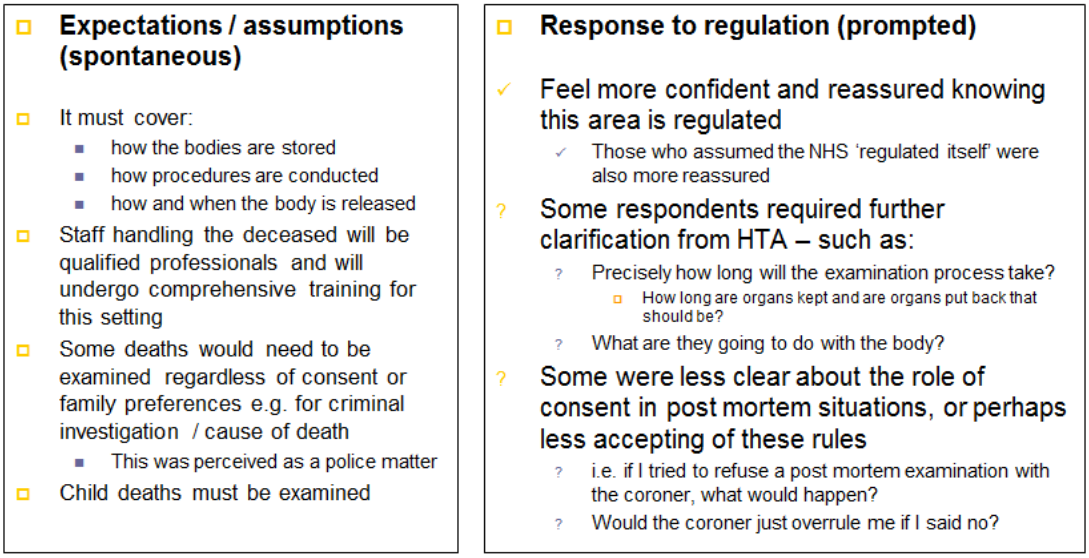
'*Transparency builds trust, and then procedures can be put in place to stop it happening again.*'

Respondents were unclear about how decisions are made where the individual has not given consent for a post mortem examination; they wanted to know about the

circumstances under which this might happen. For example, they wondered what would happen if consent for post mortem has not been given, but the death was part of a criminal investigation.

Broadly, the assumptions and expectations of respondents were satisfied by the information they were given about HTA regulation of this area.

Expectations and responses to regulation



Mortuary and post-mortem examination scenarios

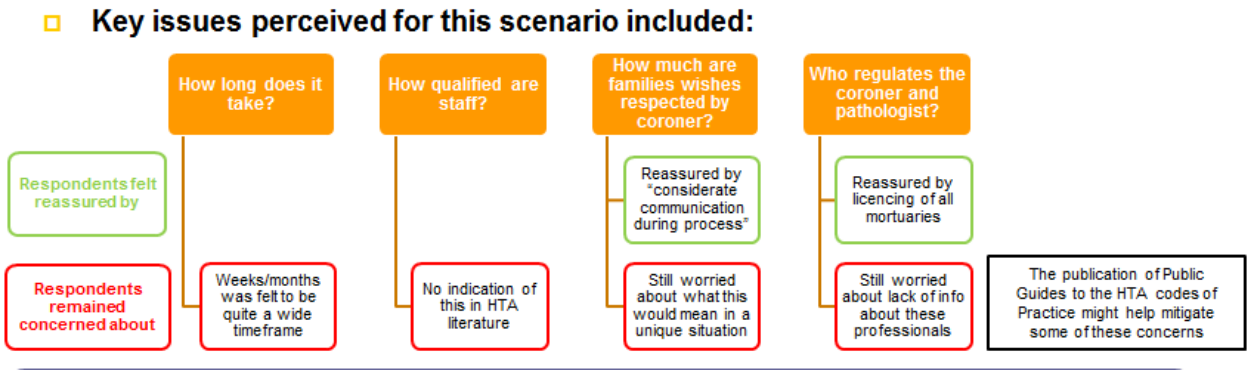
Respondents found some information about this area of regulation difficult to understand or accept and sought more explanation (which may include links to areas not regulated by HTA e.g. coroners and pathologists).

In relation to the retention of tissue, respondents were comfortable with the idea that tissue was retained in circumstances where the cause of death was unclear. It was also felt that it was right for tissue to be retained in circumstances where the cause of death was suspicious in any way (that is, where there was a suspicion of criminal activity or involvement), or if the family had reason to question the cause of

death. A small number of respondents felt that the decision should remain with the family rather than a professional body.

> '*They can say here you go, a relative of this person raped someone 30 years ago.*'

> '*If the dead person didn't give consent, then it should be up to the family to decide.*'



Reactions to retention of tissue scenario

Respondents were largely reassured by HTA's approach for the other post mortem scenarios (e.g. the examination of two babies and the incorrect release of bodies). Discussions about these scenarios were dominated by the decision to inform the family if something goes wrong. Most felt that it was unnecessary, but a minority disagreed on the basis of transparency.

> '*I guess it would be upsetting but the family have a right to know.*'

Respondents were worried by protocols that appeared to lack a human aspect; they were concerned about circumstances under which the relevant authority was not able to prioritise the upset caused to the family over the need for an embedded process.

> '*The family's needs and wishes have to come first.*'

Scenario	Spontaneous views	HTA response
Post-mortem examination of two babies	A shocking and very difficult example for all respondents. Perceived to be something that must be reported internally – however, not to families on the basis that it would cause too much distress A minority felt that the family should be notified: *"Transparency builds trust, and then procedures can be put in place to stop it happening again."*	✓ Pleased with HTA's *internal* response × Less pleased with the decision to inform the family (although not HTA's remit)
Incorrect release of bodies, mislabelling and released to the funeral director in error	This was perceived to be a priority area for regulation due to the avoidable distress that any of these types of errors would cause to families. A rigorous approach to monitoring and protocol was recommended i.e. double, checking, qualified staff and checks to be made by the funeral director also	✓ Pleased with HTA's response i.e. reporting the incidents, working together to ensure improvements and sharing learning

Reactions to adverse incident scenarios

Again, there were no significant differences in responses between the general public groups and informed individuals.

4.4 Public display

Respondents needed prompting to fully understand the concept of public display, and where and when it might apply.

Some had vague recollections of media coverage of anatomical exhibitions ('some German doctor'), and some were aware of collections such as the Herb Garrett at Guys Hospital.

Once they understood the idea, a number of factors became important:

- That more recent remains were prioritised for regulation (people who had died within the last 100 years)
- Ensuring clarity in the consent agreement when the individual concerned was still alive
- Ensuring that relatives were not shocked by the display of the deceased
- Ensuring that the display was as stipulated in the consent agreement
- Disposing of the tissue appropriately once the display was finished

Respondents did not want human tissue to be displayed inappropriately, regardless of consent, but were not sure who would judge appropriateness. It was assumed by some that the consent agreement would, or should, cover this issue.

There were some concerns that bodies or body parts might be displayed in a manner that conflicted with the deceased person's personal or religious beliefs or ethics, although no one could clearly articulate circumstances in which this might be an issue.

Maintaining dignity and adherence to the consent agreement were felt to be the main factors for public display and post-display. There was also a feeling that public display of bodies and body parts should not generate financial gain.

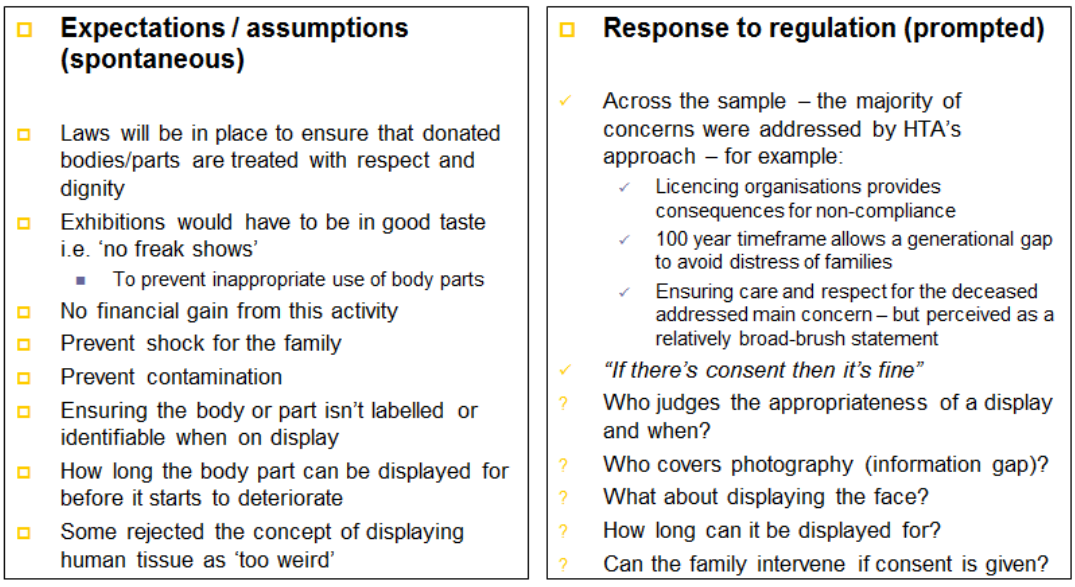
> '*People shouldn't gain financially out of this kind of activity.*'

> '*It's important that the donated body parts are treated with respect and dignity.*'

> '*In a hundred years there's not going to be anybody related to that person.*'

> '*They need to stop people setting up freak shows to stop inappropriate use of body parts.*'

Overall, respondents felt that the concerns they had about public display were addressed satisfactorily by HTA regulation on the matter.



Public display: assumptions and responses to regulation

Public display scenarios

There was noticeably less concern about regulation in this particular area.

Remaining concerns were largely about the quality of decision-making in individual circumstances, and the ongoing issue of consent. Consent was perceived as the fundamental basis for public display; and this was envisaged to be given in writing, for instance by letter, signed in presence of a witness, or in the person's will.

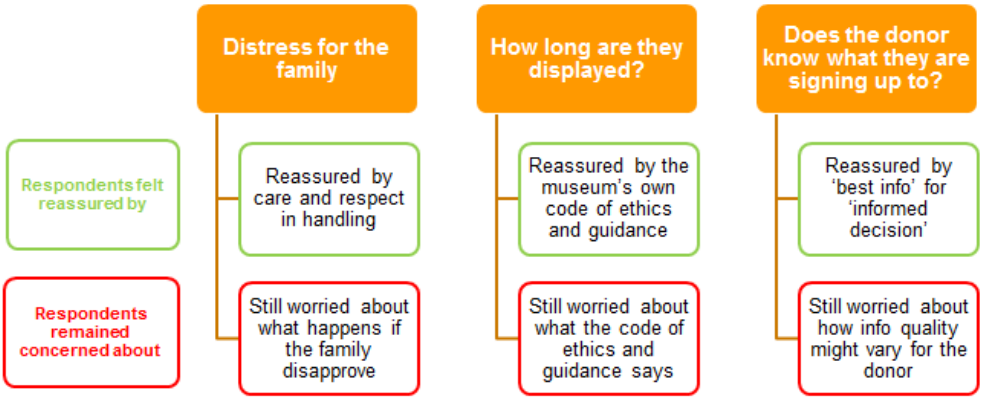
Providing consent for the use of one's body, or tissue in a public display or exhibition was assumed to be a very niche arrangement.

> '*If someone wants to do it, let them do it.*'

> '*I recently saw a production of 'Hamlet' and I was told that a real human skull was used on stage. Is this legal?*'

Overall, respondents were reassured by the regulation in place, and felt that this was not the most important area for consideration, largely because it was an unusual circumstance.

- **Key issues perceived for this scenario included:**



4.5 Research/anatomy

This was felt by many respondents to be a very important area for regulation. There were **clear concerns that an unregulated situation might lead to a 'Burke and Hare' scenario where bodies were mistreated for financial gain.**

Some respondents wanted to know specifically who and what was going to benefit from their donated body.

Overall, there was understanding that the bulk of research was for training and advances in medical knowledge and treatment. Again, respondents were reassured to know that this area was regulated.

'*It's important that this area is regulated.*'

'*I suppose it's like animal testing.*'

'*Everything like this should be regulated, it's human rights.*'

There were very strong feelings against the use of human bodies for research into area that had only cosmetic ramifications. A small number of respondents felt that an individual had a right to decide if they would donate body parts for cosmetic research, but generally cosmetic applications were met with disapproval.

'*It's about medical value, not cosmetic value.*'

A number of factors were seen as particularly in the regulation of research:

- Respecting the consent of the donor

- That the consent agreement could be updated

- That the intended likely use of the tissue was clear and accurate (where possible)

- That the use of the tissue has a clear outcome in terms of health benefit

- Disposing of the tissue appropriately once the research is finished

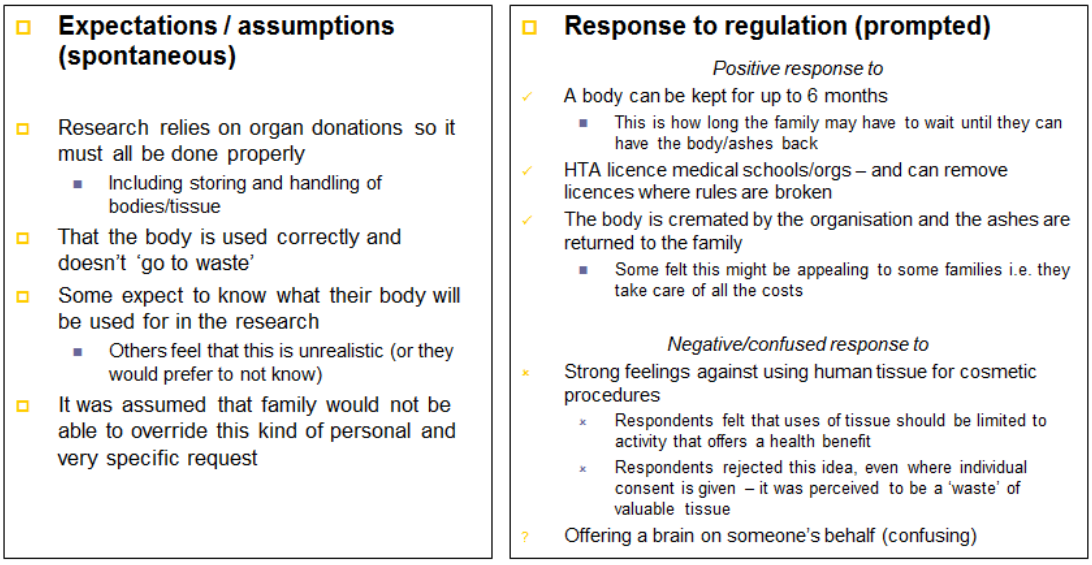
Dynamic consent was well received by respondents across the sample; it was felt to offer a more informative and ongoing dialogue. Respondents liked the idea of being updated about how their bodies/tissue could be used; and liked the idea of maintaining a dialogue about the potential uses of their tissue or bodies after death.

Respondents felt that, as well as an ongoing conversation with researchers, a conversation with family members was important, so that family members were kept aware of an individual's changing wishes. Clarity was seen as important in this respect.

> '*It's good to be kept updated and to know how you could potentially help.*'

> '*You should express clear wishes, e.g. I want to donate my organs but please don't let them take my eyes.*'

> '*Your views change as you get older and you might change your mind at a different time in your life.*'



Research/anatomy: expectations and responses to regulation

Research/anatomy scenarios

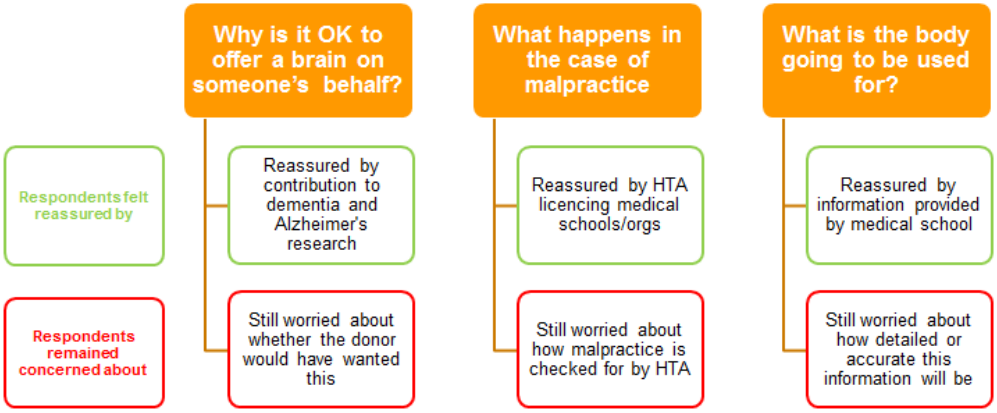
Respondents felt that consent given by the individual donor in life was the ultimate basis for research/anatomy activity, and should therefore be respected. Most felt strongly that the individual's consent agreement should be respected by the families as well as other parties, although a small number felt that they would be happy for family to make decisions on their behalf if they had not specified any particular wishes.

'*It's the individual's wishes and should therefore be respected.*'

'*It's literally my decision and should be respected.*'

There was a perception that the differences in the regulations between donating the brain and other human organs was inconsistent and need further explanation. In particular, it was unclear to some respondents why a person's brain could be donated to research without their consent but with their family's consent as opposed to body donation [?].

- **Key issues perceived for this scenario included:**



Reactions to research/anatomy scenarios

4.6 Human application

Most respondents were aware of the use of human tissue and cells for medical treatment.

Stem cell treatment in particular was recognised and understood. A large majority of respondents were comfortable with this use of human tissue and cells, although there were some concerns about storage.

However, there was a distinct lack of trust among respondents for the private sector, and some scepticism about how ethically the private sector might behave in relation to human tissue; it was felt that corners might be cut in order to save money or generate more profit.

A number of factors were felt to be important:

- Appropriate storage, and handling of tissues and cells in general
- Being able to identify suitable opportunities to donate, or privately bank
- That strict guidelines were imposed in terms of how private organisations must operate
- That donations were tested appropriately to ensure that infections/diseases were not inadvertently passed into the system

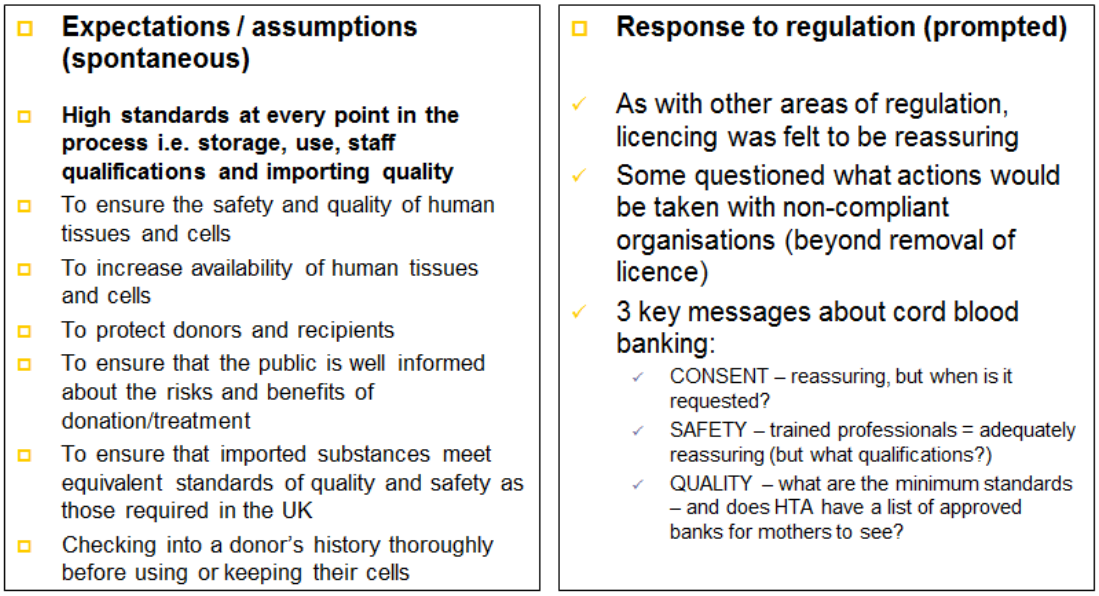
In terms of identifying opportunities for donating, or privately banking, cells and tissue, respondents wanted to see a website which would both explore and explain opportunities, and (importantly) include reassuring messages about HTA regulation.

'I would expect the HTA to regulate the company who bank these things. Like making sure your cells are stored properly and kept in a useable condition.'

'The idea of stem cell banks around the world is great; it's saving lives.'

'I would presume everything would have to be sterilised.'

Respondents expected high standards to be applied at every stage of the process (collection, storage and use) and most felt that these expectations were being met by HTA regulation.



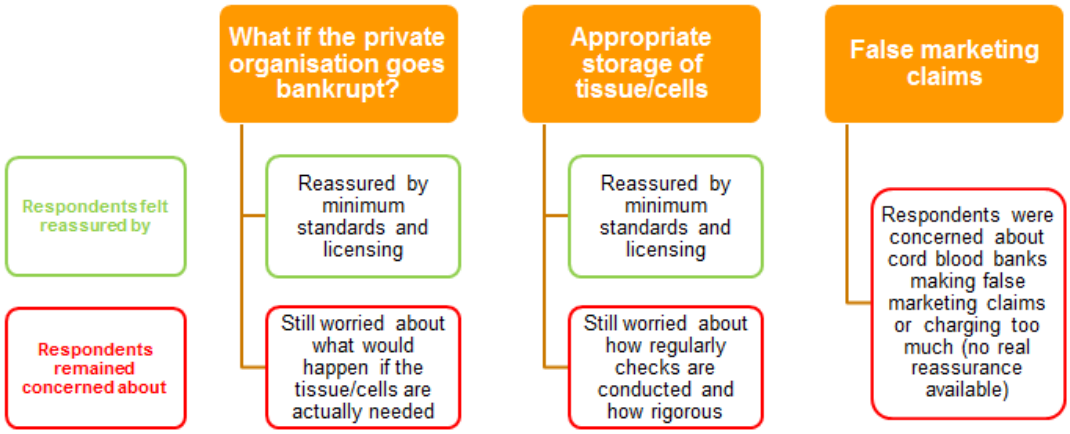
Human applications: expectations and responses to regulation

Human application scenario: 'should I bank my umbilical cord cells privately?'

Respondents perceived a number of key issues around this scenario. Marketing claims from the private sector were seen to be an area of concern, with the idea of false claims making some respondents distinctly uncomfortable. There was also a concern around how licensing of private companies could ensure staff qualifications, given that HTA does not regulate individual clinicians or healthcare professionals.

Respondents found it difficult to fully appreciate what minimum standards and licensing meant, particularly in terms of guaranteeing cord blood quality.

- **Key issues perceived for this scenario included:**



Reactions to human application scenario

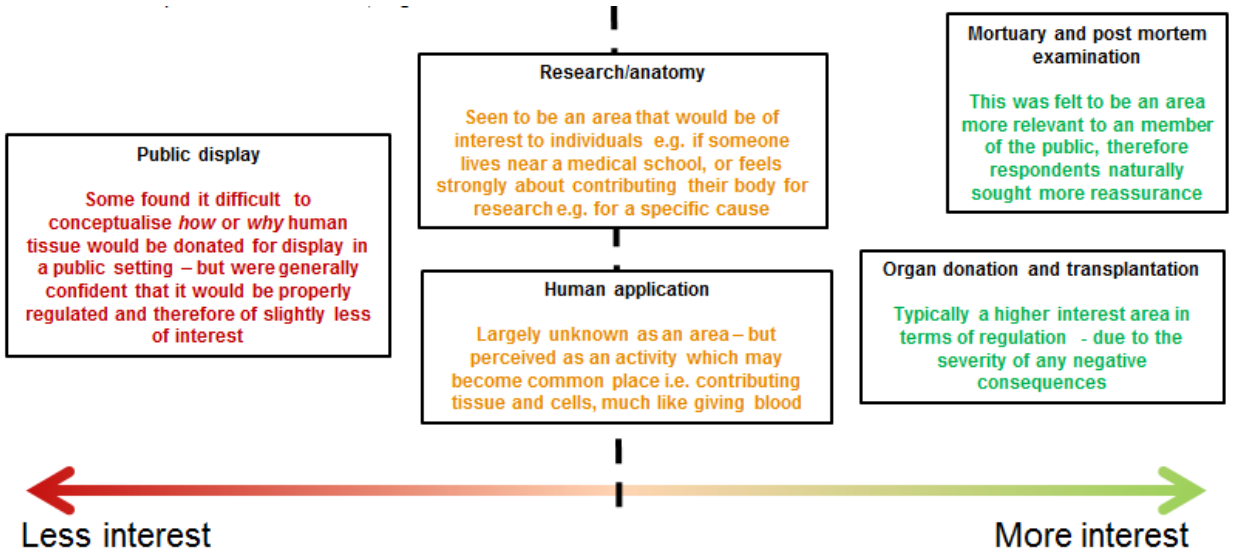
4.7 Future communications

Level of interest in areas regulated by HTA

Respondents across the general public sample felt that they were unlikely to read up or make any enquiries about information regarding any of the regulatory areas unless it became relevant to them.

Mortuary and post mortem examination were perceived to be the areas that were most likely to be relevant to them in the future.

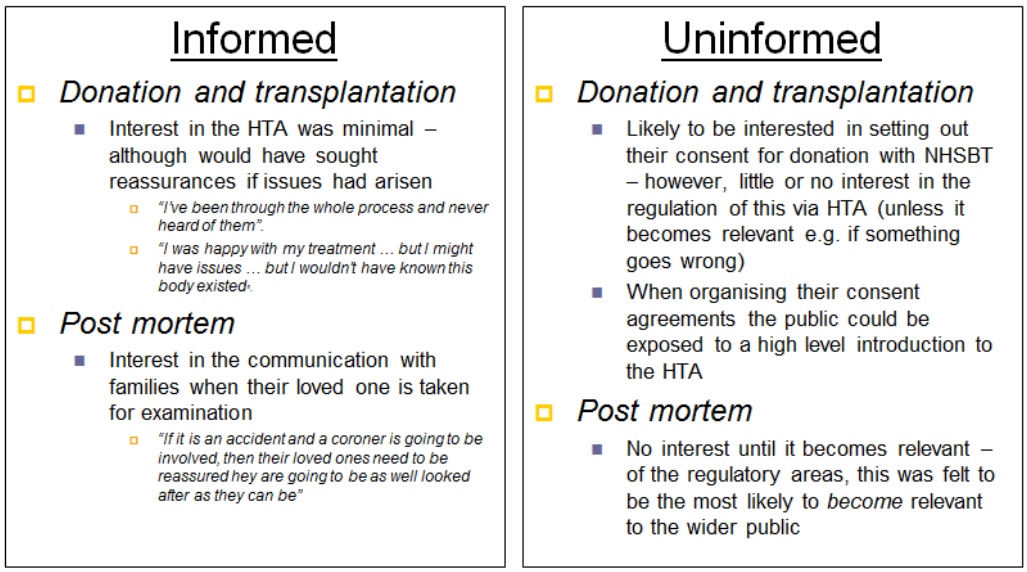
Otherwise, respondents could envisage individuals making enquires for specific purposes e.g. someone that feels inspired to donate cells, organs or tissue.



Areas of interest

There were some differences in the level of interest shown by general public and informed respondents (see table below). Broadly, respondents wanted to see HTA information to be more visible, as it was felt this would provide reassurance to the

public. More specifically, respondents wanted more information about the regulation of clinicians in general, and coroners in particular, as this was not covered by HTA.

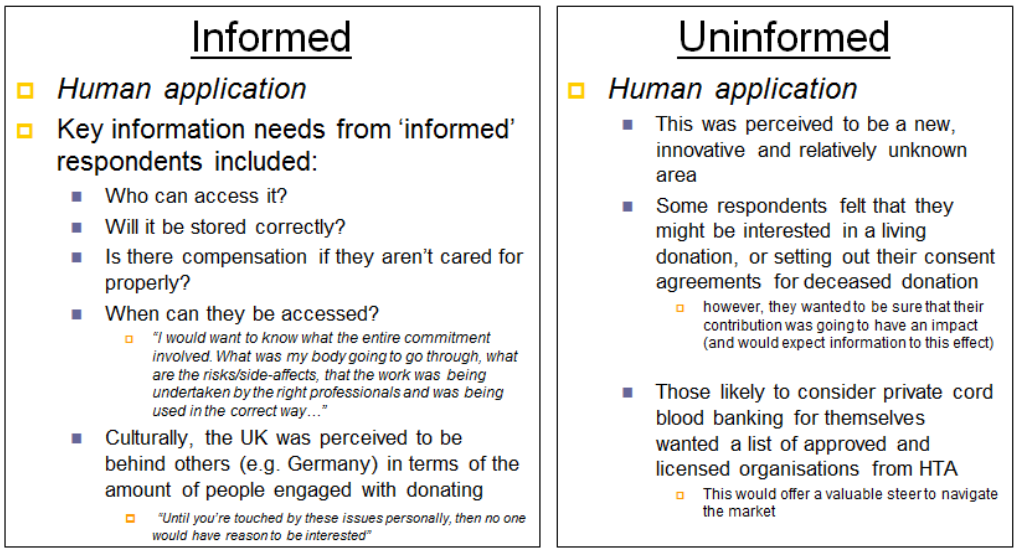


Level of interest: general public vs informed respondents

Human application processes triggered a number of questions from respondents. The general public sample were typically less aware of this area, and felt they needed to be brought up to date regarding developments and opportunities in relation to tissue and cell applications.

> '*It's risky because so little is known, it's all discovery.*'

> '*When you talk to me about cells it just makes me think about designer babies.*'



Level of interest in human application

Potential future communications

Most respondents felt that interest in the HTA would only ever be circumstance-driven.

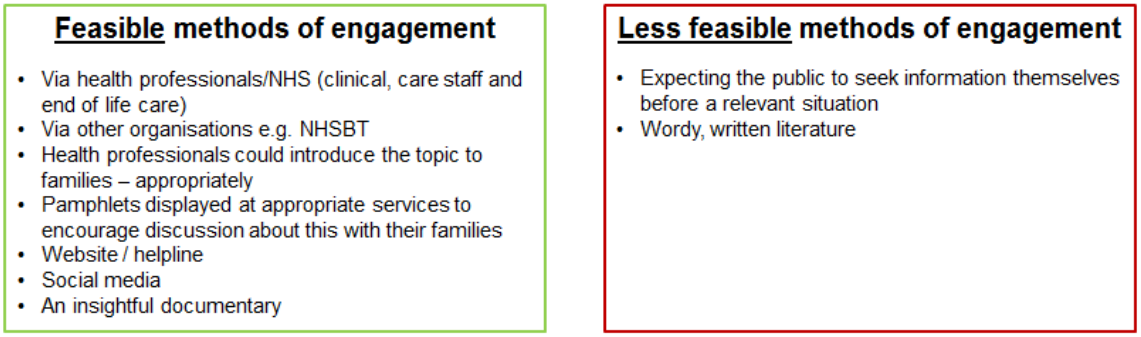
However, it was felt to be important to know of HTA's existence so that they can be contacted if and when they become relevant. Respondents wanted HTA information to be there when they needed it and wanted to be signposted towards HTA by a health professional, when relevant.

All respondents felt that, now they knew about HTA, they were confident that HTA was doing a good job of regulating, and safeguarding the public interest.

In terms of communicating about HTA, some ways of introducing the public to the HTA were perceived as more feasible than others. Overall, respondents felt that information or signposting, when it was most relevant, was the method they preferred.

> *'It's enough to know that they exist.'*

> *'I think it's important to know that they've got teeth.'*



Potential HTA engagement

5. Summary and Conclusions

Once the ideas of removal, storage and use of human tissue and organs were raised, respondents *assumed* there would be regulation of these activities. However, there was very little understanding of the breadth of these activities, with respondents most noticeably lacking an understanding of 'human application'.

In future, interest in HTA's work is likely to be circumstance-driven. Respondents could envisage the need to know about organ donation and mortuaries/post mortem and appreciated that individuals might make enquiries about human application and research and anatomy.

Once respondents became more aware of HTA's regulatory activities, they generally felt confident that the removal, storage and use of human tissue and organs was being adequately and ethically safeguarded. In general, respondents trusted HTA to act 'appropriately', and in the public interest.

Organ donation: respondents were keen to emphasise their view that the consent of an individual should be prioritised over the wishes of their family. Individual consent was a central theme of responses across the sample group and across the research questions.

Post mortems: there is clearly an information gap regarding rights (and the issue of regulation of health professionals) when a post mortem is ordered by a coroner. Respondents also expected human needs to be prioritised over process needs (for instance: what is our duty of care to the family if organs have been erroneously switched?).

Research/anatomy: respondents had specific expectations regarding consent and information (particularly in relation to the specific purposes of any research or

anatomical processes) and consent processes (dynamic consent was seen very positively by most respondents). Most were opposed to human tissue being used for cosmetic procedures.

Human application: once it was understood by respondents, this area of activity was perceived as a key area for regulation, although most respondents underestimated the extent to which this is a current (rather than a future) concern. Public distrust of private companies being involved was a key theme, as was the concern over ensuring that staff were suitably qualified. Some respondents also expressed concerns about potential contamination by infection, and wanted to know that samples and donations were appropriately tested.

When faced with a situation involving the removal, storage or use of human tissue, the general public will want to know that the *whole* of the activity is regulated. This may involve HTA collaborating with other regulators to provide information relevant to consumer experiences.

When faced with a situation involving the removal, storage or use of human tissue, respondents expected to be introduced to HTA via third party such as health professionals, other relevant organisations (e.g. NHSBT). That is, while respondents did not feel that they personally needed to know about HTA, they expected health professionals to know about them.

If not facing a situation involving the removal, storage or use of human tissue, the general public seems unlikely to be spontaneously interested in the work of HTA. However, respondents were willing to engage with, and often very interested in, case study stimulus, suggesting that there may be more creative ways of bringing HTA's work to the general public's attention.

A number of respondents were engaged by the idea that HTA was set up in response to (often vaguely recollected) scandals around the issues they regulate. This may

suggest that promoting HTA as an agency created to address and respond to perceived malpractice in relation to human tissue issues may be a potential channel for communicating about HTA, and the work they do, to the public.

Research Report Appendices

APPENDIX 1

TOPIC GUIDE

2033 Human Tissue Authority – Public Evaluation
Topic Guide v3 (Mainstage)

1. **Introductions (5 mins)**
   - Introductions to Research Works (independent research agency)
   - Awareness of HTA – briefly explain purpose of research
   - Permission to record, MRS Code of Conduct, Data Protection
   - Footage won't be used/shared further than for internal use of the client and definitely won't be used externally/put on the internet/YouTube/etc.

2. **Perceptions of risk associated with handling of human tissue and cells (5 mins)**
   - Explore collated pre-task materials i.e. to identify risks associated with handling human tissue and cells
   - Explore what concerns exist in relation to / handling of bodies / human tissue (or cell) handling in research
   - Explore any barriers to donation *Moderator explain: the difference in HTA's role re: living donation and deceased donation.*
   - Unprompted ideas/expectations in terms of how concerns could be addressed
   - What would likely reduce barriers to donation?

3. **Awareness of HTA (10 mins)**
   - Unprompted awareness of HTA
   - Prompted awareness of HTA
   - HTA's role and remit
   - Stimulus material to explore informed views toward HTA and key areas of HTA regulation/work
   - Discuss: views and feelings specifically explore questions the respondents have about HTA
   - To what extent perceived risks across different areas human tissue and cell handling are addressed by HTA (revisit previous unprompted risks)
   - Any perceived gaps or remaining concerns? How can they be addressed?

4. **HTA areas of regulation (60 mins – *roughly 10 mins per section*):**

   - ***Consent/re retention of tissue (ORGAN DONATION & TRANSPLANTATION - (STIMULUS PG 3)***
     - *[Clear description from HTA. Note: explore spontaneous views first]*
     - How much do you know about living donation? To what extent do you think it is regulated? If so, how?
     - Do you think that the regulation is useful?

- What is your current knowledge on:
  - Content for living donation
  - Opt out for living donation
- Is there anything that you have heard/known relating to OTD that might be a concern for you? If so, why is this concern? *Moderator explain that there are myths around donation and transplantation e.g. teams won't try to save you when you are marked as a donor*

➔ **Introduce *Consent/re retention of tissue* scenario and explore perceptions i.e. what course of action should be taken by HTA and what are the priorities?**

Overall,

- To what extent are you confident that your/public wishes are being respected? Why?
- Identify any unprompted areas of concern that specifically relate to consent
- Revisit any concern areas raised – how confident are you that these are all being addressed by HTA? Why?
- Introduce specific stimulus outlining HTA's regulatory approach to consent – how confident are you in these approaches? Why?
- Any perceived gaps – how might they be addressed?

- ***Public display (STIMULUS PG 5)***
  - *[Clear description from HTA, only to be used <u>after</u> spontaneous views]*
  - Do you know anything about regulation in this area? *Spontaneous and then probe: museums and galleries might be displaying material of human origin (beyond ancient remains, e.g. mummies)*
  - How do you feel about this area i.e. strongly, less strongly and why?
  - To what extent is it important that this area is regulated?
  - Is there anything specific that you would be worried about/what would your concerns be about that?
  - Body parts?

➔ **Introduce public display scenario and explore perceptions i.e. what course of action should be taken by HTA and what are the priorities?**

Overall,

- To what extent are you confident that your/public wishes are being respected? Why?
- Identify any unprompted areas of concern that specifically relate to public display
- Revisit any concern areas raised – how confident are you that these are all being addressed by HTA? Why?
- Introduce specific stimulus outlining HTA's regulatory approach to public display – how confident are you in these approaches? Why?
- Any perceived gaps – how might they be addressed?

- ***Regulation of Mortuaries* and Post mortem examination (STIMULUS PG 7)**

- *[Clear description below from HTA. Note: explore spontaneous views first]*

- The HTA licences and inspects mortuaries in England, Wales and Northern Ireland – we ensure that standards are being met and help them to improve the standard of care they provide
- Do you know anything about regulation in this area?
- Has anyone you know had to have a post mortem examination?
- How do you feel about this area i.e. strongly, less strongly and why?
- To what extent is it important that this area is regulated?
- Is there anything specific that you would be worried about/what would your concerns be about that?
- Describe your level of comfort/confidence in post mortem? *Probe: imagine a family member going into care of the mortuary*
    - What difference would it make to know that there is a statutory regulator? Why?
    - What would you want to know regarding the post-mortem, for example:
        - where the body was being stored
        - training of staff involved
    - Does the fact that the family has no say in the post-mortem; would you have any areas of concern related to this? If so, what would be your biggest concern(s)?

➔ Introduce mortuary regulation and post mortem examination scenario and explore perceptions i.e. what course of action should be taken by HTA and what are the priorities?

Overall,

- To what extent are you confident that your/public wishes are being respected? Why?
- Identify any unprompted areas of concern that specifically relate to post mortem examination
- Revisit any concern areas raised – how confident are you that these are all being addressed by HTA? Why?
- Introduce specific stimulus outlining HTA's regulatory approach to post mortem examination – how confident are you in these approaches? Why?
- Any perceived gaps – how might they be addressed?

- **Research/Anatomy *(STIMULUS PG 9)***
    - *[Clear description needed. HTA Note: explore spontaneous views first]*
    - Do you know anything about regulation in this area?
    - How much would you like to know about donating tissue and informed consent? *Probe: withy body donation, how much information is sufficient (HTA do not want to put people off donating by providing too much detail)*

- How much detail would be sufficient? What format should this information be provided in? Why?
- How do you feel about this area i.e. strongly, less strongly and why?
- To what extent is it important that this area is regulated?
- Is there anything specific that you would be worried about/what would your concerns be about that?
- Why do you think that organs cannot be bought or sold for research purposes?
- Explore perceptions of cosmetic procedures e.g. Botox, can be given by beauty therapists
  - They are required to have anatomical knowledge through using donated bodies/body parts
  - What do you think about use of these parts by non-clinicians? *Probe: Newcastle example needed*
- Introduce 'dynamic consent' – an ongoing relationship, e.g. donate to UK biobank, ongoing contact in terms of what it's used for, any more specific examples?
  - With this in mind, how would you like to interact with the organisation that is taking the body/tissue?
  - Is there anything else that might improve confidence for you? If so, what?
- How do you perceive tissue from the living vs tissue from the deceased – are there any differences in perception (i.e. from living or deceased)?
- How important is it to have had conversations about your wishes with family, and later health professionals, about your wishes after death?
  - Are there any big taboos?
  - Are you happy for family to make decisions for you?
  - Why wouldn't you want to talk about what happens to your body once you're dead?

➔ Introduce research/anatomy scenario and explore perceptions i.e. what course of action should be taken by HTA and what are the priorities?

Overall,

- To what extent are you confident that your/public wishes are being respected? Why?
- Identify any unprompted areas of concern that specifically relate to research/anatomy
- Revisit any concern areas raised – how confident are you that these are all being addressed by HTA? Why?
- Introduce specific stimulus outlining HTA's regulatory approach to research/anatomy – how confident are you in these approaches? Why?
- Any perceived gaps – how might they be addressed?

- ***Human application (STIMULUS PG 11)***
  - *[Clear description needed. HTA Note: explore spontaneous views first]*
  - Do you know anything about regulation in this area?

- How do you feel about this area i.e. strongly, less strongly and why?
- To what extent is it important that this area is regulated?
- Is there anything specific that you would be worried about/what would your concerns be about that?
- To what extent were you already aware that human tissues and cells are used for patient treatment?
- Do you understand what is meant by 'human application'?
- Has anyone donated or banked (either publically or privately) tissues or cells for human application?
    - If so, did you have any concerns about this process? Why/not?
    - What were your expectations of the regulator in the process (probe: oversight of quality and safety, ensuring marketing material is appropriate for the service being offered, reducing risk, etc.)?
- **Has anyone receieved tissues or cells for treatment?**
    - If so, did you have any concerns about this process (probe: complications associated with the procedure, risk of contracting disease, lack of effectiveness, medical errors, receiving tissue/cells from another country)?
    - What were your expectations of the regulator in this process?
- Is it important that the use of human tissues/cells is regulated? If so, why (i.e. what are the main areas/risks that should be addressed through regulation)? For example:
    - To ensure the safety and quality of these substances
    - To increase availability of such substances
    - To protect donors
    - To ensure that the public is well informed about the risks and benefits of donation/treatment
    - To ensure that imported substances meet equivalent standards of quality and safety as those required in the EU.

➔ Introduce human application scenario and explore perceptions i.e. what course of action should be taken by HTA and what are the priorities?

Overall,

- To what extent are you confident that your/public wishes are being respected? Why?
- Identify any unprompted areas of concern that specifically relate to human application
- Revisit any concern areas raised – how confident are you that these are all being addressed by HTA? Why?
- Introduce specific stimulus outlining HTA's regulatory approach to human application – how confident are you in these approaches? Why?
- Any perceived gaps – how might they be addressed?

5. <u>Overall perceptions and priorities (10 mins)</u>

- Which of the standards that HTA inspect against is the most important to you, and why?
- What would they want to know before donating / banking tissue/cells either publically or privately
    - What information could/should the HTA provide to assist members of the public who are considering donating/banking tissues/cells
- How do you feel about private tissue banks?
- What are your views on stem cell therapies and services offered by private tissue banks?
- What do you think should be done in the occurrence of misleading marketing claims?
- What are your expectations of the services being offered and of the HTA in its role as the regulator?
- What information could the HTA produce to improve confidence/manage expectations? What format should this be provided in?

6. <u>Sum up and close (10 mins)</u>

- How do you feel about the HTA now?
- What do you think are the priority areas across their remit? Why?
- How interested are you in the work of the HTA (in general and specific areas)

- Overall, how confident are you in the system, relating to:
    - How well the HTA is perceived to be carrying out their duties generally
    - Consent – are you confident that wishes are being respected?
    - Safety/safeguarding the public – based on the information provided, do you think HTA's regulatory system safeguards the public?
    - Ethics – based on the information provided, do you any remaining concerns around the ethical use of human bodies and/or tissue?

APPENDIX 2

LIST OF SCENARIOS PER SECTOR

Organ Donation and Transplantation

> ***"My eldest child wants to donate their bone marrow to their younger sibling who has cancer. My eldest child is only 5 years old. Is this legal?"***

The HTA has regulatory responsibilities for both living and deceased donation, but due to the very different natures of these situations the role differs.

For living donation: the HTA's role in living donation is to ensure that there is no incentive or coercion involved in the donation; independent Assessors will refer a case to the HTA if they think that there are grounds to suspect either of these being at play.

Example on financial incentives: A man from abroad who needed a kidney transplant came to England with his new wife, who was a match and had consented to be a living donor. There were financial irregularities picked up by the Independent Assessor – namely that money had changed hands from the husband's family to the wives' family on marriage – so it was referred to the HTA. They claimed to have a child, though the child had not been brought to England, there was no proof of the child's existence, and their stories were inconsistent. It is rare for the HTA to deny a living donation case, as where there are issues they tend to get to light earlier in the process, but in this case it was determined that there was a financial incentive in this case and the panel prevent the transplant from taking place.

Example on coercion: A living donation case involving a family and their live in nanny/au pair was referred to the HTA, which involve the mother who needed a kidney transplant, and the family's live in nanny who was the proposed donor. The case raised questions of the donor's dependence on the family, in terms of employment and housing, which may have been a factor – was there coercion being applied, or even any possibly incentives?

For deceased donation: the underlying principle of deceased donation is that organs and tissues can only be removed with appropriate consent. If your decision to donate, or not to donate, is registered on the Organ Donor Register, then as long as no one forced you to make the decision, you were aware of your actions, and had the information you needed, your decision is legally valid. The HTA does not promote organ donation, as the regulator we are concerned that appropriate consent is in place, and that any issues that come up a part of the national organ donation and transplantation network are reported and investigated as appropriate.

Example on consent: A case was referred to the HTA by NHS Blood and Transplant, the national body who coordinated blood and organ donations and transplantation.

The case involved a deceased man who had Downs Syndrome. The man had gone through options for organ donation with his carer, using an easy-read form, and the form was marked as "no" to organ donation. The man's family argued that he must not have understood what this meant, as he was the kind of person who always wanted to help other people, they were sure that he would have wanted to do the same in death and donate his organs, if he had understood the situation clearly. The family wanted the wishes recorded on the form to be overridden. Based on the evidence available, the HTA tool the decision that the registered decision must be respected, as the family's view, whilst with merit, cannot override the recorded opt-out of the deceased as we have no proof that the deceased did not fully understand the choice.

General example on consent (for discussion): Even when someone has proactively opted to become an organ donor, and has their details on the Register, their wishes can and often will be overridden by family. It can't work the other way round – your family cannot override someone's wish to opt-out, but often a family intervenes to prevent organs being removed for donation. What do the group think about this? Specialist clinicians work with families to try and increase donation rates, particularly where they sense there will be family opposition, but what power should the family have, or not, to block donations where consent to donate has been recorded?

Mortuary/Post-mortem

> ***"Is the pathologist allowed to retain tissue samples of my deceased relative?"***

Mortuaries must report any serious incidents to the HTA, the HTA's role is to then work with the mortuary and staff to ensure, where necessary, improvements are made and that learning is shared across the system so other establishments do not make a similar mistake.

Example: Following a post-mortem examination of two babies, the bodies were released to the funeral directors and sent to be prepared for burial. En route it was discovered that there had been a mix up in the mortuary and the wrong brains had been put back into the wrong bodies. As this error had been spotted in time, the bodies were returned, and the error corrected. This incident was reported to the HTA as a "near miss", and the HTA worked with the establishment to ensure adequate systems were in place so this didn't happen again. The incident was understandably distressing for the families, as they were also informed of the near miss, under the legal Duty of Candour – where NHS trusts must inform those involved of any errors which caused or may have caused harm.

General examples: The most common reasons for a reportable incident relate to the misidentification of a body, which covers the incorrect release of a body, families being shown the wrong body, or a body being mislabelled and released to the funeral director in error. These incidents will all be distressing for the families involved, and through a system of reporting the incidents to the HTA, working together to ensure

improvements are made, and sharing learning across the system, the HTA works to ensure further mistakes are minimised, and that families do not suffer the upset and distress caused by a misidentification.

Public display

> ***"I recently saw a production of 'Hamlet' and I was told that a real human skull was used on stage. Is this legal?"***

Research/Anatomy

> ***"My relative has passed away. Am I able to donate his/her body on their behalf?"***

More information of what the HTA's role is in the sector and what happens after body donation (please see PDF attached which explains this also, if that's of use to you in the focus groups):

The Human Tissue Authority (HTA) does not collect or receive bodies or other human materials, but we license and inspect the organisations that do, such as medical schools.

If an individual wants to donate their body to a medical school – which will usually be their local medical school – they need to contact them directly to arrange this.

Consent must be given by the individual donor in life – the HTA are not involved in taking consent, this is between the individual and the medical school.

The HTA's role is to make sure that these organisations remove, store, and use brains, bodies and tissues in an appropriate, respectful and well-managed way, and that the wishes of individual patients and their families are respected.

The HTA's regulation helps ensure that tissue is stored to high standards, to be of most use to healthcare training and research.

Body donations are highly valued by staff and students at medical schools. A donated body can be used for a number of purposes, which may include:

- Anatomical examination ***– teaching students or healthcare professionals about the structure and function of the human body***.
- Research – ***scientific studies which to improve the understanding of the human body.***
- Education and training – ***training healthcare professionals on surgical techniques.***

Medical schools will usually arrange for donated bodies to be cremated, unless the family requests the return of the body for a private burial or cremation, and medical

schools may also hold a committal, memorial or thanksgiving services. Further information on local arrangements can be obtained directly from the medical school.