

Generative Artificial Intelligence and Local Governance Models

Health Service Guidance

OFFICIAL

Purpose

This guidance has been created to support health services establish local protocols to ensure that generative artificial intelligence (AI) is implemented safely, provides quantifiable benefit, and is used appropriately. This guidance is specific to the use of emergent generative AI technology in Victorian health services, notably the application of large language models.

The recommendations and guidance inclusive in this document are designed to mirror the local measures that are already used to assess the benefit, safety and appropriateness of new models of care.

This guidance should be considered alongside a previous advisory, *Health service use of unregulated Artificial Intelligence (AI)*, issued on 31 July 2023.

Use of Generative Artificial Intelligence

As outlined in *Health service use of unregulated Artificial Intelligence (AI)*, The Department of Health and Safer Care Victoria do not support the clinical application of generative artificial intelligence software that is not listed on the Therapeutic Goods Administration's Australian Register of Therapeutic Goods (<https://www.tga.gov.au/resources/artg>)

For the purposes of this guidance, clinical application is defined as the application of generative AI that influences, advises, or impacts the clinical decision making and/or delivery of care.

Further information on the regulation process, including detail on definitions and exclusion criteria, can be found on the Therapeutic Goods Administration's website for Software as a Medical Device:

<https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/manufacture-guidance-specific-types-medical-devices/regulation-software-based-medical-devices>

Role of Generative Artificial Intelligence

The emergence of generative AI, specifically large language models, has been unprecedented. It is acknowledged that the underpinning technology will likely integrate into routine functions across most (if not all) industries in the near future. The Commonwealth Government and supporting organisations, like Australian Alliance for Artificial Intelligence in Healthcare, are progressing various regulatory and guidance material for the sector. In the interim, it remains the responsibility of the Department of Health and Safer Care Victoria to ensure that any application of relatively untested technology is undertaken cautiously.

Precautionary Principles

The document outlines a framework for local governance and oversight with regards to the use of generative AI. It is strongly recommended that health services implement this model before exploring how generative AI could be used.

In addition to use of local governance models, the Department of Health suggests the following principles are considered when exploring potential generative AI options:

- Unregulated generative AI is not used in cases where the outcome will directly, or indirectly, impact the quality and safety of care provided to patients and consumers (see above for the definition of clinical applications).
- Caution is taken around the handling of sensitive information and any use conforms to the requirements in the Privacy Act 1988 and Health Records Act 2001.
- Generative AI is only used in the support of and to inform “human” led tasks, never to replace them. Any outputs that have been generated by Artificial Intelligence should be reviewed and validated.
- Health services ensure that all staff using generative AI are educated on the risks and the precautions required to maintain patient and system safety.

Determining Safe Use Cases

There is currently no agreed list of use cases where generative AI could be applied without oversight and approval from the TGA. As such, each potential (non-clinical) application should be considered by health services on a case-by-case basis through local governance mechanisms.

The Digital Transformation Agency has published interim guidance for agencies on government use of generative Artificial Intelligence platforms. The case studies and recommendations in this guidance offers support that may be helpful for health services that may be considering where generative AI might offer benefit. <https://architecture.digital.gov.au/guidance-generative-ai>

Some of the common applications for generative AI include:

- Generating of first draft documents and/or templates that will be adapted or prosecuted by human users
- Optimising administrative functions
- Supporting research activities

Establishing Local Governance Models

Health services are advised to include the governance of generative AI applications within the appropriate oversight framework. For some health services, local new technologies committee may be suitable, for others a sub-committee may be preferable. The local governance model may include the following functionality:

- Each application and use case should be subject to a robust review of benefits, risk, and appropriateness. At a minimum, this would include a privacy impact assessment, a cost-benefit analysis and cyber security assessment.
- The selection and approval to use generative AI should be based on a robust evidence base that is specific to the intended use case. The extent of evidence should be appropriate for the intended use case and, for higher risk applications, may include the commissioning of a local health technology assessment to assess for safety, accuracy, privacy, practicality and equity implications when adopting any new health technology.
- The governance model should also include clear methodology to monitor and evaluate the use of new AI applications. If appropriate, this may also include the piloting and/or local testing of such technology in a safe environment.
- The local governance model should include, and be receptive to, communication and collaboration between them and the Department of Health, Safer Care Victoria, and regional Health Service Partners.

National Policy Development and Future Updates

The Department of Health and Safer Care Victoria recognise that the generative AI field is dynamic and many important decisions on safe and appropriate use are expected in the next 12 months. We are actively collaborating with other states, federal departments, and expert groups to ensure that Victorians get access to the most up-to-date information and are able to contribute to national discussions.

Notably, since the release of advisory in July 2023, the Australian Alliance for Artificial Intelligence in Healthcare (AAAIH) have published *A National Policy Roadmap for Artificial Intelligence in Healthcare*¹. Healthcare leads are encouraged to review this document and to note the recommendations outlined that seek to address safety risks, the education of our workforce and improvements needed to ensure consumers can navigate AI led systems.

The Department of Health and Safer Care Victoria will continue to offer support and guidance while the national positions and frameworks are established. Any health services that require additional advice can contact digitalhealth@health.vic.gov.au.

¹ https://www.mq.edu.au/_data/assets/pdf_file/0005/1281758/AAAIH_NationalAgendaRoadmap_20231122.pdf