

HTA Board meeting, 6 March 2025

Agenda item	4.2 Horizon Scanning
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The Board is asked to note the findings of the 2024/2025 annual horizon scanning report.
Which strategic risks are relevant?	Risk 1: Regulation Risk 2: Sector Risk 3: Staff Risk 4: Financial Risk 5: Digital
Strategic objective	Trust and Confidence
Core operations / Change activity	Change activity
Business Plan item	Establish a horizon scanning and insight process to identify and discuss emerging developments and innovation
Committee oversight?	The Board will receive an annual horizon-scanning report summarising key developments relevant to the HTA.
Finance and resource implications	NA
Timescales	Horizon scanning is an ongoing business-as-usual activity of the HTA.
Communication(s) (internal/external stakeholders)	The findings of the horizon scanning report (Annex B) will be published on the HTA website to provide transparency regarding the HTA's horizon scanning activities. Internal stakeholders will be engaged as business-as-usual.
Identified legislative implications	NA

Horizon Scanning

Purpose of paper

1. To inform the Board of developments in the high-priority horizon topics for 2024/25, identified through the HTA's horizon scanning process.
2. Highlight to the Board areas of work arising from high-priority horizon topics.

Action required

3. The Board is asked to **note** the findings of the 2024/2025 annual horizon scanning report.

Background

4. The HTA's horizon scanning activities identify and monitor developments within and adjacent to our remit, considering the current socioeconomic and political environment. By identifying these emerging topics, assessing potential impacts, and using this intelligence to inform our work, the HTA aims to ensure that its regulatory framework remains fit for purpose. This proactive approach enables the HTA to address potential risks and opportunities effectively, support the development of innovative practices, and maintain public confidence in the ethical and safe use of human tissues.
5. During 2024/25, the HTA developed a streamlined horizon scanning process, tailoring our activities to the HTA's size and remit. The development of this process considered lessons from the HTA's previous horizon work, existing internal governance systems, comparable organisations' horizon-scanning activities, and current best practices. We have used the principles of this process to create this first annual horizon scanning report.
6. Horizon scanning has also been developed to consider the environment within which the HTA regulates and licensed establishments operate. The UK is at the forefront of life sciences innovation, with the sector playing a vital role in the national economy and health strategy. Government initiatives, such as the UK Innovation Strategy, discuss the need for a culture of innovation across all sectors, including healthcare.
7. Considering this innovation culture, there is increasing discussion about the need for regulatory reform to keep pace with and support scientific and technological advances. Regulation needs to be streamlined and efficient and

should be able to adapt to emerging scientific and technological developments without compromising ethical standards or public safety. With this context, the HTA needs to understand our position within this changing regulatory landscape, ensuring the sustainability of our legislation and regulatory activities.

8. This paper provides an overview of the HTA's horizon scanning process, including topics identified as high-priority in 2024/25. The findings of this report have helped inform work and resource allocation for 2025/26.

Horizon scanning

9. The purpose of horizon scanning is to identify current and emerging topics that could influence the work of the HTA and our licensed establishments over the immediate (1-3 years), medium (3 – 5 years) and longer-term (5 – 10 years).
10. Topics are identified through various sources, including published literature, parliamentary discussions, media articles, attending conferences and events, inspection findings and stakeholder engagement. Areas of interest are then recorded on a register.
11. On an annual basis, the Executive will produce a report summarising topics that have been shortlisted from our horizon scanning register. This first report includes a high-level summary of horizon topics classified as high-priority based on the HTA's prioritisation process ([Annex A](#)). As per the agreed process, future horizon scanning reports will also consult internal and external stakeholders to reach a consensus on priority scores and shortlisted topics.

2024/25 Horizon topic prioritisation

12. Topics were scored on a scale between one and five based on their potential implications for the HTA, our licensed establishments, and the broader landscape. The HTA has implemented the widely recognised PESTLE analysis to consider any implications. This allows us to assess topics based on political, economic, sociological, technological, legal or environmental implications, including the proximity to the HTA's statutory remit.
13. Topics are also allocated a 'likelihood' score, indicating their potential time to introduction. This score considers the pace of development and the length of time until the HTA may need to take action to address the topics.
14. These scores are multiplied to calculate an overall priority score. More

information about this prioritisation process and the criteria used to allocate impact and likelihood scores are included in [Annex A](#).

15. As of the publication of this report, the HTA's horizon scanning register contains 39 horizon topics. After prioritisation using the agreed criteria, six topics were rated as high priorities, these being the highest rated topics on the list. This means their prioritisation score was between 12 and 16. The priority list represents topics within the HTA's regulatory remit and those in which we could potentially have a professional interest. The details of this scoring are as follows:

High-priority horizon topic 2024/25	Impact	Likelihood	Priority
Dignity of the deceased	4	4	16
Assessment and Recovery Centres (ARC)	4	4	16
Sale and auction of human remains	3	5	15
Artificial Intelligence (AI), digitisation and robotics in health and care	3	5	15
Funeral directors	3	4	12
Regulation of body stores	3	4	12

16. [Annex B](#) includes high-level summaries of the six high-priority horizon scanning topics. This includes the steps the HTA will implement to address these developments during the next business year.
17. In addition to the shortlisted topics, the full horizon scanning register contains several topics against which the HTA is maintaining a watching brief. An example of this is the Parliamentary Bill on Terminally Ill (Adults) End of Life. The topic is currently a matter for parliamentarians and, as of the second reading, there are no amendments of relevance to the HTA, but we will maintain a watching brief as the Bill progresses to its third reading later this year.

Conclusion

18. This paper outlines the HTA's horizon scanning activities for 2024/25 and which topics have been identified as high-priority. The Executive will continue to present the Board with an annual horizon scanning report to update them on relevant high-priority developments to the HTA's remit.

Recommendation

19. The Board is asked to **note** the findings of the 2024/2025 annual horizon scanning report.

Annex A

Horizon scanning prioritisation matrix.

		Overall score matrix				
Impact	(5) Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very high
	(4) High	4 Low	8 Medium	12 High	16 High	20 Very high
	(3) Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	(2) Low	2 Very low	4 Low	6 Medium	8 Medium	10 Medium
	(1) Very low	1 Very low	2 Very low	3 Low	4 Low	5 Medium
Priority score = Impact x Likelihood		(1) Very low	(2) Low	(3) Medium	(4) High	(5) Very high
		Likelihood				

Table 1 This table shows the matrix used to calculate the overall prioritisation score of a horizon topic, including the numerical classification of priority as very high to very low.

Likelihood scoring

Score	Likelihood of occurrence within...
(5) Very high	< 6 months
(4) High	6 months - 1 year
(3) Medium	1 - 3 years
(2) Low	3 - 5 years
(1) Very low	5 - 10 years

Table 2 This table shows the criteria used to allocate the 'likelihood' score. Identified topics are scored on their potential time to introduction, considering the pace of development and the length of time until the HTA may need to take action to address these horizon topics..

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Impact scoring

Score	Political/Legal	Economic	Social/Environmental	Technological
(5) Very high	Potential significant reputational implications/opportunities to have a voice in government response. Severe political implications. Immediate legal actions/advice required.	Above £1m >90% impact on resources, not able to absorb.	Complete change of services. Pandemic or immediate support provisions required. Included in statutory remit.	The sweeping effect, involving almost all technology resources.
(4) High	Potential reputational implications/opportunities to influence key stakeholders. Likely political implications. Legal actions may be required. Immediate policy changes are needed.	£0.5m - £1m >50 % impact on resources, unlikely to be able to absorb.	Significant service changes are expected. It is likely to be included in the statutory remit.	Extensive effect, involving most technology resources.
(3) Medium	Potential localised reputational implications/opportunities to influence a sector/geographical area. Some political impact or potential legal implications. Policy changes required.	£250k - £500k A 10%-50% impact on resources, can potentially be absorbed.	Minor or temporary changes to services. Potentially within statutory remit. Support may be required.	Wide-ranging effects involving a significant portion of technology resources.
(2) Low	Potential targeted reputational implications/opportunities to influence (e.g. practitioner confidence/local media/individuals). It could have minor political implications. Clarity on legal advice needed and policy changes may be required in future.	£50k - £250k A 3%-10% impact on resources, can most likely be absorbed.	Marginal changes to services and/or outside remit. May need to provide information to manage stakeholder expectations.	Limited effect, involving some technology resources.
(1) Very low	No reputational implications/limited opportunity to influence the outcome. Legal status secure. Policy position unaffected.	Below £50k <10% impact on resources, can absorb.	Minor changes to service. No involvement at present.	Minimal effect, involving few, if any, technology resources.

Table 3 This table shows the criteria used to allocate the 'impact' score. Identified topics are scored based on the descriptions outlined in these categories, depending on their potential implications.

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Annex B: High-level summaries of the six high-priority horizon scanning topics.

Dignity of the deceased; Body stores

Dignity of the deceased - prioritisation score: 16 (High)

Body stores - prioritisation score: 12 (High)

Funeral directors – prioritisation score: 12 (High)

Background

20. In January 2022, the Independent Inquiry into the issues raised by the David Fuller case in the mortuaries at Maidstone and Tunbridge Wells NHS Trust was established. The Inquiry also considers whether the procedures and practices in other hospital and non-hospital settings where deceased individuals are placed safeguard their security and dignity.
21. The first phase of this Inquiry concluded in November 2023 with the publication of the [phase one report](#). The Inquiry is now in its [second phase](#), with an [interim report](#) focused on the funeral sector published in October 2024. The phase two report is planned for publication in 2025.

Role of the HTA

22. The HTA regulates all mortuaries where post-mortem examinations occur in England, Wales, and Northern Ireland. Through our work with mortuaries, we help ensure that the bodies of the deceased are treated with respect in a safe and secure environment, maintaining their dignity at all times. However, it is not within the HTA's statutory remit to regulate funeral services or unlicensed body stores.
23. The Inquiry is, therefore, reviewing areas of practice that are both directly and indirectly associated with the HTA's statutory remit. This makes the potential impact of the Inquiry's findings on the organisation high.

Work to date

24. The HTA has supported the Inquiry since it was established in 2022. Most recently, the HTA Chief Executive spoke at a seminar in November 2024 on the [regulatory and oversight measures in place to safeguard the dignity and security of the deceased](#).

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25. We have also taken steps to [increase protections for the dignity of the deceased](#), as outlined in the paper presented to the Board in September 2024. This includes delivering mandatory webinars on security standards for designated individuals (DIs) in the PM sector. We have also published revised guidance on HTA Reportable Incidents¹ (HTARI) and developed a trial programme of unannounced inspections in the PM sector, commencing mid-September 2024. The September Board paper also outlines a pilot with the Welsh Government and Health Boards to deliver advisory inspections of unlicensed hospital body stores.

Next steps for 2024/25

26. The HTA will continue to support the Inquiry and will take action based on its findings and recommendations.
27. As approved and endorsed by the Board in September 2024, we will also continue to work to improve the HTA's approach to regulation of the post-mortem and related sectors, particularly to enhance protections for the dignity of the deceased.

Assessment and Recovery Centres (ARCs)

Prioritisation score: 16 (High)

Background

28. In the UK, like many countries, there is a shortfall in organs available for transplantation, leading to significant patient waiting times. Many donated organs are deemed unsuitable for transplantation due to concerns about their viability and function. However, some organs could be viable if sufficiently assessed and repaired before transplantation.
29. In 2023, the [Organ Utilisation Group's \(OUG's\) report 'Honouring the gift of donation: utilising organs for transplant'](#) made several recommendations to maximise the potential for organ transplantation from living and deceased donors.
30. The report recommended establishing national Assessment and Recovery

¹ **HTA Reportable Incidents (HTARI)** are serious incidents or near-misses in licensed mortuaries that may affect the dignity of the deceased

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Centres (ARCs). ARCs aim to bring techniques, including machine perfusion², into widespread clinical practice as soon as possible. This would support maximising the number and quality of organs available for transplant and associated logistics. The report also recommended creating a national oversight system of innovation in organ assessment, perfusion, and preservation.

31. The Department of Health and Social Care (DHSC) created the [Implementation Steering Group for Organ Utilisation \(ISOU\)](#) to implement these recommendations. In their November 2024 [implementation plan](#), the ISOU outlined its intention to progress the establishment of ARCs and innovation oversight during the 2025/26 business year, led by NHS Blood and Transplant (NHSBT). The plan indicates that if a business case is approved in quarter two of 2025/26, procurement could begin in quarter four of 2025/26.

Role of the HTA

32. The HTA oversees compliance with laws ensuring the quality and safety of the UK's organs, tissues, and cells for transplantation. This includes licensing and inspecting hospitals where activities associated with deceased and living organ donations occur and approving living donation cases. Therefore, ARCs would be within the HTA's statutory remit, meaning we would be responsible for reviewing whether Assessment and Recovery Centres (ARCs) comply with quality and safety standards.

Work to date

33. The HTA has already undertaken work to address the introduction of ARCs. In November 2022, the HTA updated 'The Quality and Safety of Organs Intended for Transplantation: A Documentary Framework' to include new directions related to ARCs. Specifically, when an organ is sent to an establishment for assessment or recovery using machine perfusion, the establishment must record and store any organ characterisation and traceability data generated during this process for 30 years.

Next steps for 2024/25

34. The HTA will assess the impact of the ISOU's implementation plan, specifically the work to introduce national ARCs. We will also engage with NHSBT to determine the action required by the HTA to ensure our regulatory frameworks and guidance remain fit for purpose.

² **Machine perfusion** is a technique that uses the circulation of oxygenated blood or preservation solutions through the organs in a near-physiological state. This allows for extended preservation times and the opportunities to assess and improve organ function before transplantation.

Sale and auction of human remains

Prioritisation score: 15 (High)

Background

35. There have previously been reports about the auction of human and ancestral remains, including human bones, shrunken heads and skulls. The British Association for Biological Anthropology and Osteoarchaeology (BABAO) has raised concerns about this practice, stating that it is unethical. In response, they have established the [Trading and Sale of Human Remains Task Force](#). This group aims to educate the public about the ethical, legal, and social ramifications of the private commercial trade in human remains.
36. At Prime Minister's Questions on [20 November 2024](#), Bell Ribeiro-Addy MP raised concerns about the sale of human remains after discussions with BABAO. She asked the government to take action to end the practice. In response, the Deputy Prime Minister, Angela Rayner, acknowledged the HTA's regulation of the public display of human remains but that this did not cover sales or purchases. She confirmed that a meeting would occur with the appropriate Minister to discuss the issue.

Role of the HTA

37. The Human Tissue Act 2004 (The Act) prevents commercial dealing in human tissue for organ donation. It also requires those holding human remains less than 100 years old for a scheduled purpose to obtain a licence from the HTA. This includes an exhibition or display where the public can view a body or relevant material from a body. However, the Act does not cover the sale or auction of human remains as artefacts.

Work to date

38. To support this discussion of the sale and auction of human remains, the HTA has engaged with and supported DHSC and the Department for Digital, Culture, Media and Sport (DCMS), including providing relevant information to inform discussions and briefings.

Next steps for 2024/25

39. The HTA will continue to engage with and support DHSC as appropriate to

support any action to address the sale or auction of human remains.

40. The HTA will develop a position statement on the sale and auction of human remains, acknowledging that this practice currently falls outside our statutory remit.

Artificial intelligence, digitisation and robotics in healthcare

Prioritisation score: 15 (High)

Background

41. Artificial Intelligence (AI) is a fast-developing technology with increasing numbers of everyday applications. AI has been applied in healthcare to enhance drug discovery, diagnostics, and patient care, supporting personalised treatment plans. It also has the potential to streamline operational activities and support administrative tasks such as creating staff rotas and resource allocation.
42. Many businesses are investing heavily in AI to reduce manual processing and improve the productivity of their workforce. The use of AI to enhance patient care and operational efficiency continues to be a priority of the current government. One of the UK Government's missions under the [plan for change](#) is '[an NHS fit for the future](#)'. The NHS [10-Year Health Plan for England](#) is being developed to aid in delivering this mission. One of the three reform shifts under this plan is titled 'analogue to digital'. This focuses on combining new technologies and digital approaches to modernise the NHS. In October 2024, the Regulatory Innovation Office (RIO) was also formed to increase the speed of innovative technology, including AI in healthcare, to market by reducing regulatory burdens.
43. AI poses unique regulatory considerations. As defined in the Government's 2023 white paper '[AI regulation: a pro-innovation approach](#),' the technology's characteristics of 'adaptivity' and 'autonomy' create the need for bespoke regulatory responses. For example, adaptability and the potential for ongoing 'training' can make explaining the intent or logic of the system's outcomes challenging. Autonomy makes it difficult to assign responsibility for outcomes. To produce reliable outputs, AI requires large quantities of high-quality data. If not, there is a risk of algorithmic outcomes perpetuating historical biases and discrimination. Consideration is also needed for data security, particularly for sensitive medical information.
44. Of note, this horizon topic does not consider the HTA's use of AI in our work or regulatory activities. The HTA's use of AI is included as a separate topic on the HTA's horizon scanning register. This is because of the distinct risks and

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opportunities related to the HTA's use of AI compared to the use and regulation of AI in our licensed establishments.

45. In February 2025 the HTA responded to a [Parliamentary Question \(PQ\)](#) on our use of AI. In response the HTA commented that we currently use the Government Communication Service (GCS) Assist tool. The tool is designed to support communications professionals in a number of areas including: the production of first draft communications products; stakeholder management; research and media handling.

Role of the HTA

46. The HTA ensures that human tissues, cells and organs are handled with dignity, used with consent and stored safely. Across all six of the HTA's sectors,³ we aim to maintain public trust and confidence in the safe handling of human tissues. This includes where AI is used in a way that would fall under or impact the HTA's statutory remit. It is therefore important for the HTA to monitoring the current or future application of AI in our sectors to determine the role of the HTA in AI's regulation, or providing guidance and support to licensed establishments.
47. As AI's application expands, it increasingly affects areas of practice within or adjacent to the HTA's statutory remit. AI has the potential to aid in organ and tissue donor-recipient matching, determine organ viability and predict treatment outcomes. AI can also be used in medical education and public display to simulate human anatomy or artefacts. This could reduce the need for interaction with human cadavers, prosecutions or specimens. AI-assisted virtual post-mortems could assist pathologists in determining the cause and time of death, reducing the need for invasive physical post-mortem procedures.

Work to date

48. The HTA has engaged with stakeholders to establish where and how licensed establishments are using, or planning to use, AI. At the HTA's stakeholder event in September 2024, roundtable discussions explored the use of AI across our six sectors. A recent stakeholder survey indicated that around a quarter of our licensed establishments currently use or plan to use AI in their work in areas such as text generation, image analysis, data processing, and predictive modelling.

Next steps for 2024/25

3 The [HTA regulates six sectors](#) involving the removal, storage and use of human tissues and cells. These are anatomy, human application, organ donation and transplantation, post-mortem, public display and research.

49. The HTA will continue to engage with stakeholders to establish areas within or adjacent to our remit where AI is or could be applied. We will use this intelligence to identify potential actions to address risks or opportunities.